NEST-ED

Technical Modules

February 2021

Newborn Essential Solutions and Technologies-Education (NEST-ED) Technical Modules provide educational support for each of the technologies included in the NEST360° bundle for newborn care. These materials are intended to strengthen locally developed neonatal and technical trainings in pre-and in-service settings and are not intended to be comprehensive technical guidelines or device-specific manuals.

FACILITATING THE CLINICAL USE AND TECHNICAL REPAIR OF TECHNOLOGIES FOR NEWBORN CARE IN LOW-RESOURCE SETTINGS

DISCLAIMER

Newborn Essential Solutions and Technologies-Education
Technical Modules

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PREFACE

This series has been designed with the intent of supporting the clinical use and technical repair of technologies in newborn care units.

Newborn Essential Solutions and Technologies-Education (**NEST-ED**) Technical Modules provide educational support for each of the technologies included in the NEST360º bundle for newborn care. These materials are intended to strengthen locally developed neonatal and technical trainings in pre- and in-service settings. Of note, these materials are not intended to be comprehensive technical guidelines or to replace the use of device-specific user and service manuals or textbooks. They are to be used to facilitate the implementation of comprehensive newborn care, including bubble CPAP, in a resource limited setting.

The NEST-ED Technical Modules were developed through a combination of international standard review, international expert feedback, and multinational NEST360º expert consensus opinion. NEST-ED Modules form the backbone of all lectures, power points, job aids, and other supportive education materials supplied by NEST360º.

ABBREVIATIONS

bCPAP	Bubble continuous positive airway pressure
BMET	Biomedical Equipment Technician
dL	Decilitre
ESD	Electrostatic Discharge
FiO_2	Increased Fractional Concentration of Oxygen
Fr	French size
HAI	Hospital acquired infections
HCWs	Healthcare workers
KMC	Kangaroo mother care
LBW	Low birth weight
LCD	Liquid Crystal Display
LED	Light-Emitting Diode
mm Hg	Millimeters of mercury
NEST-ED	Newborn Essential Solutions & Technologies-Education
NEST360°	Newborn Essential Solutions & Technologies
nm	Nanometer
O_2	Oxygen
OGT	Orogastric tube
PCB	Printed Circuit Board
ppm	Parts per million
ROP	Retinopathy of Prematurity
PSA	Pressure Swing Adsorption
PSU	Power Supply Unit
ROP	Retinopathy of Prematurity
SpO_2	Peripheral blood oxygen saturation
UPS	Uninterruptible power supply
WASH	Water, sanitation and hygiene

NOMENCLATURE

Allen keys	Hex keys
bCPAP prongs	bCPAP patient interface
Christmas tree adapter	Barbed oxygen fitting, nipple and nut adapter
Control PCB	Main PCB
Cot	Bassinet, infant crib
Flat head screwdriver	Slot head screwdriver
Flow splitter	Oxygen splitter, flow meter stand
Glucometer	Glucose meter
Hospital Acquired Infection	Iatrogenic infection, nosocomial infection
Multimeter	Digital multimeter, Avometer
Nasal prongs	Oxygen catheter, oxygen cannula, oxygen prongs
Positive Pressure	Positive end expiratory pressure, positive airway pressure
Radiant warmer	Resuscitaire, resuscitation table
Star screwdriver	Torx screwdriver
Suction pump	Suction machine

Introduction

The NEST-ED Technical Modules have been prepared to help technical staff and students understand the basics of when and how to use equipment essential to newborn care. More importantly, the Technical Modules support staff in troubleshooting common issues, as well as prepare staff to repair equipment when it breaks down or malfunctions. Modules may be used by teaching institutions, to supplement current newborn care curricula, or by hospitals, clinical departments and individuals to update their knowledge and to better facilitate the effective and safe use of newborn care equipment. Modules should be used alongside device user and service manuals to provide additional context as needed.

Whilst reading this series, navigate to the **Table of Contents** by clicking the NEST360° logo that appears at the bottom right corner of each page: NEST360°

Every module has a similar structure with sections and subsections. The sections have similar headings and subheadings to make it easy for the user to navigate them. However, words may have different meanings for the various cadres of staff reading them and so to reduce misinterpretation, the heading titles are explained below.

The NEST-ED Technical Modules are intended as a flexible resource that hospitals and partners can adapt to their specific needs. The Technical Modules consist of generic content that can be applied to any model within a device category, coupled with model specific device images that can be exchanged for alternative images depending on the devices available at your facility. Individuals who are interested in gaining access to the editable NEST-ED Technical Modules should contact the **NEST Training Materials Coordinator** (Anniina Lockwood, al90@rice.edu) or the **NEST Biomedical Tech Training Director** (Sara Liaghati-Mobarhan, slmobarhan@rice.edu).

CLINICAL PROBLEM

This section provides useful information on the clinical application of a device that would bear relevance to the biomedical team, not only to aid in their troubleshooting, but also for user training.

ASSESSMENT

This section explains how the device works, and what kinds of patients it is useful for. This section also includes comprehensive diagrams of internal and external views of the devices, including consumables that may be used with the device. This section also contains detailed descriptions of key device components (including alarms) and includes a diagram of typical device flow (including components and how they interact with each other, electrical current and fluid movement through the device if relevant).

MANAGEMENT

This section focuses on **clinical** management and provides step by step directions on how to set the device up for a patient, followed by instructions on starting the patient on the device and monitoring a patient whilst on the device. This section also describes how to remove the equipment from the patient when it is no longer needed. Although a biomedical engineer or a technician will not be responsible for providing care, understanding these steps will be useful in training and when assessing the device.

INFECTION PREVENTION

This section lays out the basic infection prevention measures that should always be taken when handling equipment, followed by directions for disinfecting the equipment both during and after use. This section also describes the crucial Infection Prevention and Control steps that are particularly relevant to biomedical engineers and technicians.

COMPLICATIONS

This section explains some of the common but serious clinical complications that relate to and can arise from the use of the equipment (e.g., complications that will be seen or directly apply to the patient). Biomedical engineers' and technicians' understanding of potential complications for the patient is crucial to ensure patient safety. This section also describes common device complications (e.g., complications that will be seen or directly apply to the device).

CARE & MAINTENANCE

This section describes where to place equipment for use, how to safely handle devices and their consumables, whether calibration is recommended, and how to decommission the equipment. Biomedical engineers and technicians are responsible for second-line care and maintenance to ensure the equipment lasts to their potential lifetime; as such, this section also lists the necessary daily, weekly, monthly and annual preventive maintenance steps required to keep the device in good working condition. First-line care and maintenance is the responsibility of the user and is described in the **NEST-ED Clinical Modules**.

TROUBLESHOOTING & REPAIR

This section describes steps that should be taken when a device malfunctions and first-line troubleshooting efforts have failed to address the issue. This section describes tools and spare parts that might be required to prepare for repairs and to troubleshoot failures, and provides a list of components commonly provided with the device to ensure that all components return to the ward post-repair. Finally, this section also explains steps for testing, repairing, and replacing specific parts of the device.

REFERENCES & ALERTS

References & alert boxes are included within each module to provide clarity on areas where recommendations are governed by published standards, evidence, and/or expert opinion. This is included for the dual purpose of facilitating (1) feedback and continuous improvement of NEST-ED Technical Modules and (2) implementer review of content for incorporation in local trainings.

? ALERT 0.0 Subject

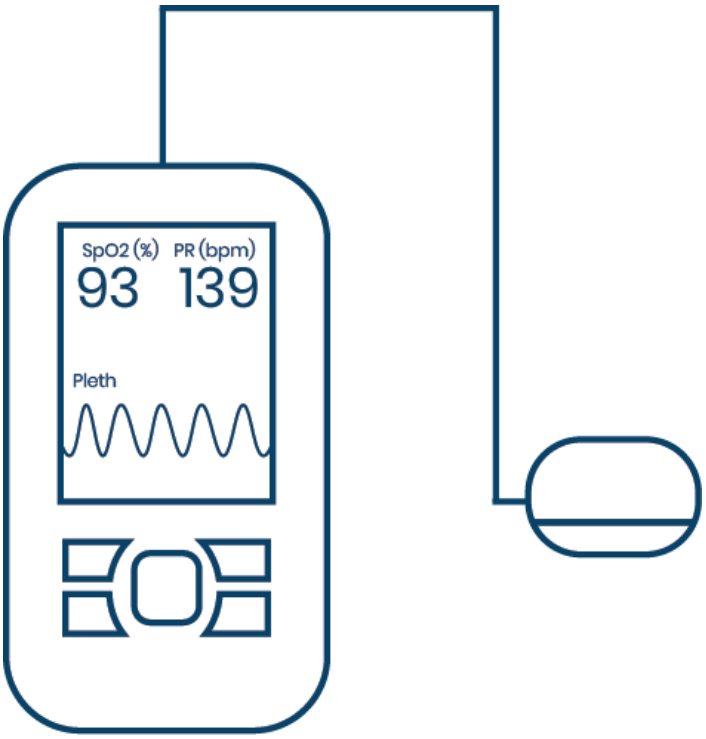
QUERY ALERT BOXES appear where there may be controversy or disagreement. In these cases, alert boxes provide background to the recommendations that are made in the body of the document. Relevant documents are cited and brief explanation of reasoning for current module content provided.

! ALERT 0.0

RECOMMENDATION ALERT BOXES appear where there are recommendations based largely on expert opinion or consensus, or to emphasize an important element of care. Relevant documents are cited and brief explanation of reasoning for current module content provided.

Respiratory Support

Pulse Oximeter



1 Clinical Problem

Assessment of oxygen saturation with a pulse oximeter is necessary in clinical management of patients in all hospital settings. In newborn care units, pulse oximeters are used during routine assessment on admission and for continuous monitoring of patients.

Pulse oximeters should also be used during treatment for all sick or at-risk patients, or those on oxygen therapy **(1.1a, 1.1b)**, CPAP **(1.2)**, or any form of assisted ventilation. **(1.3)**

1.1a Oxygen concentrator.

1.1b Oxygen cylinder.

1.2 Bubble CPAP.

1.3 Ventilator.

2 Assessment

Peripheral pulse oximetry is a non-invasive method of measuring pulse rate and oxygen saturation (oxygen bound to haemoglobin in the capillaries) using infrared & red light.

Pulse oximeters may be used to help determine the severity of an infant's illness by evaluating if blood oxygen saturation (SpO_2) is low and if respiratory support is needed. Pulse oximeters also may be used to assess the success of treatment and determine a need for increasing or decreasing respiratory interventions to achieve target SpO_2. Pulse oximeters may be:

- Fixed/tabletop **(2.1)** (for continuous reading of one patient)
- Handheld **(2.2)** (for continuous or spot reading of vital signs)

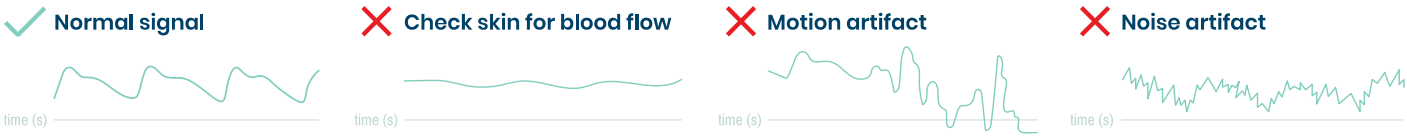
- Finger clip **(2.3)** (for spot reading of vital signs; **only appropriate for adult or older paediatric patients. NOT recommended for use in neonatal patients**)

2.1 Fixed pulse oximeter

2.2 Handheld pulse oximeter

2.3 Finger clip oximeter; not for use in neonatal patients.

To facilitate more accurate readings, patient signal should be both strong and stable. Patient movement, blood flow and external sources of light may impact the stability of the patient's trace. Examples of a "normal signal" and potential "poor traces" are below. **(2.4)**



2.4 Trace examples. Blood saturation is recorded over time.

The same tabletop and handheld pulse oximeter can be used for adult, paediatric, and neonatal patients. The alarm settings on the pulse oximeter should be changed accordingly and appropriately sized probes used. Probe size will vary depending on patient age. **Finger clip pulse oximeters are not recommended for use in neonatal patients.**

Normal SpO_2 for neonatal patients should be:

- **90%–100% if not on oxygen**
- **90–95% on oxygen (Alert 2.1)**

If SpO_2 readings are less than 90% 15 minutes after birth, the patient should be considered for supplemental oxygen therapy (see oxygen concentrator module). **Assess that the reading accurately reflects the clinical situation of the patient by checking the correspondence between oxygen saturations, heart rate, and clinical condition.**

? Alert 2.1 Oxygen targets in newborns

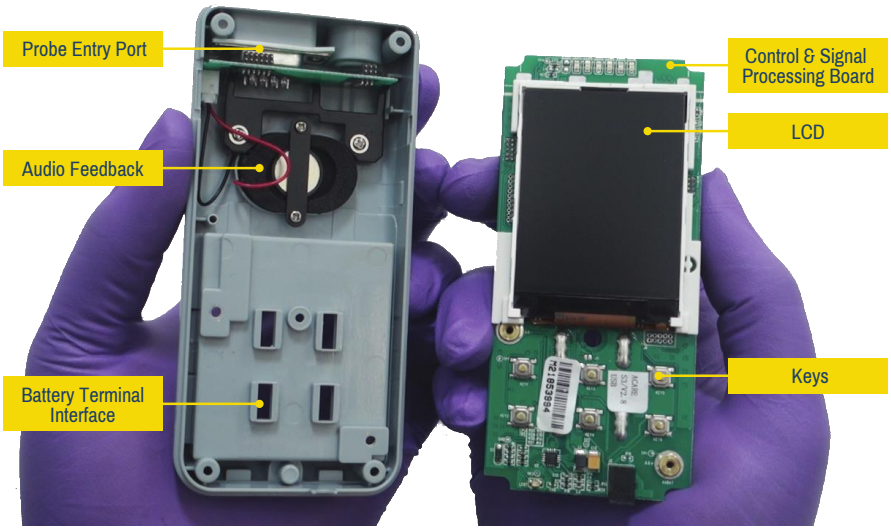
Exact oxygen saturation targets for premature newborns remains an area of controversy. However, most authorities agree that saturations between 90–95% are reasonable to minimise complications associated with low and high oxygen levels, including death, neurodevelopmental impairment, and retinopathy of prematurity.[1–4]

HOW IT WORKS

Oxygen is carried in the bloodstream by binding to haemoglobin in red blood cells. Each haemoglobin can carry four oxygen molecules and at that point becomes 100% saturated. The colour of blood depends on how much haemoglobin is saturated with oxygen. Haemoglobin that is carrying oxygen is called oxygenated haemoglobin (oxyhaemoglobin) and appears bright red, while deoxygenated haemoglobin (deoxyhaemoglobin) appears dark red.

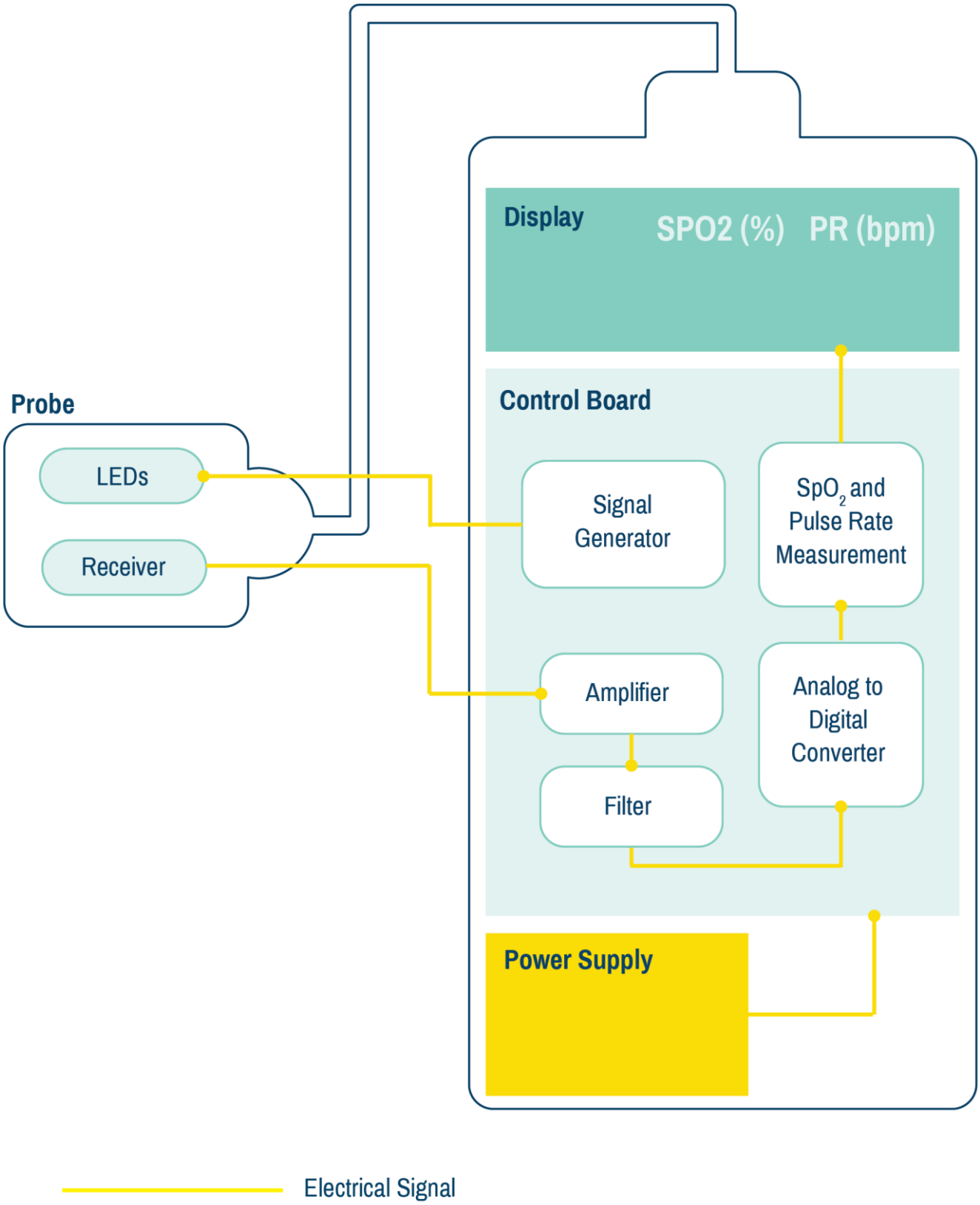
Pulse oximeters differentiate between the light absorbing properties of oxygenated haemoglobin and deoxygenated haemoglobin at two different wavelengths in red spectrum and use this differential and changes in local blood volume (resulting from heartbeat pulses) to calculate SpO_2 of pulsating arterial blood.

2.5 Main external components of a pulse oximeter.



2.6 Main internal components of a pulse oximeter.

TYPICAL DEVICE FLOW



MAIN COMPONENTS

The following device components should be similar regardless of model. However, specific locations, visual setup and component type may vary by brand and device model. Refer to model service and user manuals if different from the displayed model for more device-specific information.

LCD

A typical pulse oximeter displays the oxygen saturation, heart rate and the plethysmograph (or waveform of measured pulses). Some additional features may include perfusion index, battery power, alarm limits, and visible (and audible) warning lights and indicators.

Probe

The probe is made up of a sensor, cable and attachment head and is the first point of failure for most pulse oximeters.

The pulse oximeter probe sensor has two main components: a photodiode and a pair of LEDs that emit red and infrared light (typically in wavelengths of 660 nm and 940 nm, respectively). These components may be arranged transmissively (with the LEDs and photodetector arranged opposite to each other, with the body measurement site in between) or reflectively (with the LEDs and photodetector arranged next to each other, along the body; in this instance, the photodetector collects light signals bounced back from the body tissue). The most common of these probes is transmissive, making selecting the correct location critical to collect a measurement. When attached to the peripheral tissue (ear, finger or foot), oxyhaemoglobin partially absorbs the infrared light (at a 940 nm wavelength) and deoxyhaemoglobin (venous and capillary) absorbs red light (at a 660nm wavelength). The non-absorbed transmissive or reflective light signals are then detected by the photo detector.

Pulse oximeter probes may be proprietary to the device brand or generic. The entry port should exactly match the end of the probe. In most ports, there is only one way to correctly connect the probe. Generic probes may need an adapter to fit into the pulse oximeter device port. The adapter typically has a proprietary end and a generic entry port.

Control Circuit Board

Located internally, the control circuit board mainly consists of memory circuits, multiplexers, current to voltage converters, filters and a microprocessor.

The control PCB identifies and isolates the absorbance of the pulsatile fraction of arterial blood component light signals from the absorbance due to non-pulsatile light signals from capillary blood. These signals then undergo amplification, filtration and artefacts rejection. The microprocessor determines the percent of oxygen in the blood by comparing the concentration of oxyhaemoglobin to deoxyhaemoglobin at two different light wavelengths using the formula below.[5]

$$SpO_2 = \frac{O_2H_b}{O_2H_b + H_b} \times 100\%$$

O_2H_b = oxyhaemoglobin

H_b = deoxyhaemoglobin

Formula 2.1 SpO_2 Calculation

3 Management

Management covers how to use the pulse oximeter, including set up for a patient, patient commencement, care whilst on the device and removal of the patient from the device. These instructions are helpful for a biomedical engineer or technician both in user training and in assessing the appropriate functionality of the device.

SETTING UP FOR A PATIENT

1. Follow hand washing procedures.
2. Collect:
    - Pulse oximeter
    - Pulse oximeter probe
    - 70% alcohol solution
    - Cotton swab
3. Connect the probe. **(3.1)**
    - Check the shapes of the pulse oximeter port and the external probe sensor. If these are not the same size, an adapter is needed. This should be provided with the pulse oximeter.
    - Connect the probe connector to the pulse oximeter probe port, paying attention to the orientation of the probe and probe port. Be careful not to bend the pins as the probe is inserted.
4. Turn on pulse oximeter by pressing and holding the power button. **(3.2)** The display should turn on.

3.1 Connect probe.

3.2 Turn on pulse oximeter.

5 Check for a red light on the probe. If the probe displays a red light, take steps to prepare patient for device. If the probe does not display a red light, follow the guidelines in **Pulse Oximeter: Troubleshooting & Repair | If the pulse oximeter is turning on, but no trace is showing**.

6 Clean the pulse oximeter probe thoroughly using alcohol and a cotton swab.

STARTING A PATIENT

Follow hand-washing procedures. Select best location on patient to collect reading (e.g., on the wrist/foot or fingers/toes) and clean location with alcohol and gauze.

1 Adhesive (disposable) wrap probe:

- Remove the wrap probe from its packaging and peel from its plastic base.
- Place the part of the tape with the sensor, sensor side down, on the wrist whilst palm-side up or on the sole of the foot. The wrist is only suitable for preterm babies.
- Wrap the adhesive strip around the wrist or foot to secure in place.

2 Rubber (reusable) wrap probe: **(3.3)**

- Place the part of the wrap probe with the sensor, sensor side down, on the wrist whilst palm-side up or on the sole of the foot. **(3.4)**
- Wrap the rubber connecting strip around the wrist or foot **(3.5)**, thread through hole and tighten to secure in place. **(3.6)** Ensure the light and sensor are opposite each other.

3 Clip probe:

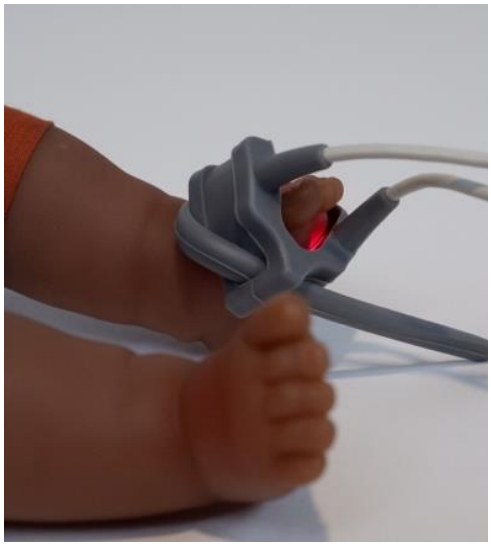
- Squeeze tips of the clip probe to open. Place gently on patient's fingers or toes and release.

Wrap and clip probes should be firmly placed without need to be held. **The probe should not be so tight as to cause pressure on the skin or impair circulation.**

3.3 Rubber wrap probe.

3.4 Rubber wrap probe is placed sensor-side down on the sole of the foot.

3.5 Wrap rubber connecting strip around foot.



3.6 Thread through hold & tighten to secure.

CARING FOR A PATIENT

1. Allow the patient's trace to stabilise before reading SpO_2 and heart rate. **(3.7)** These should correspond to patient's clinical condition. If they do not correspond, reposition the probe to ensure good contact with the patient.
2. Record SpO_2 and heart rate in patient documentation. Pulse oximeters are inaccurate for readings under 70%; readings between 20% and 60% do not correlate to clinical deterioration or improvement. **(Alert 3.1)** A low reading should alert you to look for a problem with the probe fixation, baby or oximeter.
3. If continuously monitoring patient, periodically check the sensor site **(3.8)** during monitoring for evidence of skin damage. If the pulse oximeter probe is attached too tightly, inappropriately or too long at one site, pressure sores may develop. The warmth of the light may irritate the skin of a premature baby which is why the probe needs regular repositioning.

3.7 Allow the patient's trace to stabilise.

3.8 Check sensor site for signs of skin damage.

Alert 3.1 Accuracy Thresholds for Pulse Oximeters

WHO-UNICEF Technical Specifications and Guidance for Oxygen Therapy Devices[8] lists accuracy of ±2% between 70–100% SpO_2 as a minimum requirement for all types of pulse oximeters. Additionally, during NEST360˚ technical testing and review, most (if not all) devices were only tested by the manufacturer to guarantee accuracy within a certain precision between 70–100%.

REMOVING A PATIENT

Removing the probe from the patient varies based on the type of probe in use:

1. **If using an adhesive wrap probe:** peel adhesive away from patient and pull probe away from patient. Disinfect probe site on patient and wrap probe with 70% alcohol if reusing.
2. **If using a rubber wrap probe:** unthread rubber connecting strip through the hole. Pull probe away from patient. Disinfect probe site on patient and the wrap probe with 70% alcohol.
3. **If using a clip probe:** press on the tips of the clip probe to open. Gently pull away from patient. Disinfect probe site on patient and clean probe with 70% alcohol.

4 Infection Prevention

Routine and adequate cleaning of medical devices is critical to prevent hospital-acquired infections in newborn care units.

CLINICAL INFECTION PREVENTION

1. Clean hands with soap and water or 70% alcohol before and after assessing a patient using a pulse oximeter or handling any probes that will be used on a patient.
2. Ensure that all patient-related consumables (including probes) are new or have been cleaned thoroughly before use. Any patient-related consumables must be cleaned before they are used to assess another patient using the pulse oximeter.
3. When using the pulse oximeter, the device should be placed in a secure location to prevent drops and breakages. **The device should never be placed inside a bed, cot or bassinet.**

DISINFECTION AFTER USE

1. Clean reusable probes with 70% alcohol. Adhesive probes are specified for single-use; if reusing, disinfect sensor with alcohol. **(Alert 4.1)**
2. If pulse oximeters or patient consumables (including probes) are not cleaned thoroughly before use, infection can be transmitted. Care should be taken particularly for consumables marked as single-use but are reused (such as adhesive wrap probes). Between patients, wipe down the pulse oximeter with alcohol. **(4.1)** Be careful not to submerge or drip alcohol onto the pulse oximeter or any of its cables.

4.1 Wipe down the pulse oximeter probe and pulse oximeter with alcohol-soaked gauze between patients.

Alert 4.1

While many pulse-oximeter probes are designed to be single use devices, cost and logistical constraints make this unrealistic in many low resource settings. Recommendations for cleaning single use devices were taken from Infection Prevention and Control: Reference Manual for Health Care Facilities with Limited Resources, Jhpiego.[7] Vigilance by healthcare workers to assess that pulse-oximeter readings correlate to patient's heart rate and clinical condition is especially critical when re-using probes meant for single-use. It is not known how rapidly pulse-oximeter probes degrade or become inaccurate with re-use.

BMET INFECTION PREVENTION

1. Any piece of equipment used in providing patient care must be handled carefully, as it may be contaminated and have the potential to spread infection.
2. Clean and disinfect pulse oximeter housing and components whilst wearing PPE as appropriate (e.g., rubber gloves, apron, face protection, etc.) **before any repairs or maintenance are made.**
3. Avoid any contact between used piece of equipment and skin, mucosa or clothing.
4. Post-maintenance decontamination of all tools and surfaces used should be done with 70% alcohol or according to manufacturer guidelines. Do not use equipment until it has fully dried following decontamination.

? Alert 4.2 Disinfecting Equipment

Disinfection of equipment should always comply with manufacturer guidelines. WHO recommends 0.5% dilution of chlorine (0.5% or > 100ppm available sodium hypochlorite) as the standard disinfectant for materials and surfaces contaminated by blood or body fluids.[8] For metal and rubber surfaces, which may be corroded by chlorine, 70% alcohol is also commonly utilised for low level disinfection.

Other appropriate low-level disinfectants include quaternary ammonium, improved hydrogen peroxide and Iodophor germicidal detergent.[7] Phenolic germicidal detergent is also identified but should not be used in neonatal wards since affordable, effective alternatives are available; and, there are concerns it may cause hyperbilirubinemia and/or neurotoxicity in neonates.[9]

See dedicated NEST360° module on Infection Prevention and Control for further details on risks, benefits and utilisation of chemical disinfectants. For comprehensive guidance on infection prevention and control we recommend utilising Reference Manual for Health Care Facilities with Limited Resources Infection Prevention and Control (Caston-Gaa & Ruparelia, 2018).

5 Complications

Equipment in newborn care units are highly specialised. Without proper knowledge and skills, this equipment can be potentially dangerous for the infants, families and care providers.

CLINICAL COMPLICATIONS

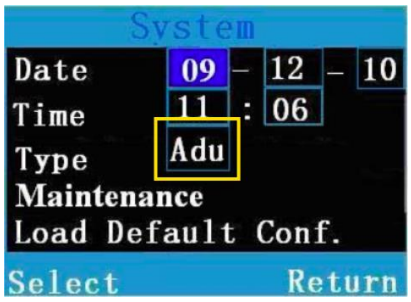
- **Misdiagnosis:** a poor trace **(5.1)** may contribute to misdiagnosis and can result from:
  - **Hypovolaemia/hypotension:** poor peripheral perfusion may cause a false reading
  - **Movement:** may create noise on the trace or delay the stabilisation of the trace
  - **Peripheral cyanosis/anaemia:** poor oxygen delivery to the tissues, compromises measured saturation. **Saturation readings below 70% are not reliable as clinical guides.**
  - **Hypothermia:** causes poor peripheral perfusion, which can provide an inaccurate representation of the oxygen saturation within the blood.
- **Pressure sores:** if the pulse oximeter probe is attached too tightly, inappropriately or too long at one site, pressure sores may develop. The warmth of the light may irritate the skin of a premature baby which is why the probe needs regular repositioning.

DEVICE COMPLICATIONS

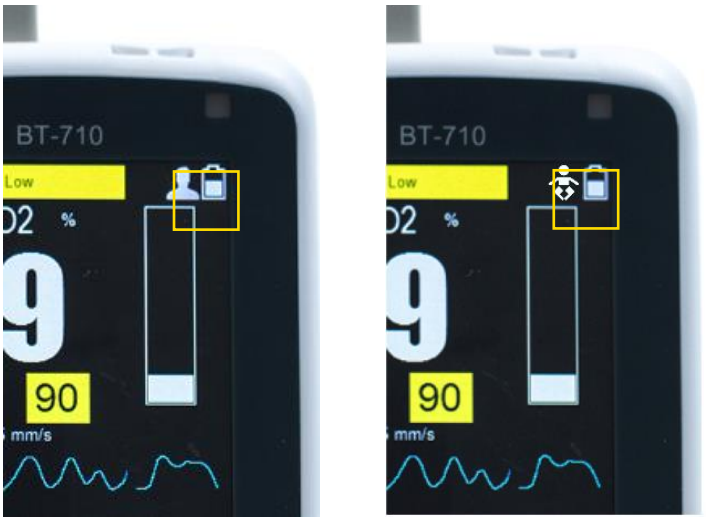
- **Poorly fitting probes can lead to inaccurate saturation measurements:** if the probe is too large for the patient, the probe will shift in place, creating issues both in terms of inconsistent measurement due to multiple contact points as well as the potential to have

no direct contact points with the skin. If the probe is too small for the patient, blood flow may be constricted. Also, the light and sensor must be positioned opposite each other.

- **Patient movement:** as the patient moves, the contact point between the probe and the patient moves along the patient's skin. This movement provides an inconsistent measurement because it samples from various contact points in the skin, rather than remaining in the same contact point of tissue. This may cause the reading to be noisy or take time to stabilise. Some oximeters designed for newborns have purpose-built motion-cancelling algorithms to minimise false readings and alarms.
- **Strong light:** if strong light (e.g., phototherapy, exam lights, or sunlight) is on a probe sensor, the light signal from the pulse oximeter probe may be drowned out by the stronger environmental light, leading to incorrect results. A cloth covering of the sensor site will protect it from bright light.
- **Oximeter alarm settings:** pulse oximeters may have adult, paediatric, and neonatal settings in the same device. **(5.2)** Pulse oximeters are usually set to a default adult setting. If the pulse oximeter is not set to neonatal parameters, alarms may sound inappropriately. If settings are visually incorrect, check the user manual for device-specific instructions on changing the settings.



5.1 Pulse oximeter set to adult.



(A) (B)

5.2 Icons designating adult (A) and neonatal (B) settings.

6 Care & Maintenance

Biomedical engineers and technicians are responsible for second-line care and maintenance to ensure equipment lasts to their potential lifetime.

POWER SOURCE

A pulse oximeter is powered by replaceable or rechargeable **(6.1)** batteries. If using a rechargeable device, users should regularly charge the pulse oximeter when not in use to ensure power in the event of an outage.

6.1 Rechargeable pulse oximeter with power port and charging cable.

WARD LOCATION

The device and associated probes should be stored in a clean, dry, and secure area. When using the pulse oximeter, the device should be placed in a secure location to prevent drops and breakages. The device should never be placed inside a bed, cot or bassinet. All patient-related consumables should be stored in a clean, dry location. Keep cleaned probes separate from those waiting to be cleaned. Any cables should be loosely wrapped and secured, preventing sharp bends, pinches or kinks, which will decrease their lifetime.

DEVICE CALIBRATION

Manufacturers do not recommend calibration for any pulse oximeter components. Pulse oximeters automatically remove any variation or gain because the pulse oximeter algorithm uses a data ratio calculation to assess SpO_2.

DECOMMISSIONING

Assuming appropriate use and consistent maintenance, a pulse oximeter may last three years or longer. Reusable pulse oximeter probes may last up to six months or longer. Product developers define the probe cabling and connections to the sensor and probe head as the weakest parts of the device. Probes should be handled with care and users should be given consistent reminders about the correct use of the probe to extend its life.

Pulse oximeters are relatively low-cost; in such models, component breakages (i.e., control PCBs and LCDs) may cost more to repair than to replace. In those cases, decommissioning may be the most sensible option. A notable exception to this is the pulse oximeter probe, which is typically considered a long-lived consumable rather than a spare component. If the LCD or control PCB is still in good condition, these parts may be repurposed for other devices. Typically, the control PCB should only

be repurposed for devices of the same manufacturer and model, although components from the circuit board may be desoldered and repurposed independently.

PREVENTIVE MAINTENANCE

After Each Use

- [ ] Between patients, turn off the pulse oximeter. Wipe down the pulse oximeter housing and probe components with 70% alcohol. Be careful not to submerge or drip alcohol onto the pulse oximeter or any of its cables.
- [ ] Check all parts are present and connected.
- [ ] Check cables are not twisted and remove from service if any damage is visible.

See **Pulse Oximeter: Disinfection After Use** and **Alert 4.1** for more information.

Weekly

- [ ] Unplug, remove equipment cover (if applicable), clean and disinfect exterior surface with 70% aclohol
- [ ] Tighten any loose screws and check parts are fitted tightly.
- [ ] Check operation of all lights, indicators and visual displays.
- [ ] Check probe disconnection alarm.
- [ ] Document preventive maintenance actions taken.

Monthly

- [ ] Perform **Weekly** preventive maintenance steps.
- [ ] Test the pulse oximeter functionality:
    - [ ] Set up the device for use. Turn on the pulse oximeter. Connect probe and check for a red light.
    - [ ] Connect a clip probe and test readings on your finger for normal saturations (above 90%).
- [ ] Document preventive maintenance actions taken.

Quarterly

- [ ] Perform **Monthly** preventive maintenance steps.
- [ ] Assess the control PCB and battery terminals for any liquid, rust or electrical damage.
- [ ] Document preventive maintenance actions taken.

Annually

- [ ] Perform **Quarterly** preventive maintenance steps.
- [ ] Confirm supply of spare pulse oximeter probes and batteries are adequate to support estimated replacement for next year.
- [ ] Document preventive maintenance actions taken.

7 Troubleshooting & Repair

Biomedical engineers & technicians are responsible for providing rapid maintenance, troubleshooting & repair support for users.

PREPARE FOR REPAIR

ACCESSIBLE TOOLS	SPARE PARTS	DEVICE CHECKLIST
Digital multimeter Philips, star & flat head screwdrivers Needle-nosed pliers Wire strippers Allen keys Fine grain sandpaper	Probe Batteries Charger (if applicable) LCD screen Control PCB Buttons	☐ Pulse oximeter ☐ Pulse oximeter probe ☐ Charger (if applicable) ☐ Probe adapter (if applicable)

TROUBLESHOOTING FAILURES

The pulse oximeter does not turn on.

Probable Cause: Discharged or damaged batteries

Components to Check: Battery level (if rechargeable) or voltage and physical condition
Power switch physical integrity & continuity
Control PCB physical & electrical integrity and continuity

The pulse oximeter turns on, but no trace is displayed.

Probable Cause: Damaged or incompatible probe

Components to Check: Probe physical condition, security & compatibility
Control PCB physical & electrical integrity and continuity

The pulse oximeter turns on, but buttons do not respond to pressure.

Probable Cause: Fluid damage

Components to Check: Internal button physical condition

The pulse oximeter turns on, but takes time to stabilise the trace.

Probable Cause: Movement or light interference

Components to Check: Patient movement
Measurement site perfusion, condition & cleanliness
Environmental ambient light

Discoloured or black spots obstruct view of the display.

Probable Cause: Damaged LCD

Components to Check: LCD physical integrity

REPAIR & REPLACE

Where technically possible and not likely to obstruct clinical care, repairs may be made within the newborn care ward. Use discretion to determine if this is appropriate or if the device should be removed to the biomedical workshop for more testing or repair.

Testing, repairing & replacing the batteries

The pulse oximeter battery is typically responsible for powering all display, measurement and alarm functions. If the pulse oximeter is not turning on, the batteries should be visually assessed for rust or other physical damage. **(7.1)** Depending on the severity of the damage, rust or other build-up present on the battery terminals can be gently scraped off with very fine sandpaper or dissolved with an appropriate agent depending on battery type (vinegar for alkaline batteries and a paste of baking soda with water if acidic). **Wear goggles and rubber gloves throughout the cleaning process.**

Both the voltage across the battery terminals and the continuity of the wires from the battery to the control board should be tested and the battery or wires replaced if necessary. Specifications for battery voltage should be available in the manufacturer's service manual.

(A) (B)

7.1 (A) Battery build-up over time (B) New battery.

Testing, repairing & replacing the probe

The pulse oximeter cabling and connections to the sensor and probe head are the weakest parts of the device. Remove the probe by holding the probe close to the base and gently extract it. **The probe cable should never be pulled on to remove the probe from the device.** Replace with a new probe and test SpO_2 levels. **(7.2, 7.3)**

Pulse oximeter probes are typically difficult to fully repair; best practice is to replace with a new probe when possible. Generic sensors are not always compatible with all pulse oximeters, even if the probe goes easily into the probe port. If a red light is showing on the probe sensor but no trace is displayed, the generic sensor may not be compatible with the pulse oximeter model. **(7.4)**

7.2 Remove probe by base connector.

7.3 Visually compare probe and probe port.

7.4 Not all probes will work with all pulse oximeters.

Testing & replacing control PCB and associated components

In most cases, if one element of the control PCB has malfunctioned, the entire control PCB should be replaced. Visually assess the PCB for burnt or damaged components. **(7.5 – 7.9)** Internal wiring continuity leading from the power supply to the control PCB and from the control PCB to various controls may also be assessed for replacement.

! Alert 7.1

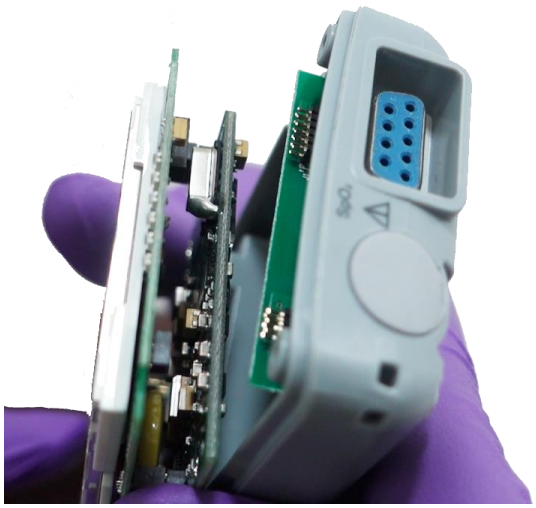
Printed Circuit Boards (PCBs) contain components that are sensitive to electrostatic discharge (ESD) and can damage the board if not handled properly. As when handling any ESD-sensitive PCB, observe standard ESD safety procedures. **Pulse oximeter circuit boards are very small and easy to damage.** If repairs are needed on the circuit boards, perform all maintenance gently and with extreme caution to avoid unnecessary damage.

7.5 Unscrew the back of the pulse oximeter.

7.6 Gently pry off the back housing.

7.7 Open pulse oximeter to view components.

7.8 Remove key pad and assess components.



7.9 Gently pull up circuit boards to replace.

Assessing & repairing the buttons

Check that the device is disconnected from all sources of power before visually assessing the buttons for fluid damage internally. **(7.10, 7.11)** If fluid is present near or on the buttons or control PCB, wipe the fluid from the unit thoroughly using a non-abrasive cloth.

If the buttons are damaged beyond repair, contact the manufacturer to request a replacement part.

7.10 Confirm location on circuit board for key components.

7.11 Check the keys for water damage.

Assessing light & movement interference

If strong light (e.g., phototherapy, exam lights, or sunlight) is on a probe sensor, the light signal from the pulse oximeter probe may be drowned out by the stronger environmental light, leading to incorrect results. A cloth covering of the sensor site will protect it from bright light.

If a patient is particularly active, the contact point between the probe and the patient may move along the patient's skin. This movement provides an inconsistent measurement because it samples from various contact points in the skin, rather than remaining in the same contact point of tissue. This may cause the reading to be noisy or take time to stabilise. Some oximeters designed for newborns have purpose-built motion-cancelling algorithms to minimise false readings and alarms.

Testing & replacing the LCD

The LCD is typically damaged due to incorrect use, particularly when the user pushes with too much force on the screen. If the damaged areas do not hinder viewing or use of the display, the pulse oximeter may be used without significant issues. However, if the damaged areas prevent easy use, the LCD should be replaced. **(7.12)** Contact the manufacturer to request a replacement part specific to the pulse oximeter model. In some cases, the LCD is soldered on to the circuit board; in these instances, request a replacement board as necessary.

7.12 If the LCD is removable, gently prise off the housing and replace.

? **Alert 7.2** Repurposing Parts

In some cases, parts on the unit may be replaced with a repurposed or recycled part from another piece of equipment being used for parts. **Repurposed parts should be considered with caution and guidance from the manufacturer to ensure specifications of the repurposed part is compatible with the equipment.** This includes spare parts and accessories that may not be compatible with multiple systems.

8 References

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4. Polin, R. A. & Bateman, D. Oxygen-Saturation Targets in Preterm Infants. *N. Engl. J. Med.* 368, 2141–2142 (2013).
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8. World Health Organization, Regional Office for the Western Pacific, World Health Organization, & Regional Office for South-East Asia. *Practical guidelines for infection control in health care facilities.* (World Health Organization, Regional Office for Western Pacific ; World Health Organization, Regional Office for South-East Asia, 2004).
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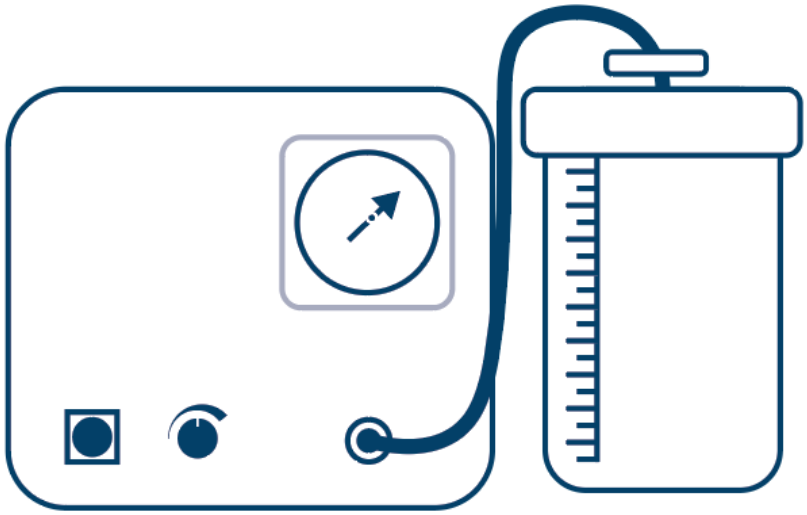
Respiratory Support

Suction Pump



1 Clinical Problem

Suctioning is an essential procedure within multiple hospital settings. In newborn care units, suction pumps are used to remove obstructions from blood or secretions in the mouth, nose or upper airway.

Suction pumps may be used in newborn patients to help remove obstructions from blood or secretions in the mouth, nose, or upper airway.

2 Assessment

A suction pump uses an internal pump to create negative pressure.

A suction pump may be tailored to adult **(2.1)** or paediatric patients. **(2.2)** Although adult suction pumps may be able to reach the therapeutically recommended suctioning levels for paediatric or neonatal patients, the vacuum range is much higher and it is difficult or impossible to control for the low ranges required for neonatal patients. **Use of an adult pump to treat neonatal patients is not encouraged.**

2.1 Adult suction pump.

2.2 Paediatric suction pump.

Low pressure suctioning may also be provided through the use of penguin suction devices, reusable devices made of a flexible silicone, which can be used to provide low pressure suctioning. **(2.3) Penguin suction devices can be sterilised with autoclaving or high-level disinfection with**

boiling water or chemical processing. Although suction bulbs **(2.4)** may also be used for low-level suctioning, they are not autoclavable, are difficult to clean, and are not recommended due to greater infection risk between patients.

2.3a Penguin suction device.

2.3b Open penguin suction device.

2.4 Suction bulb: not recommended.

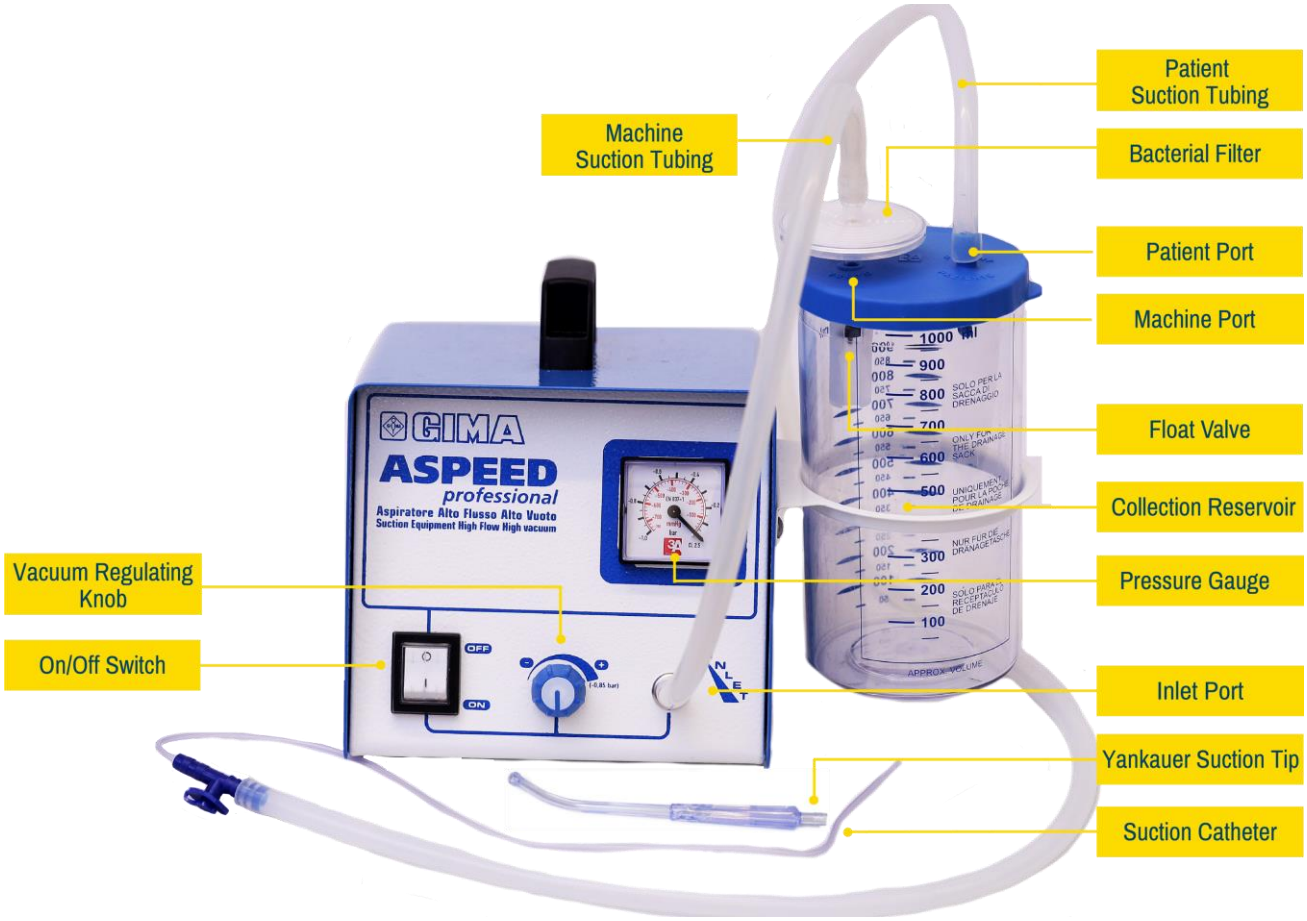
When using a suction pump, neonatal patients should be suctioned gently, no deeper than the eye can see and only within a range of 60 to 100 mmHg of negative pressure and for a period less than 10 seconds.[1]

HOW IT WORKS

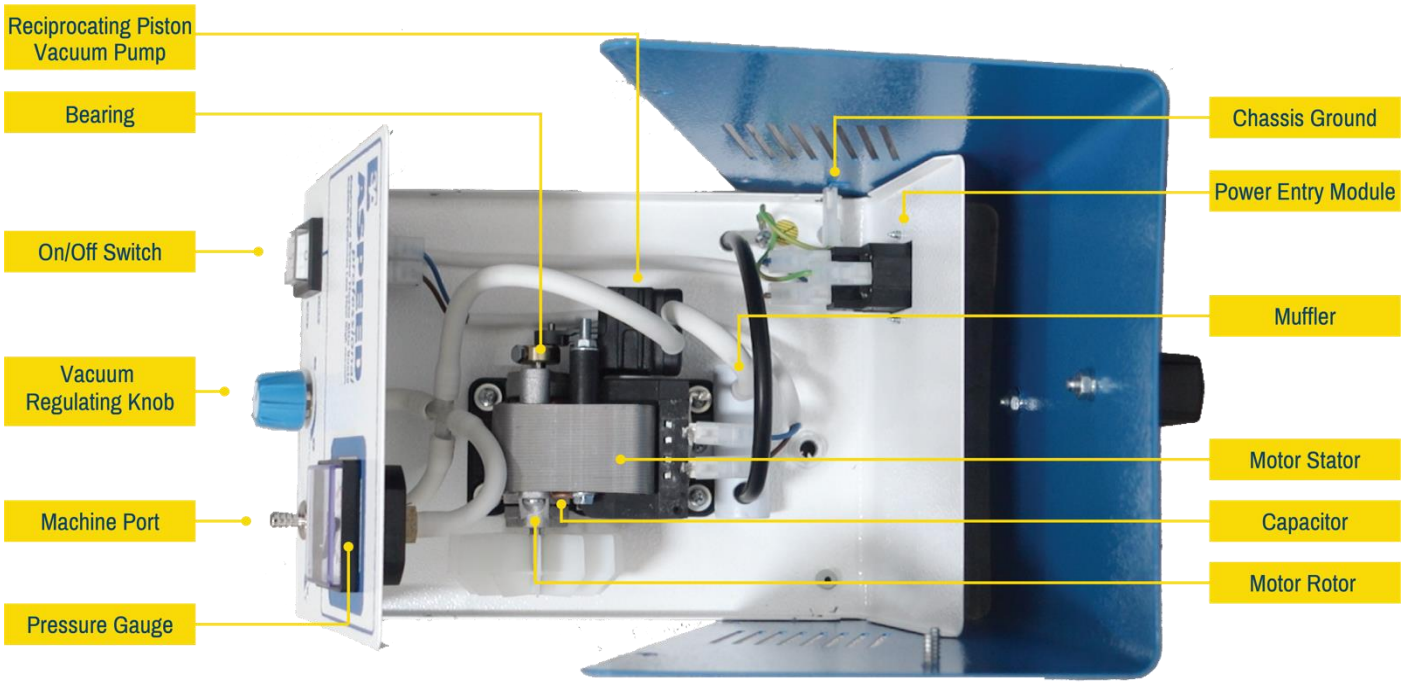
A suction pump uses an internal pump to create a partial vacuum in a collection reservoir through which suction fluid is collected. The partial vacuum creates negative pressure inside the **collection reservoir** and draws fluid from the patient via device tubing and suction catheter and into the collection reservoir. The collection reservoir sits between the suction pump and suction catheter. Inside the collection reservoir is an overflow **float valve** to prevent suction fluids from entering the machine. An **antibacterial filter** is placed between the collection reservoir and machine to prevent bacteria from entering into the suction pump.

The suction system should be sealed (not exposed to atmosphere) from end to end. When there is a leakage or crack in any part of the system, the atmospheric pressure will find a shorter route to balance the pressure, preventing the device from suctioning appropriately. Suction pumps can either be driven by an electric motor or manually by a foot operated pedal.

Standard external and internal device components are annotated below in **Figures 2.5** and **2.6**. Components should be similar regardless of model. However, specific locations, visual setup and component type may vary by brand and device model. Refer to service and user manuals if model in use is different from the displayed version.

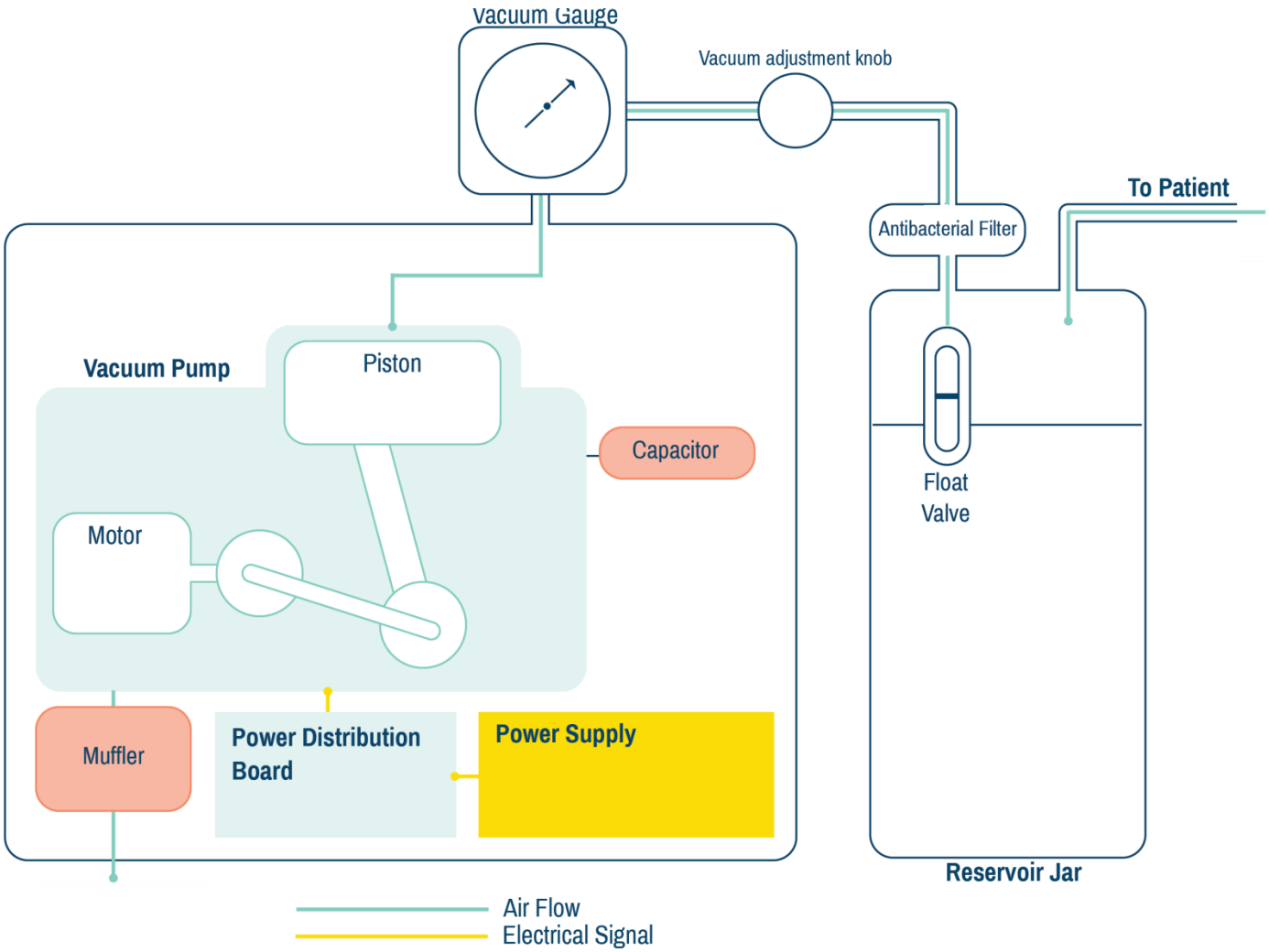


2.5 Major external components of a suction pump.



2.6 Major internal components of a suction pump.

TYPICAL DEVICE FLOW



MAIN COMPONENTS

The following device components should be similar regardless of model. However, specific locations, visual setup and component type may vary by brand and device model. Refer to model service and user manuals if different from the displayed model for more device-specific information.

Bacterial Filter

All suction pumps have an antibacterial filter fitted between a collecting reservoir and the machine. Their function is to stop any bacteria or pathogens from the suction fluids from penetrating into the pump and eventually into the environment. Bacterial filters have a direction, which is usually indicated on the filter. **Always make sure it is fitted in the correct orientation and location for effective filtration.** Some suction pumps have a secondary bacterial filter fitted internally in the machine.

Collection Reservoir

Container that collects suctioned fluids. The collection reservoir lid must be well sealed to the collection reservoir to ensure the system retains vacuum and have an overflow float valve installed to monitor fluid level.

Float valve

An overflow float valve is fitted in the collection reservoir to protect the machine and pump from damage. Its function is to stop suctioning when the collection reservoir is filled with fluids. As the fluids are filling, it pushes the floater up until it closes the suction inlet port thereby blocking vacuum at the catheter end. **The overflow float valve must be placed in the correct orientation to work properly.** If the suction pump is used without a float valve or with a non-functioning float valve, when the collection reservoir is full, body secretions/fluids may overflow into the pump inside the machine and damage the pump (by short circuiting the motor or clogging the internal pump assembly).

Vacuum pump

The pump is responsible for generating vacuum in the system. Pumps are typically diaphragm and piston or vane pumps. Diaphragm and piston vacuum pumps draw air through a series of valves as the volume of the cylinder changes continuously, creating a partial vacuum. The diaphragm or piston is driven by a motor. Vane vacuum pumps consist of a rotor, which is mounted eccentrically and vanes that move radially outwards under spring force as they rotate inside circular housing. Continuous vane rotation creates the vacuum.

Vacuum gauge

Indicates the magnitude/strength of suction set by the user using the adjustment knob.

Vacuum adjustment knob

Used to regulate the amount of vacuum in the system. For neonates, the vacuum range is usually set between **-60 to -100 mmHg**. The knob works by admitting atmospheric air into the system.

Muffler

At the exhaust side of the pump, a muffler is fitted to reduce noise as the pump expels air into the atmosphere.

Prime mover

The source of power that drives the vacuum pump to generate suction, the prime mover can be a foot pedal or an electric motor. Electric motors may be powered via AC or DC power. DC motors are used in battery powered or rechargeable suction machines. DC motors may pose a challenge to maintain because brushes or commutators can wear out and they additionally require adaptors for charging (AC mains power to DC). AC motors are inductive and do not require brushes or a commutator. They require a starting capacitor.

Capacitor

Used in AC motor powered suction pumps, capacitors start and keep the motor running. The most common capacitor used in small suction units is a capacitor start motor or a permanent split capacitor. These types of capacitors are embedded in the winding circuits.

3 Management

Management covers how to use the suction pump, including set up for a patient, patient commencement, care whilst on the device, and removal of the patient from the device. These instructions are helpful for a biomedical engineer or technician both in user training and in assessing the appropriate functionality of the device.

SETTING UP FOR A PATIENT

1 Collect: **(3.1)**

- Suction pump with collection reservoir
- Suction pump filter (if not already attached to pump)
- Short suction tubing
- Long suction tubing
- Appropriately sized suction catheter or Yankauer suction tip
- Water

2 Visually inspect the suction pump's collection reservoir. If there are secretions present **(3.2)**, dispose of the secretions appropriately, clean the reservoir and device tubing and reassemble. For more details on cleaning, refer to **Suction Pump: Infection Prevention: Disinfection After Use**.

3.1 Materials needed to use a suction pump.

3.2 Suctioned fluid in reservoir.

3 If a filter is not already attached to the collection reservoir, place the filter in the lid of the collection reservoir at the port labelled "Vacuum." Using the short suction tubing, connect the inlet of the suction filter on the suction pump collection reservoir to the suction pump outlet port. (3.3)

4 Connect long suction tubing to the collection reservoir outlet port labelled "Patient." **(3.4)**

5 Plug power cable into device. **(3.5)** Plug the power cable into socket outlet and turn on suction pump.

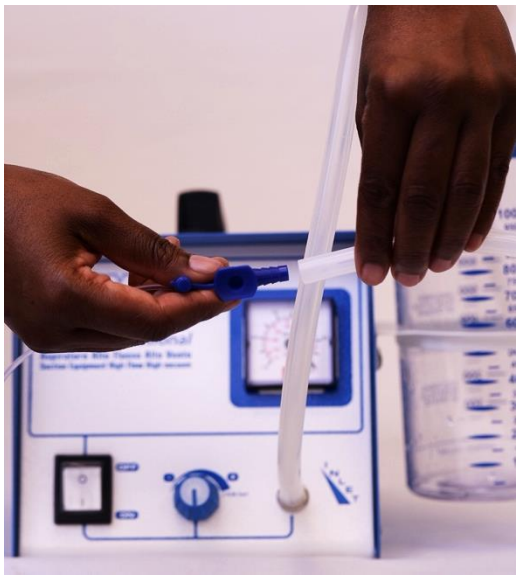
3.3 Connect short tubing to filter & inlet port.

3.4 Connect long suction tubing to collection reservoir outlet labelled "patient."

3.5 Connect power cable to device.

6 Connect the suction catheter or Yankauer suction tip to the long suction tubing. **(3.6)**

7 Using the suction regulator, adjust the suction vacuum to the desired level within safe neonatal levels (60 to 100 mmHg). Test the suction functionality by suctioning a small amount of water. **(3.7)**



3.6 Connect suction catheter or Yankauer suction tip to long sucker tubing.

3.7 Adjust suction vacuum to desired safe level and test by suctioning water from container.

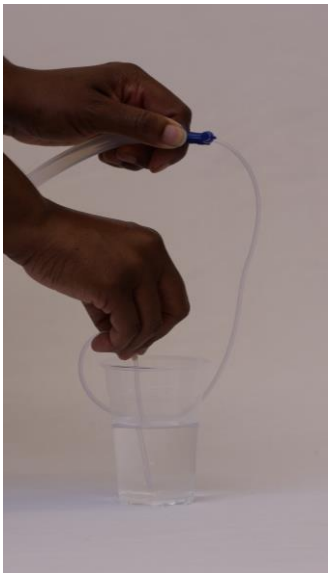
STARTING A PATIENT

1. Collect:
    - Appropriately sized suction catheter or Yankauer suction tip
    - Suction pump with collection reservoir and tubing in place
    - Sterile water or saline
2. Follow hand washing protocol.
3. Plug suction machine into power outlet and turn on.
4. Connect suction catheter marked with appropriate suction depth or Yankauer suction tip to long suction tubing. (3.11)
5. Using the suction regulator, adjust the suction vacuum to the desired level, maintaining safe vacuum levels for neonates. Test the suction functionality by suctioning the water.
6. **When using a suction catheter:** If using a suction catheter: determine suction depth by measuring from the nose to the ear and halfway back. Mark this distance with a small piece of tape. Interrupt vacuum by pinching the catheter or blocking vacuum hole on the catheter and insert **gently** into the patient's mouth or nostril to the point marked by the tape. When introducing catheter into the nose do so following the floor of the nose. Release the pinch on the catheter slowly as you withdraw the catheter from the mouth or nostril, gently rotating until it is completely removed. **(3.12)**
7. **For thicker secretions or meconium, it may be necessary to use a Yankauer suction tip.** If using a Yankauer suction tip, suctioning should only be conducted as far as can be visually assessed. Some Yankauer suction tips may require a hole at the hub of the sucker to be occluded for suctioning pressure.
8. Allow the patient to visibly recover from the procedure. While waiting, suction sterile water or saline with the catheter to rinse. **(3.13)** Repeat this process on the other side of the mouth or nostril.
9. Repeat steps 5 through 7 until all secretions are removed. **Suctioning should be a gentle procedure. Do not suction too vigorously or too long.** Suction only until the reservoir is ¾

full; if it reaches this point, remove collection jar and dispose of contents before continuing.

3.11 Connect suction catheter or Yankauer suction tip to long sucker tubing.

3.12 Pinch catheter and insert gently in nostril to point marked by tape.



3.13 Rinse catheter with water.

CARING FOR A PATIENT

Observe suctioned contents carefully whilst suctioning procedure is taking place:

- If fresh blood starts to be suctioned, trauma may have been caused to the oral or nasopharyngeal cavities. Decrease the force with which the suction catheter is being inserted into the patient's nose or mouth and the frequency with which suctioning is being conducted.
- If stomach contents are being suctioned, the patient's suction catheter is being inserted into the oesophagus. Recheck the suction depth measurement.

REMOVING A PATIENT

Gently withdraw the suction catheter from the patient's passageway.

4 Infection Prevention

Routine and adequate cleaning of medical devices is critical to prevent hospital-acquired infections in newborn care units.

CLINICAL INFECTION PREVENTION

1. Clean hands with soap and water or alcohol before and after initiating treatment using a suction pump or handling any tubing that will be used on a patient. Refer to local guidelines for extensive recommendations.
2. Ensure that all patient-related tubing and consumables (including suction catheters and collection reservoirs) are new or have been cleaned thoroughly before use (if following re-use guidelines). Any patient-related tubing must be cleaned (following the ward protocol) before it is used to suction another patient. Tubing should be hung to dry after disinfection and should not touch the floor or other unsanitary surfaces whilst drying.
3. When re-using suction tubing there is a risk of infection if inadequately cleaned. If the machine is not cleaned after each use, it can become a source of infection for patients in the ward. **Suction catheters and Yankauer suction tips should never be reused unless they can withstand high-level disinfection or boiling.** Suction catheters and Yankauer suction tips that will be used for one patient may be rinsed with water, labelled and left at the patient's bedside. **(Alert 4.1)**
4. All patient-related consumables should be stored in a clean, dry location. Tubing should be stored in loose rolls, preventing sharp bends and kinks, which will decrease its lifetime

Alert 4.1

Electrical suction pumps and associated equipment, if not re-processed or cleaned appropriately between patients, pose a significant infection risk. Please refer to WHO Technical Specifications for Resuscitation Equipment chapter 2.6 or Infection Prevention and Control: Reference Manual for Health Care Facilities with Limited Resources, Jhpiego Module 6 for more detailed guidance on reprocessing of equipment associated with suction pumps.[1,2]

DISINFECTION AFTER USE

1. Gently disconnect the suction catheter or Yankauer suction tip from the suction tubing and discard appropriately. If catheter or Yankauer suction tip can withstand high-level cleaning, immediately begin hospital protocol for disinfection. **Delay in initiating cleaning of reused medical devices can lead to the need for more intensive cleaning procedures to remove pathogens.**
2. Turn off and unplug the suction pump, if not using with another patient. Check filter. If filter is obviously dirty or wet, replace. (4.1) Refer to user manual for specific instructions on when to change the filter.

3. Disinfect the suction pump pressure gauge controls using gauze and 70% alcohol.
4. The suction pump housing should be cleaned according to ward guidelines for surface disinfection.
5. All tubing and collection reservoir should be cleaned after each patient.
    - Remove the collection reservoir from suction pump. **(4.2)** Dispose of contents and disinfect reservoir appropriately, **wearing gloves, a mask and apron to ensure staff safety**. Return collection reservoir to suction pump and store in secure location until next use.
    - Remove short and long suction tubing pieces. Follow hospital protocol for tubing disinfection.

4.1 Check if the filter is dirty.

4.2 Remove the collection reservoir.

BMET INFECTION PREVENTION

1. Any piece of equipment used in providing patient care must be handled carefully, as it may be contaminated and have the potential to spread infection.
2. Clean and disinfect suction pump housing and components whilst wearing PPE as appropriate (e.g., rubber gloves, apron, face protection, etc.) **before any repairs or maintenance are made.** Avoid any contact between used piece of equipment and skin, mucosa or clothing.
3. Post-maintenance, decontaminate all tools and surfaces used with 70% alcohol or according to manufacturer guidelines. Do not use equipment until it has fully dried following decontamination.

? Alert 4.2 Disinfecting Equipment

Disinfection of equipment should always comply with manufacturer guidelines. WHO recommends 0.5% dilution of chlorine (0.5% or > 100ppm available sodium hypochlorite) as the standard disinfectant for materials and surfaces contaminated by blood or body fluids.[3] For metal and rubber surfaces, which may be corroded by chlorine, 70% alcohol is also commonly utilised for low level disinfection.

Other appropriate low-level disinfectants include quaternary ammonium, improved hydrogen peroxide and Iodophor germicidal detergent.[2] Phenolic germicidal detergent is also identified but should not be used in neonatal wards since affordable, effective alternatives are available; and, there are concerns it may cause hyperbilirubinemia and/or neurotoxicity in neonates.[4]

See dedicated NEST360° module on Infection Prevention and Control for further details on risks, benefits and utilisation of chemical disinfectants. For comprehensive guidance on infection prevention and control we recommend utilising Reference Manual for Health Care Facilities with Limited Resources Infection Prevention and Control (Caston-Gaa & Ruparelia, 2018).

5 Complications

Equipment in newborn care units are highly specialised. Without proper knowledge and skills, this equipment can be potentially dangerous for the infants, families and care providers.

CLINICAL COMPLICATIONS

- **Low oxygen levels (hypoxia):** if a patient is on oxygen, nursing or clinical staff must remove oxygen treatment to suction effectively. This interruption in treatment may worsen patient's hypoxia. The patient should be placed back on oxygen as soon as the cavities of the nose and mouth are clear.
- **Trauma:** incorrect or excessive suctioning of the nose and mouth may cause trauma to the mucosal surfaces.
- **Vomiting:** incorrect measurement of the suction catheter or suctioning too far may stimulate the gag reflex and induce vomiting, which poses the risk of potential aspiration.
- **Vagal stimulation:** inappropriately deep suctioning can cause vagal stimulation resulting in apnoea or bradycardia.

DEVICE COMPLICATIONS

- **Device positioning:** suction pumps are not heavy devices but are frequently positioned on walls or shelves. This is appropriate **if appropriately secured during use**. If improperly secured, suction pumps may fall, causing permanent or fatal damage, particularly to small neonatal patients.

6 Care & Maintenance

Biomedical engineers and technicians are responsible for second-line care and maintenance to ensure equipment lasts to their potential lifetime.

POWER SOURCE

Suction pumps may be powered by mains or battery power **(6.1)** or manually via a foot or hand pump. **(6.2)** If a suction pump is battery powered, it should be taken off its charger **only as necessary** to ensure that it is charged for use in the event of a power blackout.

6.1 Battery-powered suction machine.

6.2 Foot-powered suction machine.

WARD LOCATION

Suction pumps should be secured in an accessible location where medical staff can regulate vacuum easily, but where the pump is not at risk of falling, and the pump cable is not posing a tripping hazard. Suction consumables should be kept nearby for easy access.

DEVICE CALIBRATION

Although the suction pump's pressure gauge can be calibrated, the cost to request calibration from the manufacturer or local calibration companies is typically too disproportionately expensive for the cost of the machine to justify calibration.

DECOMMISSIONING

Assuming appropriate use and consistent maintenance, a suction pump may last for five to seven years or longer. Paediatric suction pumps are generally low-cost; in such models, component breakages (i.e., pump assemblies) may cost more to repair than to replace. These should be decommissioned and replaced if possible. When decommissioning, pump housing may be repurposed for other devices; pump components (i.e., pistons) are typically worn past reuse and should be discarded.

PREVENTIVE MAINTENANCE

After Each Use

- [ ] Turn off and unplug the suction pump. Empty suction collection reservoir and disinfect using 70% alcohol solution.
- [ ] Check the bacterial filter. If discoloured or wet, replace.
- [ ] Disinfect the suction pump pressure gauge controls and suction pump housing using gauze and 70% alcohol.

See **Suction Pump: Disinfection After Use** and **Alert 4.2** for more information.

Weekly

- [ ] Check the bacterial filter for discolouration or other damage.
- [ ] Turn on the suction pump and allow the pump to run for 15 minutes.
- [ ] Test the operation of the float valve by shaking the empty collection reservoir with lid in place and noting the rise and fall of the internal floating piece.
- [ ] Visually assess the condition of the device housing and collection reservoir for physical damage (e.g., cracks or chips).
- [ ] Document preventive maintenance actions taken.

Monthly

- [ ] Perform **Weekly** preventive maintenance steps.
- [ ] **Test the vacuum capacity** of the suction pump:
    - [ ] Set up the device for use. Plug the power cable in and turn the power switch to ON. Leave the machine on for 1 minute.
    - [ ] Using the suction regulator, adjust suction vacuum to the desired level within safe neonatal levels (60 to 100 mmHg). Test the suction functionality with some water.
    - [ ] Observe pump's functionality for noises or smells outside standard operation.
- [ ] Document preventive maintenance actions taken.

Quarterly

- [ ] Perform **Monthly** preventive maintenance steps.
- [ ] Measure grounding integrity and casing leakage current.
- [ ] **Clean motor and motor brushes:**
    - [ ] Remove two motor brushes from motor, noting orientation.
    - [ ] Using compressed air, blow dust out of motor. If motor brushes show signs of build-up, gently clean with fine sandpaper. Replace motor brushes in original orientation.
- [ ] Document preventive maintenance actions taken.

Annually

- [ ] Perform **Quarterly** preventive maintenance steps.
- [ ] Confirm supply of spare bacterial filters, pump assemblies, vacuum gauges, collection reservoirs and lids are adequate to support estimated replacement for next year.
- [ ] Document preventive maintenance actions taken.

7 Troubleshooting & Repair

Biomedical engineers and technicians are responsible for providing rapid maintenance, troubleshooting & repair support for users.

PREPARE FOR REPAIR

Accessible Tools	Spare Parts	Device Checklist
Digital Multimeter Philips, star & flathead screwdrivers Needle-nosed pliers Wire strippers Spanners (8, 10, 12, 14, 17) Phase tester	Fuses Power cable Tubing Bacterial filter Suction regulator knob Gauge Pump assembly or piston & diaphragm Collection reservoir Collection reservoir lid	☐ Suction pump ☐ Short suction tube ☐ Long suction tube ☐ Collection reservoir & lid ☐ Bacterial filter ☐ Power cable (if detachable)

TROUBLESHOOTING FAILURES

The suction pump is not turning on.

Probable Cause: Faulty power supply

Components to Check:
Power cable continuity
Power switch physical integrity & continuity
Power entry module fuse(s) physical integrity & continuity
Power supply unit continuity & voltage

The suction pump motor runs but the pump is not suctioning.

Probable Cause: Activated float valve or damaged collection reservoir

Components to Check:
Float valve activation
Suction regulator knob, collection reservoir and lid
External and internal tubing physical integrity

The suction pump motor runs but the pump is not suctioning well.

Probable Cause: Damaged internal pump assembly or collection reservoir

Components to Check: Pump assembly and collection reservoir physical integrity
External and internal tubing physical integrity

The suction pump makes noise outside of normal operational sound.

Probable Cause: Damaged internal pump assembly

Components to Check: Pump assembly and motor bearing physical integrity
Muffler, vibration suppressors and cover/screws physical integrity

The suction pump emits a foul odour when in use.

Probable Cause: Fluid contamination

Components to Check: Pump assembly fluid damage
Float valve & bacterial filter physical integrity

REPAIR & REPLACE

Where technically possible and not likely to obstruct clinical care, repairs may be made within the newborn care ward. Use discretion to determine if this is appropriate or if the device should be removed to the biomedical workshop for more testing or repair.

Alert 7.1

All testing, repair and replacement steps should be conducted with the power to the device switched off and the power cable removed from mains power, unless otherwise stated.

Testing & replacing the power supply fuses

Fuses may be located both on the suction pump housing and on the power supply cable. Fuse integrity may be visually assessed or evaluated by testing the continuity across the fuse. Always refer to the manufacturer specifications for replacement fuses to ensure that the device remains electrically sound in standard operation.

7.1 Assess the housing for fuses.

7.2 Open the fuse drawer and inspect the fuses. Test with a multimeter.

Testing & replacing the power switch

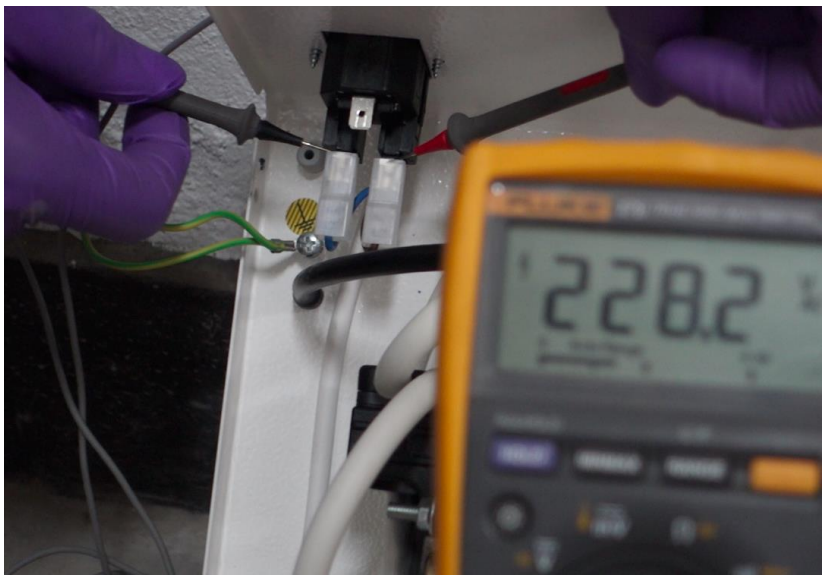
Power switches should be tested in both the off and on positions to confirm functionality. In the **On** position, the switch terminals should be continuous. In the **Off** position, the switch terminals should show a high resistance, or **OL** in most multimeters.

If the switch shows continuity or discontinuity inappropriately, assess the switch for visible physical or electrical damage. If the switch is visibly damaged or dislodged, assess whether the part can be repaired with glue or solder. If it cannot be easily repaired, replace the switch. Always refer to the manufacturer specifications for replacement switches to ensure that the device remains electrically sound in standard operation.

Testing & replacing the power supply unit

Visually assess the power supply unit for fluid damage before testing the voltage delivery through the unit. If fluid is present near or on the power supply unit, **check that the device is disconnected from all sources of power** and wipe the fluid from the unit thoroughly using a non-abrasive cloth.

Testing the power supply unit cannot be completed without checking the alternating voltage at the power supply unit. **This should be completed with caution**, as the power to the device must be switched on to accurately measure the voltage delivered. If the power supply unit or module is damaged, contact the manufacturer to request a replacement part and repair instructions.

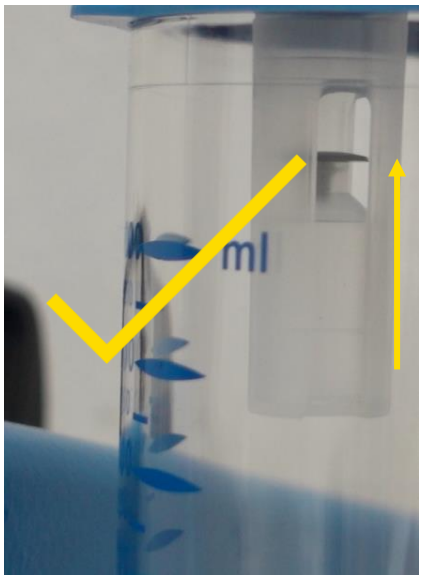


7.3 Check the voltage at the power supply module using a multimeter.

Testing & replacing the float valve

The overflow float valve is fitted in the collection reservoir to protect the machine and pump from fluid damage. If the overflow float valve has been physically damaged, installed in the wrong orientation or is not installed on the collection reservoir lid, any fluid overflow will enter into the internal pump assembly through the bacterial filter, potentially damaging the internal pump assembly.

If the collection reservoir has consistently activated the float valve, dried fluids within the valve may cause it to stick, blocking the suction pump from suctioning. Test the float valve by shaking it gently back and forth between fingers: the floater should move as it is shaken. If the float valve appears deteriorated or damaged, replace.



7.4 Correct float valve orientation.

7.5 Incorrect float valve orientation.

7.6 Float valve installation: push in until firmly secured.

Testing & replacing the collection reservoir & lid

Suction pump circuits must be sealed (not exposed to atmosphere) from end to end. If there is a leakage or crack in any part of the system, the atmospheric pressure will find a shorter route to balance the pressure, preventing the device from suctioning appropriately. A cracked collection reservoir or lid also presents additional risk of infection for those using or maintaining the suction pump. Visually assess the collection reservoir for any cracks, damage or blockages. Repair or replace if possible.

7.7 Assess the collection reservoir for cracks.

7.8 Remove the lid to inspect and replace.

Testing & replacing internal or external tubing

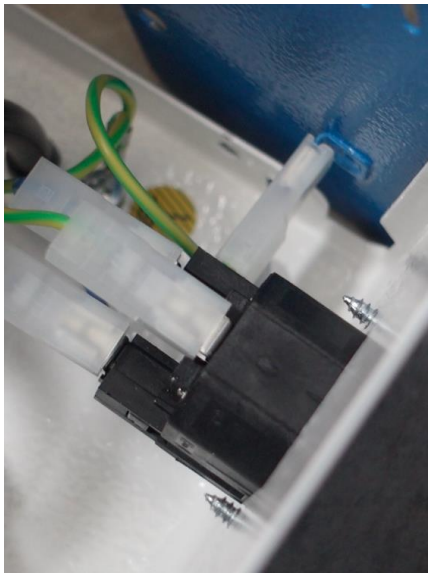
Leak testing may contribute to inaccurate or low vacuum. Tubing can be assessed for leaks by running soapy water or foam along the suspected tubing, pipes and fittings during operation and checking for bubbles or movement of the liquid.

Repairing & replacing the internal pump assembly

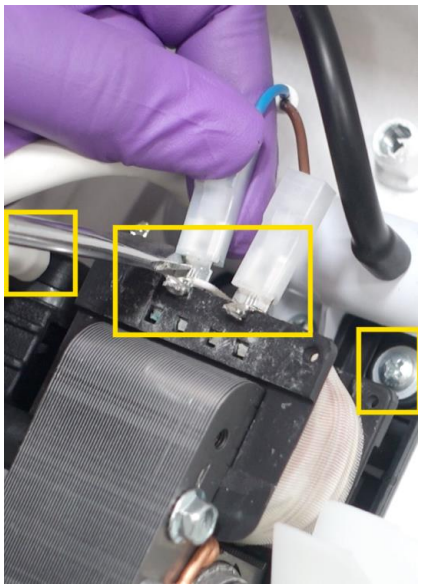
The internal pump assembly may be damaged through fluid entering the internal system or over time through standard wear and tear. If fluid has entered the internal pump assembly, the pump should be disassembled, cleaned with alcohol and dried thoroughly. The internal pump assembly and electrical components should be tested and visually assessed for damage. In most cases, if one element of the internal pump assembly has been damaged due to wear and tear, the entire assembly should be replaced.

7.9 Unscrew housing to access the pump.

7.10 Visually inspect the pump and internal condition.

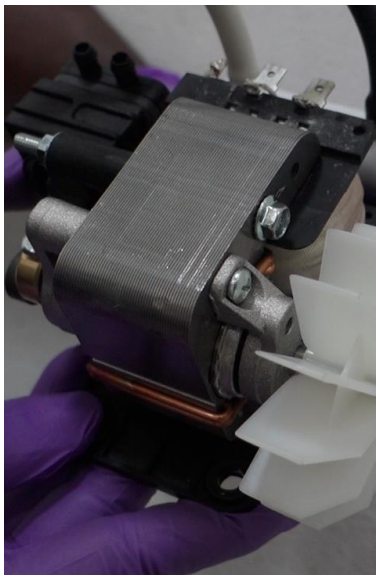


7.11 Remove chassis ground to prevent damage during repair.



7.12 Remove pump assembly at all connection points.

7.13 Inspect pump assembly for damage to components.

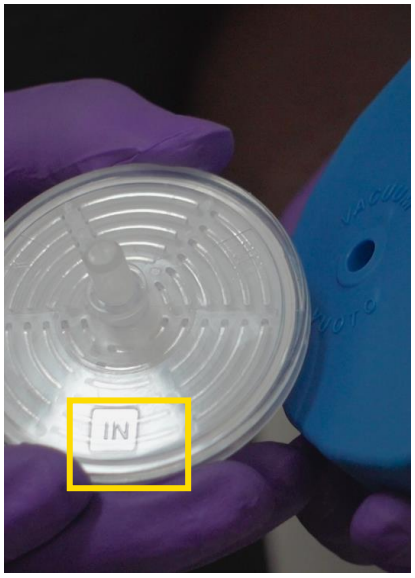


7.14 Replace assembly if needed.

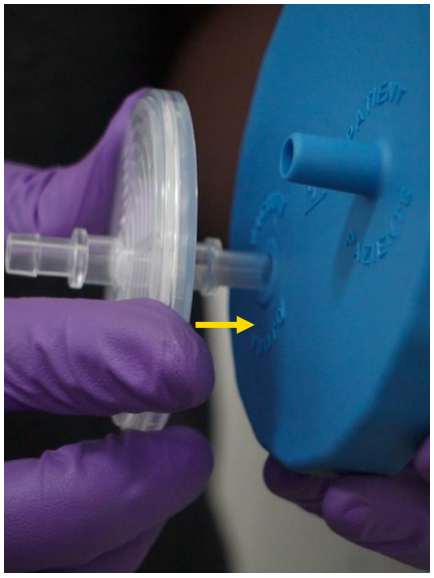
Assessing & replacing the bacterial filter

The bacterial filter is used in circuit with the suction pump to filter out any aerosolised particles or bacteria from the blood and secretions suctioned from a patient. The bacterial filter paper is placed within a housing of hard plastic to keep it in place. If the bacterial filter is wet or discoloured, it should be immediately replaced with a new filter.

The bacterial filter is directional. Filters should have visible markings to clarify the direction in which the flow should enter. Refer to **Suction Pump: Assessment:** Typical Device Flow and the device's manual to confirm that the bacterial filter is placed in the correct location and orientation. Some models may have a port for the bacterial filter on the collection reservoir lid, whilst others may have the bacterial filter in a tubing circuit between the collection reservoir and the pump. Care should be taken when putting the bacterial filter into place to prevent the bacterial filter housing from snapping.



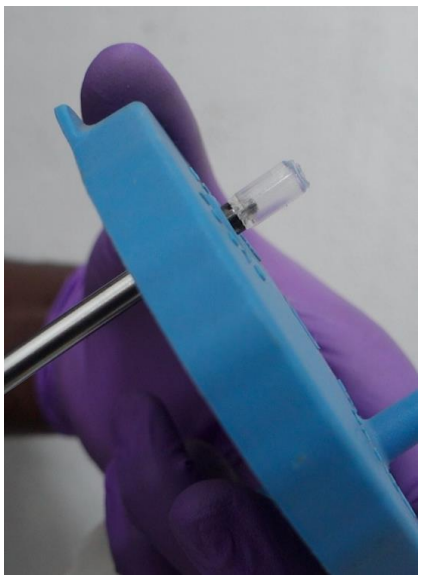
7.15 Check direction before inserting filter.



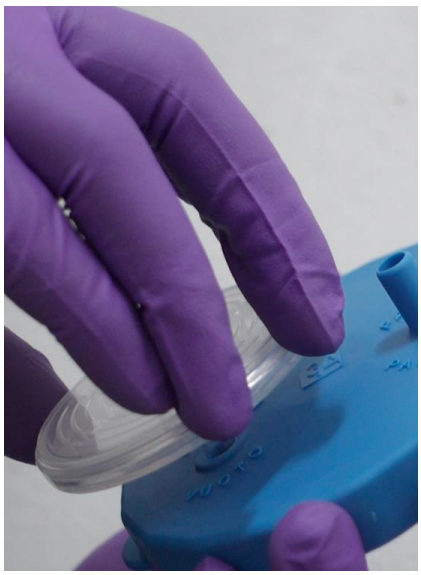
7.16 Gently insert filter into the "Vacuum" port.

7.17 Keep the filter in place throughout use.

7.18 If the filter is placed too roughly into the port, it may snap.



7.19 Push the snapped piece through the port using a screwdriver or other thin object.



7.20 Replace the broken filter with a new filter.

? Alert 7.2 Repurposing Parts

In some cases, parts on the unit may be replaced with a repurposed or recycled part from another piece of equipment being used for parts. **Repurposed parts should be considered with caution and guidance from the manufacturer to ensure specifications of the repurposed part is compatible with the equipment.** This includes spare parts and accessories that may not be compatible with multiple systems.

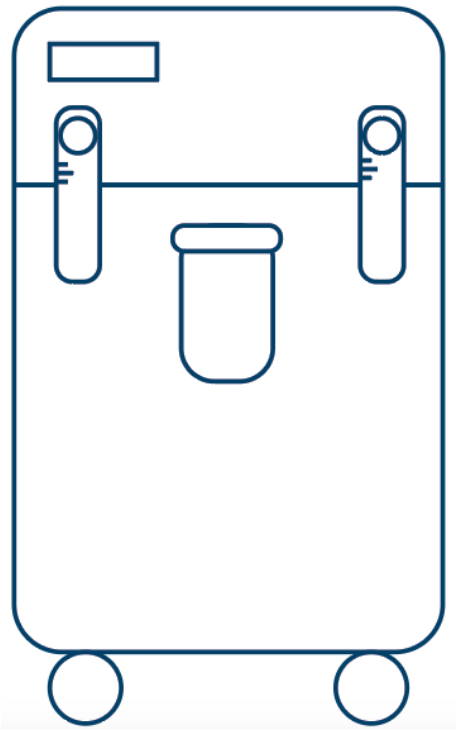
8 References

1. *WHO technical specifications for neonatal resuscitation devices*. (World Health Organization, 2016).
2. Curless MS, Ruparelia CS, Thompson E, and Trexler PA, eds. 2018. Infection Prevention and Control: Reference Manual for Health Care Facilities with Limited Resources. Jhpiego: Baltimore, MD.
3. World Health Organization, Regional Office for the Western Pacific, World Health Organization, & Regional Office for South-East Asia. *Practical guidelines for infection control in health care facilities*. (World Health Organization, Regional Office for Western Pacific ; World Health Organization, Regional Office for South-East Asia, 2004).
4. Sharma, G., Zaka, N. & Hailegebriel, T. Infection Prevention and Control at Neonatal Intensive Care Units. (2018).

Respiratory Support

Oxygen Therapy

Oxygen Concentrator



1 Clinical Problem

Oxygen concentrators are used in multiple hospital settings. In newborn care units, oxygen concentrators are used as standalone or partner devices to deliver oxygen therapy.

Concentrators may be used to share oxygen between multiple patients using a flow splitter or used with other treatment devices such as continuous positive airway pressure (CPAP) devices. Supplemental oxygen is indicated for sick children, especially those with low blood oxygen saturation levels (typically SpO_2<90%), which has many clinical causes.

2 Assessment

Oxygen concentrators (2.1) provide a source of oxygen with typical maximum cumulative output flow rates of 5, 8, 10 or 20 L/min. Both maximum and minimum flow capacity depend on device model.

Oxygen concentrators are one of the most commonly used sources of oxygen therapy, concentrating 85-95.5% oxygen from ambient air using two sieve beds containing a substance that adsorbs nitrogen at high pressures.

2.1 Typical oxygen concentrators.

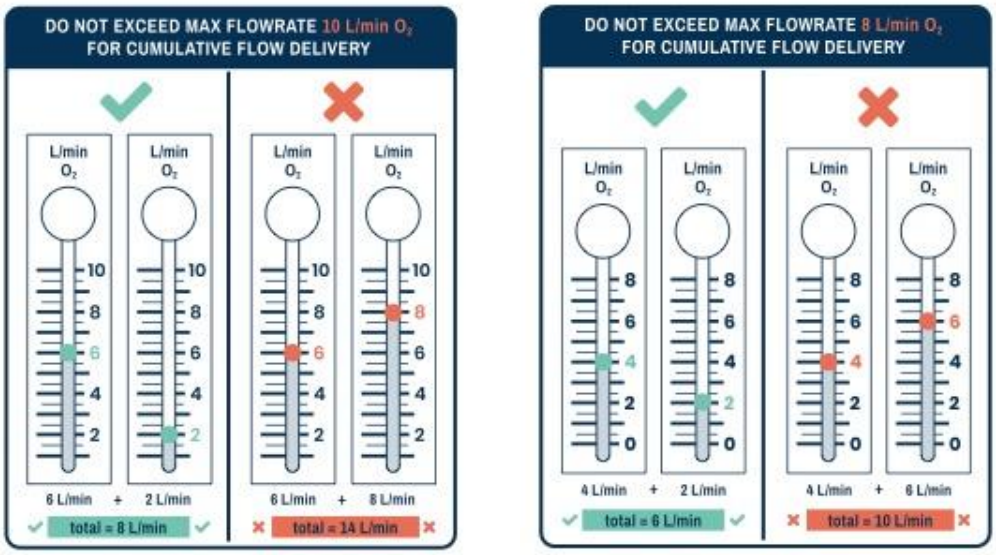
Oxygen concentrators may have one or two oxygen output ports that may be used to supply oxygen directly to one or two patients or to multiple patients at low flows using a flow splitter. Each output port has an flowmeter that can be adjusted to regulate flow from that port. Oxygen can be delivered using both ports simultaneously.

Oxygen concentrators may provide oxygen via two types of flow:

- **Intermittent/pulse flow:** provides puffs of oxygen into nasal passageway at typical breathing rates.
- **Continuous**: provides constant oxygen delivery at a steady rate.

In intermediate care newborn units, concentrators with continuous oxygen delivery are required for most applications.

Typically, all flowmeters on an oxygen concentrator are graduated to the maximum capacity of the concentrator (e.g. if maximum flow capacity is 10L/min then there may be 2 flowmeters on the device each graduated to 10L/min flow, as in **2.2**). However, while both flowmeter ports may be used simultaneously, the maximum flowrate at which the device can produce 85-95.5% oxygen remains the same (e.g., a 10 L/min oxygen concentrator can only produce 10 L/min of oxygen at a time, regardless of the number of ports or splitters in use). **Combined flowrate from all ports during use must not exceed the total recommended flow rate.** Should the combined flowrate go over the maximum capacity of the oxygen concentrator, the produced oxygen purity will drop, decreasing the oxygen delivered to the patient.



(A) (B)

2.2 Sample safety labels for **(A)** 10 L/min and **(B)** 8 L/min concentrators: delivered oxygen from all oxygen ports should not exceed maximum oxygen capacity.

Neonatal patients should reach SpO_2 levels of 90–95% by 15 minutes after birth. If oxygen is needed it is recommended to give between 0.5-1 L/min.[1] Whilst on oxygen, regular monitoring should be conducted including the use of a pulse oximeter to ensure that this saturation range is maintained for the duration of treatment. Ideally, patients suffering from severe respiratory distress should have continuous pulse oximetry monitoring throughout care to prevent hypo- or hyperoxia.[1]

HOW IT WORKS

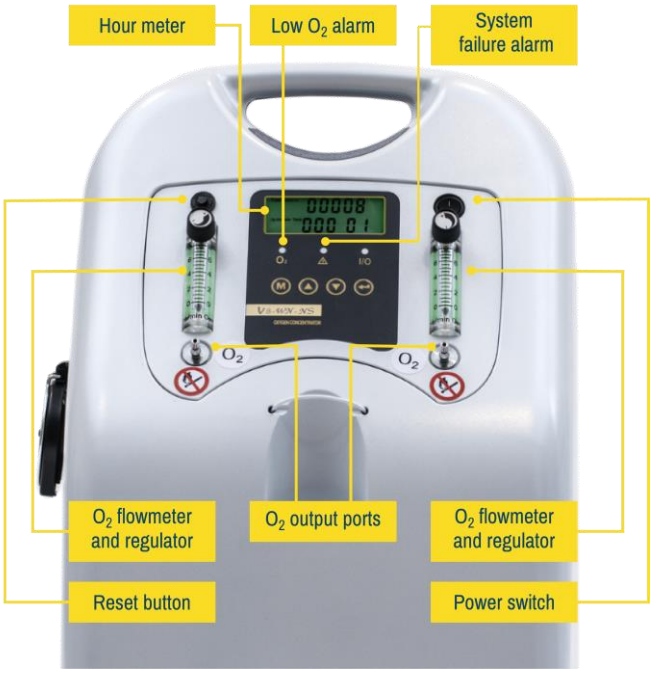
An oxygen concentrator operates on the principle of Pressure Swing Adsorption (PSA) using a microporous granulated molecular sieve material called zeolite. Zeolite has the property of selectively adsorbing (trapping) nitrogen from air at high pressure and desorbing (releasing)

nitrogen at low pressure hence the name pressure swing (swinging between low and high). For the purposes of an oxygen concentrator, the zeolite is contained in two cylindrical canisters called **molecular sieve beds**.

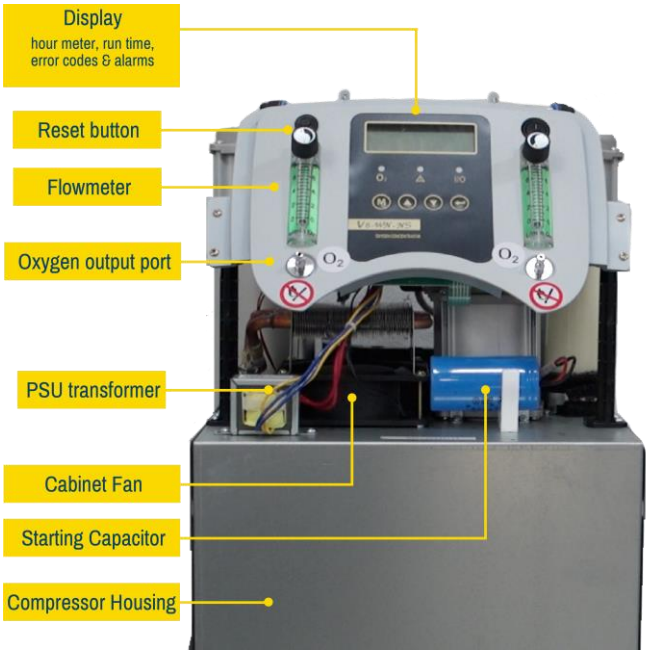
Air at atmospheric pressure of 14.7 psi (101 kPa, 1.01 bar) is filtered and drawn into the concentrator by the cabinet **fan** and **compressor**. The compressor raises the air pressure to about 30 psi (206 kPa, 2.1 bar) and feeds it into one of the molecular sieve beds (controlled by the **feed & waste valves**). Nitrogen is adsorbed by the zeolite granules while oxygen is allowed to pass. The residual oxygen is collected at the molecular sieve bed outlet port into the product tank. After 10 to 15 seconds the zeolite will be saturated with nitrogen. At this point, it can no longer adsorb further and the supply of compressed air is automatically switched to the second molecular sieve bed where it undergoes the same sieving process.

Concurrently, the pressure in the first molecular sieve bed is reduced to atmospheric pressure by venting it back to the atmosphere. This allows the trapped nitrogen to be released from the zeolite back to the atmosphere. By releasing nitrogen, the zeolite becomes regenerated and ready for the next cycle. By having two sieve beds a continuous supply of oxygen is ensured. There is no lag in production as the molecular sieve beds alternate between oxygen production and zeolite regeneration.

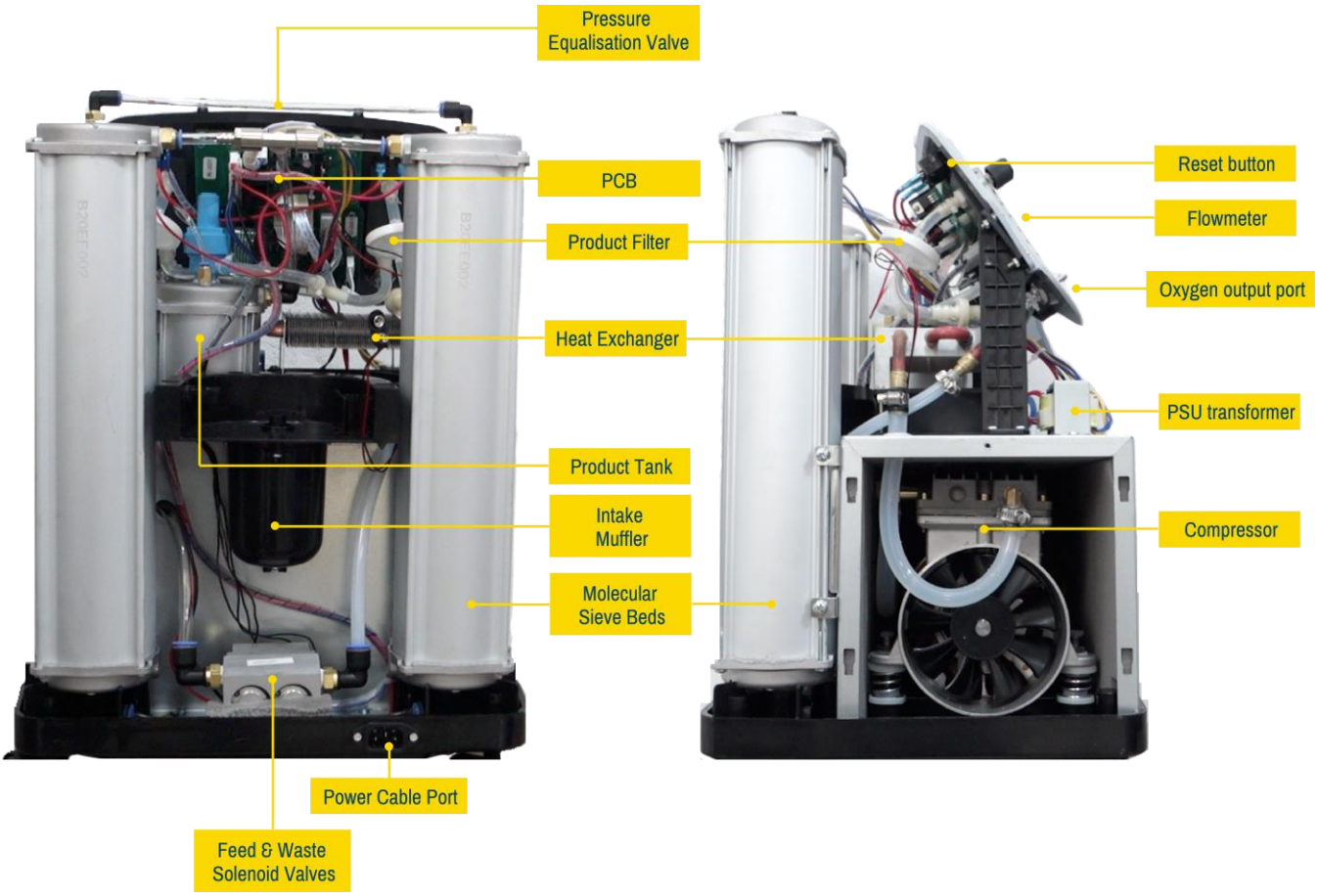
Standard external and internal device components are annotated below in **Figures 2.5** and **2.6**. Components should be similar regardless of model. However, specific locations, visual setup and component type may vary by brand and device model. Refer to service and user manuals if model in use is different from the displayed version.



2.4 (a) External components (front view).

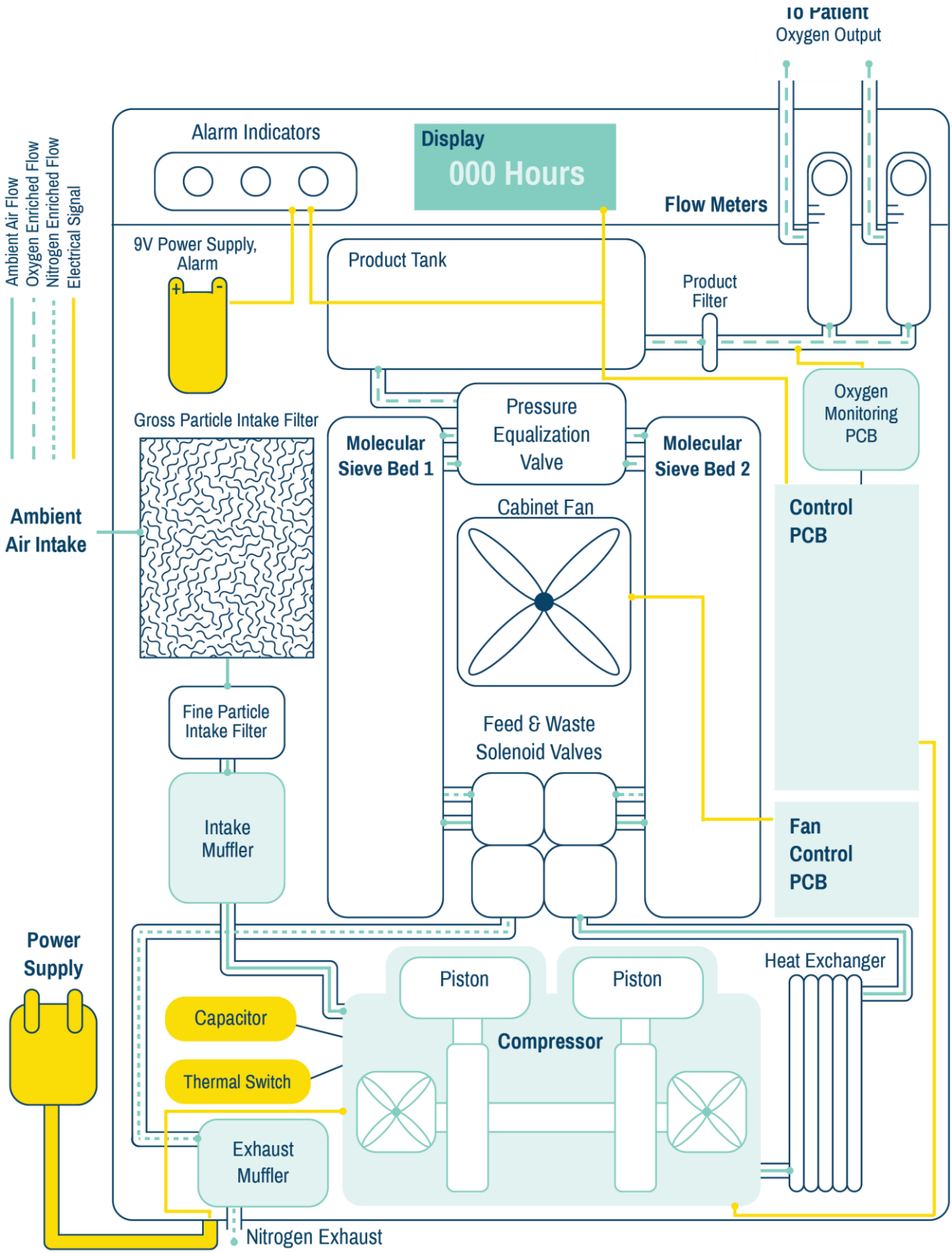


2.4 (b) Internal components (front view).



2.5 Internal components (back and side view).

TYPICAL DEVICE FLOW

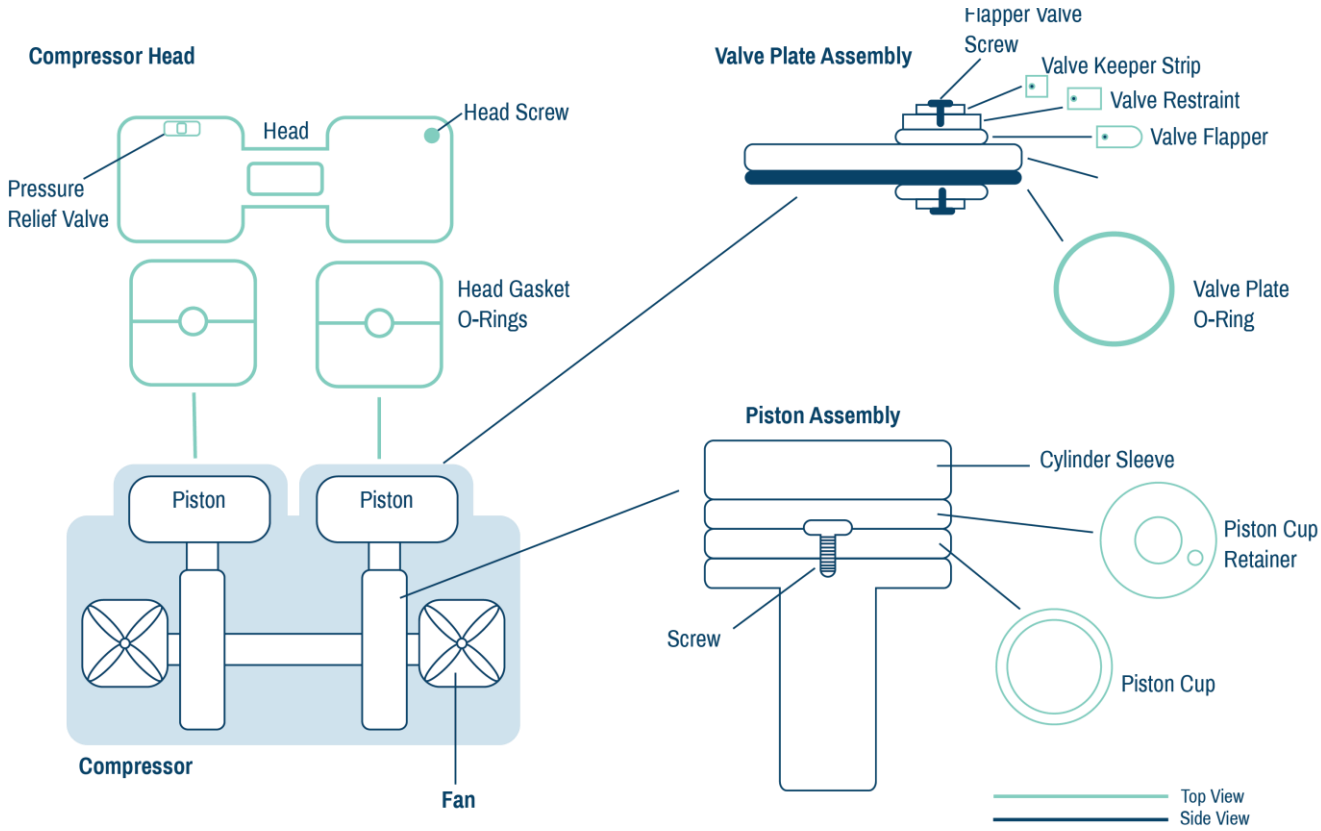


MAIN COMPONENTS

The following device components should be similar regardless of model. However, specific locations, visual setup and component type may vary by brand and device model. Refer to model service and user manuals for more device-specific information.

Compressor

Pressurises ambient air by reducing its volume. As the ambient air pressurises, heat is produced. A typical compressor assembly is displayed in **2.6**. Compressor output refers to how much compressed air the compressor can produce. This depends upon the model of the compressor, stroke size, bore size and cup seal condition. Some compressors may have a pressure relief valve (an automatic, typically spring-loaded mechanism that opens when the compressor experiences increased pressure to discharge the excess air into the atmosphere).



2.6 A typical compressor.

Starting capacitor

Starts and runs the compressor and keeps the auxiliary compressor motor coil running.

Heat exchanger

Reduces the temperature of the compressed air which has heated during the compression process.

Thermal switch

Cuts power to the compressor once the compressor running temperature exceeds maximum heat threshold.

Control PCB

Controls the opening and closing of the solenoid valves. It also controls all electronic and electrical components of the unit including alarms, pressure transducers and oxygen monitor circuits.

Molecular sieve beds

Canisters that contain zeolite (typically aluminum silicate), which adsorbs nitrogen from air at high pressures. Compressed air enters the sieve beds from the compressor at high pressure which allows the zeolite to adsorb the nitrogen in air, leaving 85-95.5% oxygen-enriched gas.

Oxygen monitoring PCB

Consists of an in-built oxygen analyser, typically ultrasonic, which monitors oxygen concentration in produced airflow. The oxygen monitoring PCB also processes output signal of the analyser in a pass/fail fashion.

Solenoid valves

Solenoid valves are electrically controlled valves with two main components: a solenoid (an electric coil with a movable electromagnetic plunger) and a valve. Solenoid valves remain at their "normal" position (open or closed) until an electric current creates a magnetic field to force the plunger up and open or close the valve.

In oxygen concentrators, solenoid valves are used to control feed and waste processes through the molecular sieve beds. **Feed valves** direct and regulate the flow of ambient air from the compressor to the sieve beds, while **waste valves** direct and regulate the exhaustion of nitrogen out of the sieve beds.

Equalisation valve

The equalisation valve plays two critical roles in the Pressure Swing Adsorption process:

1. It facilitates pressurization and nitrogen purging of the sieve under depressurizing cycle.
2. It directs some of the oxygen produced in one sieve to the other thus reducing energy requirements and increasing efficiency.

The equalisation valve may be a solenoid or mechanical valve.

Cabinet fan

The cabinet fan pulls ambient air into the unit and circulates air throughout insides of concentrator, cooling internal components. This component typically has its own PCB that controls power and rate information to the fan.

Pressure regulator

Controls the oxygen pressure as it leaves the product tank. This is typically set by the manufacturer to 20 psi (138 kPa, 1.4 bar).[2]

Check valve

Prevents backflow of oxygen after air has been processed through the sieve beds.

Intake muffler

Minimises noise from compressor suction as air enters compressor.

Exhaust muffler

Minimises noise of nitrogen-rich air exhaust and discharges this air from concentrator.

Product tank

Reservoir where oxygen is kept before proceeding to the outlet ports. This tank stores a small amount of oxygen that is released when the device is turned off or power is lost.

Pressure relief valve

Reservoir where oxygen is kept before proceeding to the outlet ports. This tank stores a small amount of oxygen that is released when the device is turned off or power is lost.

Oxygen output ports

Product output ports; these ports may have free flowing oxygen or require a Christmas tree adapter to be connected to allow flow.

Fine particle intake filter

Internal to the machine, either composed of filter paper or thick white felt filter. Filters particles from air to protect the compressor.

Gross particle intake filter

External to the machine, very porous and only intended to filter out large particles.

Product filter

Filters fine particles from product oxygen stream prior to administration to patient. Unlike other filters, intended for use of unit lifetime.

Hour meter

Records the device's cumulative running time.

Reset button

Circuit breaker; resets the unit after electrical overload shutdown.

Alarm battery

Provides power to audible alarm speaker to ensure alarms sound during a power outage. Typically 9V.

Alarms

Alarms may be audible, visual or both. LED indicators may illuminate to indicate low oxygen output levels, flow restriction, high/low pressure, power supply failure, and high temperature. Some oxygen concentrators may have specific codes that designate each failure; refer to the model-specific user and service manual for more information.

Flowmeter and regulator knobs

Controls and displays the oxygen delivery rate to the patient(s) in L/min

3 Management

Management covers how to use the oxygen concentrator, including set up for a patient, patient commencement, care whilst on the device and removal of the patient from the device. These instructions are helpful for a biomedical engineer or technician both in user training and in assessing the appropriate functionality of the device.

SETTING UP FOR A PATIENT

1. Plug oxygen concentrator's power cable into the oxygen concentrator **(3.1a)** and into the wall and turn on power at socket. Turn on concentrator. **(3.1b)**

3.1 (a) Plug in the oxygen concentrator.

3.1 (b) Turn on the oxygen concentrator.

2 Set flow to desired rate. If machine has not been turned on, allow to run for five minutes or until indicator light **(3.2)** shows that concentrator is providing appropriate concentration of oxygen for treatment. Check that no alarms sound on the machine.

3 If the patient's healthcare provider has determined the patient requires humidification, assist the healthcare worker to ensure humidifier is correctly connected to the concentrator. **(Alert 3.1)**

Alert 3.1

Per WHO recommendation in *WHO Oxygen Therapy for Children* and *WHO Technical Specifications and Guidance for Oxygen Therapy Devices*, when oxygen is delivered at higher than standard flow rates (> 1L/min for neonatal and 2L/min for infant patients), humidification is necessary.[1,2] Ultimately, the decision to humidify low flow oxygen or not is a clinical one which is influenced by oxygen source (tank, concentrator), oxygen flow, climate, patient age, resource availability and clinical status. If used in series with another device, humidification should be added after the device and just prior to the patient interface to prevent moisture build-up in the ancillary device.

4 Perform hand washing protocols. Connect appropriately sized nasal prongs to oxygen port on machine **(3.3)** or to humidifier (if using).

3.2 The "Low Oxygen" alarm indicates that produced concentrations are lower than 85%.

3.3 Connect correctly sized nasal prongs to oxygen port.

5 Test that oxygen flow has begun by placing your finger near the nasal prongs, ensuring that flow commences. This can also be tested by submerging the nasal prongs in clean water and checking for bubbles **(3.4)**, also known as the "Bubble Test." [3]

3.4 Submerging the nasal prongs in water should produce bubbles.

4 Infection Prevention

Routine and adequate cleaning of medical devices is critical to prevent hospital-acquired infections in newborn care units.

CLINICAL INFECTION PREVENTION

1 Housing of the oxygen concentrator should be cleaned according to ward guidelines for disinfecting surfaces.

2 Clean hands with soap and water or 70% alcohol before and after placing a patient on oxygen or handling any tubing that will be used on a patient.

3 Ensure that all patient-related tubing or interfaces are new or has been cleaned thoroughly and dried as per re-use guidelines. Any patient-related tubing or interfaces must be cleaned immediately after use; If reusing, immediately begin hospital protocol for disinfection of any patient-related tubing or interfaces. Delay in initiating cleaning of reused medical devices can lead to the need for more intensive cleaning procedures to remove pathogens. If not reusing, discard appropriately. **(Alert 4.1)**

4 Tubing should be hung to dry after disinfection and should not touch the floor or other unsanitary surfaces whilst drying. Any item falling on the floor is contaminated and must be thoroughly recleaned.

Alert 4.1

Respiratory circuits and humidifiers associated with oxygen delivery are generally intended as single use devices. However, in areas with limited resources or challenging supply chains, this equipment is often re-used. When re-processing single use devices it is extremely important that the cleaning process is not delayed following completion of use. If equipment is not re-processed promptly or adequately between patients, it poses a significant infection risk. Please refer to the **Reference Manual for Health Care Facilities with Limited Resources Infection Prevention and Control, Module 6**[4] for more detailed guidance on the re-processing of single use devices.

DISINFECTION AFTER USE

1. Turn off and unplug the oxygen concentrator. If reusing tubing, immediately begin hospital protocol for disinfection.
2. Housing of the oxygen concentrator should be cleaned according to ward guidelines for disinfecting surfaces. Flowmeter controls and LEDs should be cleaned using 70% alcohol after every use. **(Alert 4.2)**

BMET INFECTION PREVENTION

1. Any piece of equipment used in providing patient care must be handled carefully, as it may be contaminated and have the potential to spread infection.
2. Clean and disinfect oxygen concentrator housing and components whilst wearing PPE as appropriate (e.g., rubber gloves, apron, face protection, etc.) **before any repairs or maintenance are made.** Avoid any contact between used piece of equipment and skin, mucosa or clothing.
3. Post-maintenance, decontaminate all tools and surfaces used with 70% alcohol or according to manufacturer guidelines. Do not use equipment until it has fully dried following decontamination.

Alert 4.2 Disinfecting Equipment

Disinfection of equipment should always comply with manufacturer guidelines. WHO recommends 0.5% dilution of chlorine (0.5% or > 100ppm available sodium hypochlorite) as the standard disinfectant for materials and surfaces contaminated by blood or body fluids.[5] For metal and rubber surfaces, which may be corroded by chlorine, 70% alcohol is also commonly utilised for low level disinfection.

Other appropriate low-level disinfectants include quaternary ammonium, improved hydrogen peroxide and Iodophor germicidal detergent.[4] Phenolic germicidal detergent is also identified but should not be used in neonatal wards since affordable, effective alternatives are available; and, there are concerns it may cause hyperbilirubinemia and/or neurotoxicity in neonates.[6]

See dedicated NEST360° module on Infection Prevention and Control for further details on risks, benefits and utilization of chemical disinfectants. For comprehensive guidance on infection prevention and control we recommend utilising Reference Manual for Health Care Facilities with Limited Resources Infection Prevention and Control (Caston-Gaa & Ruparelia, 2018).

5 Complications

Equipment in newborn care units are highly specialised. Without proper knowledge and skills, this equipment can be potentially dangerous for the infants, families and care providers.

DEVICE COMPLICATIONS

- **Inadequate oxygen concentrations:** if the oxygen concentrator indicates inadequate concentrations of oxygen **(Alert 5.1)**, oxygen concentration has dropped below 82% and machine maintenance is needed. Replace the concentrator or switch to backup oxygen cylinder supply if available; if not available, increase monitoring frequency to ensure clinical stability until concentrator can be replaced or maintained.

6 Care & Maintenance

Biomedical engineers and technicians are responsible for second-line care and maintenance to ensure equipment lasts to their potential lifetime.

POWER SOURCE

Oxygen concentrators may be powered via mains or grid power with a voltage protector in line, or a rechargeable battery, depending on the model.

WARD LOCATION

The concentrator should be located in a clean, dry, well-ventilated space. The back of the concentrator should be 30-35 cm away from the nearest wall to ensure that air can freely flow into the concentrator. Ideally, the concentrator is placed close to oxygen splitters or other ancillary equipment in use. To facilitate access, it should also be placed in a location that is easily viewed and accessed by ward staff.

DEVICE CALIBRATION

Manufacturers do not recommend calibration for any oxygen concentrator components.

DECOMMISSIONING

Assuming appropriate use and consistent maintenance, an oxygen concentrator may last up to 7 years.[7] Generally, it is more fiscally responsible to repair oxygen concentrators when necessary, although there are some low-cost models that may be cheaper to replace rather than repair. Most components on an oxygen concentrator can be repurposed; exceptions are typically molecular sieve beds, which will become contaminated over time with moisture in the air.

PREVENTIVE MAINTENANCE

After Each Use

- [ ] Turn off and unplug the oxygen concentrator. Use gauze and 70% alcohol or diluted chlorine to thoroughly wipe the oxygen flowmeter controls, control panel and power button. See **Oxygen Concentrator: Disinfection After Use** and **Alert 4.2** for more information
- [ ] Visually inspect oxygen concentrator components and location.

Weekly

- [ ] Visually assess and clean the external gross particle intake filter.
- [ ] Visually assess the internal fine particle intake filter. Clean or replace if needed. See **Oxygen Concentrator: Troubleshooting & Repair:** Assessing, cleaning & replacing intake filters for more detail.
- [ ] Turn on and allow the oxygen concentrator to run for 15 minutes. Confirm that no alarms are audibly or visually activated.
- [ ] Document cumulative hours run and preventive maintenance actions taken.

Monthly

- [ ] Perform **Weekly** preventive maintenance steps.
- [ ] Test the **power loss alarm**: while the oxygen concentrator is plugged in and turned on, turn off the power at the wall socket. An alarm should sound.
- [ ] Test the **oxygen concentration output** at both the minimum and maximum flow range of the oxygen concentrator using an oxygen analyser:
    - Remove humidifier bottle if on device. Moisture can damage the analyser.
    - Turn on the oxygen concentrator. Allow the concentrator to run for 5 minutes.
    - Connect an oxygen analyser to the outlet port and wait for reading to stabilise.
    - Assess concentration and output flow rate at both minimum and maximum flow rates on all oxygen outlet ports.

    If an analyser is not available, observe the 'Low Oxygen' LED indicator.
- [ ] Visually assess the internal housing and compartments for dust. Blow clean if necessary.
- [ ] Document cumulative hours run and preventive maintenance actions taken.

Quarterly

- [ ] Perform **Monthly** preventive maintenance steps.
- [ ] Audibly assess the concentrator for sounds outside of standard operation.
- [ ] Measure grounding integrity and casing leakage current.
- [ ] Document cumulative hours run and preventive maintenance actions taken.

Annually

- [ ] Perform **Quarterly** preventive maintenance steps.
- [ ] Confirm supply of spare power supply units, sieve beds, control PCBs, solenoid valves, compressor rebuild kit, intake filters and power cables are adequate to support estimated replacement for next year.
- [ ] Document cumulative hours run and preventive maintenance actions taken.

7 Troubleshooting & Repair

Biomedical engineers & technicians are responsible for providing rapid maintenance, troubleshooting & repair support for users.

PREPARE FOR REPAIR

TOOLS ACCESSIBLE	SPARE PARTS	DEVICE CHECKLIST
Digital multimeter Phillips, star & flathead screwdrivers Allen keys Adjustable wrench Needle nose pliers Wire strippers Phase tester Oxygen analyser Compressed air blower Oscilloscope Permanent marker Pressure gauge	Power supply unit Power cable Gross & fine particle intake filters Control PCB Flowmeter assembly Control, oxygen monitoring & fan PCB Solenoid valves Starting capacitor Compressor and rebuild kit Crimp or zip ties	☐ Oxygen concentrator ☐ Power cable (if detachable) ☐ Gross particle intake filter ☐ Oxygen tubing or nasal prongs

TROUBLESHOOTING FAILURES

The oxygen concentrator is not turning on.

Probable Cause: Faulty power supply

Components to Check:
Power cable continuity
Reset button/circuit breaker activation & continuity
Power switch physical integrity & continuity
Power entry module fuse(s) physical integrity & continuity
Power supply unit continuity & voltage
Control PCB physical & electrical integrity and continuity

The concentrator turns on, but a 'Low Oxygen Concentration' indicator is activated.

Probable Cause: Contaminated sieve beds, worn compressor or blocked filters leading to low internal pressure

Components to Check:
Cumulative flow delivered
Gross and fine particle intake filter condition
Sieve bed operating pressure
Compressor physical condition
Control and Oxygen Monitoring PCB physical & electrical integrity & continuity
Solenoid valves resistance & magnetisation

The concentrator turns on, but no flow comes from the oxygen ports.

Probable Cause: Blocked oxygen port or displaced internal tubing

Components to Check:
Oxygen outlet port physical condition
Internal tubing seal & placement

The concentrator turns on, but the compressor periodically shuts down.

Probable Cause: Overheated compressor or restricted airflow

Components to Check:
Device placement
Fan and fan components' functionality, physical and electrical condition
Thermal switch continuity
Internal tubing condition
Compressor starting capacitor functionality

The concentrator turns on, but a loud popping sound is emitted from the device.

Probable Cause: Compressor relief valve release due to high system operating pressure

Components to Check:
Internal tubing condition
Sieve bed operating pressure
Solenoid valves resistance
Compressor & compressor relief valve condition
Control PCB physical & electrical integrity & continuity

The concentrator turns on, but the compressor does not start.

Probable Cause: Overheated or cold compressor

Components to Check:
Internal temperature assessment
Compressor starting capacitor functionality
Internal electrical connections
Control PCB physical & electrical integrity & continuity

Reset button trips repeatedly when power switch is 'On'.

Probable Cause: Poor mains power quality or faulty reset button

Components to Check:
Mains power quality
Internal electrical connections
Compressor electrical integrity
Control PCB electrical integrity & continuity
Reset button electrical integrity

The concentrator flow meter bead(s) fluctuate more than ¼ L/min.

Probable Cause: Leakage or loose internal connection

Components to Check:
Cumulative flow delivered
Internal tubing condition
Flowmeter physical condition
Gross and fine particle intake filter condition
Sieve bed operating pressure
Compressor physical condition
Control & Oxygen Monitoring PCB physical & electrical integrity & continuity
Solenoid valves resistance

REPAIR & REPLACE

Where technically possible and not likely to obstruct clinical care, repairs may be made within the newborn care ward. Use discretion to determine if this is appropriate or if the device should be removed to the biomedical workshop for more testing or repair. **Always refer to the manufacturer's user and service manual before beginning any repair procedures.**

Alert 7.1

All testing, repair and replacement steps should be conducted with the power to the device switched off and the power cable removed from mains power, unless otherwise stated.

Testing & replacing the power supply fuses

Fuses may be located both on the oxygen concentrator housing and on the power supply cable. Fuse integrity may be visually assessed or evaluated by testing the continuity across the fuse. Always refer to the manufacturer specifications for replacement fuses to ensure that the device remains electrically sound in standard operation.

Testing & replacing the power switch

Power switches should be tested in both the off and on positions to confirm functionality. In the **On** position, the switch terminals should be continuous. In the **Off** position, the switch terminals should show a high resistance, or **OL** in most multimeters.

If the switch shows continuity or discontinuity inappropriately, assess the switch for visible physical or electrical damage. If the switch is visibly damaged or dislodged, assess whether the part can be

repaired with glue or solder. If it cannot be easily repaired, replace the switch. Always refer to the manufacturer specifications for replacement switches to ensure that the device remains electrically sound in standard operation.

Testing & replacing the power supply unit or module

Testing the power supply unit cannot be completed appropriately without checking the alternating voltage at the power supply unit. **This should be completed with caution**, as the power to the device must be switched on to accurately measure the voltage delivered. If the power supply unit or module is damaged, contact the manufacturer to request a replacement part.

Testing & replacing control PCB and associated components

In most cases, if one element of the control PCB has malfunctioned, the entire control PCB should be replaced. Visually assess the PCB for burnt or damaged components. **(7.1 – 7.6)** Internal wiring continuity leading from the power supply to the control PCB and from the control PCB to the other components may also be assessed for replacement. **(Alert 7.2, Alert 7.3)**

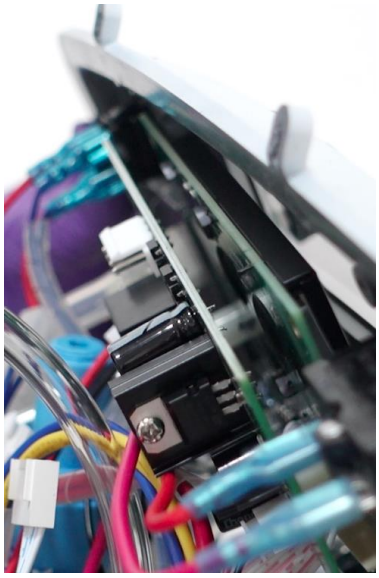
Alert 7.2

Printed Circuit Boards (PCBs) contain components that are sensitive to electrostatic discharge (ESD) and can damage the board if not handled properly. As when handling any ESD-sensitive PCB, observe standard ESD safety procedures.

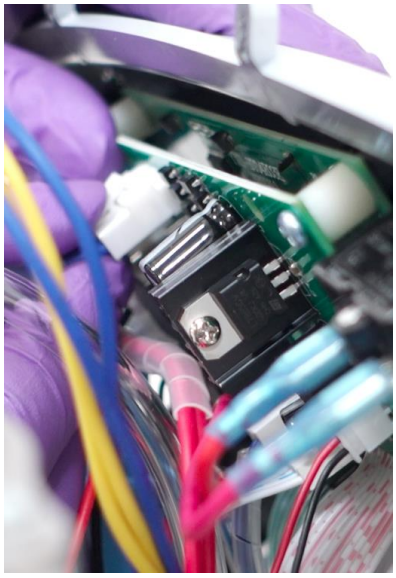
7.1 Unscrew the housing.

7.2 Remove the housing to access internal components.

7.3 Unscrew and slide the front housing off of the device.



7.4 Identify the control PCB. Visually assess all PCBs for issues.



7.5 If a PCB needs to be replaced, disconnect wiring.

7.6 Unscrew the circuit boards from the concentrator housing. Replace as needed.

Alert 7.3

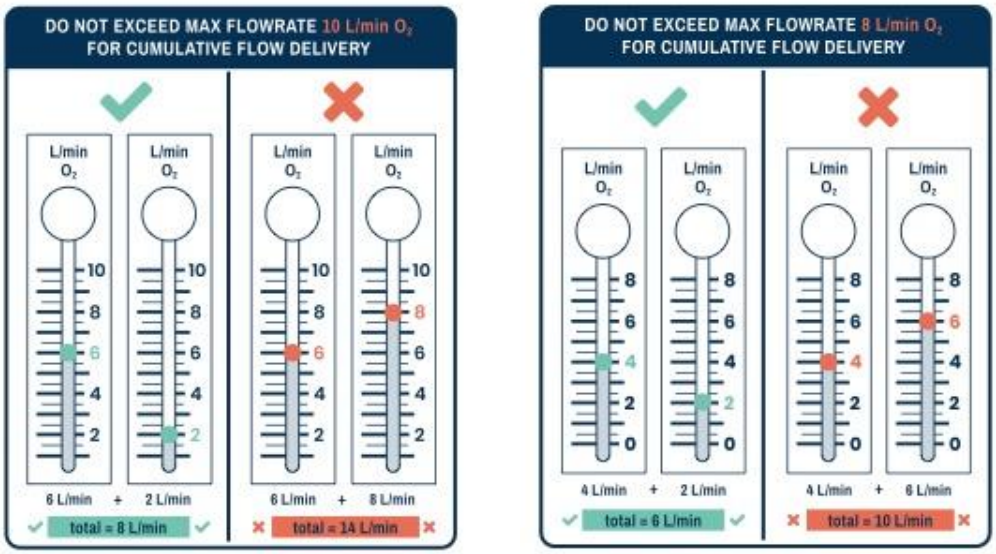
When disassembling and reassembling devices, **it is** critical that all parts are connected back to the sections of the circuit board that they were initially in. For more complicated devices, it is best to take photographs of the repair process as steps are conducted. These photos can then be used as a reference with the manufacturer's service manual when putting the device back together. **Connecting and turning on a device in the wrong component orientation can cause permanent damage to a device.**

Assessing cumulative flow delivery

Although both oxygen flowmeters on an oxygen concentrator are graduated to the maximum capacity of the machine and may be used simultaneously, the maximum flowrate at which the device can produce recommended purity of oxygen remains the same (e.g., a 10 L/min oxygen concentrator can only produce 10 L/min of oxygen at a time, regardless of the number of ports or splitters in use). Should the combined flowrate go over the maximum capacity of the oxygen concentrator, the produced oxygen purity will drop, decreasing the oxygen delivered to the patient. **Users should be oriented on cumulative flow and a safety label placed on the oxygen concentrator to facilitate safe use. (7.7)**

To assess the cumulative flow delivery, oxygen flow rates from all oxygen ports (in L/min) should be summed and compared to the maximum oxygen capacity for the concentrator model (in L/min). If this exceeds the maximum oxygen capacity, the oxygen flow rates must be decreased until their cumulative flow is within model specifications.

Over the oxygen concentrator's lifetime, the maximum output flow rate that can be produced whilst retaining 90% to 95% oxygen concentrations may decrease by 1 or 2 L/min. This can be improved by replacing or rebuilding the compressor and sieve beds but indicates that the oxygen concentrator is nearing the end of its usable lifetime and should be considered for decommission.



(A) (B)

7.7 Sample safety labels for **(A)** 10 L/min and **(B)** 8 L/min concentrators: delivered oxygen from all oxygen ports should not exceed maximum oxygen capacity.

Testing & repairing the oxygen outlet ports

Over time, oxygen outlet ports may accumulate deposits or debris that block oxygen flow from the concentrator. Ports should be visually inspected using a penlight and cleaned using ear swabs or forceps wrapped in gauze soaked in 70% alcohol.

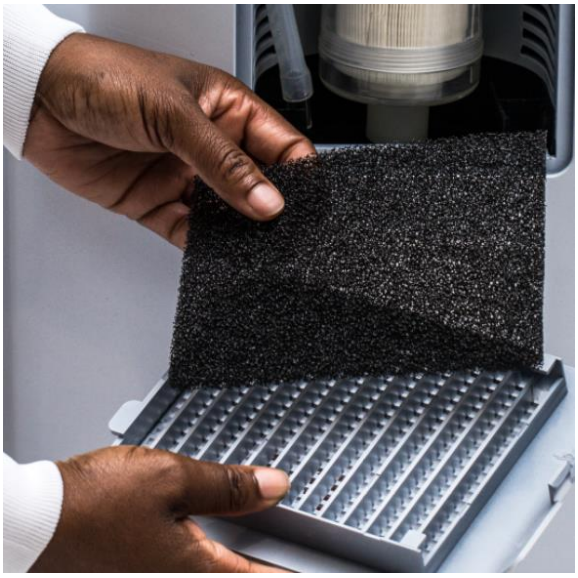
Testing & replacing internal tubing components

Leaks may contribute to both low operating pressure and accelerated failure of molecular sieve beds. Internal tubing can be assessed for leaks by running oil-free, mild or diluted soapy water or leak-testing foam along the suspected tubing, pipes and fittings during operation and checking for bubbles or movement of the liquid.

Internal tubing may have springs in place to protect from kinks or bends. When replacing tubing, remember to remove the springs and replace in the new tubing.

Assessing, cleaning & replacing intake filters

Frequency of maintenance increases in hot, humid and/or dusty operating environments. As the gross **(7.8)** and fine **(7.9)** particle intake filters become clogged with dust or other debris, intake airflow to the compressor becomes constricted and decreases the efficacy of the PSA process. Intake filters should be assessed and cleaned regularly whilst wearing appropriate PPE (including gloves, a face mask and safety glasses, if available). **The fine particle intake filter should be replaced after every 5 000 hours of use.**



7.8 Gross particle intake filter.

7.9 Fine particle intake filter.

Clean the gross particle intake filter:

1. Pull gross particle intake filter gently from the back of the oxygen concentrator. Replace with spare.
2. Put the filter in warm, soapy water and swirl gently to remove debris.
3. Remove from soapy water and rinse with clean water. Place in **shaded** area until completely dry. Store as spare filter until next cleaning is required.

Cleaning the fine particle intake filter:

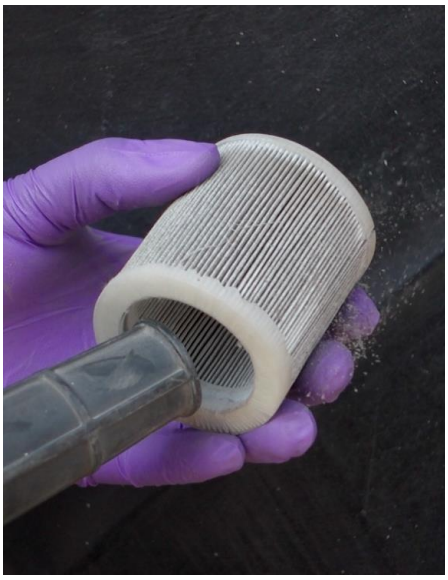
1. Open the oxygen concentrator housing. The fine particle intake filter is internal to the device, although the exact position varies by oxygen concentrator model.
2. Remove the fine particle intake filter. Replace with spare filter. **(7.10 – 7.12)**
3. Take the filter to an outside or well-ventilated area. Hold the filter firmly a distance away from and downwind of any individuals. Use compressed air to blow dirt and debris off the filter. If compressed air is not available, a pen or pencil may also be used to firmly strike the internal filter. **(7.13 – 7.14)**
4. Dust clouds will rise off the filter. Continue striking or blowing compressed air until dust no longer comes off and the colour has visibly lightened.
5. Assess the condition of the fine particle intake filter. If the filter is not damaged, store as spare filter until next cleaning is required. **The fine particle intake filter should be replaced after every 5 000 hours of use.**

7.10 Remove the fine particle intake filter from the concentrator.

7.11 Unscrew and separate the two parts of the plastic housing for the filter paper cylinder.

7.12. Remove the filter paper cylinder from the assembly.

7.13 Wearing PPE and using compressed air, clean all components of the fine particle intake filter separately.

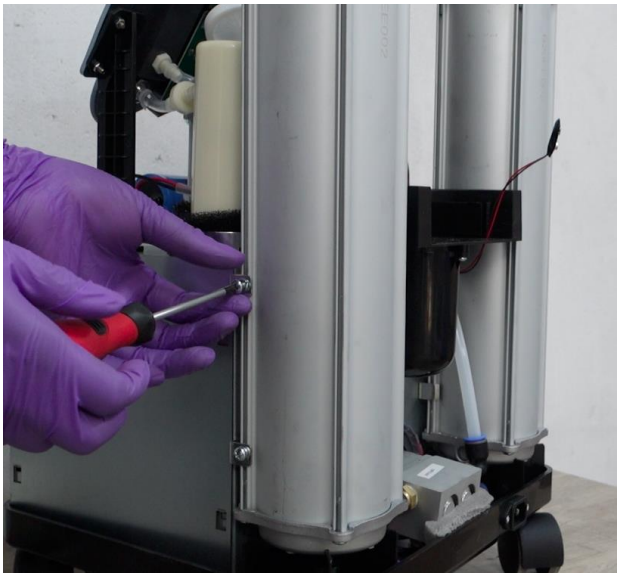


7.14 Dust should blow off the filter paper.

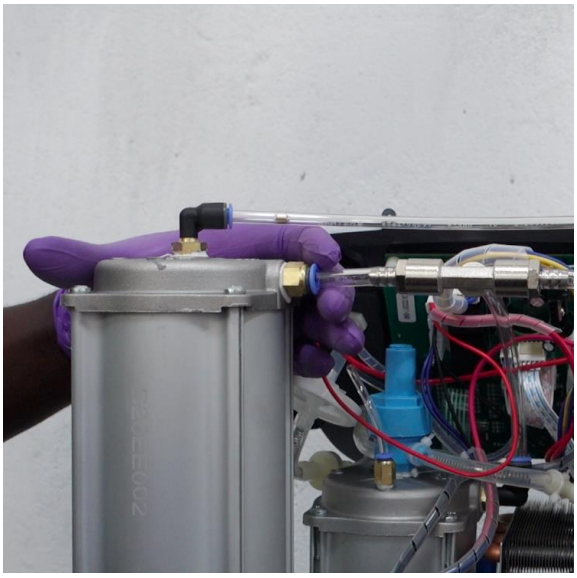
Testing & replacing sieve beds

With lack of use or with age, the molecular sieve materials within sieve beds may become contaminated with water molecules. This decreases the amount of open space for the nitrogen in ambient air to bind to during PSA cycles and obstructs airflow over the molecular sieve. This contamination decreases the efficacy of the oxygen concentrator. High operating pressure and low oxygen concentration levels may indicate that the sieve beds have been contaminated and need to be replaced. **(7.15 – 7.18)**

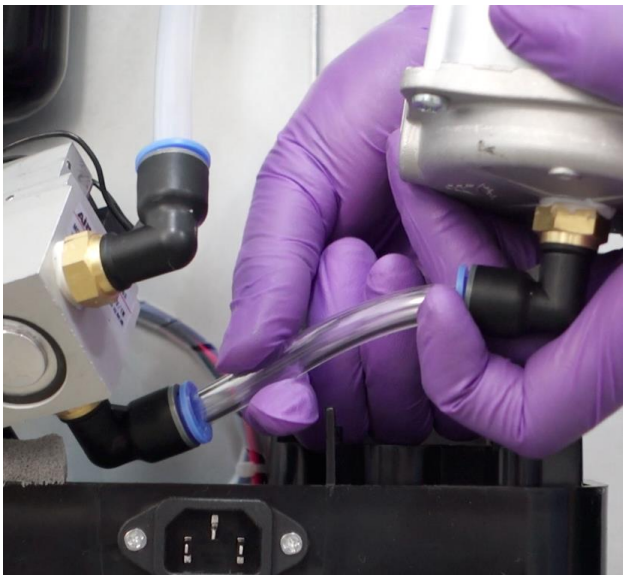
Sieve beds should be replaced in pairs. While replacing, sieve bed spares should be temporarily sealed with tape until installation is complete to prevent contamination of the molecular sieve from the moisture in the ambient air. After installation of the spare sieve beds, careful leak testing should be conducted to ensure that there are no small leaks that may contaminate the newly installed sieve beds. See O**xygen Concentrator: Troubleshooting & Repair:** Testing & replacing internal tubing components for more information.



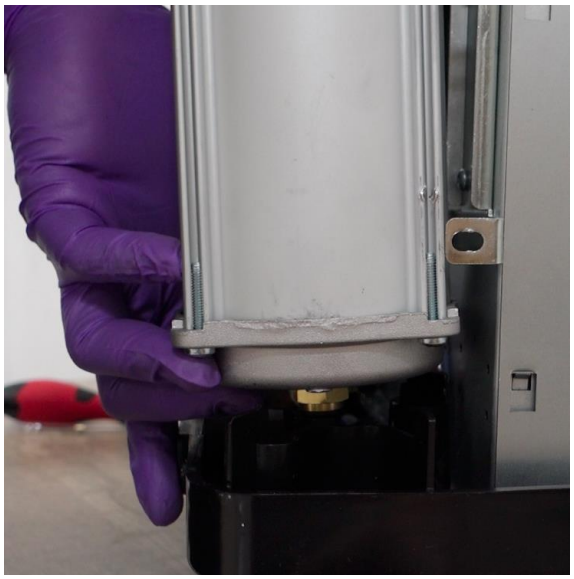
7.15 Unscrew sieve beds for replacement.



7.16 Remove attached tubing from the sieve beds by pressing the blue holding piece towards the sieve beds and pulling the tubing simultaneously.



7.17 Remove sieve bed tubing from the feed & waste solenoid valves.



7.18 Replace the sieve beds in pairs, following grooves along sieve bed housing to snap into place.

Testing & replacing the compressor and its components

Compressor output depends upon the model of the compressor, stroke size, bore size, and cup seal condition. The cup seals form the seal between the piston and the cylinder wall. As the cup seals wear, the compressor's output begins to gradually decrease. This reduction in compressor output results in less air for the sieve beds and decreases the production of oxygen. The condition of the compressor's cup seals, bearings, and other components can also result in a noticeably louder running sound.

Compressor units may be serviced by replacing internal cup seals and bearings using a compressor rebuild kit. **(7.19 – 7.26)** If rebuilding the compressor using a rebuild kit is not sufficient to repair the compressor, the entire compressor unit may also be replaced.

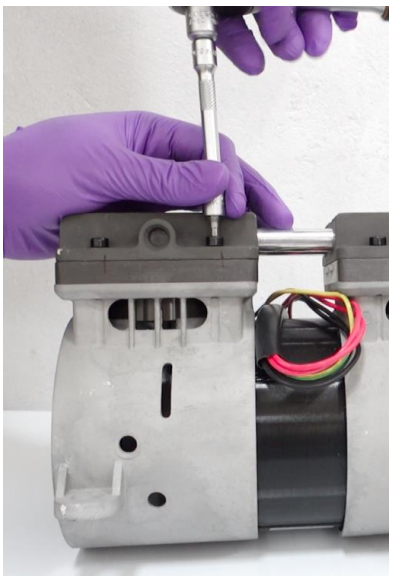
Alert 7.4

When reassembling the compressor after replacing the compressor kit, assemble the compressor sleeve, plates and cups before reattaching. It is important that the compressor plates and cups have adequate purchase in the compressor sleeves; if this is not done in the first attempt, push the compressor plate and cup through the sleeve and try again. Always nest the plate within the cup before pushing into the compressor sleeve.

Compressor segments are directional. Always label the sides of the compressor with permanent ink to ensure the correct pieces are installed for the correct side.

7.19 Slide panel up to access compressor.

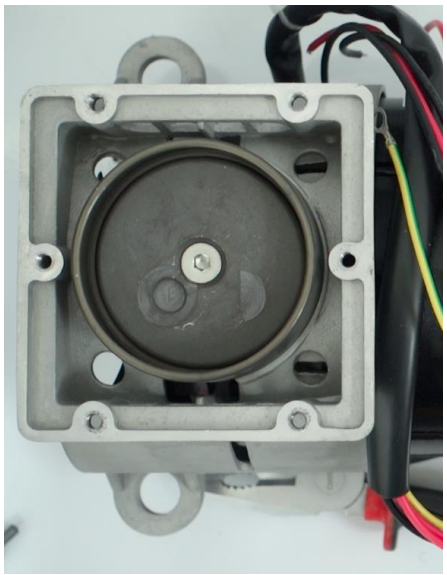
7.20 Mark sides of the compressor.



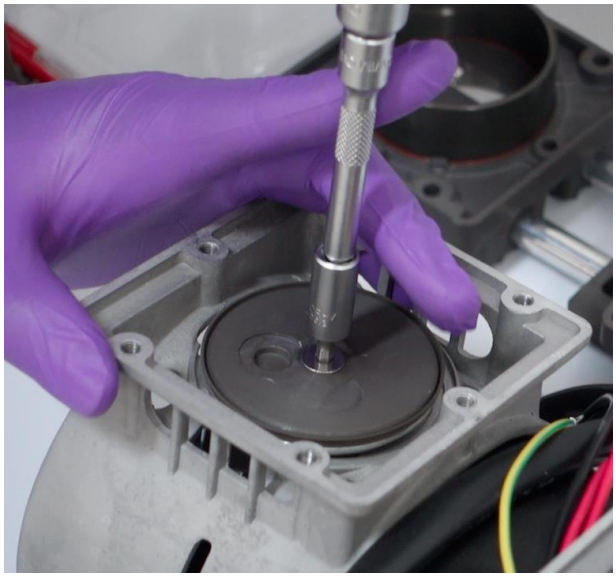
7.21. Use a ratchet to remove the bolts securing compressor head.

7.22 Lift off compressor head & assess head gaskets for damage.

7.23 Turn over valve plate and assess o-rings and reeds for damage. Replace if necessary.



7.24. Remove compressor sleeves & assess for visible damage. Clean interior with alcohol & cotton swab.



7.25 Remove the screw holding the compressor piston plate & cup in place. **Do this slowly to prevent stripping the screw.**

7.26 Check the compressor piston plates and cups for damage. Replace as needed.

The compressor relief valve and starting capacitor may also need replacement. These parts should be interchangeable with components of equivalent specifications, which can usually be determined from the component housing or device service manual.

Testing & replacing solenoid valves

Solenoid valves may be tested using a multimeter or by checking the magnetisation of the coils during operation. Valve coil resistance specifications for feed, waste and equalisation valves should be available from the manufacturer or service manual for a specific model. Coil specifications may vary within a model or between AC ratings.

Magnetisation can be tested by holding the metal tip of a magnetized screwdriver over the exposed top of the valve stem in the centre of the coil. When the coil becomes energized (magnetized) the tip of the screwdriver should be pulled down onto valve stem, indicating the valve coil is functional.

Solenoid valves may be serviced by replacing the internal coil or the entire solenoid valve assembly. The internal coil is directional and must be replaced in the same orientation as it was removed.

Assessing & replacing the fan

Most fan-related failures are due to physical damage to the fan itself or electrical damage to the fan PCB. The fan can be visually assessed for repair and replacement. The most common electrical damage to the fan PCB is the burnout of the fan transformer, which can be visually or electrically assessed. As in most PCB-based repairs, if one element of the PCB has been damaged, the entire PCB should be replaced.

Testing & replacing the thermal switch

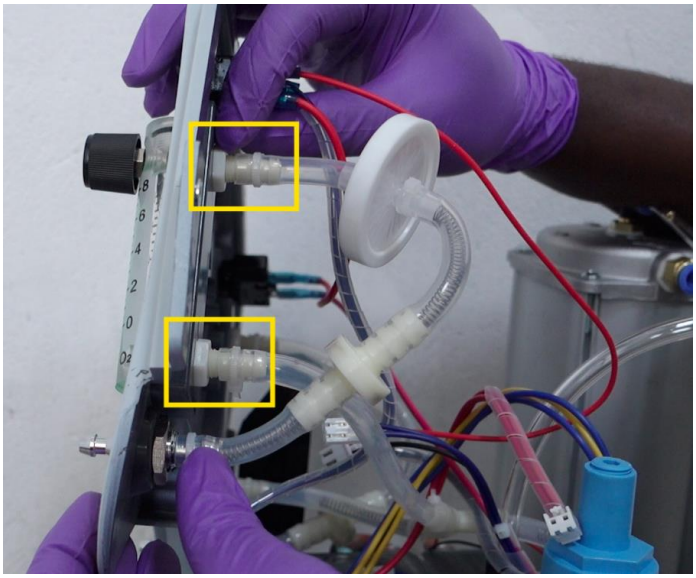
The thermal switch shuts down the compressor when it exceeds a high temperature threshold. The oxygen concentrator may keep running the fan to allow for more rapid cooling, but it will not be able to fully turn on until cooler temperatures are reached within the concentrator. The thermal switch may become faulty over time due to poor power quality or consistently high running temperatures. A faulty thermal switch will prevent the compressor from running even during

standard operating temperatures. Test the electrical integrity of the thermal switch using a multimeter; if a replacement is needed, contact the manufacturer for appropriate spares.

Assessing, repairing & replacing the flowmeter

The flowmeter may be damaged through user error or through lack of use and preventive maintenance over time. User error is design dependent; if the flowmeter is not designed to prevent the flowmeter bead from falling into the regulating knob channel, the flowmeter bead can be damaged or crushed as the flowmeter is closed. In most cases, the flowmeter bead is not a spare part and this damage will require the entire flowmeter assembly to be replaced.

The flowmeter may also develop debris or deposits that affect the movement of the flowmeter bead within the flowmeter channel. This can be repaired by taking apart and cleaning the flowmeter. **(7.27)**



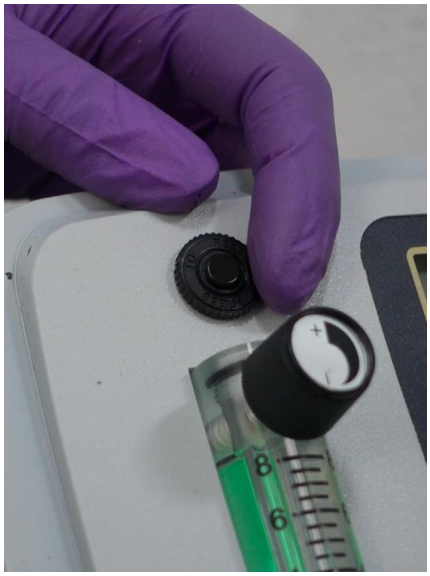
7.27 Points to remove flowmeter for replacement, cleaning or repair.

Assessing power quality

A qualitative measurement of power quality can be taken using an oscilloscope to observe the shape of the AC voltage delivered at the mains socket. If noise or other interference is visible on the voltage sine wave, the power quality is poor. Poor power quality contributes to the general accelerated failure of electrical components in medical devices, as do frequent differences in voltage delivered (e.g., lags and surges). If poor power quality is noted (either through observation or qualitative measurement) an in-line voltage stabilizer can be installed at a facility or ward level.

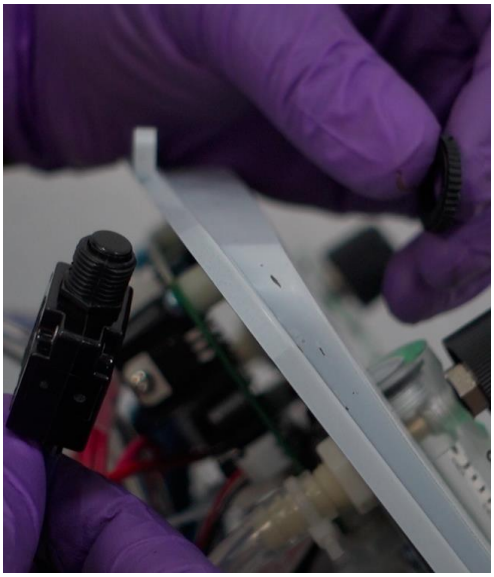
Assessing & replacing the reset button

The reset button is a circuit breaker that shuts down the concentrator completely when it experiences an electrical overload. The reset button may become faulty over time due to poor power quality. A faulty reset button will continuously shut down the concentrator repeatedly on any circuit it is plugged into, regardless of the power quality. This can be tested by assessing the power quality or voltage delivered from the mains power circuit the concentrator is on. If the power quality is acceptable, the reset button should be replaced. **(7.28 – 7.30)**



7.28 Front view of the reset button.

7.29 Unscrew ring housing reset button on the front of the concentrator.



7.30 Remove reset button and replace if needed.

? **Alert 7.5** Repurposing Parts

In some cases, parts on the unit may be replaced with a repurposed or recycled part from another piece of equipment being used for parts**. Repurposed parts should be considered with caution and guidance from the manufacturer to ensure specifications of the repurposed part is compatible with the equipment.** This includes spare parts and accessories that may not be compatible with multiple systems.

8 References

1. Oxygen therapy for children. (World Health Organization, 2016).
2. *WHO-UNICEF technical specifications and guidance for oxygen therapy devices.* (World Health Organization and the United Nations Children's Fund (UNICEF), 2019).
3. World Health Organization. T*echnical specifications for oxygen concentrators.* (World Health Organization, 2016).
4. Curless MS, Ruparelia CS, Thompson E, and Trexler PA, eds. 2018. *Infection Prevention and Control: Reference Manual for Health Care Facilities with Limited Resources.* Jhpiego: Baltimore, MD.
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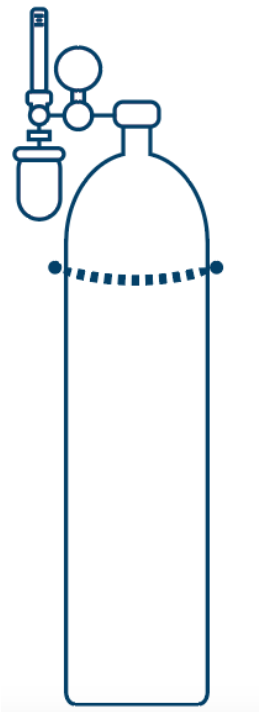
6. Sharma, G., Zaka, N. & Hailegebriel, T. *Infection Prevention and Control at Neonatal Intensive Care Units*. (2018).
7. Bradley, B. D. et al. *A retrospective analysis of oxygen concentrator maintenance needs and costs in a low-resource setting: experience from The Gambia.* Health Technol. 4, 319–328 (2015).

Respiratory Support

Oxygen Therapy

Oxygen Cylinder



1 Clinical Problem

Oxygen cylinders are used within multiple hospital settings. In newborn care units, an oxygen cylinder may be used as a standalone source of oxygen.

Oxygen cylinders may be used to provide supplemental oxygen directly to hypoxic patients, shared between patients using a flow splitter or used with other treatment devices such as continuous positive airway pressure devices. Supplemental oxygen is indicated for sick children, especially those with low blood oxygen saturation levels (SpO_2<90%) which has many clinical causes.

2 Assessment

Oxygen cylinders (2.1) may be used as backup to oxygen concentrators in case of power outage or transport, or as a primary means of delivering oxygen therapy to a patient. Cylinders may be piped to a particular area of the health facility using a walled oxygen system, or used directly within the patient area.

Oxygen cylinders are usually made of a steel or aluminium alloy and are distinguished from other cylinders by having a black body with white shoulders and top. The capacity of oxygen is rated in litres which indicates the amount of oxygen the tank can store. Cylinder sizing follows an alphabetical system. Each letter corresponds to the capacity in litres of that particular cylinder; cylinder sizes include D, E, F, G, J and corresponding capacities are 340, 680, 1360, 3400 and 6800 litres, respectively.[1]

2.1 Typical oxygen cylinders.

2.2 Typical transport cylinder.

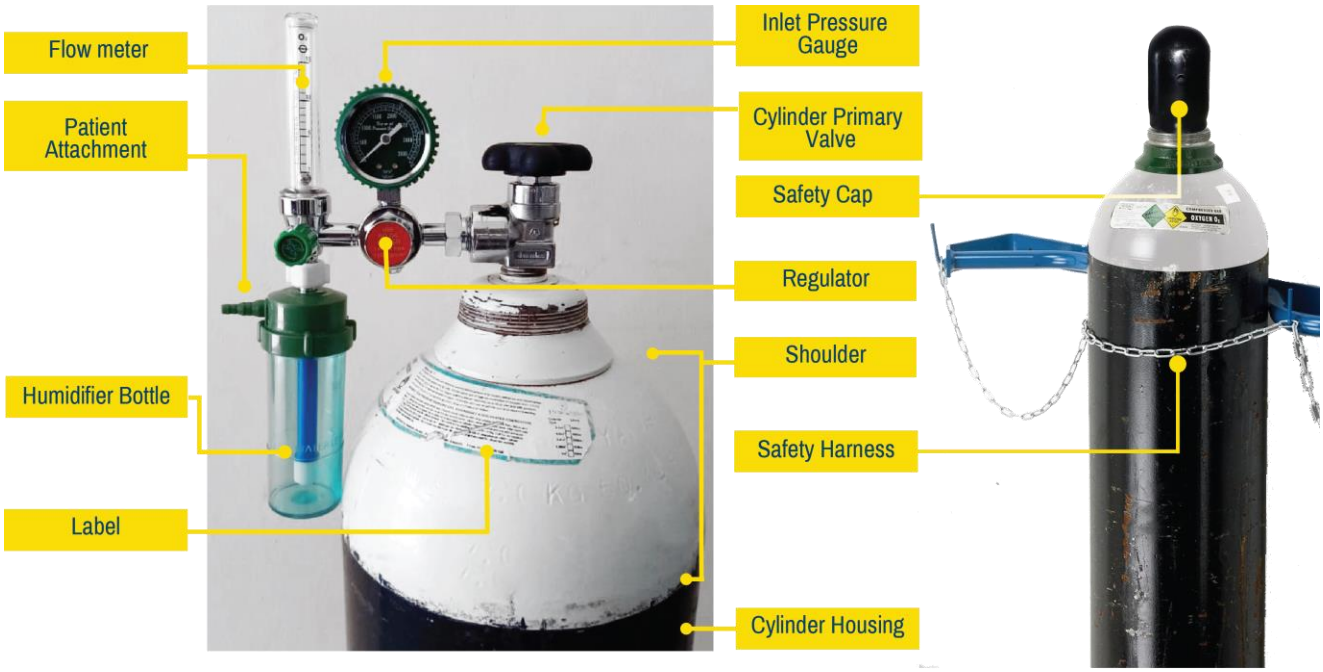
HOW IT WORKS

Oxygen cylinders are durable vessels filled with **medical grade oxygen** from an external source (e.g., a generation plant at a health facility or privately-owned company). In oxygen generation plants, oxygen cylinders are filled with oxygen at high pressures of 137 bar (13 700 kPa, 1987 psi) to 200 bar (20 000 kPa, 2 901 psi).[1] This pressure acts as a driver to push oxygen out of the cylinder when opened for use.

From the oxygen cylinder body, the oxygen passes through a **pressure gauge**. The pressure gauge indicates both the pressure and the contents; as the content pressure drives the oxygen release, the pressure decreases as the contents decrease. The indicated pressure is thus directly proportional to amount of oxygen remaining in the cylinder.

Before being given to a patient, the highly compressed oxygen passes through a **pressure regulator** to reduce its pressure to suitable levels for treatment. From the pressure regulator the oxygen passes through the **flow regulator** (or flowmeter) where the flow is set and delivered to the patient or another oxygen delivery device (e.g., a CPAP, flow splitter, nebulizer). The flowmeter should be read in the correct orientation and angle; if the flowmeter is vertical, it should be installed in a vertical orientation and read at eyelevel.

Some oxygen cylinders may also be made of different materials so they can be used as transport cylinders (smaller and on castors or wheels) or MRI cylinders (smaller, on wheels, and made of a material that will not interact with the MRI).



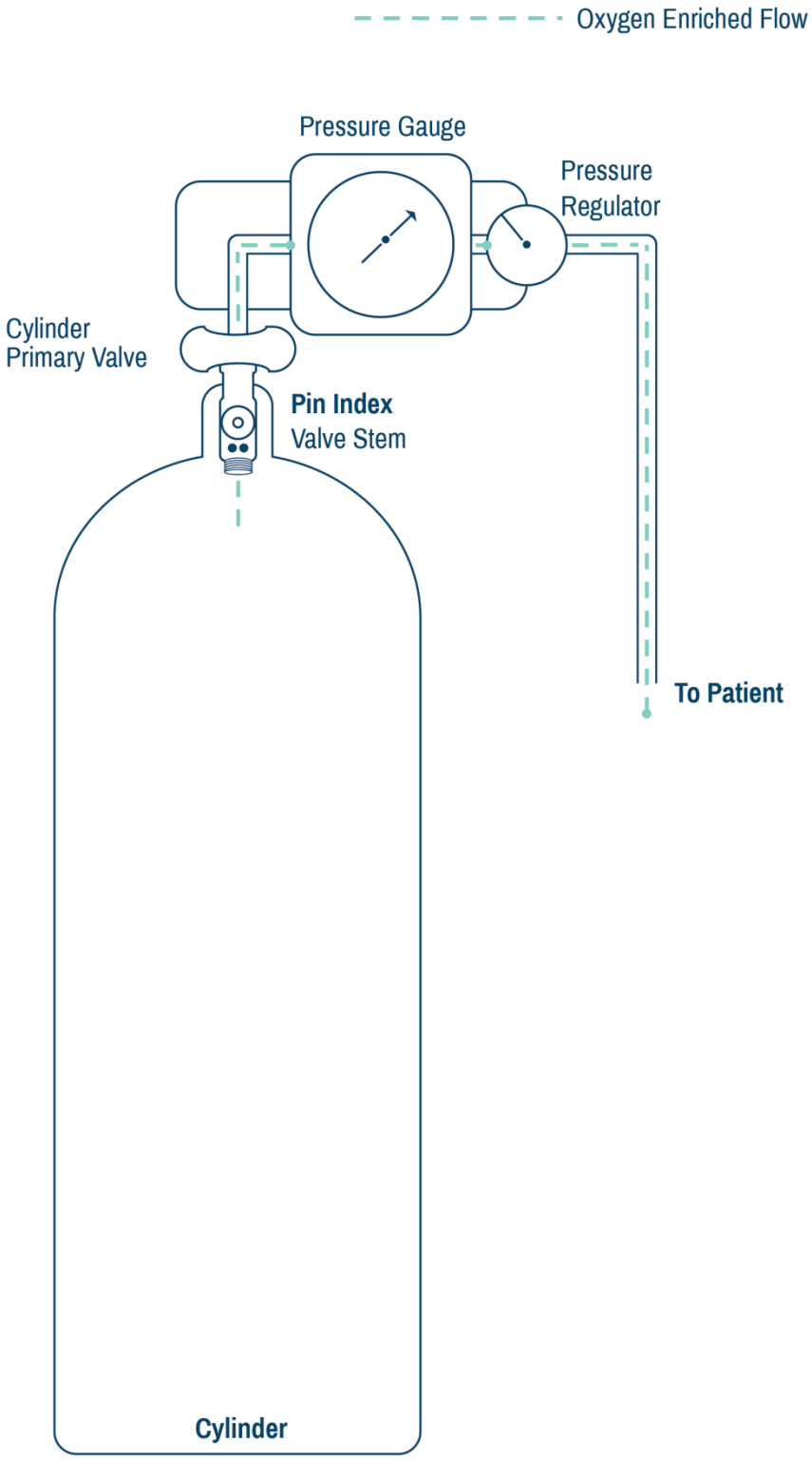
2.3 Major components of oxygen cylinders.

Oxygen cylinders may also be stored in oxygen distribution manifolds (groups of cylinders linked in parallel), which are largely used for piping oxygen for small patient loads. A distribution manifold is a bank that can hold more than one cylinder simultaneously (particularly useful for piped systems). Distribution manifolds are defined by both the number of cylinders and banks they have (e.g., a 2x2 manifold has two banks with two cylinders on each bank).

Distribution manifolds typically have two equal banks (sets) of cylinders attached; one is the primary manifold which is used first and the other is on standby for use when the primary manifold runs out. This ensures a continuous supply of oxygen to the pipeline. Manifolds are usually semi-automated or manually operated, although back-up manifolds may be automated (with a pressure transducer for change-over between the banks).

Between the two banks, there is a double-stage regulator to adjust the pressure going into the lines according to the number of outlets installed (capped between 0 to 13 bar). Each cylinder has its own valve that connects it to the main line and is connected to this main line valve using a pigtail with a safety wire (a high-pressure hose); in the event the hose ruptures, the wire will stay in place rather than hitting someone at high speeds due to the pressure. The pigtail is connected to the cylinder with a bullnose or pin index connection. **All cylinders are chained or strapped into place to reduce potential for projectile hazards.**

TYPICAL DEVICE FLOW



MAIN COMPONENTS

The following device components should be similar regardless of model. However, specific locations, visual setup and component type may vary by brand and device model. Refer to model service and user manuals if different from the displayed model for more device-specific information.

Housing

Oxygen cylinder housing is usually made of steel or aluminium alloy and distinguished from other gas cylinders by a black body and white collar.[2]

Label

Identifies contents and provides safety and sizing information.

Primary valve

Manually operated; opens the oxygen outlet port for oxygen flowing to the patient through pressure and flow regulators.

Cap

Safety covering for the primary valve.

Safety harness

The safety harness secures the oxygen cylinder to a specific location for added protection against compressed gas projectile safety.

Inlet pressure gauge

Indicates the real time pressure value in the oxygen cylinder. The pressure gauge reading is directly proportional to the amount oxygen in the cylinder.

Pressure regulator

Used to reduce the oxygen cylinder outlet pressure to a level that is safe for patient use. It can be adjustable or fixed and is usually set at 3.45 bar (345 kPa, 50 psi).[1]

Flow regulator

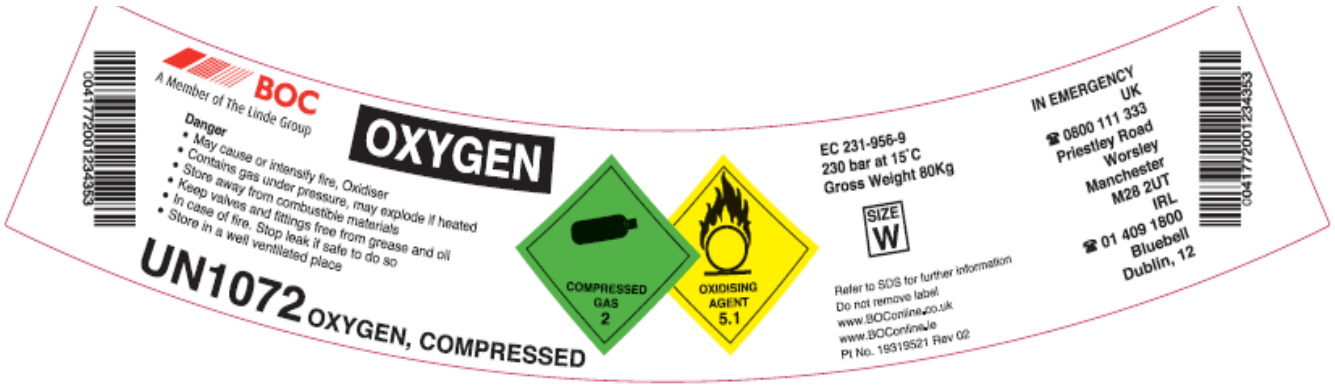
Flowmeter; controls and displays the oxygen delivery rate to the patient(s) in L/min. Since neonates require **low flows**, flow meters with precision of at least 0.1 L/min should be used. There are special ultra-low flowmeters available for use with neonates with precision adjustments of 0.02–0.03 L/min which, especially in settings which do not utilise blenders, can be particularly useful to provide necessary oxygen to neonates and minimising hyperoxia. However, ultra-low flowmeters are not

always available. **Great care should be taken to ensure safe oxygen administration when adjusting the oxygen flow through a standard flowmeter to monitor saturations and avoid hyperoxia, because the standard flowmeter does not allow for very low flow titrations.** When possible, cylinder oxygen intended for neonatal patients should be blended with ambient air to prevent harm, through an oxygen blender attachment or blending mask (e.g., a Venturi mask or blender).

SAFETY SYSTEMS

Since cylinders may be used to store a range of different gases, several different safety systems are employed to avoid interchanging cylinders that can lead to administering wrong gases to a patient or refilling a cylinder with a wrong gas:

- **Labelling:** Identifies contents and provides safety and sizing information. Cylinder labels typically contain the name and chemical symbol of the gas, cylinder contents in litres, tare weight (weight when empty), maximum cylinder pressure, cylinder size code and directions for use. **(2.4)**[3] Cylinder sizing follows a standard alphabetical order with each letter indicating its oxygen capacity. Each letter corresponds to the capacity in litres of that particular cylinder; cylinder sizes include D, E, F, G, J and corresponding capacities are 340, 680, 1360, 3400 and 6800 litres, respectively.[1]



2.4 Oxygen cylinder labelling.

- **Colour-coding:** cylinders can be distinguished by colour. ISO standards specify that an oxygen cylinder can be distinguished from other cylinders by a black body and white shoulders and top,[2] **although colour-coding varies by context and should be confirmed for local standards.** Colour should not be used as a primary way of differentiating cylinders due to this lack of universal standardisation and colour variation due to chemical changes of paint pigments with time.
- **Pin index:** usually employed in smaller cylinders, the pin index safety system identifies gas cylinders with specifically positioned holes below the outlet port. The valve can then only be connected to a yoke or pressure regulator with a matching pair of pins. **(2.5)**
- **Diameter index or bullnose:** most commonly employed in bigger cylinders, the pressure regulator bullnose of a particular gas will only connect to a bullnose valve of a cylinder of a similar gas. The nip and nut assembly of the bullnose connector is different for each type of gas. **(2.6)** Oxygen (DISS 1240) has been assigned 9/16"-18 thread connections as its DISS identifier.[4]

2.5 Pin Index Safety System.

2.6 Bullnose / Diameter Index Safety System.

3 Management

Management covers how to use the oxygen cylinder, including set up for a patient, patient commencement, care whilst on the device and removal of the patient from the device. These instructions are helpful for a biomedical engineer or technician both in user training and in assessing the appropriate functionality of the device.

SETTING UP FOR A PATIENT

1. Clean hands with soap and water or 70% alcohol before and after placing a patient on oxygen or handling any tubing that will be used on a patient.
2. Make sure the oxygen cylinder is in an upright position and is secured to a wall or stable object.
3. Assemble the pressure regulator and the flowmeter and connect them to the cylinder using the pin index connector. The flowmeter **must be upright** (vertical to the floor) to be read correctly. Tighten all connections and make sure there are no leaks. Ensure that the cylinder's flowmeter is closed.
4. Slowly open the primary valve (using the cylinder key or hand-wheel). Check the amount of oxygen in the cylinder by reading the pressure gauge.
5. Connect the oxygen delivery device (e.g., nasal cannula, Venturi mask, bCPAP, etc.). Adjust the flowrate required with the flowmeter regulator.
6. If the patient's healthcare provider has determined the patient requires humidification, assist the healthcare worker to ensure a humidifier is correctly connected to the concentrator. If oxygen needs are greater than 4 L/min, a humidifier is recommended.[5,6] **(Alert 3.1)**

Alert 3.1

Per WHO recommendation in *WHO Oxygen Therapy for Children* and *WHO Technical Specifications and Guidance for Oxygen Therapy Devices*, when oxygen is delivered at higher than standard flow rates (> 1L/min for neonatal and 2L/min for infant patients), humidification is necessary.[1,6] Ultimately, the decision to humidify low flow oxygen or not is a clinical one which is influenced by oxygen source (tank, concentrator), oxygen flow, climate, patient age, resource availability and clinical status. If used in series with another device, humidification should be added after the device and just prior to the patient interface to prevent moisture build-up in the ancillary device.

7 Test that oxygen flow has begun by listening for a hissing sound at the patient end of the delivery device (e.g., nasal prongs). This also can be tested by submerging the nasal prongs in clean water and checking for bubbles **(3.1)**, also known as the "Bubble Test".[5]

3.1 Submerging the nasal prongs in water should produce bubbles.

4 Infection Prevention

Routine and adequate cleaning of medical devices is critical to prevent hospital-acquired infections in newborn care units.

CLINICAL INFECTION PREVENTION

1 Clean hands with soap and water or 70% alcohol before and after placing a patient on oxygen or handling any tubing that will be used on a patient.

2 Ensure that all patient-related tubing or interfaces are new or has been cleaned thoroughly and dried as per re-use guidelines. Any patient-related tubing or interfaces must be cleaned immediately after use; If reusing, immediately begin hospital protocol for disinfection of any patient-related tubing or interfaces. Delay in initiating cleaning of reused medical devices can lead to the need for more intensive cleaning procedures to remove pathogens. If not reusing, discard appropriately. **(Alert 4.1)**

3 Tubing should be hung to dry after disinfection and should not touch the floor or other unsanitary surfaces whilst drying. Any item falling on the floor is contaminated and must be thoroughly recleaned.

Alert 4.1

Respiratory circuits and humidifiers associated with oxygen delivery are generally intended as single use devices. However, in areas with limited resources or challenging supply chains, this equipment is often re-used. When re-processing single use devices it is extremely important that the cleaning process is not delayed following completion of use. If equipment is not re-processed promptly or adequately between patients, it poses a significant infection risk. Please refer to the **Reference Manual for Health Care Facilities with Limited Resources Infection Prevention and Control, Module 6**[7] for more detailed guidance on the re-processing of single use devices.

4 The housing of the oxygen cylinder should be cleaned according to ward guidelines for disinfecting surfaces, or by wiping down with soapy water.

5 Ensure the primary valve is tightly shut in between patients and whilst being stored.

DISINFECTION AFTER USE

1 Close the flowmeter on the cylinder. Clean the flowmeter, gauge and dials using 70% alcohol after every use. **(Alert 4.2)**

2 Dispose of water within humidifier bottle and, if reusing humidifier and tubing, immediately remove and begin hospital protocol for disinfection. **(Alert 4.1)**

BMET INFECTION PREVENTION

1 Any piece of equipment used in providing patient care must be handled carefully, as it may be contaminated and have the potential to spread infection.

2 Clean and disinfect oxygen cylinder housing and components whilst wearing PPE as appropriate (e.g., rubber gloves, apron, face protection, etc.) **before any repairs or maintenance are made.** Avoid any contact between used piece of equipment and skin, mucosa or clothing.

3 Post-maintenance, decontaminate all tools and surfaces used with 70% alcohol or according to manufacturer guidelines. Do not use equipment until it has fully dried following decontamination.

Alert 4.2 Disinfecting Equipment

Disinfection of equipment should always comply with manufacturer guidelines. WHO recommends 0.5% dilution of chlorine (0.5% or > 100ppm available sodium hypochlorite) as the standard disinfectant for materials and surfaces contaminated by blood or body fluids.[8] For metal and rubber surfaces, which may be corroded by chlorine, 70% alcohol is also commonly utilised for low level disinfection.

Other appropriate low-level disinfectants include quaternary ammonium, improved hydrogen peroxide and Iodophor germicidal detergent.[7] Phenolic germicidal detergent is also identified but should not be used in neonatal wards since affordable, effective alternatives are available; and, there are concerns it may cause hyperbilirubinemia and/or neurotoxicity in neonates.[9]

See dedicated NEST360° module on Infection Prevention and Control for further details on risks, benefits and utilization of chemical disinfectants. For comprehensive guidance on infection prevention and control we recommend utilising Reference Manual for Health Care Facilities with Limited Resources Infection Prevention and Control (Caston-Gaa & Ruparelia, 2018).

5 Complications

Equipment in newborn care units are highly specialised. Without proper knowledge and skills, this equipment can be potentially dangerous for the infants, families and care providers.

DEVICE COMPLICATIONS

- **Fire**: oxygen is an agent of combustion, meaning fire will burn more readily in its presence. Never use grease or oil to lubricate parts of the oxygen cylinder.
- **Pressurised gas**: oxygen cylinders are filled at very high pressures and **must be chained** to secure in place. **(5.1)** Accidently tipping over a high-pressurised oxygen cylinder can easily dislodge the valve stem, creating a high-speed projectile. This projectile can move with sufficient speed and strength to break through cement walls, posing an extreme danger to surrounding patients, health staff and hospital infrastructure. **(5.2) The safety cap must be on the cylinder when the pressure regulator is not attached. (Alert 5.1)**

5.1 Appropriate oxygen cylinder securing system.

5.2 Damage from a pressurised oxygen cylinder breaking through a cement wall.

- **Cylinder empty**: the primary valve on the cylinder must be turned off completely when the cylinder is not in use. It is not uncommon for the valve to be left partially open, slowly emptying the cylinder. Excessive force in closing the valve should be avoided as it may result in stripping the threading.

Alert 5.1

Irresponsible use of high pressurised oxygen cylinders could easily result in a disaster, serious injury or death for patients or staff on the ward. **Strict adherence to safety protocol, maintenance and proper use is critical when using oxygen cylinders.**

6 Care & Maintenance

Biomedical engineers and technicians are responsible for second-line care and maintenance to ensure equipment lasts to their potential lifetime.

POWER SOURCE

Oxygen cylinders are not powered.

WARD LOCATION

Oxygen cylinders should always be kept well-secured and safe from tipping or dropping, ideally along a wall with securing chains anchored into the wall. **Oxygen cylinders should not be placed precariously, tilted or located without securing chains in the middle of walking areas**. Store in well ventilated, clean and dry conditions. Oxygen cylinders should be well labelled and easily distinguishable from other cylinders. Keep away from contaminants like oil and grease and sources of heat or ignition. **Always use a secure trolley when transporting cylinders.** Oxygen cylinders may also be stored in oxygen manifolds for smaller patient loads. Equivalent requirements for safe securing of cylinders apply.

DEVICE CALIBRATION

Pressure gauges require yearly calibration. This should be completed by calibration professionals in accordance with the accuracy class of the pressure gauge. Low pressure gauges may be calibrated with air or gas; however, due to the high pressure range in oxygen cylinders, it may be safer to use liquid .

Oxygen cylinders require hydrostatic testing every 3, 5 or 10 years to ensure that the cylinder can safely hold maximum fill pressure. Hydrostatic testing checks the structural integrity of the oxygen

cylinder by filling the cylinder with water and pressuring it above its normal operating limit. If the cylinder expands under pressure beyond acceptable limits, the cylinder must be decommissioned.[10]

DECOMMISSIONING

Oxygen cylinders are usable as long as they are in physically good condition. As the use of oxygen cylinders is high-risk, physical damage should be taken seriously and cylinders decommissioned if structural integrity is compromised or if they fail hydrostatic testing. In these cases, if the primary valve stem is still in good condition, it may be reused and the cylinder housing repurposed. Components used with oxygen cylinders may also be reused or repurposed (e.g., oxygen regulators, flowmeters).

PREVENTIVE MAINTENANCE

After Each Use

- [ ] Turn the primary valve to close the oxygen cylinder. Use gauze and 70% alcohol or diluted chlorine to thoroughly wipe the oxygen flowmeter controls and primary valve.

  See **Oxygen Cylinder: Disinfection After Use** and **Alert 4.1** for more information.

- [ ] Visually inspect oxygen cylinder components and location. Ensure that cylinder is securely chained in place.

Weekly

- [ ] **Check the regulator:**
  - Assemble the pressure regulator and the flowmeter and connect them to the cylinder using the pin index connector. Tighten all connections and make sure there are no leaks. Ensure that the cylinder's flowmeter is closed.
  - Slowly open the primary valve (using the cylinder key or hand-wheel). Check the amount of oxygen in the cylinder by reading the pressure gauge.
  - Open the flowmeter its lowest setting and flush the pressure gauge and flow meter with oxygen for 2 minutes.
  - Confirm that there are no audible sounds of leakage and that the flow meter can go up to its maximum delivery rate.
- [ ] Examine the outside of the cylinder for dents, burns or grease.
- [ ] Document pressure reading and preventive maintenance actions taken.

Monthly

- [ ] Perform **Weekly** preventive maintenance steps.
- [ ] Visually assess the filling port for debris, grease and signs of corrosion.
- [ ] Document pressure reading and preventive maintenance actions taken.

Quarterly

- [ ] Perform **Monthly** preventive maintenance steps.
- [ ] Assess oxygen cylinder infrastructure in ward for accessibility of securing chains and patient access.
- [ ] Document pressure reading and preventive maintenance actions taken.

Annually

- [ ] Perform **Quarterly** preventive maintenance steps.
- [ ] Request **Pressure Gauge Calibration**.
- [ ] Check dates for hydrostatic testing for all cylinders. If necessary, request **hydrostatic testing**.
- [ ] Confirm supply of spare pressure gauges, pressure regulators, O-ring/sealing gaskets, securing chains and oxygen tubing are adequate to support estimated replacement for next year.
- [ ] Document pressure reading and preventive maintenance actions taken.

7 Troubleshooting & Repair

Biomedical engineers and technicians are responsible for providing rapid maintenance, troubleshooting and repair support for users.

PREPARE FOR REPAIR

ACCESSIBLE TOOLS	SPARE PARTS	DEVICE CHECKLIST
Phillips, star & flathead screwdrivers Allen keys Adjustable wrench Needle nose pliers Soapy water Oxygen analyser Pressure gauge	Primary valve Pressure gauge Pressure regulator O-ring / sealing gasket Tubing Crimp or zip ties Flow regulator	☐ Oxygen cylinder ☐ Pressure regulator ☐ Pressure gauge ☐ Flow regulator

TROUBLESHOOTING FAILURES

No oxygen is emitted from the oxygen cylinder.

Probable Cause: Faulty pressure regulator or loose connection

Components to Check: Pressure gauge and regulator physical condition
Remaining gas volume
O-ring / sealing gasket physical condition

The oxygen cylinder is emitting an audible hiss.

Probable Cause: Leakage or loose connection

Components to Check: Tubing & component physical condition
O-ring / sealing gasket physical condition

Oxygen is flowing, but flowmeter ball is not moving or the pressure gauge does not show any pressure.

Probable Cause: Debris in flowmeter connection circuit or pressure gauge fault

Components to Check: Flowmeter physical condition
Pressure gauge and regulator physical condition

REPAIR & REPLACE

Oxygen cylinders should be removed to the biomedical workshop for testing or repair. **(7.1)**

Alert 7.1

All testing, repair and replacement steps should be conducted with the oxygen cylinder secured to a wall or bracket, unless otherwise stated.

Testing & replacing the pressure regulator

Close the primary valve and remove the pressure regulator. Visually inspect the pressure regulator for physical damage on the external housing and the valve outlet for debris that may be obstructing flow or allowing leaks. Remove any debris with a clean, dry cloth. Connect the regulator with another oxygen cylinder to test its functionality. If a replacement regulator is needed, check the oxygen cylinder specifications before purchasing and installing a replacement. **Tape, epoxy and other glues should not be used to prevent leaks on oxygen cylinder connections.**[11] Assess that the pressure displayed is as expected for the cylinder contents; if this reading is low, the pressure regulator and cylinder connection may be leaking.

Testing & replacing the tubing components

Leaks may contribute to both low oxygen flow delivery and accelerated oxygen use. Tubing can be assessed for leaks by running soapy water or foam along the suspected tubing, pipes and fittings during operation and checking for bubbles or movement of the liquid.

Testing & replacing O-rings/sealing gaskets

Sealing gaskets are present at various points in the oxygen cylinder circuit and should be checked if leaks are present in the system. Remove the pressure regulator and check the condition of the Bodok seal fitted between the cylinder and the regulator. If deteriorated, replace. If a humidifier or flowmeter is in circuit, check the O-rings at each of these points for deterioration.

Testing & replacing the flowmeter

The flowmeter may be damaged through user error or through lack of use and preventive maintenance over time. User error is design dependent; if the flowmeter is not designed to prevent the flowmeter bead from falling into the regulating knob channel, the flowmeter bead can be damaged or crushed as the flowmeter is closed. In most cases, the flowmeter bead is not a spare part and this damage will require the entire flowmeter assembly to be replaced.

The flowmeter may also develop debris or deposits that affect the movement of the flowmeter bead within the flowmeter channel. This can be repaired by taking apart and cleaning the flowmeter.

Alert 7.2

Correct parts **must be used when repairing or replacing components of the oxygen cylinder.** If correct parts are unavailable, liaise with a local oxygen cylinder supply company for appropriate replacement parts. Using incorrect parts can lead to fire, physical damage and oxygen waste.

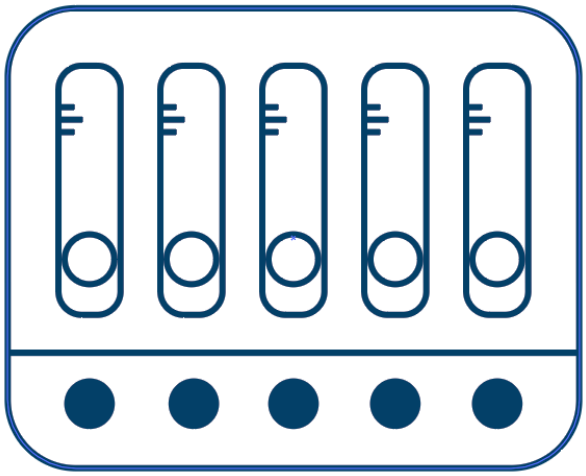
8 References

1. *WHO-UNICEF technical specifications and guidance for oxygen therapy devices*. (World Health Organization and the United Nations Children's Fund (UNICEF), 2019).
2. ISO/TC 58/SC 4. *ISO 32:1977: Gas cylinders for medical use — Marking for identification of content*. https://www.iso.org/.
3. British Compressed Gases Association. Technical Information Sheet 6 - Gas Cylinder Identification Label and Colour Code Requirements. *BCGA TSC2* BCGA TIS 6, (2018).
4. CGA. *Standard for Diameter Index Safety System (Noninterchangeable Low Pressure Connections for Medical Gas Applications)*. https://portal.cganet.com/ (2019).
5. World Health Organization. *Technical specifications for oxygen concentrators*. (World Health Organization, 2016).
6. *Oxygen therapy for children*. (World Health Organization, 2016).
7. Curless MS, Ruparelia CS, Thompson E, and Trexler PA, eds. 2018. Infection Prevention and Control: Reference Manual for Health Care Facilities with Limited Resources. Jhpiego: Baltimore, MD.
8. World Health Organization, Regional Office for the Western Pacific, World Health Organization, & Regional Office for South-East Asia. *Practical guidelines for infection control in health care facilities*. (World Health Organization, Regional Office for Western Pacific ; World Health Organization, Regional Office for South-East Asia, 2004).
9. Sharma, G., Zaka, N. & Hailegebriel, T. Infection Prevention and Control at Neonatal Intensive Care Units. (2018).
10. ISO/TC 58/SC 4. *ISO 10461:2005: Gas cylinders — Seamless aluminium-alloy gas cylinders — Periodic inspection and testing*. https://www.iso.org/.
11. BOC Limited. *PTFE tape and oxygen service*. https://www.boconline.co.uk/.

Respiratory Support

Oxygen Therapy

Flow Splitter



1 Clinical Problem

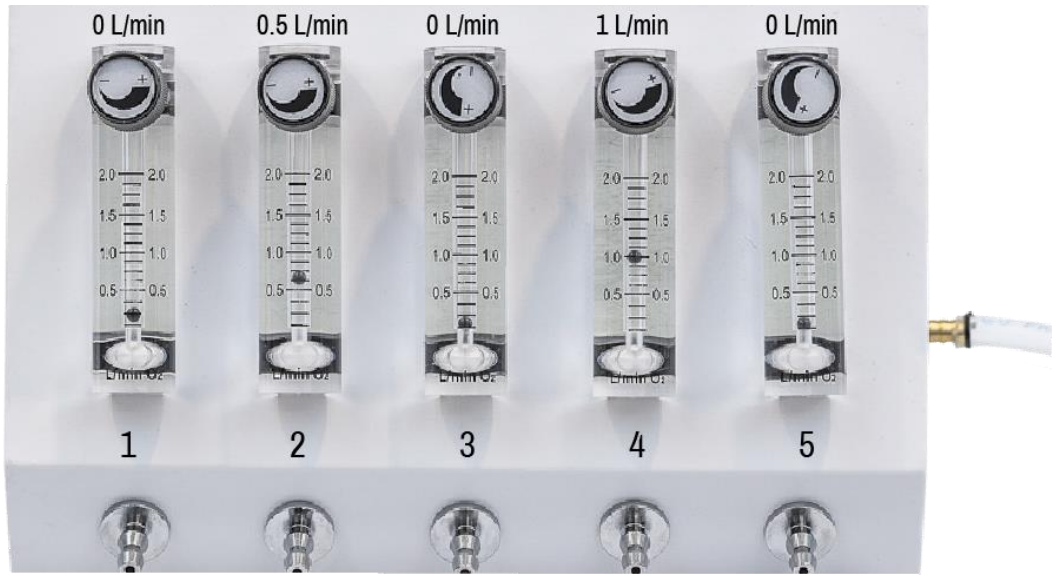
Flow splitters are used exclusively within the newborn and paediatric wards to deliver oxygen to several patients from a single oxygen source.

Supplemental oxygen is indicated for sick children, especially those with low blood oxygen saturation levels (SpO_2<90%) which has many clinical causes. Flow splitters are not typically used in adult wards due to their restriction to low flows, which do not meet typical adult treatment needs.

2 Assessment

Flow splitters are accessory devices that divide oxygen from one source to several patients at independent, adjustable flow rates. Maximum flow delivered per device depends on model and ranges from 1 to 2 L/min.

Flow splitters **(2.1)** may be used with any oxygen concentrator, oxygen cylinder or piped oxygen to provide low flow supplemental oxygen to patients. Flow splitters may also be combined with CPAP if the oxygen source and splitter flow meter have the capacity for the flow rates required. This technical module will provide visual guidelines for the use of flow splitters with an oxygen concentrator source, although **these may be applied to the use of flow splitters with any other oxygen source**.



2.1 Typical flow splitter.

Flow splitters may be adjustable or pre-set:

- **Adjustable:** Oxygen flow is divided by branching secondary tubes from a primary tube with one end connected to the oxygen source and the distal end closed. **(2.5)** All secondary tubes are equally spaced and have the same diameter and cross-section. Each flow meter operates independently and can be adjusted individually to the preferred flowrate as prescribed by medical personnel.
- **Pre-Set:** oxygen flowrates on each oxygen outlet are fixed. These systems are usually fastened directly to the oxygen concentrator or cylinder.

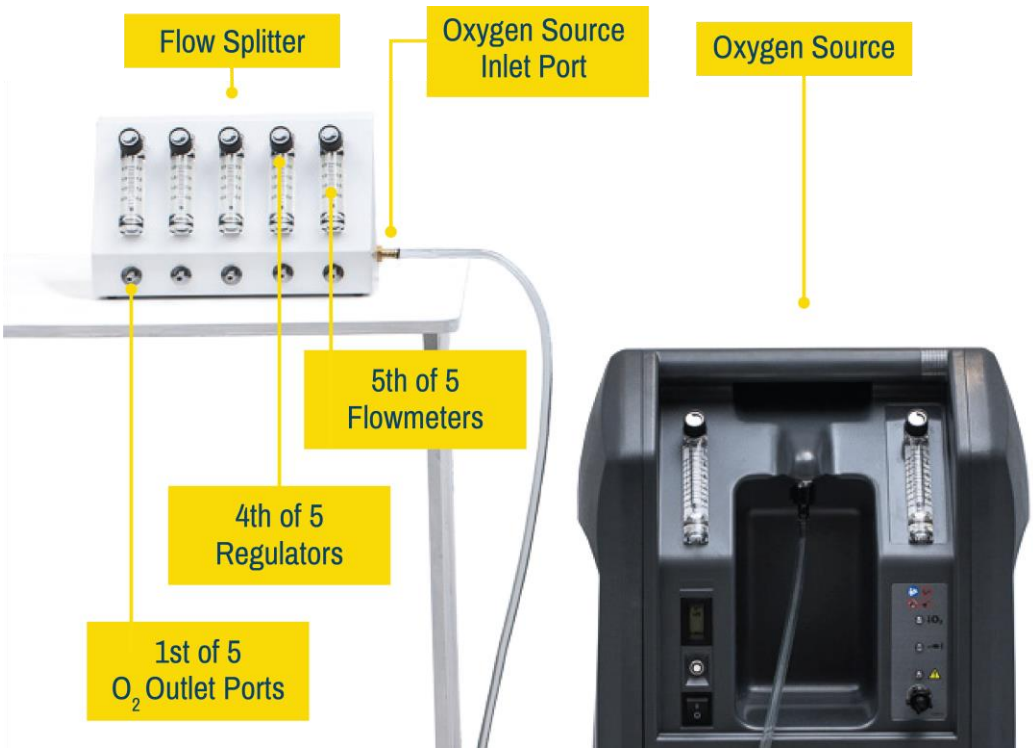
Neonatal patients should reach SpO_2 levels of 90–95% by 15 minutes after birth. If oxygen is needed it is recommended to give between 0.5-1 L/min per WHO standard.[1] Whilst on oxygen, regular monitoring should be conducted including use of a pulse oximeter to ensure that this saturation range is maintained for the duration of treatment. **(2.2)** Ideally, patients suffering from severe respiratory distress should have continuous pulse oximetry monitoring throughout care.[1]

2.2 SpO_2 levels should be monitored regularly and remain between 90 – 95%.

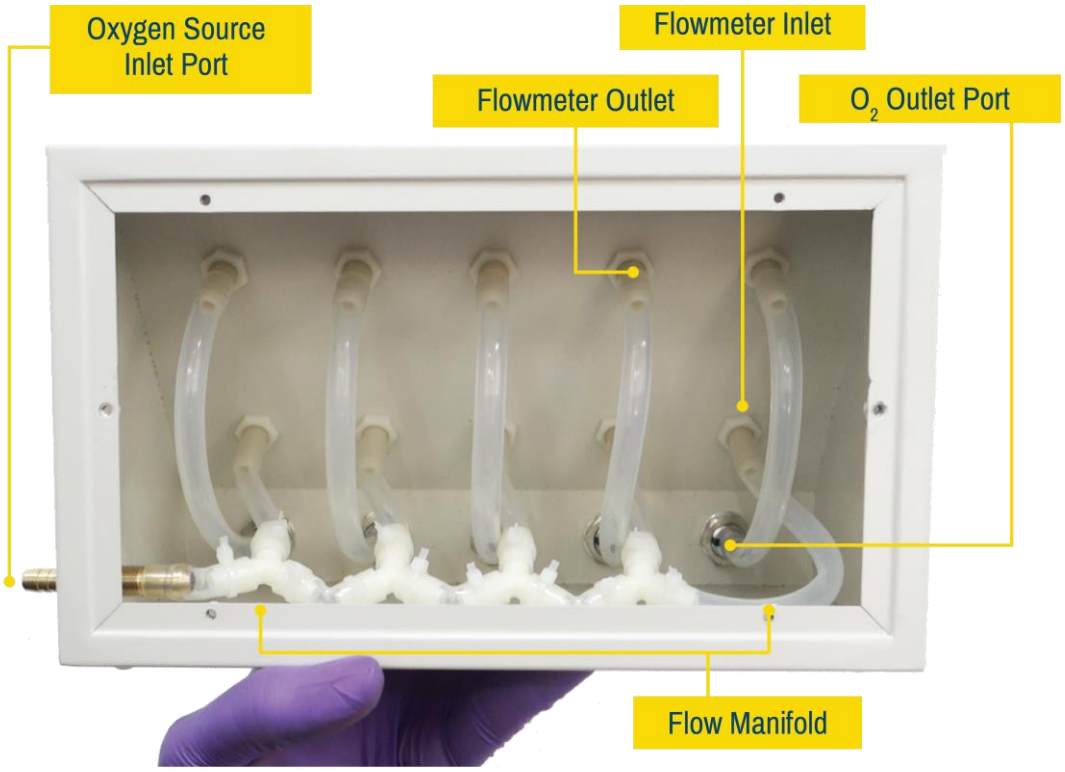
HOW IT WORKS

A flow splitter has internal tubing with individual flow meters that split incoming oxygen flow coming from an oxygen source (i.e., oxygen concentrator or cylinder). **(2.2)** Oxygen flow splitters generally provide low flow rates, from 0.1 up to a maximum of 2 L/min from each port. **The oxygen concentration delivered through an oxygen flow splitter remains unchanged from that of the source.** Any discrepancies from the oxygen source or tubing circuit will affect the oxygen delivered at the outlets of the flow splitter.

Standard external and internal device components are annotated below in **Figures 2.3** and **2.4**. Components should be similar regardless of model. However, specific locations, visual setup and component type may vary by brand and device model. Refer to service and user manuals if model in use is different from the displayed version.



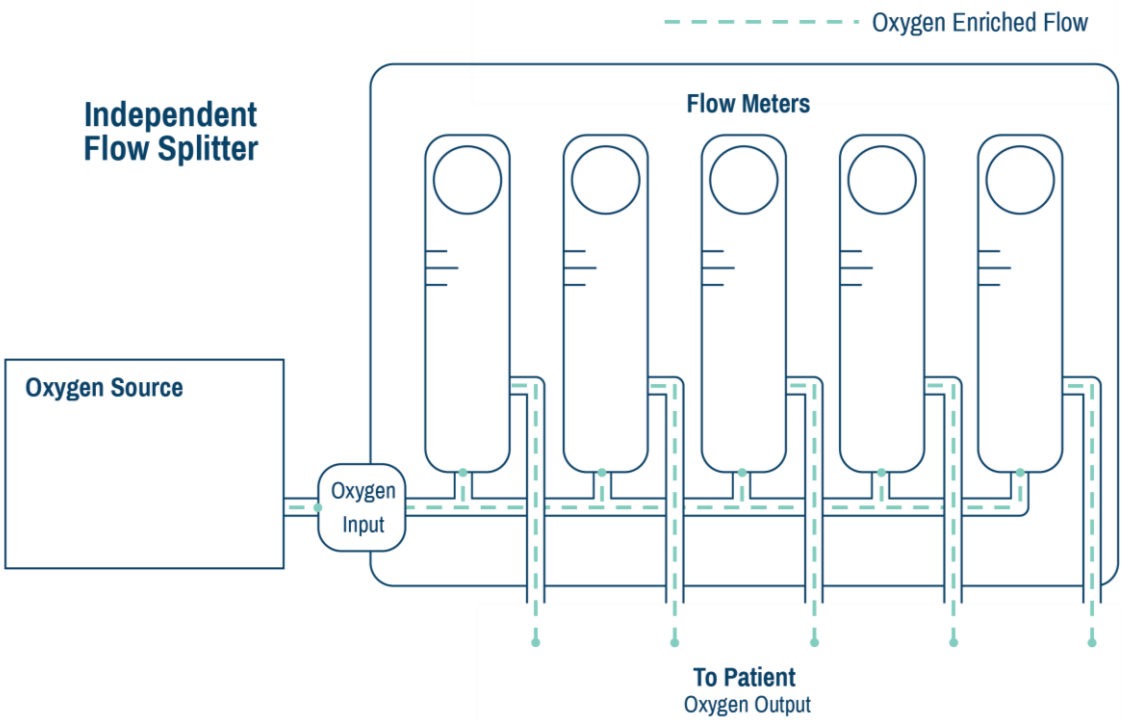
2.3 External flow splitter components.



2.4 Internal flow splitter components.

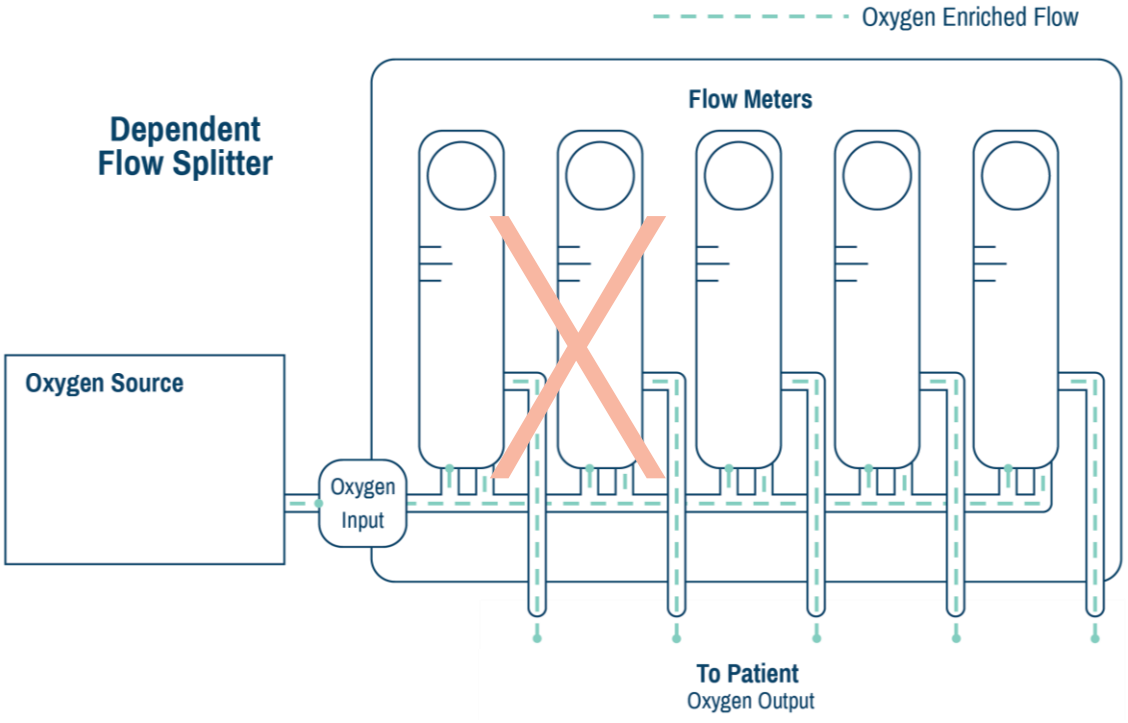
TYPICAL DEVICE FLOW

Flow splitters should be designed to have independent flow regulation; changing the flow rate at one port should have no (or only temporary) effect on the other ports. **(2.5)**



2.5 Flow of oxygen in an independently regulated flow splitter.

If the flow splitter is designed such that individual flow meters provide feedback into the general oxygen flow circuit, flows may be dependent: as one port flow is changed, other port flows may change. **(2.6)** These flow splitters should be changed for flow splitters with independent as quickly as possible to ensure reliable treatment.



2.6 Flow of oxygen in a dependently regulated flow splitter.

MAIN COMPONENTS

The following device components should be similar regardless of model. However, specific locations, visual setup and component type may vary by brand and device model. Refer to model service and user manuals if different from the displayed model for more device-specific information.

Oxygen Source Inlet port

The inlet port is the oxygen inlet source, typically located on the side of the device.

Outlet port

Flow splitters usually have four to five oxygen outlet ports, individually controlled by flow meters. Oxygen ports not in use should remain closed.

Flow meter

The flow meter, or flow regulator, controls and displays the oxygen delivery rate to the patient(s) in L/min, from 0.1 up to a maximum of 2 L/min from each port. The flow meter is marked for low flow rates, with individual graduations from 0.1 to 0.5 L/min to provide the low flow rates needed in neonatal or infant patients.

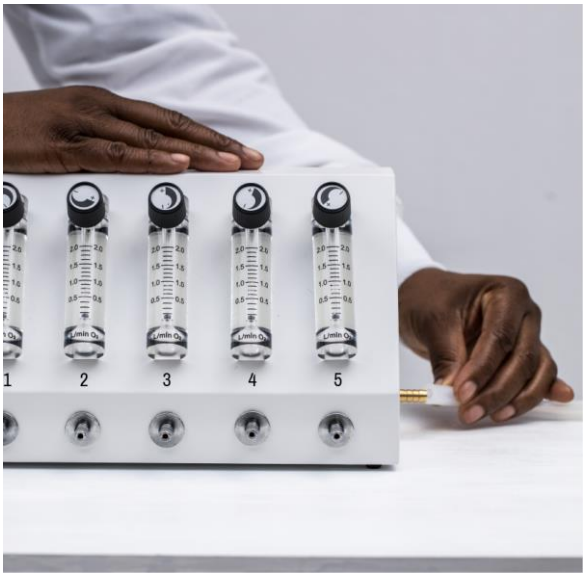
3 Management

Management covers how to use the flow splitter, including set up for a patient. Patient commencement, care whilst on oxygen and removal of the patient from oxygen are generic to oxygen therapy care guidelines. These instructions are helpful for a biomedical engineer or technician both in user training and in assessing the appropriate functionality of the device.

SETTING UP FOR A PATIENT

1. Ensure oxygen flow splitter is secured in a location where it cannot be easily dislodged and where staff can easily view and adjust the flow meter regulators on the splitter. **(3.1)** Open flow meters.

3.1 The oxygen splitter is securely placed with easy access to flow meters.

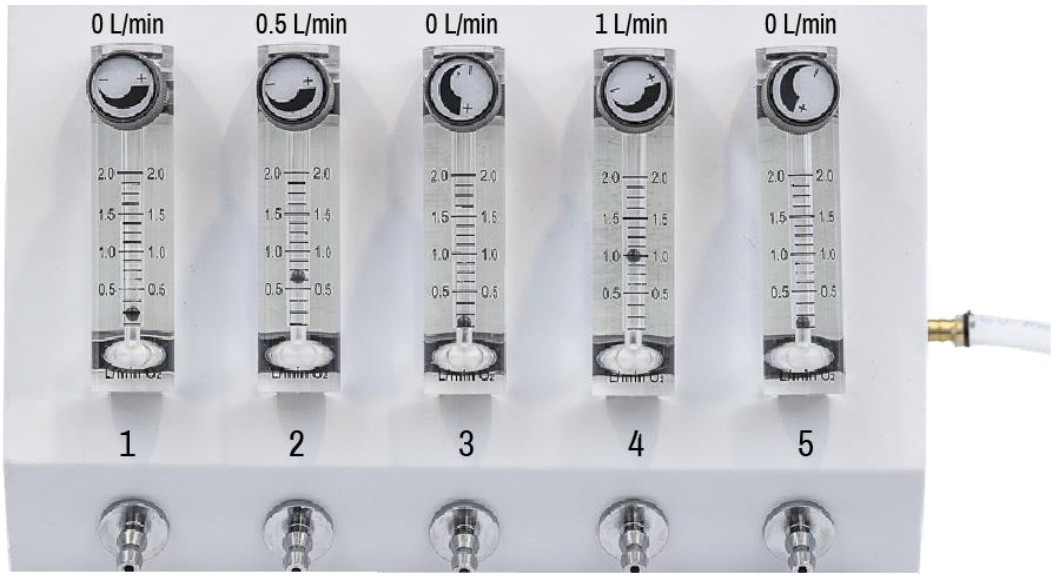


3.2 Connect flow splitter tubing from oxygen outlet to flow splitter inlet port.

2 Connect oxygen splitter tubing from oxygen outlet source to oxygen splitter inlet port. **(3.2)**

3 Assess level of oxygen needed from oxygen source. The source of oxygen (e.g., the concentrator, oxygen cylinder or piped oxygen) must be adjusted to provide a flow of at least 1 L/min oxygen **more** than the total requirement from all the ports that are in use. **(3.3)**

For example: If 2 ports are in use (one port is set at 1 L/min, one port is set at 0.5 L/min) and three ports are shut, the total supply of oxygen required from the concentrator is **2.5 L/min** (i.e., 0 + 0.5 + 0 + 1 + 0 (+1 extra L) = **2.5 L/min**)

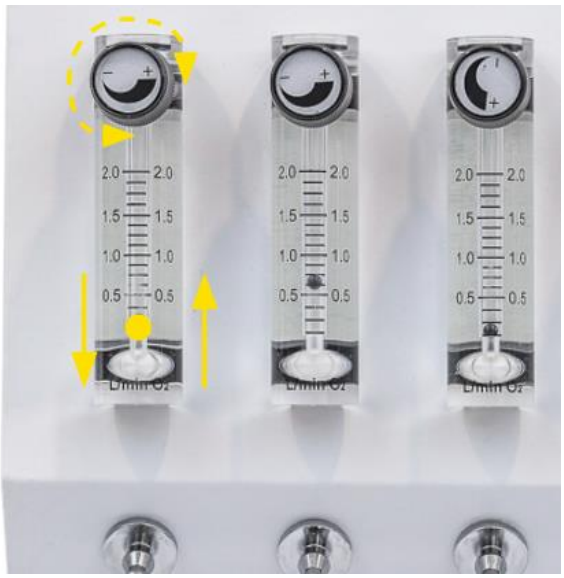


3.3 Assess level of oxygen needed from oxygen source.

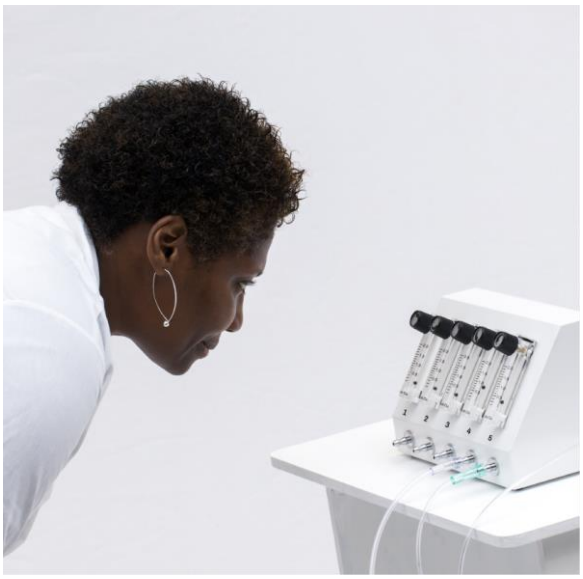
4 Turn on oxygen at source. The flow meter beads on the oxygen splitter should pop up.

5 Adjust the flow meter regulators individually to the required flow rates **(3.4)**, observing the L/min at eyelevel. **(3.5)** The flow rates at the other outlet ports should not change as a single port is adjusted. If being used with an oxygen concentrator, some cyclical variation may occur.

6 Check that the ports have been numbered and number oxygen tubing to prevent infants receiving an incorrect flow. When changing flows for one patient, ensure that any other patients also on the flow splitter are receiving the correct amounts of oxygen.



3.4 Adjust flow meter regulators individually.



3.5 Observe provided L/min at eye level.

4 Infection Prevention

Routine and adequate cleaning of medical devices is critical to prevent hospital-acquired infections in newborn care units.

CLINICAL INFECTION PREVENTION

1 Clean hands with soap and water or 70% alcohol before and after placing a patient on oxygen or handling any tubing that will be used on a patient.

2 Ensure that all patient-related tubing is new or has been cleaned thoroughly and dried as per re-use guidelines. **(Alert 4.1)** Any patient-related tubing must be cleaned before it is used to place another patient on nasal prongs. Nasal prongs are especially difficult to clean thoroughly. Tubing should be hung to dry after disinfection and should not touch the floor or other unsanitary surfaces whilst drying. Any item falling on the floor is contaminated and must be cleaned thoroughly again.

3 The housing of the flow splitter should be cleaned according to ward guidelines for disinfecting surfaces, or by wiping down with soapy water followed by 70% alcohol. Flow splitter oxygen ports should be cleaned using forceps wrapped in gauze and soaked in 70% alcohol.

4 Clean any used equipment that has been in contact with patient or staff.

DISINFECTION AFTER USE

1 Turn off the oxygen source. Disconnect oxygen tubing from source and flow splitter. If reusing tubing, immediately remove and begin hospital protocol for disinfection as outlined in **Oxygen Therapy: Infection Prevention**.

2 Clean the flow splitter housing and regulators using 70% alcohol after every use. **(Alert 4.1)**

BMET INFECTION PREVENTION

1 Any piece of equipment used in providing patient care must be handled carefully, as it may be contaminated & have the potential to spread infection.

2 Clean & disinfect flow splitter housing & components whilst wearing PPE as appropriate (e.g., rubber gloves, apron, face protection, etc.) **before any repairs or maintenance are made.**

3 Avoid any contact between used piece of equipment & skin, mucosa or clothing.

4 Post-maintenance, decontaminate all tools and surfaces used with 70% alcohol or according to manufacturer guidelines. Do not use equipment until it has fully dried following decontamination.

? Alert 4.1 Disinfecting Equipment

Disinfection of equipment should always comply with manufacturer guidelines. WHO recommends 0.5% dilution of chlorine (0.5% or > 100ppm available sodium hypochlorite) as the standard disinfectant for materials and surfaces contaminated by blood or body fluids.[2] For metal and rubber surfaces, which may be corroded by chlorine, 70% alcohol is also commonly utilised for low level disinfection.

Other appropriate low-level disinfectants include quaternary ammonium, improved hydrogen peroxide and Iodophor germicidal detergent.[3] Phenolic germicidal detergent is also identified but should not be used in neonatal wards since affordable, effective alternatives are available; and, there are concerns it may cause hyperbilirubinemia and/or neurotoxicity in neonates.[4]

See dedicated NEST360° module on Infection Prevention and Control for further details on risks, benefits and utilisation of chemical disinfectants. For comprehensive guidance on infection prevention and control we recommend utilising Reference Manual for Health Care Facilities with Limited Resources Infection Prevention and Control (Caston-Gaa & Ruparelia, 2018).

5 Complications

Equipment in newborn care units are highly specialised. Without proper knowledge and skills, this equipment can be potentially dangerous for the infants, families and care providers.

DEVICE COMPLICATIONS

- **Device positioning:** flow splitters are heavy devices and are frequently positioned on walls or shelves. This is appropriate **if well secured**. If improperly secured, flow splitters may fall onto patients, causing potential permanent or fatal injury.
- **Independent flows:** flow splitters should be designed to have independent flow regulation. If the flow splitter is not designed correctly, flows may be dependent: as one port flow is changed, other port flows may change. These splitters should be exchanged for one that has independent flow. If a dependent flow splitter is available, nursery staff should take care when changing flows for one patient and ensure that any other patients also on the flow splitter are receiving correct amounts of oxygen.
- **Flow delivery**: staff should always check the oxygen prongs for oxygen flow before placing patient on machine. If there is no flow, follow steps to troubleshoot in **Flow Splitter: Troubleshooting & Repair**.

6 Care & Maintenance

Biomedical engineers and technicians are responsible for second-line care and maintenance to ensure equipment lasts to their potential lifetime.

POWER SOURCE

Flow splitters are not powered.

WARD LOCATION

Flow splitters should be mounted and secured in a location where nursing staff can regulate and view flows easily, e.g., securely mounted on a wall within easy and reachable access. The splitter should be able to be adjusted at eye level. If possible, the surface on which the splitter is mounted should have a raised edge to prevent the device from falling. Clinical and nursing staff should be encouraged to number the ports and tubing to prevent infants receiving an incorrect flow.

Tubing leading from the flow splitter may be fixed to the wall to distribute oxygen to several cots without the tubing being trailed across the floor. Technical staff should measure flow rates at the patient end of this tubing and compare them to the set flow rate at the splitter to ensure flow rate is as expected. If installing in this manner, numbering of ports and tubing is essential to correctly manage patients. For comprehensive guidance on setting up such an installation we recommend referencing the **WHO Medical Device Technical Series: Technical Specifications for Oxygen Concentrators** (2015).

DEVICE CALIBRATION

Manufacturers do not typically recommend calibration for any flow splitter components.

DECOMMISSIONING

Assuming appropriate use and consistent maintenance, a flow splitter may last up to 4 years or longer. Flow splitters vary widely in cost. Decisions to decommission should be taken based on a comparison of repair to replacement cost. Both internal tubing and intact flow meters may be repurposed for other devices, although care should be taken to ensure that components meet the specifications required for the device into which they are installed.

PREVENTIVE MAINTENANCE

After Each Use

- [ ] Turn off the oxygen source. Use gauze and 70% alcohol or diluted chlorine to thoroughly wipe the oxygen flow meter controls and ports.

  See **Flow Splitter: Disinfection After Use** and **Alert 4.1** for more information.

Weekly

- [ ] Visually inspect flow splitter components.
- [ ] Use gauze and 70% alcohol to clean the housing of the flow splitter.
- [ ] Connect to an oxygen source, open all ports to maximum delivery rate and flush the flow splitter with oxygen for 15 minutes to clear the flow splitter of any ambient humidity-related buildup.
- [ ] Document preventive maintenance actions taken.

Monthly

- [ ] Perform **Weekly** preventive maintenance steps.
- [ ] Visually assess the oxygen ports for dust and debris. Clean using forceps wrapped in gauze and soaked in alcohol if necessary.
- [ ] Document preventive maintenance actions taken.

Quarterly

- [ ] Perform **Monthly** preventive maintenance steps.
- [ ] Using an oxygen analyser or independent flow meter and pressure gauge, assess the delivery rate and pressure for each flow splitter port.
- [ ] Document preventive maintenance actions taken.

Annually

- [ ] Perform **Quarterly** preventive maintenance steps.
- [ ] Confirm supply of spare flow meters and tubing are adequate to support estimated replacement for next year.
- [ ] Document preventive maintenance actions taken.

7 Troubleshooting & Repair

Biomedical engineers & technicians are responsible for providing rapid maintenance, troubleshooting & repair support for users.

PREPARE FOR REPAIR

ACCESSIBLE TOOLS	SPARE PARTS	DEVICE CHECKLIST
Forceps or tweezers Soapy water Phillips, star & flathead screwdrivers Cotton buds Pressure gauge	Flow meter Tubing Crimp or zip ties	☐ Flow splitter ☐ Oxygen source tubing ☐ Oxygen tubing or nasal prongs

TROUBLESHOOTING FAILURES

No oxygen flows from any outlet ports of the splitter.

Probable Cause: Oxygen source connection or functionality issue

Components to Check:
Oxygen source connection and functionality
Flow splitter outlet port physical condition
Internal tubing seal & placement

The flow meter ball fluctuates when flow rates are adjusted.

Probable Cause: Leakages in flow splitter or source connections

Components to Check:
Oxygen source oxygen setting, connection & functionality
Internal tubing seal & placement
Flow meter physical condition

The flow meter ball is missing or stuck at the top of the flow meter.

Probable Cause: Damaged / stuck flow meter ball

Components to Check: Flow meter physical integrity

No oxygen flows from some of the outlet ports.

Probable Cause: Blocked oxygen port or internal displaced tubing

Components to Check: Flow splitter outlet port physical condition
Flow meter physical condition

REPAIR & REPLACE

Where technically possible and not likely to obstruct clinical care, repairs may be made within the newborn care ward. Use discretion to determine if this is appropriate or if the device should be removed to the biomedical workshop for more testing or repair. **(Alert 7.1)**

Troubleshooting the oxygen source

Flow splitters function by distributing flow from a single oxygen source to 4 to 5 outlet ports. If the oxygen source is not connected adequately, well maintained or turned to the appropriate output settings, flow delivery rates and oxygen at the flow splitter outlet ports will be unable to deliver therapeutic oxygen concentrations and delivery flows.

If using a flow splitter with a dual port oxygen concentrator, the cumulative flow delivery of the source should also be assessed. Although both oxygen flow meters on a dual port oxygen concentrator are graduated to the maximum capacity of the machine and may be used simultaneously, the maximum flowrate at which the device can produce recommended purity of oxygen remains the same (e.g., a 10 L/min oxygen concentrator can only produce 10 L/min of oxygen at a time, regardless of the number of ports or splitters in use). Users should ensure that the combined flowrate during use does not exceed the capacity of the machine.

Testing & repairing the flow splitter outlet ports

Over time, oxygen outlet ports may accumulate deposits or debris that block oxygen flow from the concentrator. Ports should be visually inspected using a penlight and may be cleaned using cotton buds or forceps wrapped in gauze soaked in 70% alcohol. **(7.1)**

7.1 Clean debris from outlet ports with an ear swab soaked in 70% alcohol.

Testing, reconnecting & replacing the tubing components

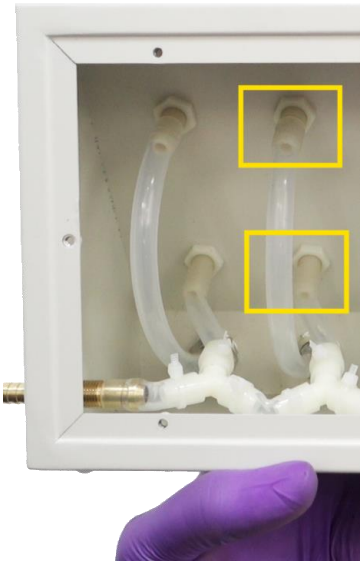
Leaks or displaced tubing may contribute to both low oxygen flow delivery and increased flow meter fluctuation. Open the device and assess all tubing for loose or detached fittings. Tubing can be assessed for leaks by running soapy water or foam along the suspected tubing, pipes and fittings during operation and checking for bubbles or movement of the liquid.

Testing & replacing the flow meter

The flow meter may be damaged through user error or through lack of use and preventive maintenance over time. User error is design dependent; if the flow meter is not designed to prevent the flow meter bead from falling into the regulating knob channel, the flow meter bead can be damaged or crushed as the flow meter is closed. In most cases, the flow meter bead is not a spare part and this damage will require the entire flow meter assembly to be replaced.

The flow meter may also develop debris or deposits that affect the movement of the flow meter bead within the flow meter channel. This can be repaired by disconnecting, disassembling and cleaning the flow meter. **(7.2 – 7.4)**

7.2 Open housing to access internal tubing.



7.3 Disconnect flow meter at inlet and outlet barbed connectors.

7.4 Remove flow meter and clean or replace.

? Alert 7.1 Repurposing Parts

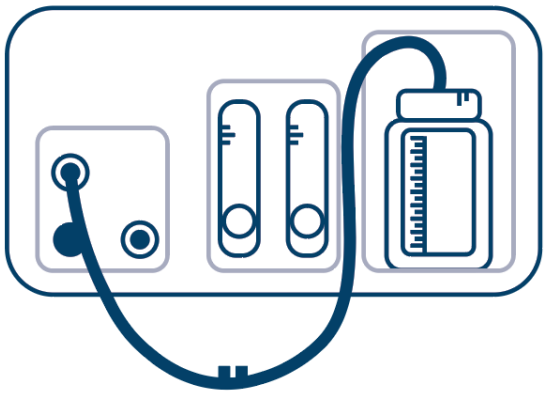
In some cases, parts on the unit may be replaced with a repurposed or recycled part from another piece of equipment being used for parts. **Repurposed parts should be considered with caution and guidance from the manufacturer to ensure specifications of the repurposed part is compatible with the equipment.** This includes spare parts and accessories that may not be compatible with multiple systems.

8 References

1. *Oxygen therapy for children*. (World Health Organization, 2016).
2. World Health Organization, Regional Office for the Western Pacific, World Health Organization, & Regional Office for South-East Asia. *Practical guidelines for infection control in health care facilities*. (World Health Organization, Regional Office for Western Pacific ; World Health Organization, Regional Office for South-East Asia, 2004).
3. Curless MS, Ruparelia CS, Thompson E, and Trexler PA, eds. 2018. *Infection Prevention and Control: Reference Manual for Health Care Facilities with Limited Resources.* Jhpiego: Baltimore, MD.
4. Sharma, G., Zaka, N. & Hailegebriel, T. Infection Prevention and Control at Neonatal Intensive Care Units. (2018).

Respiratory Support

Bubble CPAP



1 Clinical Problem

Bubble CPAP (bCPAP) devices are used within the newborn care ward to provide positive pressure to increase fractional concentration of oxygen (FiO_2) and decrease work of breathing in newborns with respiratory distress.

Although continuous positive airway pressure devices may be used to treat adult symptoms of respiratory distress (or trouble breathing), bCPAP treatment is used mainly in neonatal or paediatric patients.[1] bCPAP is used to address physiological symptoms of respiratory distress in patients who are able to spontaneously breathe, but has minimal impact on patients with neurological (or, brain-related) damage leading to respiratory distress (e.g., birth asphyxia). **bCPAP should only be used when essential newborn care is in place, equipment is functioning, oxygen is available, staff are adequately trained in bCPAP and close monitoring can be assured.**

bCPAP may be used to treat neonatal patients who are born prematurely or with increased work of breathing, designated by nasal flaring, grunting, head nodding, severe recession, respiratory rate >60, or an oxygen requirement of 0.5 to 1 L/min with peripheral blood saturations of <90%, in premature or term infants.

? Alert 1.1 bCPAP & low flow oxygen context

Scale and delivery of neonatal care is critical. However, data has shown that rapid scale up of neonatal care without sufficient attention to safety has long term negative consequences for neonatal morbidity[2] and is likely a contributor to the epidemic of preventable blindness due to retinopathy of prematurity (ROP) in these settings.[3]

Supplemental oxygen is life-saving. However, when given in doses that are too high, it has also been associated with various complications (ROP,[4] bronchopulmonary dysplasia,[5] periventricular leukomalacia and prolonged ventilation[6]). When using any form of oxygen therapy, it is important to closely monitor blood oxygen saturation (SpO2) levels in order to balance risks and benefits of supplemental oxygen. Exact blood oxygen saturation targets for premature newborns remain an area of controversy. However, most authorities agree that SpO2 between 90-95% is reasonable to minimise complications associated with low and high oxygen levels.[7–10]

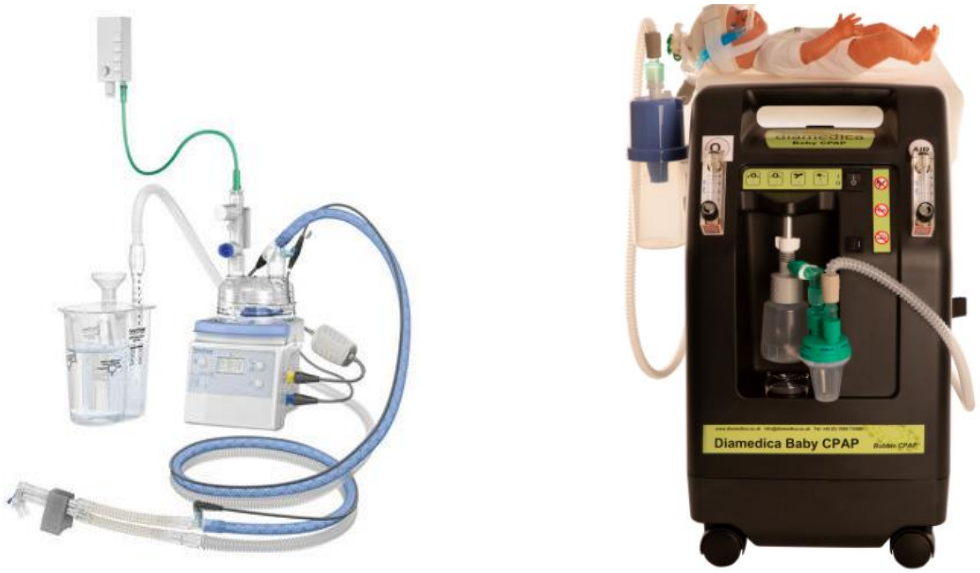
bCPAP outside the neonatal period is not addressed by NEST360° materials.

2 Assessment

Infants born prematurely have underdeveloped lungs which are unable to produce sufficient surfactant for effective respiration. Without treatment, the baby becomes exhausted with the work of breathing, and progressive alveolar collapse leads to low blood oxygen levels.

Surfactant is a substance produced by the lungs that reduces surface tension on the alveoli and prevents alveolar collapse. Structurally immature lungs (as in premature or young neonatal patients) have decreased compliance and tend towards collapse. Without adequate surfactant, the alveoli collapse more readily and remain collapsed, even during inhalation, which prevents gas exchange. The baby's work of breathing increases with attempts to reinflate the collapsed alveoli.

bCPAP devices **(2.1)** provide continuous positive pressure generated by bubbling a blend of air and oxygen through a constant depth of water. Tightly fitting nasal prongs or a mask connect the patient to this source of pressure to increase the baseline pressure in the lungs. This decreases work of breathing for the patient and improves oxygenation.



2.1 Typical bubble CPAP devices.

bCPAP devices range in complexity from vitals measured (e.g., saturations/respiratory rates measured on the device) to outputs (e.g., humidified pressure vs pure pressure). **(Alert 2.1)** Form factor varies by model, although most models follow a standard pressure circuit design. Normal therapeutic pressures used in bCPAP devices range from 5 to 10 cm of water. As bCPAP delivers a blend of air and oxygen, staff should also carefully monitor patients for oxygen saturation using a pulse oximeter. Neonatal patients should reach oxygen saturations of 90-95% by 15 minutes after birth.

? Alert 2.1: Use of humidification in bCPAP

Some bCPAP units use heated and humidified gas in the circuit although the exact benefits of humidification in non-invasive ventilation (i.e., bCPAP) in terms of survival, complications from therapy & morbidity are not well established.

Potential benefits of heating and humidification could include increased comfort, decreased upper airway mucosal injury and decreased convective heat losses which may lead to hypothermia (directly related to mortality).Potential drawbacks to heated humidification may include hospital-acquired infection and high financial and human resource cost. Hospital-acquired infection is particularly influential, especially in settings where clean water may not be readily available and humidifiers, which are typically meant for one-time use, are being cleaned and re-used between patients.[11] Adding heated humidified gas may increase the unit cost of the bCPAP unit.[12] High human resource cost may impact both repair and preparation costs of non-invasive ventilation units which may limit not only their use, but availability of this life saving technology within resource-limited settings.[12]

In summary, based mostly on expert opinion, it is likely that heated and humidified air is most important for the smallest newborns <1-1.25kg although this has never been explicitly studied. There is evidence from Malawi that unheated un-humidified bCPAP can be used successfully to decrease mortality of infants without excessive reports of upper airway complications, but physiological implications in terms of morbidity and mortality (hypothermia & weight gain) were not explicitly studied. Of note, survival of infants >1.5kg on un-heated un-humidified air bCPAP in this study[13] were similar to survival of infants >1.5kg in Rwanda on heated and humidified bCPAP.[14]

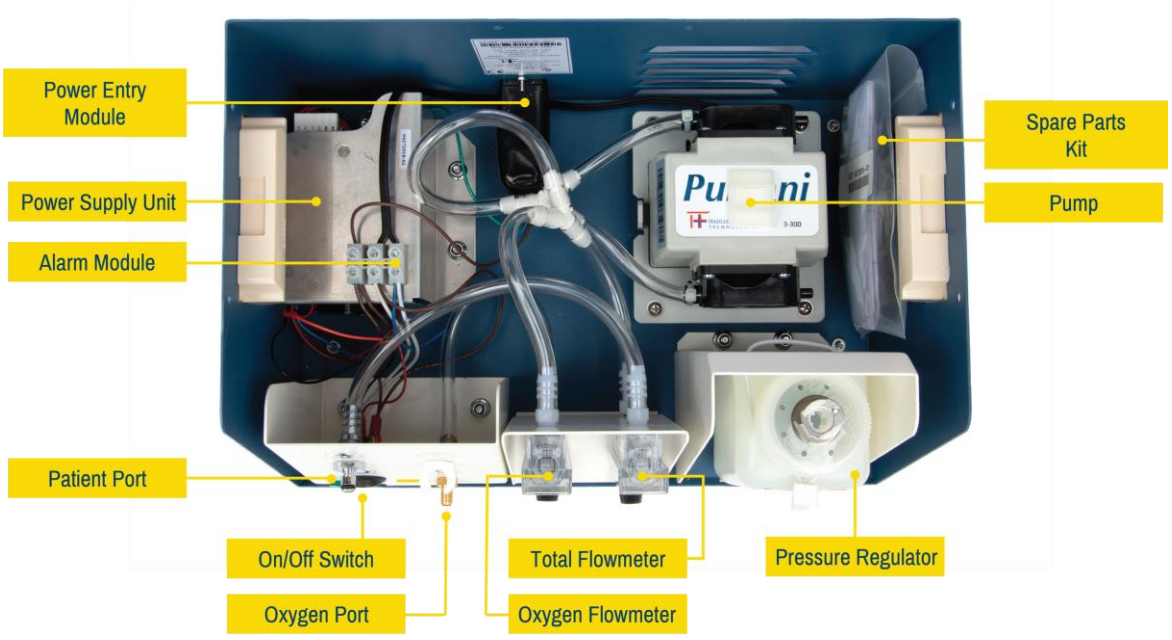
At this time, based on expert opinion and available literature, it does not appear that the benefits of humidification outweigh the potential risks/drawbacks for infants >1kg.

HOW IT WORKS

A bCPAP device uses an internal **pump** to bring in and compress ambient air through an **intake filte**r. Simultaneously, an oxygen source is connected (or integrated into the device). Oxygen from the oxygen source is blended with the ambient air to provide a user-specified concentration of inspired oxygen (FiO_2) which is fed through the **inspiratory tubing** to the patient. In traditional CPAP circuits, gentle pressure is then created by placing the distal end of the **expiratory tubing** in water, placing the **patient interface** (tightly fitting nasal prongs or a mask) in the centre of the circuit between the blended flow and the **pressure regulator**. Pressure levels vary depending on the length of tubing immersed. Basic or improvised bCPAP models may not rely on electricity or a pump to generate flow, but use the flow created by the oxygen source.

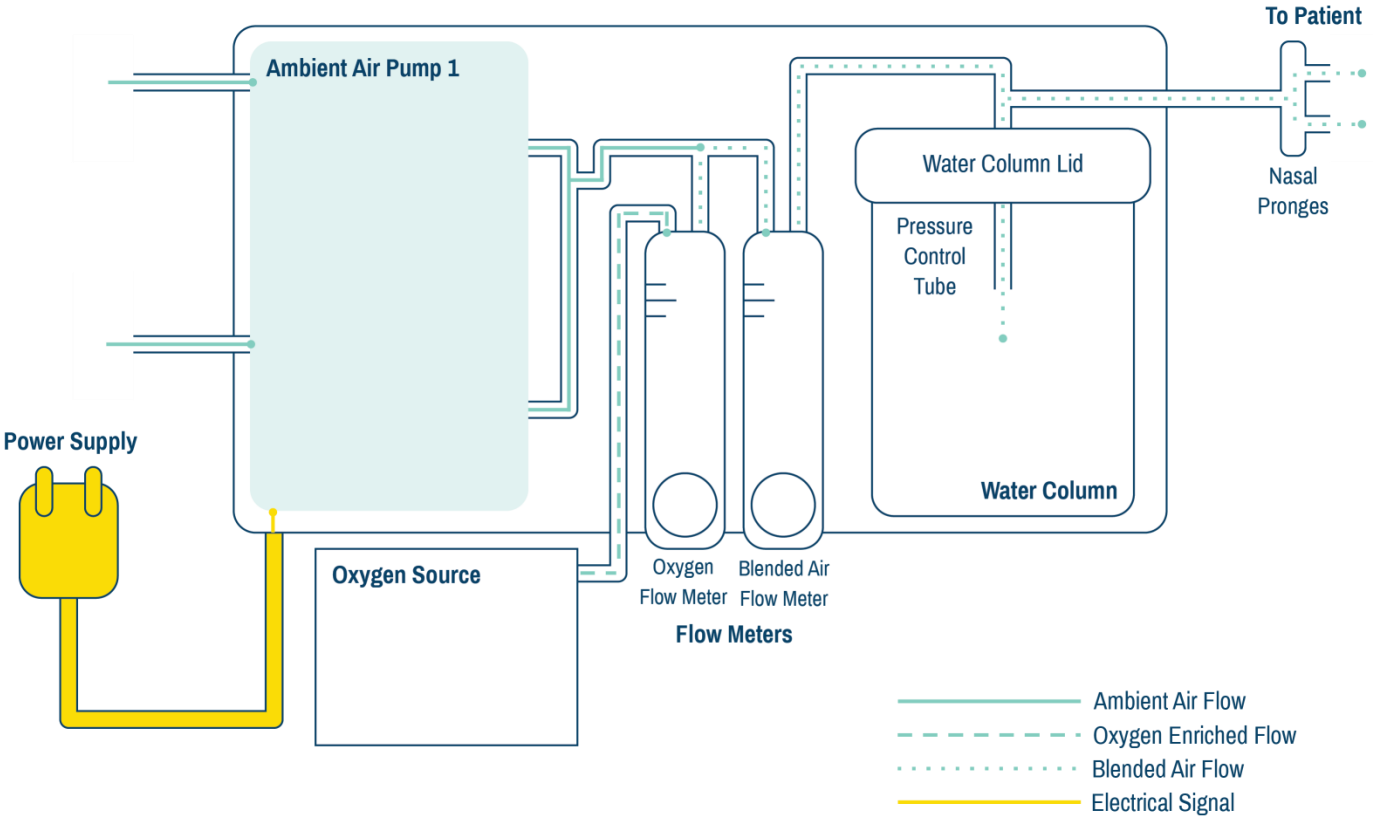
Standard external and internal device components are annotated below in **Figures 2.2** and **2.3**. Components should be similar regardless of model. However, specific locations, visual setup and component type vary by brand and device model. Refer to service and user manuals to identify components if model in use is different from the displayed version.

2.2 External components of a bCPAP device.



2.3 Internal components of a bCPAP device.

TYPICAL DEVICE FLOW



MAIN COMPONENTS

The following device components should be similar regardless of model. However, specific locations, visual setup and component type may vary by brand and device model. Refer to model service and user manuals if different from the displayed model for more device-specific information.

Power entry module

Located at the back of the machine and houses the entry point for the power cable from the mains power outlet.

Power supply unit (PSU)

Located internally within the unit, the PSU converts AC mains power (110 or 220 V) to lower voltage regulated DC power. The basic components within a power supply are a transformer, rectifier, voltage regulator and filters. The bCPAP power supply unit powers the internal pump and may connect to a Power Failure Alarm to activate in the event of a power outage.

Pump

Located internally within the unit, the pump brings in ambient air to blend with oxygen from an external or integrated oxygen source. The pump type depends on the model of bCPAP in use but is commonly an inductive diaphragm pump with two diaphragms connected to each other by an intermediate shaft with magnets at its opposite ends. Two inductive coils are wrapped around the intermediate shaft and are alternately energised to produce an induced magnetic field.

The action of the inductors pulls or releases the shaft to pull or push the diaphragms. On each induction cycle, one diaphragm will be pulled while the other will be pushed in reciprocating fashion. As one diaphragm admits air, the other diaphragm expels air from the system.

Pump intake filter

Filters gross particles from ambient air before the air is processed through the pump system.

Pressure regulator

A water reservoir placed at the end of the expiratory circuit that provides pressure using water level. Pressure levels vary depending on the length of tubing immersed.

Oxygen source

Oxygen sources may be external to the bCPAP or internally integrated. Any oxygen sources may be used with independent bCPAPs (e.g., oxygen concentrators, cylinders or piped oxygen) although care should be taken to ensure that the pressure of the oxygen source is within manufacturer specifications.

Oxygen flowmeter

Regulates the continuous volume flow rate of oxygen from an external or integrated source.

Total flowmeter

Regulates the continuous volume flow rate of blended air. The total flowmeter allows the user to regulate the delivered FiO_2.

Inspiratory tubing

In a standard bCPAP circuit, the inspiratory tubing connects from the device to the patient, carrying flow from the device to the patient via tubing and tightly sealed nasal prongs. Gaskets or sealing rings are typically placed on the patient port of the device or within the patient circuit tubing to ensure a tight seal, which is essential for effective treatment.

Expiratory tubing

In a classic bCPAP circuit, the expiratory tubing connects from the patient to the device at the pressure regulator.

Patient interface

In a classic bCPAP circuit, the patient interface is typically wide, soft plastic nasal prongs or a tightly fitting mask.

3 Management

Management covers how to use the bCPAP device, including set up and preparing for a patient, patient commencement, care whilst on the device and removal of the patient from the device. These instructions are helpful for a biomedical engineer or technician both in user training and in assessing the appropriate functionality of the device.

SETTING UP FOR A PATIENT

1 Collect: (**3.1**)

- bCPAP machine
- Power cable
- Inspiratory & expiratory tubing
- CPAP prongs

- Connectors
- Oxygen tubing
- Oxygen source

3.1 (a) Collect bCPAP supplies.

3.1 (b) Oxygen sources that can be considered for use with a bCPAP.

2 Position the bCPAP device at a secure location near the patient being considered for bCPAP treatment. Plug the power cable into the back of the machine **(3.2)** and plug into a socket or extension.

3.2 Plug the power cable into the device.

3.3 Pull bottle strap out and begin to remove bottle.

3.4 Fill bottle with clean water to desired settings (6cm).

3 Pull the bottle strap gently away from the bottle and remove the bottle. **(3.3)** Unscrew the lid and fill with clean tap water to desired initial settings. **(3.4)** Most patients will start with pressure levels of 6 cm of water. Re-screw the bottle lid to the bottle and place back in bottle holder.

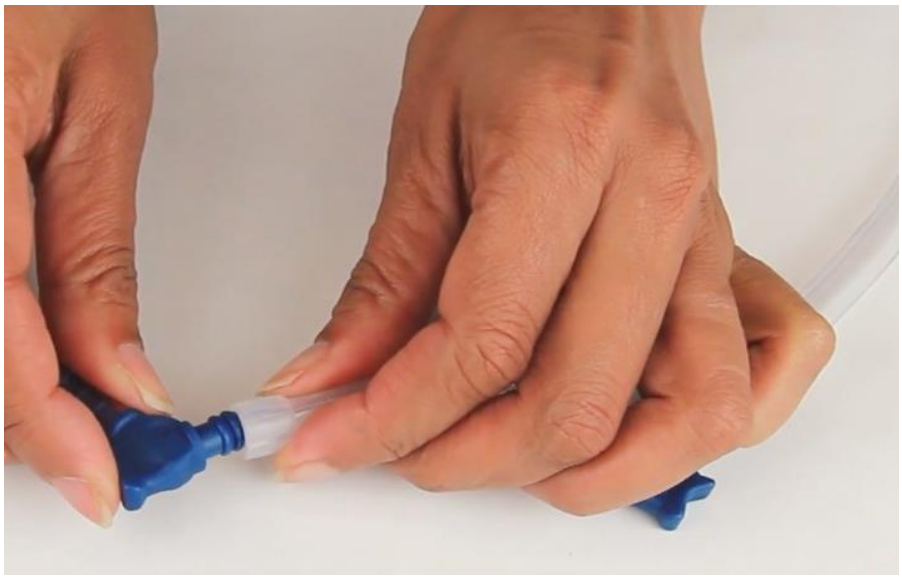
4 Connect the inspiratory tubing to the Patient Port (indicated by the baby icon) **(3.5)** and the expiratory tubing to the Bottle Port. **(3.6)**

3.5 Connect inspiratory tubing to patient port.

3.6. Connect & brace long expiratory tubing in bottle bracket

5 Connect the CPAP prongs between the inspiratory and expiratory tubing. **(3.7)**

6 Turn on the bCPAP device. **(3.8)**



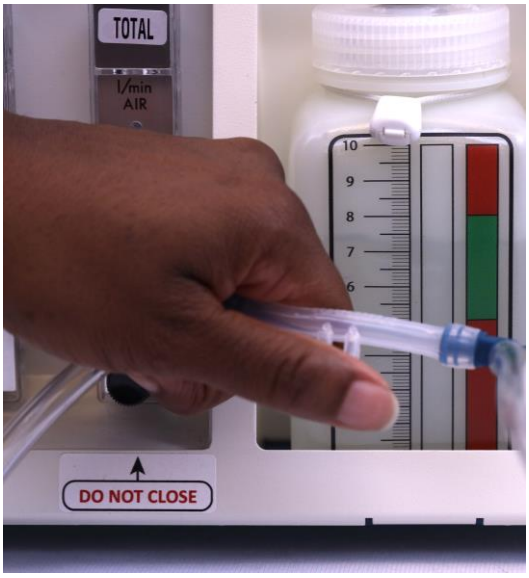
3.7 Connect bCPAP prongs between inspiratory and expiratory tubing.

3.8 Turn on bCPAP.

7 Open the oxygen flowmeter. Using oxygen tubing, connect the oxygen source to the bCPAP device. **(3.9)**

8 Test the bubbling of the bCPAP device by occluding the CPAP prongs with your fingers. **(3.10)** If the water within the water bottle bubbles, the bCPAP device is ready for use.

3.9 Connect Tubing to the oxygen port.



3.10 Occlude bCPAP prongs to test bubbling.

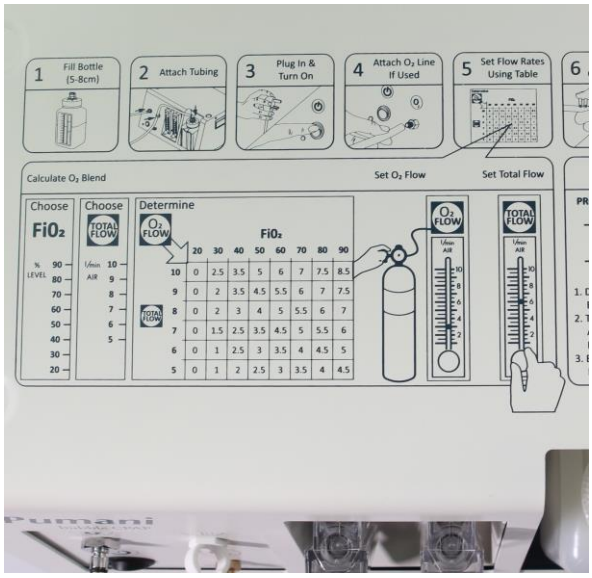
PREPARING A PATIENT

1. Clinical or nursing staff should place the patient on oxygen and keep the baby warm whilst preparing for bCPAP. Staff should suction if clinically indicated and insert an orogastric feeding tube if clinically applicable to prevent obstruction of the pressure delivery.
2. Staff should select bCPAP prong size from 000 to 5 based on nostril size. bCPAP prongs should completely fill the patient's nostrils. If prongs do not fill the nostril completely, the pressure delivered to the patient will be decreased. If nostrils turn a white colour the prongs are too tight and should be exchanged for the next size down.

STARTING A PATIENT

1. Staff should collect: **(3.11)**
    - Appropriately sized bCPAP prongs
    - Hat
    - 2-mL syringe filled with normal saline
    - Hat clips OR
    - 2 rubber bands & 4 safety pins
2. Clinical and nursing staff should turn on the bCPAP device and connect oxygen source, place hat on patient and determine and set initial settings for pressure, total flow and oxygen concentration (FiO2) for the patient. Staff can determine oxygen flow using FiO_2 and total flow as shown on the oxygen blending table printed on top of device. **(3.12)**

3.11 Collection of materials.



3.12 Set initial total flow and FiO_2 settings & determine needed oxygen flow.

3 Connect correctly sized bCPAP prongs to the inspiratory and expiratory tubing. Retest the bubbling by pinching the bCPAP prongs shut.

4 If the water within the pressure regulating bottle bubbles, staff should place a drop of saline within each nostril and gently insert the prongs into the nostrils until the line on the bCPAP prongs is **just** visible, leaving 1 mm of space between the prongs and the nasal septum to protect the nasal septum. **(3.13)**

3.13 Insert bCPAP prongs until prong line is just visible (1mm space).

3.14 Secure inspiratory and expiratory tubing using clips.

5 Inspiratory and expiratory tubing should be secured to the patient to prevent displacement of the patient circuit. **(3.14)** If hat clips are provided with the bCPAP device, they may be used for this purpose. If they are unavailable, clinical staff may also secure using rubber bands & safety pins:

- Insert two safety pins into the brim of the hat on each side of the head. Pins should open away from the baby's face and should go only through the folded brim of the hat. **Pins should never touch the patient's skin.**
- Hold the inspiratory tubing in place between the two safety pins. **(3.15)** Wrap the rubber bands around the safety pins on either side of the tubing to secure. Repeat for the expiratory tubing on the other side of the patient's face. **(3.16)**

Healthcare staff should be encouraged to recheck the prongs are securely placed within the nose and inserted to the correct distance. Sometimes a small folded cloth placed under the baby's shoulders may help keep the neck in a neutral position and improve air flow.

3.15 Pin placement.

3.16 Patient circuit secured using elastics.

CARING FOR A PATIENT

1. Clinical or nursing staff should monitor vital signs (including respiratory rate, heart rate, oxygen saturation, and temperature), work of breathing, nasal blockages, abdominal distension and nasal septum trauma or breakdown 4 hourly or more frequently. Staff should also provide nasal saline drops at each monitoring point. Increases in treatment should be made progressively and the patient should be reassessed 15 minutes after any setting change. Pressures should be kept within 5 to 8 cm H_2O unless otherwise advised by a consultant.
2. At every monitoring point, staff should also confirm that prongs, tubing, hat and water are appropriate for effective care and that the bCPAP device is functioning well and all parts are in place. One mnemonic to help with this is **DOPE**:
    - **D:** Displacement of prongs
    - **O:** Obstruction of prongs or tubing
    - **P:** Patient problem (e.g., pneumothorax)
    - **E:** Equipment failure (e.g., power cut, tubing leak, see complications section)

If the bCPAP device is not bubbling, troubleshoot the device and patient circuit.

REMOVING A PATIENT

The patient should be weaned gradually from bCPAP to room air.

4 Infection Prevention

Routine and adequate cleaning of medical devices is critical to prevent hospital-acquired infections in newborn care units.

CLINICAL INFECTION PREVENTION

1. Clean hands with soap and water or 70% alcohol before and after placing a patient on bCPAP or handling any tubing that will be used on a patient.
2. Ensure that all patient-related tubing (including prongs, inspiratory, and expiratory tubing) is new or has been cleaned thoroughly and dried as per re-use guidelines. **(Alert 4.1)** Any patient-related tubing must be cleaned before it is used to place another patient on bCPAP. Nasal prongs are especially difficult to clean thoroughly. Tubing should be hung to dry after disinfection and should not touch the floor or other unsanitary surfaces whilst drying. Any item falling on the floor is contaminated and must be cleaned thoroughly again.
3. All patient-related consumables should be stored in a clean, dry location. Tubing should be stored in loose rolls, preventing sharp bends or kinks which will decrease the lifetime of the tubing.

DISINFECTION AFTER USE

1. Turn off bCPAP and dispose of water within pressure regulating water bottle.
2. Discard hat and follow protocols for cleaning tubing if reusing prongs, inspiratory and expiratory tubing. If patient consumables are not cleaned thoroughly before use, infection can be transmitted. Care should be taken particularly for consumables marked as single-use but practically reused.
3. Clean bCPAP device housing using a swab soaked in alcohol. Total and oxygen flowmeter regulator controls should be disinfected after each use using a cotton swab or gauze soaked in 70% alcohol.

BMET INFECTION PREVENTION

1. Any piece of equipment used in providing patient care must be handled carefully, as it may be contaminated and have the potential to spread infection.
2. Clean and disinfect bCPAP housing and components whilst wearing PPE as appropriate (e.g., rubber gloves, apron, face protection, etc.) **before any repairs or maintenance are made.**

3 Avoid any contact between used piece of equipment and skin, mucosa or clothing.

4 Post-maintenance, decontaminate all tools and surfaces used with 70% alcohol or according to manufacturer guidelines. Do not use equipment until it has fully dried following decontamination.

Alert 4.1 Disinfecting Equipment

Disinfection of equipment should always comply with manufacturer guidelines. WHO recommends 0.5% dilution of chlorine (0.5% or > 100ppm available sodium hypochlorite) as the standard disinfectant for materials and surfaces contaminated by blood or body fluids.[15] For metal and rubber surfaces which may be corroded by chlorine, 70% alcohol is also commonly utilised for low level disinfection.

Other appropriate low-level disinfectants include quaternary ammonium, improved hydrogen peroxide and Iodophor germicidal detergent.[16] Phenolic germicidal detergent is also identified but should not be used in neonatal wards since affordable, effective alternatives are available; and, there are concerns it may cause hyperbilirubinemia and/or neurotoxicity in neonates.[17]

See dedicated NEST360° module on Infection Prevention and Control for further details on risks, benefits and utilisation of chemical disinfectants. For comprehensive guidance on infection prevention and control we recommend utilising Reference Manual for Health Care Facilities with Limited Resources Infection Prevention and Control (Caston-Gaa & Ruparelia, 2018).

5 Complications

Equipment in newborn care units are highly specialised. Without proper knowledge and skills, this equipment can be potentially dangerous for the infants, families and care providers.

CLINICAL COMPLICATIONS

- **Nasal blockage:** the bCPAP prongs and nostrils can become blocked with mucus which may result in increased respiratory distress and impaired oxygen delivery resulting in hypoxia.
- **Necrotic nasal septum:** incorrectly sized or applied bCPAP prongs may result in pressure on the nasal septum with resultant necrosis (tissue breakdown).
- **Pneumothorax**: pneumothorax is air outside the lung but inside the chest cavity. Delivery of bCPAP may occasionally cause a pneumothorax which presents as sudden deterioration and increased respiratory distress.

DEVICE COMPLICATIONS

- **Pressure leakages:** if the water in the bottle is not bubbling, it is likely that the patient is not getting therapeutic pressures. Clinical and nursing staff should assess the patient for

common clinical issues that may cause this (e.g., the patient's mouth being open, non-CPAP-related tubing affecting the seal on the nostrils). Technical staff should assess the device for tubing kinks or leakage.

- **Power failure:** bCPAP should ideally always use outlets that have a source of backup power. If the power supply fails and patients are **NOT** on outlets with back-up power they should be moved to outlets where back up power is available. If no back up power is available, the baby should receive oxygen from an oxygen cylinder until they can be safely returned to bCPAP.

6 Care & Maintenance

Biomedical engineers and technicians are responsible for second-line care and maintenance to ensure equipment lasts to their potential lifetime.

POWER SOURCE

bCPAP devices are usually powered via mains power. Some units may have an optional charging battery that can be used in the event of a blackout. In the event of a power failure, the patient should be immediately removed from the device as prongs in the nose without flow could lead to respiratory failure. Basic or improvised bCPAP models may not rely on electricity to generate flow, but use the flow created by the oxygen source.

WARD LOCATION

The bCPAP device should be secured in an easily accessible and visible location near an oxygen source where nursing staff can regulate flows and manage patients easily, but where it is not at risk of falling. All consumables required to place a patient on bCPAP should be near the device and readily available to start treatment. bCPAP devices vibrate during use; ensure that the vibration is not causing excess sound (e.g., if placed on a table with metal instruments that will vibrate with the bCPAP device).

DEVICE CALIBRATION

Manufacturers do not typically recommend calibration for any bCPAP components.

DECOMMISSIONING

Assuming appropriate use and consistent maintenance, a bCPAP device may last up to 3 years or more. The internal pump assembly is intended to last the lifetime of the device and should not require replacement. Should the pump break down, the device should be considered for decommissioning and replacement. Internal tubing, flowmeters and housing may be considered for repurposing for other devices although care should be taken to ensure that the specifications of the parts (e.g., the internal diameter and length of the tubing, the capacity of the flowmeters) align with the device needing repair.

PREVENTIVE MAINTENANCE

After Each Use

- [ ] Turn off and unplug the bCPAP device. Use gauze and 70% alcohol or diluted chlorine to thoroughly wipe the Total and Oxygen flowmeter regulator controls. Between patients, disinfect the housing, patient circuit tubing and pressure regulating bottle.

  See Bubble CPAP: Disinfection After Use and Alert 4.1 for more information.

- [ ] Visually inspect bCPAP device components.

Weekly

- [ ] Turn on the bCPAP device to a total flow of 10 L/min (or max total flow, if gradated higher on the Total Flowmeter) and allow to run while connected to an oxygen source at 2 L/min for at least 15 minutes to clear the bCPAP device of any ambient humidity-related buildup.
- [ ] Document preventive maintenance actions taken.

Monthly

- [ ] Perform **Weekly** preventive maintenance steps.
- [ ] While the bCPAP device is plugged in and turned on:
  - **Test the Total Flow capacity:** verify that the Total Flowmeter reaches 10 L/min (or max total flow, if gradated higher on the Total Flowmeter) when not connected to an oxygen source.
  - **Test the bubbling functionality:** fill the pressure regulating bottle to 6 cm of water. Connect the patient circuit tubing and prongs. Occlude the prongs or kink the tubing to block flow. The pressure regulating bottle should bubble.
  - **Test the Power Failure alarm:** turn off the power at the wall socket. An alarm should sound (if model-applicable).
- [ ] Document preventive maintenance actions taken.

Quarterly

- [ ] Perform **Monthly** preventive maintenance steps.
- [ ] Measure grounding integrity and earth and casing leakage current.
- [ ] Document preventive maintenance actions taken.

Annually

- [ ] Perform **Quarterly** preventive maintenance steps.
- [ ] Confirm supply of spare pump filters, regulator bottles, patient circuits, fuses and power cables are adequate to support estimated replacement for next year.
- [ ] Document preventive maintenance actions taken.

7 Troubleshooting & Repair

Biomedical engineers & technicians are responsible for providing rapid maintenance, troubleshooting & repair support for users.

PREPARE FOR REPAIR

ACCESSIBLE TOOLS	SPARE PARTS	DEVICE CHECKLIST
Digital multimeter Phillips, star & flat head screw drivers Needle nose pliers Soapy water Wire strippers	Power supply unit Power cable Pump filter Flowmeter assembly Sealing O-rings or gaskets Crimp or zip ties	☐ bCPAP device ☐ Power cable (if detachable) ☐ Pressure regulating bottle ☐ Patient circuit tubing (inspiratory & expiratory)

TROUBLESHOOTING FAILURES

The bCPAP does not turn on.

Probable Cause: Faulty power supply

Components to Check:
Power cable continuity
Power switch physical integrity & continuity
Power entry module fuse(s) physical integrity & continuity
Power supply unit continuity & voltage

The bCPAP turns on, but the Total Flow does not reach its maximum when not connected to an oxygen source.

Probable Cause: Internal leak or obstructed pump filter

Components to Check:
Internal tubing seal & placement
Outlet port sealing O-ring physical integrity
Pump filter physical integrity
Pump physical integrity

The bCPAP turns on, but air does not flow from the outlet or patient port.

Probable Cause: Obstructed outlet port, flowmeter or internal leak

Components to Check:
Outlet port physical integrity
Internal tubing seal & placement
Flowmeter physical integrity

The bCPAP turns on, but the Oxygen or Total Flowmeter does not rise.

Probable Cause: Obstructed flowmeter or internal leak

Components to Check:
Flowmeter physical integrity
Internal tubing seal & placement

The bCPAP turns on, but the water in the pressure regulating bottle is not bubbling when connected to a patient.

Probable Cause: Internal or patient circuit leak

Components to Check:
Internal tubing seal & placement
Outlet port sealing O-ring physical integrity
Patient circuit attachment

REPAIR & REPLACE

Where technically possible and not likely to obstruct clinical care, repairs may be made within the newborn care ward. Use discretion to determine if this is appropriate or if the device should be removed to the biomedical workshop for more testing or repair.

! Alert 7.1

All testing, repair and replacement steps should be conducted with the power to the device switched off and the power cable removed from mains power, unless otherwise stated.

Testing & replacing the power supply fuses

Fuses may be located both on the bCPAP housing and on the power supply cable. Fuse integrity may be visually assessed or evaluated by testing the continuity across the fuse. Refer to manufacturer specifications for replacement fuses to ensure that the device remains electrically sound in standard operation.

Testing & replacing the power switch

Power switches should be tested in both the off and on positions to confirm functionality. In the **On** position, the switch terminals should be continuous. In the **Off** position, the switch terminals should show a high resistance, or **OL** in most multimeters.

If the switch shows continuity or discontinuity inappropriately, assess the switch for visible physical or electrical damage. If the switch is visibly damaged or dislodged, assess whether the part can be

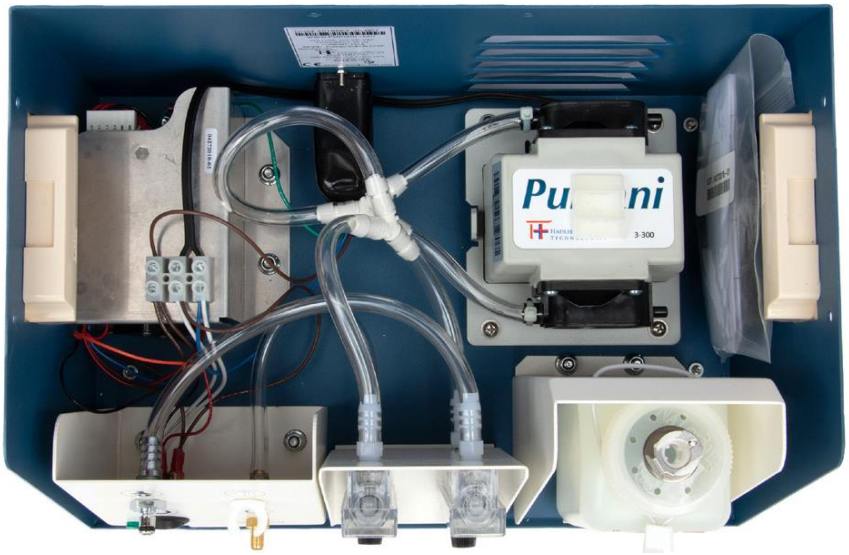
repaired with glue or solder. If it cannot be easily repaired, replace the switch. Refer to the manufacturer specifications for replacement switches to ensure that the device remains electrically sound in standard operation.

Testing & replacing the power supply unit or module

Testing the power supply unit cannot be completed appropriately without checking the alternating voltage at the power supply unit. **This should be completed with caution**, as the power to the device must be switched on to accurately measure the voltage delivered. If the power supply unit or module is damaged, contact the manufacturer to request a replacement part.

Testing & repairing internal leakages

Internal leakages or displaced tubing may contribute to both low Total Flow and delivered pressure. Internal tubing can be assessed for leaks by running soapy water or foam along the suspected tubing, pipes and fittings during operation and checking for bubbles or movement of the liquid. If tubing is displaced, consult the service manual or a functioning device for tubing attachments. **(7.1, 7.2)** Crimp tubing in place with metal crimps or secure with zip ties.



7.1 Correct internal tubing placement.

7.2 Displaced internal tubing.

Testing & repairing the patient or outlet port

Over time, outlet ports may accumulate deposits or debris that block oxygen or pressure flow from the bCPAP. **(7.3)** Ports should be visually inspected using a penlight and may be cleaned using ear swabs or forceps wrapped in gauze soaked in 70% alcohol.

Gaskets or sealing rings are typically placed on the patient port of the device to ensure a tight seal, which is essential for effective treatment. These gaskets may break down with regular cleaning over time. **(7.4)** As the patient port sealing ring deteriorates, the seal on the patient port becomes less secure and affects pressure delivery to the patient. The patient port sealing ring should be replaced as soon as deterioration is observed.

7.3 Patient port.

7.4 Deteriorating patient port seal.

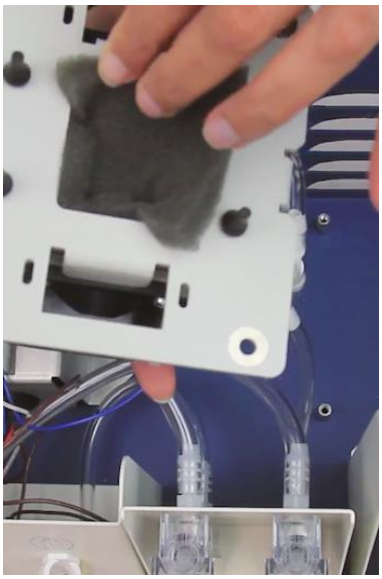
Testing & replacing the pump and pump filter

As the pump intake filter becomes clogged with dust or other debris, intake airflow to the pump becomes constricted and decreases the capacity of the Total Flowmeter. The pump filter should be assessed and cleaned or replaced as needed when the Total Flowmeter is unable to reach its full capacity.

If the filter is clean or has been replaced recently and the Total Flowmeter is still unable to reach its full capacity, the pump should be replaced. **(7.5 – 7.7)** Contact the manufacturer to request a replacement part.

7.5 Unscrew the pump housing.

7.6 Turn over the pump to assess the pump filter. If visibly dirty, replace.



7.7 Push in the replacement pump filter until it fits flush to the housing.

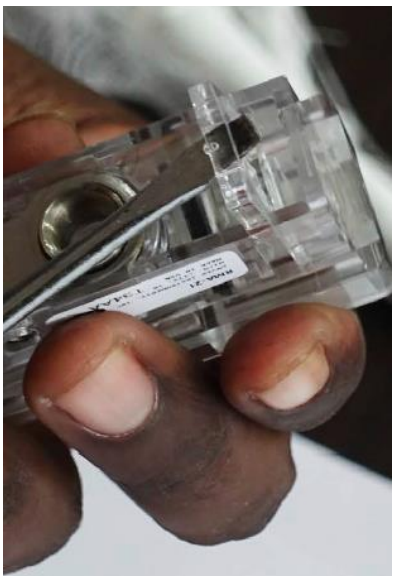
Testing, cleaning & replacing flowmeters

The flowmeter may be damaged through user error or through lack of use and preventive maintenance over time. User error is design dependent; if the flowmeter is not designed to prevent the flowmeter bead from falling into the regulating knob channel, the flowmeter bead can be

damaged or crushed as the flowmeter is closed. In most cases, the flowmeter bead is not a spare part and this damage will require the entire flowmeter assembly to be replaced.

The flowmeter may also develop debris or deposits that affect the movement of the flowmeter bead within the flowmeter channel. **(7.8)** This can be repaired by taking apart and cleaning the flowmeter. When cleaning the flowmeter, use caution during removal of all components as they are small and easily misplaced. **(7.9 – 7.14)**

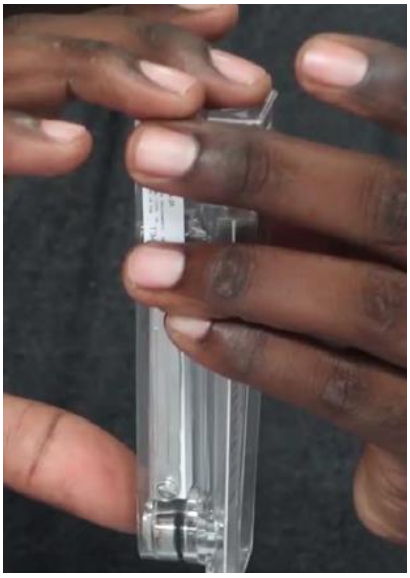
7.8 Debris development in the base of the flowmeter channel



7.9 Slide out the locking plate.

7.10 Remove sealing bolt.

7.11 Carefully remove the ball from the flowmeter chamber.



7.12 Pour rubbing alcohol, or water into the flowmeter barrel. Shake gently to remove debris.

7.13 Prepare a cleaning rod by wrapping a wire with gauze.

7.14 Insert the cleaning rod in the flowmeter barrel and clean.

Testing the patient circuit attachment

bCPAP therapy relies on a tight seal to produce effective pressure in the lungs. Nasal prongs should fully fill the nostrils and the patient's mouth should not be open. If the prongs are well-fitted in the nostrils, nursing staff can troubleshoot the circuit by removing them and occluding the prongs by pinching them shut.

? Alert 7.2 Repurposing Parts

In some cases, parts on the unit may be replaced with a repurposed or recycled part from another piece of equipment being used for parts. **Repurposed parts should be considered with caution and guidance from the manufacturer to ensure specifications of the repurposed part is compatible with the equipment.** This includes spare parts and accessories that may not be compatible with multiple systems.

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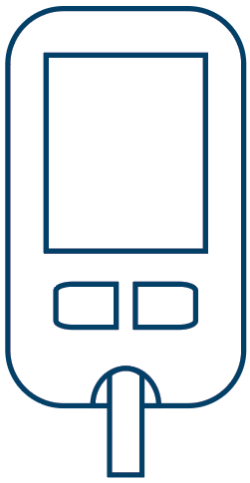
Point-of-Care Diagnostics

Glucometer



1 Clinical Problem

Blood glucose measurement using a glucometer is necessary in clinical assessment and management of patients in all hospital settings. In newborn care units, glucometers are used during routine assessment for all infants on admission.

Glucometers should also be used during continuing management for all sick or at-risk patients. Hypoglycaemia or low blood glucose may present symptomatically (as jitteriness, irritability, lethargy, seizures, etc.) or asymptomatically.[1] It is important to identify hypoglycaemia as it may lead to permanent harm.

2 Assessment

Hypoglycaemia occurs in 10% of healthy neonates and directly contributes to both morbidity and mortality.2,3 It is the most common medical emergency to occur in neonatal patients.

Glucometers **(2.1)** provide a rapid measurement of approximate whole blood glucose level to guide treatment for patients with mild to severe hypo- or hyperglycaemia.[1] Where available, point of care tests should be confirmed by laboratory analysis when hypo- or hyperglycaemia is persistent, recurrent, or there is concern about accuracy of the point of care device.

2.1 Glucometers.

2.2 Glucometer test strips.

There are multiple types of glucometers, including portable and benchtop. **(2.1)** Glucometer test strips are specific to model. **(2.2)** Most guidelines suggest that glucose levels in all neonatal patients should not fall below **2.5 mmol/L** (45 mg/dL). **(Alert 2.1)**

Alert 2.1

As many glucometers are designed to monitor hyperglycaemia in diabetic adults and children, not all glucometers are able to accurately measure hypoglycaemia in neonatal patients.[4,5] Accuracy at the lower ranges of glucose to assess hypoglycaemia is the priority of monitoring in newborn patients. To appropriately assess neonatal hypoglycaemia, glucometers used in neonatal wards should be accurate within ± 3.6 mg/dL at 54mg/dL. The **NEST360° Qualified Technologies for Newborn Care in Low-Resource Settings** & **Newborn Technology Landscape** technical documents outline commercially available and in-development glucometers appropriate for use in neonatal care.

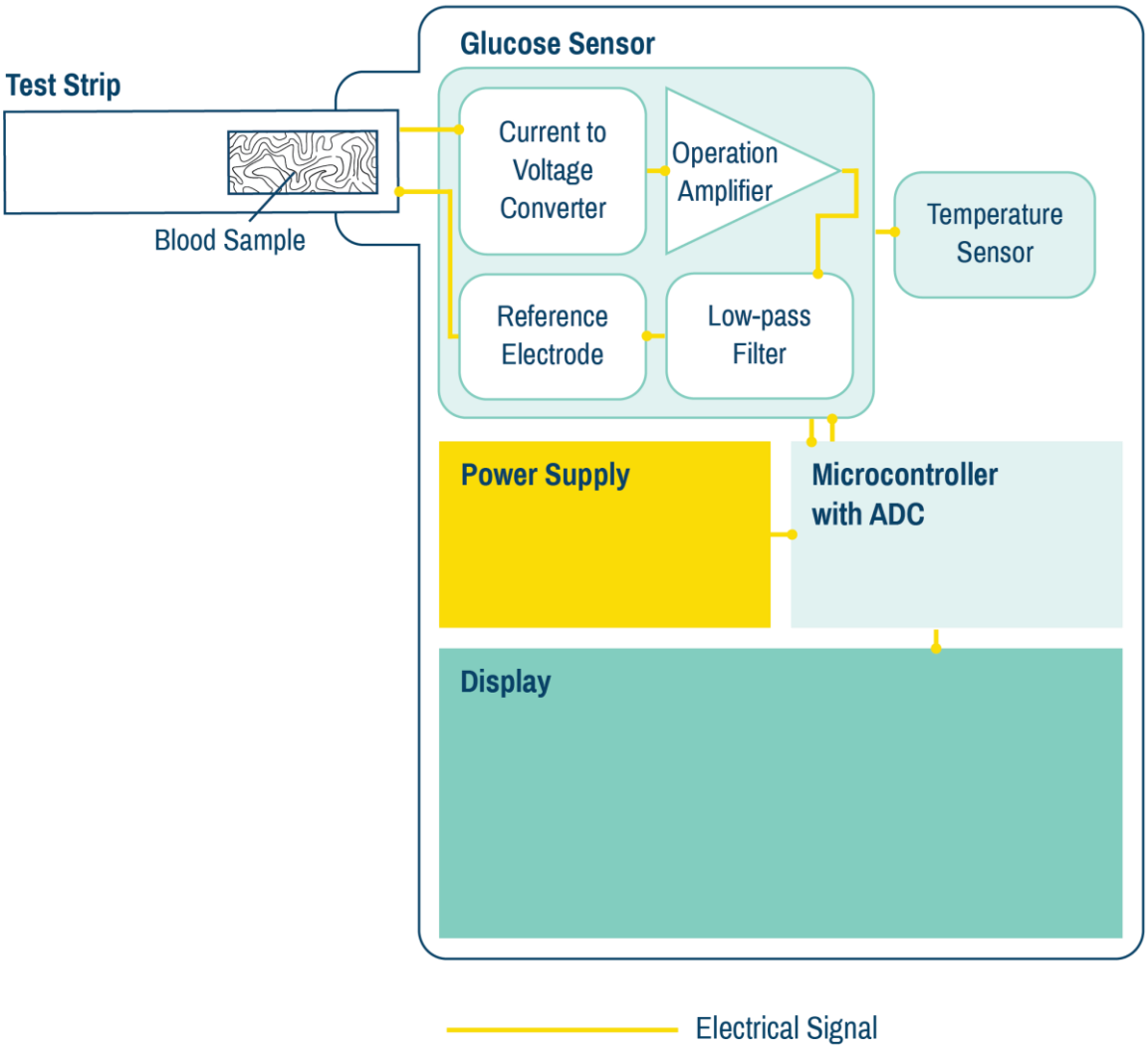
Glucose test strips that change colour according to a visual scale are also available for measuring glucose levels. **These are not recommended due to their poor accuracy and subjective nature of measurement.**

HOW IT WORKS

Glucometers use **test strips** with a glucose oxidase electrode. Glucose in the blood reacts with glucose oxidase on the strip, generating a current which is then measured and analysed to determine an estimated blood glucose level. Standard external and internal device components are annotated below in **Figure 2.3**. Components should be similar regardless of model. However, specific locations, visual setup and component type may vary by brand and device model. Refer to service and user manuals if model in use is different from the displayed version.

2.3 Glucometer main components.

TYPICAL DEVICE FLOW



MAIN COMPONENTS

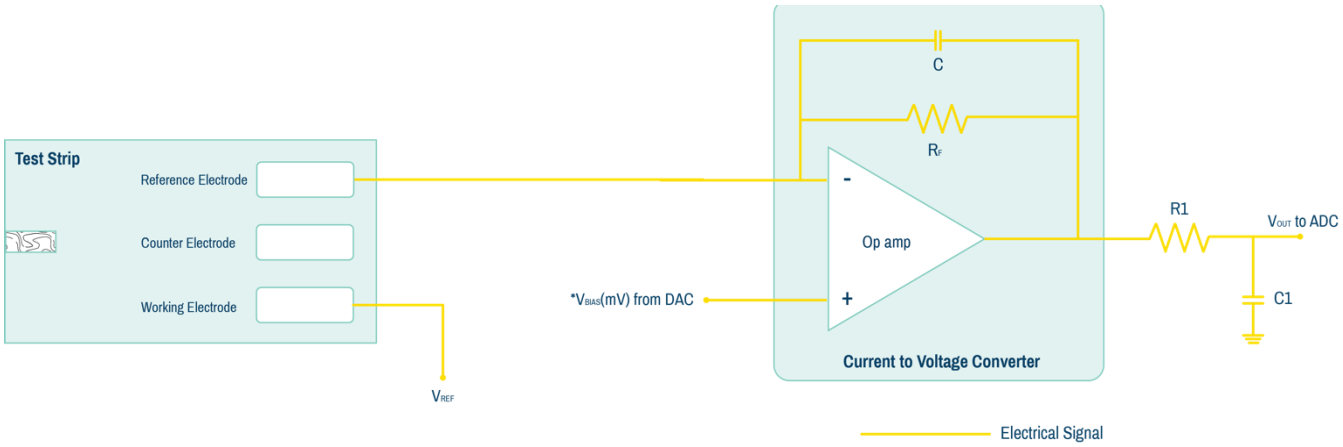
The following device components should be similar regardless of model. However, specific locations, visual setup and component type may vary by brand and device model. Refer to model service and user manuals if different from the displayed model for more device-specific information.

LCD / display screen

The LCD or display screen is on the front of the device and represents the main control and display area for the device.

Glucometer strip

A typical test strip has three main terminals or electrodes; the working electrode, reference electrode and counter electrode. **(2.4)** Glucose oxidase chemical reactions take place and produce electrons at the working electrode which is directly connected to a current-to-voltage converter. The counter electrode supplies current to the working electrode.



2.4 A typical test strip circuit.

Control PCB

The control PCB ranges from basic to extensive by glucometer model, but typically contains connections to the LCD, control panel and strip port and processes signals from the glucometer strip to the display.

Battery

The rechargeable or disposable battery powers the LCD and measurement functionality without the need for mains power.

Strip ejector

In some models, a strip ejector is present that aids in the ejection of the glucometer strip without requiring the user to physically touch the strip. This provides additional infection protection for the user and patient from the blood on the used strip.

3 Management

Management covers how to use the glucometer, including set up for a patient, patient commencement, care whilst using the device and concluding the assessment of the patient. These instructions are helpful for a biomedical engineer or technician both in user training and in assessing the appropriate functionality of the device.

SETTING UP FOR A PATIENT

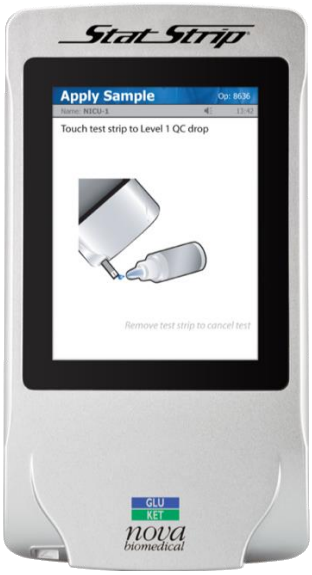
1. Collect: **(3.1)**
    - Glucometer
    - Glucometer strips
    - Control solutions
2. Turn on the glucometer. This may be completed by pressing the power button of the glucometer or inserting a glucometer strip into the glucometer strip port.

3.1 Collect glucometer, test strip & control solutions.

3.2 Insert strip.

3. Fully insert a test strip into the meter. **(3.2)** The strip should click into place.
4. A **Quality Control** test should be conducted daily. If this has not been completed, perform a test using the control solutions provided with the glucometer **(3.3)**, or a solution of known glucose content. The solution should be placed on the strip as with a normal sample. **(3.4)** The results should appear within seconds as a **Pass**. **(3.5)**

3.3 Collect control solutions.

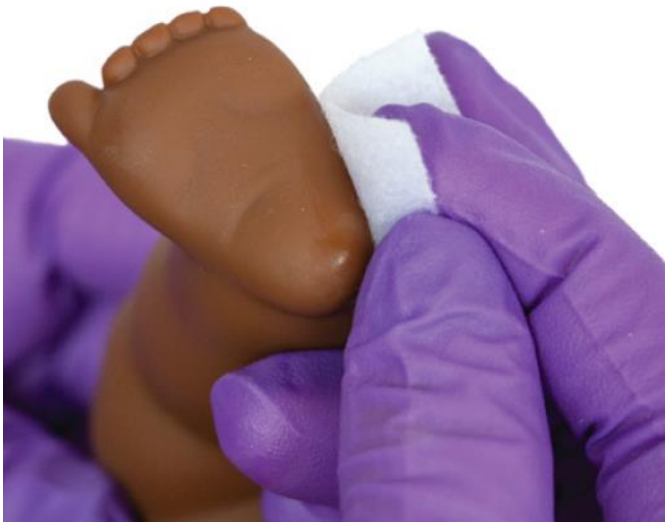


3.4 Allow the strip to absorb a drop of the control solution.

3.5 The control solution should test as a **Pass**.

PREPARING A PATIENT

1 Clinical or nursing staff should take neonatal glucometer readings from the skin on the outer edge of the patient's heel. The site should be cleaned using cotton wool soaked in alcohol and allowed to dry before samples are taken. **(3.6) Blood glucose samples should never be taken from the finger of a neonate. Areas of skin with low blood flow, swelling, inflammation or infection should be avoided.**

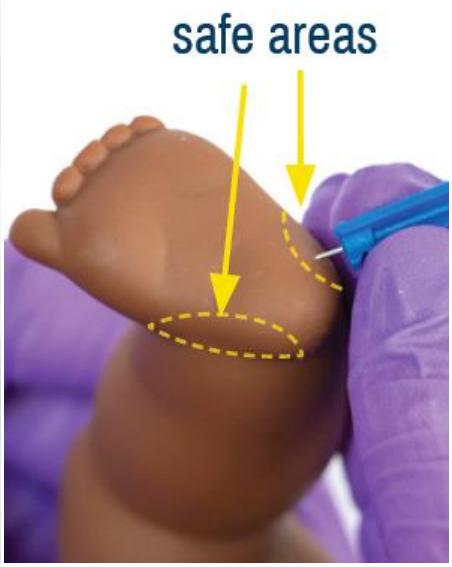


3.6 Clean outer edge of the patient's heel using cotton/gauze soaked in alcohol.

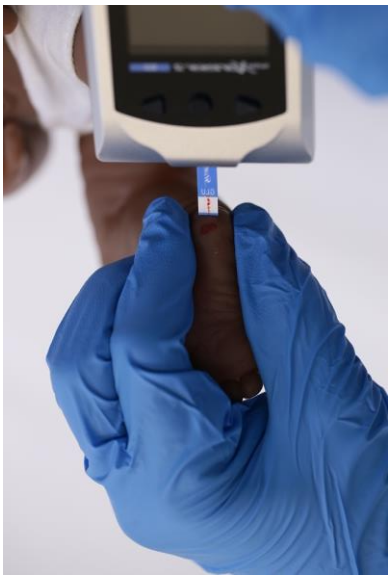
ASSESSING A PATIENT

1. Collect: **(3.7)**
    - Glucometer
    - Glucometer strips
    - Gloves
    - Alcohol swab
    - Lancet
    - Cotton wool
2. Insert glucometer strip into glucometer and ensure it is turned on.
3. Using the lancet, clinical or nursing staff should prick the disinfected outer edge of the heel. **(3.8)** A blood drop should form. If this does not occur, the heel may be massaged to generate the blood drop.
4. Clinical or nursing staff should wipe the first drop from the patient's skin and an additional blood drop generated. Clinical or nursing staff can then collect the second blood drop on the tip of the glucometer strip. **(3.9)** The glucometer should automatically absorb the blood drop.

3.7 Collect assessment materials.

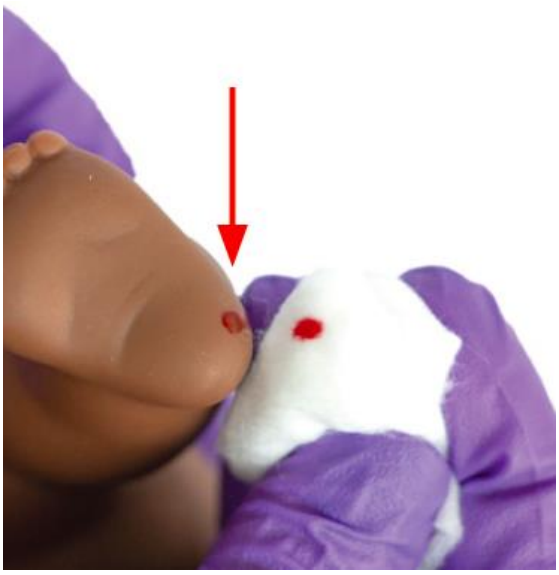


3.8 Prick disinfected outer edge of heel using lancet.



3.9 Collect blood drop on glucometer strip.

5. Using a dry cotton swab, clinical or nursing staff should apply pressure to the heel to stop the bleeding. **(3.10)**
6. Blood glucose level will be displayed as a number on the glucometer screen. **(3.11)** Clinical or nursing staff should read and record the glucose levels. They should then compare the measurement with the clinical condition of the patient and repeat the test if necessary.



3.10 Apply pressure to stop bleeding.

3.11 Read & record glucose levels.

7 Staff should compare glucose levels to normal standards[6] and take interventions according to clinical guidelines. **(Alert 3.1)** Whenever hypoglycaemia is found and treated, the blood glucose should be rechecked 30 minutes after intervening.

Alert 3.1 International standards for hypoglycaemia management

American Academy of Pediatrics, Pediatric Endocrine Society and WHO are all in agreement that glucose levels below 2.5 mmol/L (45 mg/dL) signify hypoglycaemia in newborns. However, they differ on the specific actions that should be taken and how aggressively to manage glucose levels below 45 mg/dL (2.5 mmol/L). For a full discussion of management of hypoglycaemia in newborns, these documents should be referenced and local practices put into place by clinical and nursing staff.[7–9]

CONCLUDING ASSESSMENT

Remove the glucose strip from the glucometer and dispose of strip in hazardous waste container. Dispose of the used lancet in sharps container. Remove gloves, dispose in hazardous waste container, and wash hands.

4 Infection Prevention

Routine and adequate cleaning of medical devices is critical to prevent hospital-acquired infections in newborn care units.

CLINICAL INFECTION PREVENTION

1. Clean hands with soap and water or alcohol before and after assessing a patient using a glucometer or handling any materials that will be used on a patient (e.g., a lancet). **Gloves should be worn throughout the process of taking a blood glucose measurement and disposed of immediately after concluding the measurement.**
2. Always thoroughly clean the patient's skin before taking a measurement using a glucometer. Inadequate cleaning of the skin may result in an infection. Taking a sample from a site with a skin infection also poses the risk of infection dissemination.
3. Ensure that all patient-related consumables are new before use. Materials used in blood glucose measurements **should never be reused**.
4. All patient-related consumables should be stored in a clean, dry location. Glucometer measurement strips should be stored in an airtight container and according to hospital policy.
5. Follow universal precautions of handling sharps.

DISINFECTION AFTER USE

1. Remove the glucose strip from the glucometer and dispose of strip in hazardous waste container. Dispose of used lancet in sharps container. Remove gloves, dispose in hazardous waste container, and wash hands.
2. Wipe down the glucometer with 70% alcohol. **(4.1)** Be careful not to submerge or drip alcohol onto the glucometer, particularly in its glucometer strip reading slot. **(Alert 4.1)**

4.1 Wipe down the glucometer with 70% alcohol.

BMET INFECTION PREVENTION

1. Any piece of equipment used in providing patient care must be handled carefully, as it may be contaminated and have the potential to spread infection.
2. Clean and disinfect glucometer housing and components whilst wearing PPE as appropriate (e.g., rubber gloves, apron, face protection) **before any repairs or maintenance are made. (Alert 4.1)**
3. Avoid any contact between used piece of equipment and skin, mucosa or clothing.
4. Post-maintenance, decontaminate all tools and surfaces used with 70% alcohol or according to manufacturer guidelines. Do not use equipment until it has fully dried following decontamination.

? Alert 4.1 Disinfecting Equipment

Disinfection of equipment should always comply with manufacturer guidelines. WHO recommends 0.5% dilution of chlorine (0.5% or > 100ppm available sodium hypochlorite) as the standard disinfectant for materials and surfaces contaminated by blood or body fluids.[10] For metal and rubber surfaces, which may be corroded by chlorine, 70% alcohol is also commonly utilised for low level disinfection.

Other appropriate low-level disinfectants include quaternary ammonium, improved hydrogen peroxide and Iodophor germicidal detergent.[11] Phenolic germicidal detergent is also identified but should not be used in neonatal wards since affordable, effective alternatives are available; and, there are concerns it may cause hyperbilirubinemia and/or neurotoxicity in neonates.[12]

See dedicated NEST360° module on Infection Prevention and Control for further details on risks, benefits and utilisation of chemical disinfectants. For comprehensive guidance on infection prevention and control we recommend utilising Reference Manual for Health Care Facilities with Limited Resources Infection Prevention and Control (Caston-Gaa & Ruparelia, 2018).

5 Complications

Equipment in newborn care units are highly specialised. Without proper knowledge and skills, this equipment can be potentially dangerous for the infants, families and care providers.

CLINICAL COMPLICATIONS

- **Bruising:** inappropriate / repeated attempts to collect blood for glucose testing may result in bruising.
- **Bleeding:** if pressure is not applied post blood collection bleeding may persist for a short period of time. Continued bleeding may indicate an underlying bleeding disorder.
- **Artery, nerve or bone damage:** the back or the inner part of the heel should not be used for blood collection. This may cause artery, nerve, or bone damage.
- **Pain:** the lancet prick can cause pain; appropriate soothing measures should be employed.
- **Infection:** rarely infection may occur at the site if infection precautions are not adequate.

DEVICE COMPLICATIONS

- **Falsely high readings:** dextrose gel or substances on the skin can affect readings. If you record a very high reading in a patient who is otherwise showing symptoms of hypoglycaemia, consider recleaning the patient's skin and retaking the measurement.
- **Expired glucose strips:** outdated or improperly stored glucose strips can produce inaccurate readings. Make sure the lid is kept tightly on the strip container as humidity damages the strips. When possible, unexpired glucometer strips should be used.

6 Care & Maintenance

Biomedical engineers and technicians are responsible for second-line care and maintenance to ensure equipment lasts to its potential lifetime.

POWER SOURCE

A glucometer is powered by replaceable or rechargeable **(6.1)** batteries. If using a rechargeable device, users should regularly charge the glucometer when not in use to ensure power in the event of a power outage.

WARD LOCATION

The glucometer and associated glucometer testing strips should be stored in a clean, dry and secure area. As glucometers are fairly small, care should be taken to ensure that they remain on the ward and accessible for use when required. If the glucometer has a docking or charging station, it should be kept on the dock or charging station when not in use. **(6.2)**

6.1 Low battery warning.

6.2 Glucometer on its charging port.

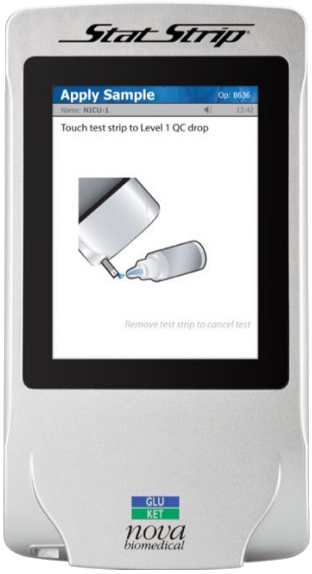
DEVICE CALIBRATION

Quality Control assessments are recommended for most glucometers on a regular basis. This may range from daily to biweekly or monthly. Manufacturer recommendations should be followed to advise frequency.

A **Quality Control** test using the control solutions provided with the glucometer **(6.3)** may be used to check the glucometer. Most glucometers with this functionality will have a specific Quality Control testing mode that should be navigated to within the device menu. The solution should be placed on the strip as with a normal sample. **(6.4)** The results should appear within seconds as a **Pass**. **(6.5)** If the device does not pass the **Quality Control** test, contact the manufacturer to recommend steps to repair, calibrate or replace as needed.

If control solutions are not available, a solution of known glucose content may also be used to check the glucometer. This can be performed as a normal patient test; assessors should compare the resulting reading with the known glucose content of the sample. If the device shows results inconsistent with the known glucose content, contact the manufacturer to recommend steps to repair, calibrate or replace as needed.

6.3 Collect control solutions.



6.4 Allow the strip to absorb a drop of the control solution.

6.5 The control solution should test as a **Pass**.

DECOMMISSIONING

Assuming appropriate use and consistent maintenance, a glucometer may last from 6 months to 3 years, depending on the model. In most instances, glucometer failures are irreparable and decommissioning and replacement is required. If the LCD or control PCB is still in good condition, these parts may be repurposed for other devices. Typically, the control PCB should only be repurposed for devices of the same manufacturer and model, although components from the circuit board may be desoldered and repurposed independently. **(Alert 7.2)**

PREVENTIVE MAINTENANCE

After Each Use

- [ ] Turn off the glucometer. Use gauze and 70% alcohol or diluted chlorine to thoroughly wipe the LCD, control solution bottles and housing of the glucometer. Dispose of used strips appropriately.

  See **Glucometer: Disinfection After Use** and **Alert 4.1** for more information.

- [ ] Visually inspect glucometer components.

Weekly

- [ ] Visually assess the glucometer strip port for fluid or physical damage.
- [ ] Inspect the condition of the glucometer battery, including its charge level and physical integrity.
- [ ] Document cumulative hours used (if available) and preventive maintenance actions taken.

Monthly

- [ ] Perform **Weekly** preventive maintenance steps.
- [ ] Conduct a **Quality Contr**ol test using the control solutions provided with the glucometer, or a solution of known glucose content, with the nursing or clinical staff. Place this solution on the strip as with a normal sample.
- [ ] Document cumulative hours used (if available) and preventive maintenance actions taken.

Quarterly

- [ ] Perform **Monthly** preventive maintenance steps.
- [ ] Document cumulative hours used (if available) and preventive maintenance actions taken.

Annually

- [ ] Perform **Quarterly** preventive maintenance steps.
- [ ] Confirm supply of spare glucometer batteries, glucometer strips & control solutions are adequate to support estimated replacement for next year.
- [ ] Document cumulative hours used (if available) and preventive maintenance actions taken.

7 Troubleshooting & Repair

Biomedical engineers and technicians are responsible for providing rapid maintenance, troubleshooting and repair support for users.

PREPARE FOR REPAIR

ACCESSIBLE TOOLS	SPARE PARTS	DEVICE CHECKLIST
Digital multimeter Phillips, star & flat head screw drivers Allen keys Needle nose pliers Forceps Gauze Alcohol	LCD Batteries	☐ Glucometer ☐ Glucometer charging port (if applicable) ☐ Glucometer strips ☐ Quality control solutions

TROUBLESHOOTING FAILURES

The glucometer is not turning on.

Probable Cause: Discharged batteries

Components to Check: Battery level (if rechargeable) or voltage and physical condition

The glucometer is giving results incompatible with patient condition.

Probable Cause: Expired or incorrect strips

Components to Check: Glucostrips expiry date and brand
Firmware edition & condition
Control PCB electrical & physical integrity

The glucometer is not providing a reading.

Probable Cause: Damaged circuit board or glucostrip entry port

Components to Check: Control PCB electrical & physical integrity
Glucostrip entry port physical integrity

Discoloured or black spots obstruct view of the display.

Probable Cause: Damaged LCD

Components to Check: LCD physical integrity

REPAIR & REPLACE

Where technically possible and not likely to obstruct clinical care, repairs may be made within the newborn care ward. Use discretion to determine if this is appropriate or if the device should be removed to the biomedical workshop for more testing or repair.

Testing & replacing the batteries

The glucometer battery is responsible for powering all display measurement and alarm functions. If the glucometer is not turning on, the batteries should be visually assessed for rust or other physical damage. **(7.1)** Depending on the severity of the damage, rust or other build-up present on the battery terminals can be gently scraped off with very fine sandpaper.

Both the voltage across the battery terminals and the continuity of the wires from the battery to the control board should be tested and the battery or wires replaced if necessary. Specifications for battery voltage should be available in the manufacturer's service manual.

7.1 Battery build-up. Remove build-up using fine sandpaper.

Testing & replacing the glucometer strips

Outdated or improperly stored glucose strips can produce inaccurate readings. The lid should be kept tightly on the strip container as humidity damages the strips. When possible, unexpired glucometer strips should be used. If the strips may have been contaminated, perform a **Quality Control** test to assess their stability.

Testing & replacing control PCB and associated components

In most cases, if one element of the control PCB has malfunctioned, the entire control PCB should be replaced. Visually assess the PCB for burnt or damaged components. Internal wiring continuity leading from the power supply to the control PCB may also be assessed for replacement. **(Alert 7.1)**

! Alert 7.1

Printed Circuit Boards (PCBs) contain components that are sensitive to electrostatic discharge (ESD) and can damage the board if not handled properly. As when handling any ESD-sensitive PCB, observe standard ESD safety procedures.

Testing & repairing the glucostrip entry port

The glucometer strip entry port may be damaged from liquid or fluid spill into the entry port. Visually inspect the port for debris build-up. If build-up is present, use a pair of forceps wrapped in alcohol-soaked gauze to **gently** clean the glucometer strip entry port.

Testing & replacing the LCD

The LCD is typically damaged due to incorrect use, particularly when the user pushes with too much force on the screen. If the damaged areas do not hinder viewing or use of the display, the glucometer may be used. However, if the damaged areas prevent easy use, the LCD may be replaced. Contact the manufacturer to request a replacement part specific to the glucometer model.

? Alert 7.2 Repurposing Parts

In some cases, parts on the unit may be replaced with a repurposed or recycled part from another piece of equipment being used for parts. **Repurposed parts should be considered with caution and guidance from the manufacturer to ensure specifications of the repurposed part is compatible with the equipment.** This includes spare parts and accessories that may not be compatible with multiple systems (e.g., circuit boards, glucometer strips).

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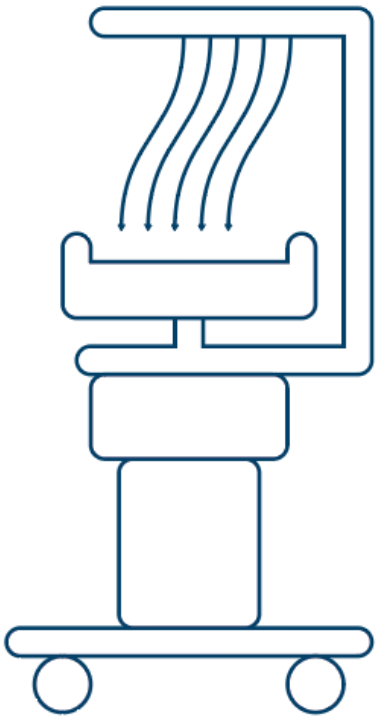
Thermal Management

Radiant Warmer



1 Clinical Problem

Radiant warmers may be used both within the Nursery ward and the Labour or Obstetrics ward. Warmers are used exclusively for newborn or infant patients.

Newborn babies can drop their body temperature within minutes. They must be kept warm from the moment of birth, during their time in the labour ward and when transferred to the nursery. Even small drops in temperature increase the likelihood of mortality. **(Alert 1.1)** [1–3]

Alert 1.1

Body temperature less than 36°C at birth has been recognised as an independent risk factor for death in preterm infants.[1–4]

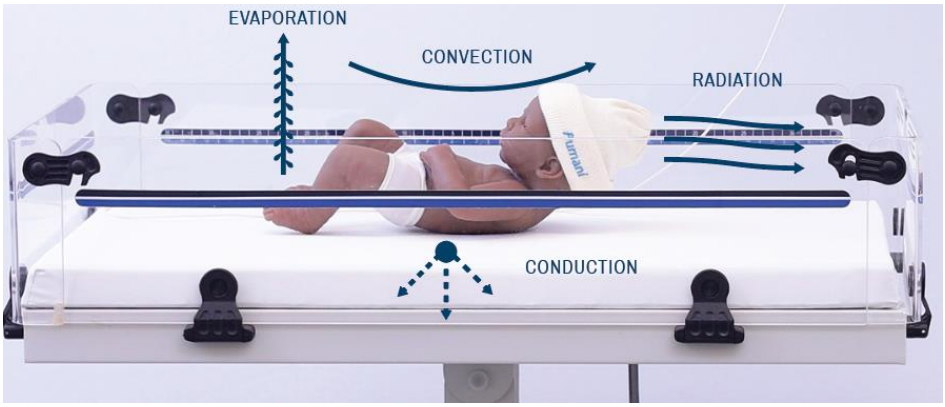
Radiant warmers may be used on all neonatal patients admitted to the nursery ward, but is especially critical for those with prematurity, low birth weight, reduced growth, low body temperature or undergoing procedures.

2 Assessment

However warm a room may feel to an adult, a neonate can lose heat. This heat loss in neonatal patients is rapid, with low body temperature (hypothermia) directly contributing to mortality.[1–4] Radiant warmers use overhead heating elements to provide radiating heat ensuring maintenance of normal body temperature (normothermia).

Newborn babies lose heat through four main mechanisms.[5] **(2.1)**

- **Evaporation:** water loss through the skin.
- **Radiation:** heat radiating from the warmer patient towards cooler surfaces (e.g., windows or walls).
- **Conduction:** direct heat travelling from warmer surface of the skin to the cooler mat or cot on which the patient rests.
- **Convection:** air currents move heat away from the skin/body.



2.1 Mechanisms of heat loss.

Radiant warmers provide infants with a radiating heat to minimise heat loss and energy requirements for heat production, decreasing the risks of low blood sugar and increased work of breathing associated with hypothermia. **(2.2)** Radiant warmers provide an area where resuscitations, procedures, and short-term observation can take place while keeping the baby warm. Warmers may vary in complexity, including only heating functionality or heating functionality with resuscitation and oxygen equipment. All warmers include a temperature probe that provides information on the patient's temperature. **(2.3)**

2.2 Typical radiant warmer.

2.3 Typical temperature probe.

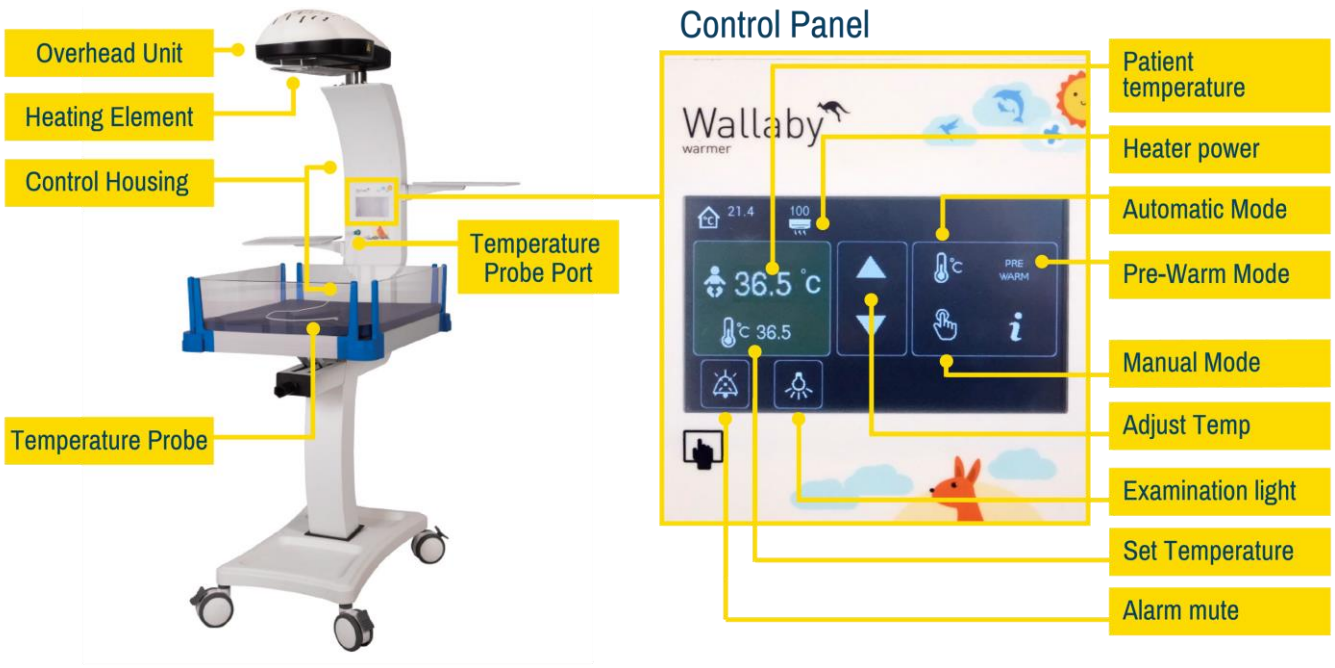
Normothermic axillary temperature in neonates ranges from 36.5°C to 37.5°C.[3,5] Every effort must be made to keep a baby's temperature within the normal range as temperature below 36°C is an independent risk factor for death in newborns.[2,4]

HOW IT WORKS

Radiant warmers heat in various modes, the names and availability of which may vary based on device: **(2.4)**

- **Prewarm:** provides constant low heat for a short amount of time (typically 10 minutes or less) to warm the cot underneath the warmer. Prewarming protects the patient from conductive heat loss caused by a cold mattress.
- **Automatic:** also called **servo** or **baby mode**; uses a temperature probe on the baby to automatically adjust heat provided to maintain the patient's temperature within an acceptable range.

- **Manual:** provides a constant, unadjusting heat that is set by the user. **Patients should never be left unattended if being treated in manual mode.**

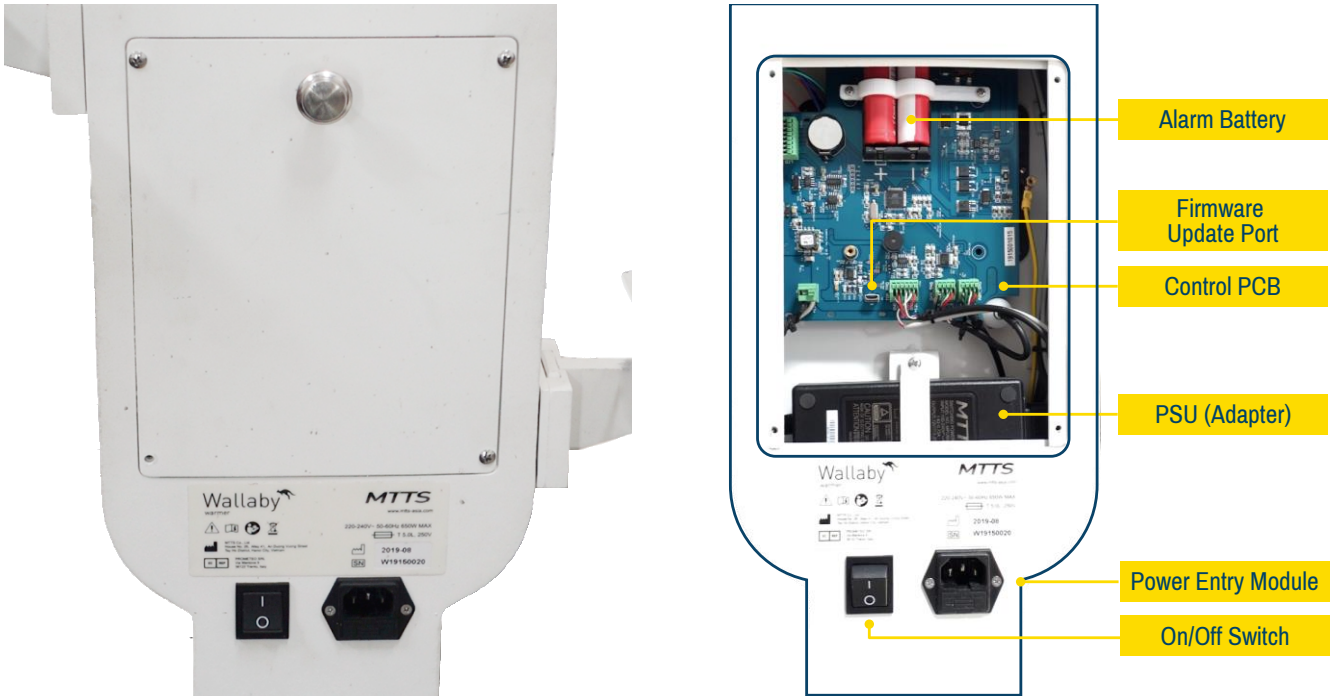


2.4 Major external components & modes of a radiant warmer.

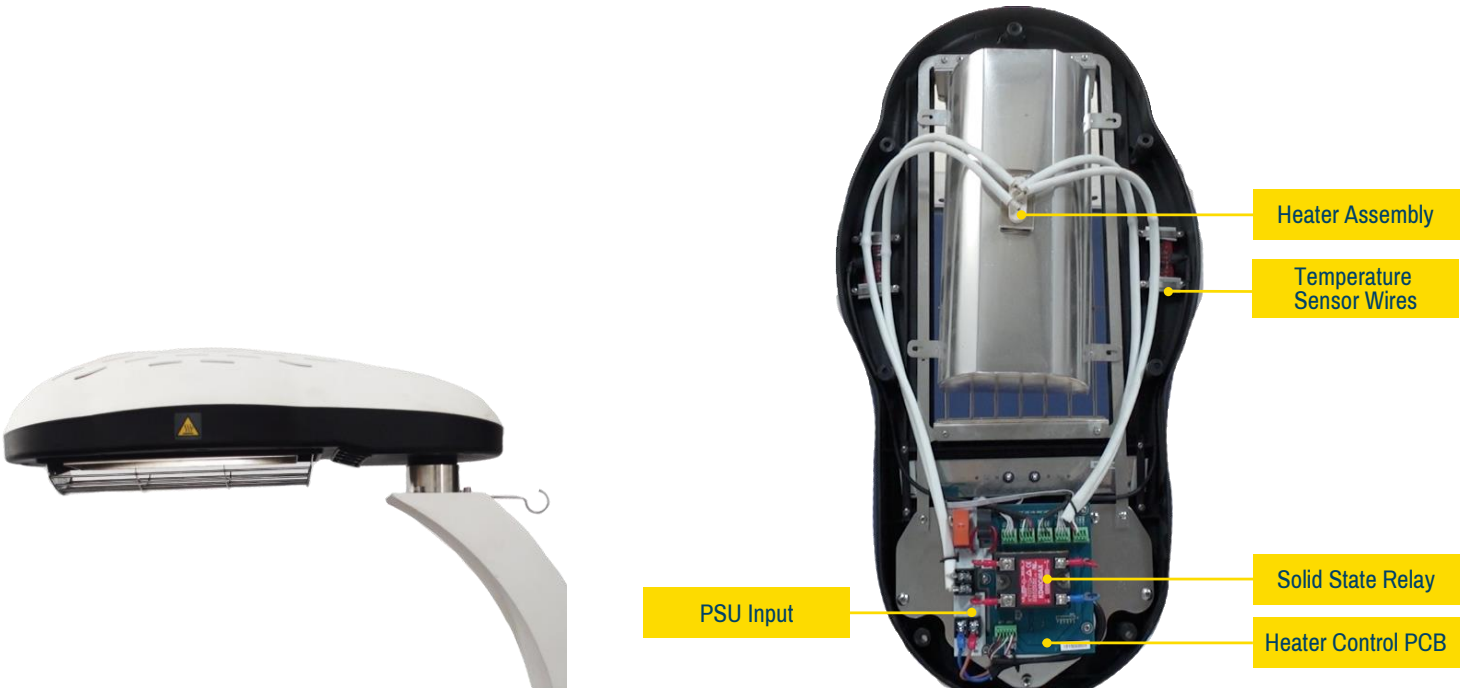
A radiant warmer consists of a mounted overhead heating mechanism that may be transported or kept stationary with lockable castors. This heating mechanism consists of **heating elements** (typically made of ceramic or quartz). In both types of heating elements, an optically designed parabolic reflector is fitted into the heating element housing to direct the heat energy towards the **baby cot**. The baby cot may be part of the radiant warmer or the heating elements may be independent (as in phototherapy lights). Heat output from the heating elements is controlled by the main controller, which in turn is dictated by user input. In some units, a separate module is fitted to control the heater output.

The core temperature of the baby is continuously monitored by the **temperature probe** connected to the device and placed over the baby's liver. Body temperature changes can be seen in real-time on a small LCD panel. Radiant warmers are also fitted with **audiovisual alarms** to attract the attention of the medical or technical staff when a problem occurs.

Standard internal device components are annotated below in **Figures 2.5** and **2.6**. Components should be similar regardless of model. However, specific locations, visual setup and component type may vary by brand and device model. Refer to service and user manuals if model in use is different from the displayed version.

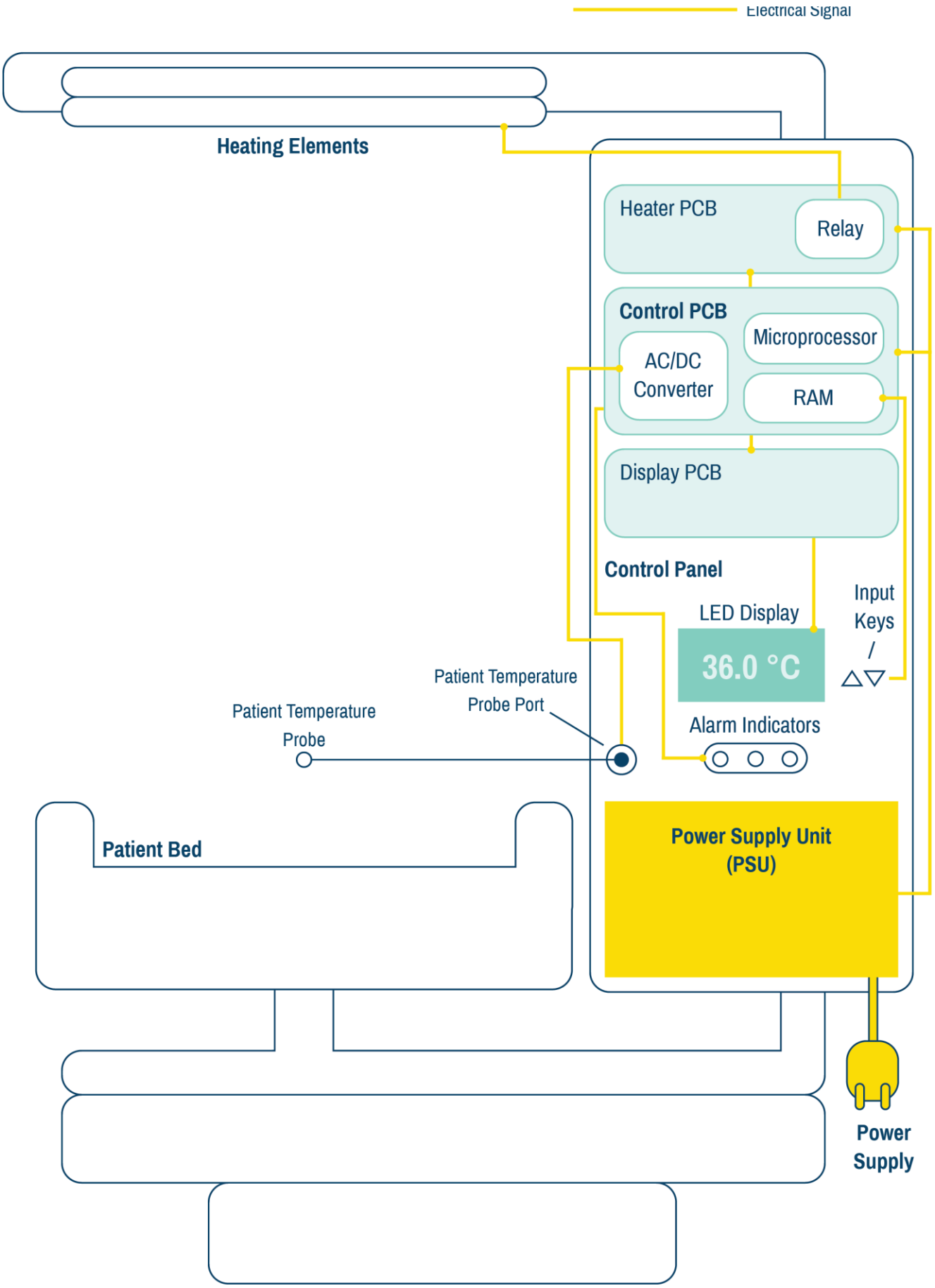


2.5 Major internal components of a radiant warmer control housing.



2.6 Major internal components of a radiant warmer overhead unit.

TYPICAL DEVICE FLOW



MAIN COMPONENTS

The following device components should be similar regardless of model. However, specific locations, visual setup and component type may vary by brand and device model. Refer to model service and user manuals if different from the displayed model for more device-specific information.

Power switch

The power switch is usually a rocker switch located on the back or side of the unit. This switch must be in the "on" position to power the radiant warmer and view the control panel.

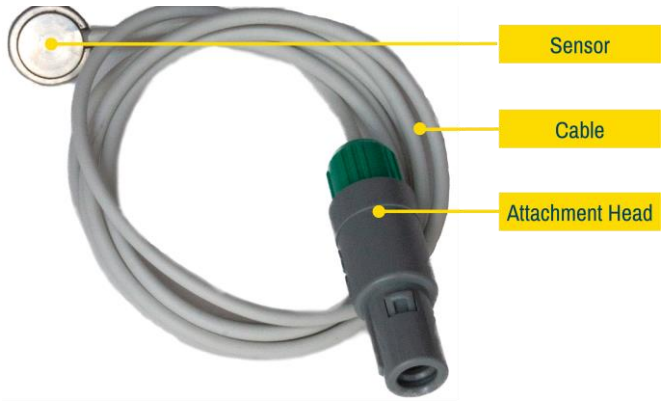
Control Panel

A control panel, usually located on the front of the radiant warmer, includes functions for operating the radiant warmer and a display of readings to assist in clinical care. Most control panels include an LCD that displays readings from the temperature probe, the set temperature for the warmer, the heat power output, fault codes, alarms, and other status readings based on the manufacture's design.

Radiant warmer controls may be located on an LCD touchscreen or may be physical buttons, knobs, or switches on the warmer. These controls are used to select the warming mode, set desired patient temperature and adjust heater output. Some radiant warmer control panels will maintain settings from the last use. For this reason, always advise the clinical or nursing staff to check the settings before initiating a patient.

Patient temperature probe

The manufacturer includes a patient temperature probe that is designed to be used with their radiant warmer model. The patient temperature probe is made up of a sensor, cable and attachment head. The patient temperature sensor should be placed on the baby's skin over the liver to read the body temperature.



2.7 Typical temperature probe.

The patient temperature probe sensor is typically made of a thermocouple that measures and feeds the patient's temperature back to the control PCB's microcontroller. The microcontroller uses the patient's temperature readings to provide feedback to the control system, which will adjust the heater output based on the comparison between the actual baby core temperature measured by the probe and the user set value (as in servo/automatic mode) or to turn off the heater (as in manual mode).

Patient temperature probe port

The patient temperature probe port on the unit is designed to fit the manufacture's specified patient temperature probe cable. The port end of the cable is inserted into the port. This cable links the control system and the patient temperature probe to provide the patient's temperature readings to the PCB microcontroller.

Power Supply Unit (PSU)

PSUs are located internally in the radiant warmer and are usually **linear** or **switch-mode power supplies**. The main function of the PSU is to convert 110/220 VAC mains power to low voltage regulated DC power for use in other electronic circuits in the system as per design. PSUs typically include a transformer, rectifiers, voltage regulators, and filters.

Control PCB

The control PCB includes the microcontroller and regulates all the system operations and electronic circuits. All auxiliary control units, if fitted, report to the main control PCB. The control system's microcontroller performs regular self-tests during operation. Whenever the system detects an issue with the temperature control system or working state, the device will issue a corresponding visual or audio alarm.

The LCD, the heater output, alarms, and monitoring of system operations are controlled through the control PCB. Comparator circuits on the control PCB compare the signal from temperature probes and the set temperature value (as in servo/automatic mode). It uses this input to control the heater output using relays (either solid state or electromechanical) which switch the heating element on/off to maintain the set temperature.

Heating elements

There are two main types of heating elements used in radiant warmers: ceramic and quartz. They are usually between 800 W or 1000 W, and they release radiant heat in the far infrared wavelength that is easily absorbed by the neonate's body.

- **Ceramic heating elements** use a heating wire (e.g., nichrome) encapsulated in a ceramic material. When power is applied the ceramic plate warms and radiates heat to the cot.
- **Quartz heating elements** consist of a coiled heating element enclosed in a quartz tube. When electricity is applied, the quartz warms, and radiates heat to the baby cot.

Both ceramic and quartz elements use an optically designed parabolic reflector that is fitted to project heat energy onto the baby cot.

Internal battery

Usually rechargeable, the internal battery operates alarms and temperature monitoring and display for 6 to 8 hours during power failure. The internal battery is usually linked to the control PCB and, in most modern models, is recharged as the radiant warmer is in use on mains power.

Firmware

Radiant warmer firmware is the software that carries out the basic functions of the radiant warmer. This software is stored in the memory within the radiant warmer's hardware. The manufacturer may issue occasional updates to the firmware that will need to be applied to existing radiant warmers per the manufacturer's instructions.

Audiovisual alarms

The control PCB's microcontroller performs regular self-tests during operation. Whenever the system detects an issue with the temperature control system or working state, the device will issue a corresponding visual and/or audio alarm or error code. The common alarms found on radiant warmers are:

- **Temperature Alarm**: works only in servo/automatic mode. It activates when the baby's temperature (measured by the patient temperature probe) deviates from the user set temperature by ±0.5 to 1°C (depending on model). A visual alarm flashes and is followed by an audible alarm.
- **Probe Failure Alarm**: works only in servo/automatic mode. It activates when the probe fails electronically, or when the probe is disconnected from the warmer. During a probe failure, the heater deactivates and a visual alarm flashes followed by an audio alarm.
- **System Failure Alarm**: activates when systems fail or calibration deviates from expected values.
- **Heater Failure Alarm**: activates when a heater defect is detected.
- **Power Failure**: activates when a power failure is detected. Battery power supports this audible alarm during power outages.

Manufacturers may include different alarms and error codes based on model. Refer to the manufacturer user or service manual for a complete description of alarms and error codes.

Baby cot

Some radiant warmers include an attached baby cot. The cot often includes removable side panels that should be in place and secure when the baby is in the cot to prevent falls. The cot may also include a knob underneath the cot to adjust the position of the cot.

3 Management

These instructions are helpful for a biomedical engineer or technician both in user training and in assessing the appropriate functionality of the device. Management covers how to use the radiant warmer, including set up for a patient, patient commencement, care whilst on the device and removal of the patient from the device.

SETTING UP FOR A PATIENT

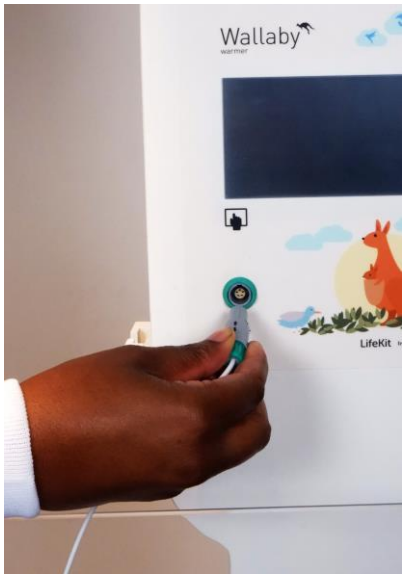
1. Plug power cable into the radiant warmer. **(3.1)** Plug power cable into a wall socket & surge protector if available. Switch on the power. **(3.2)**
2. Select manual setting at 25% or **Prewarm** setting (if available on model). **(3**.3)

3.1 Plug in the radiant warmer.

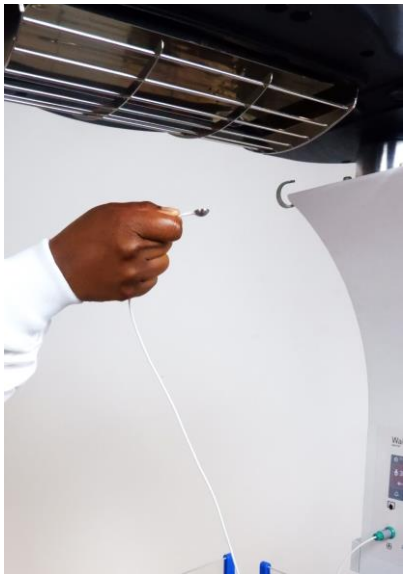
3.2 Switch on the power.

3.3 Select Pre-Warm setting to warm bedding.

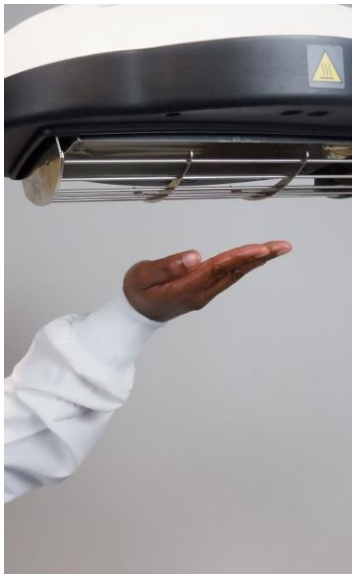
3. Plug temperature probe into the infant temperature probe port. **(3.4)** Hold temperature probe in hand and move hand directly under overhead heating elements to check for heat. **(3.5)** You should be able to feel heat emitting from the heating elements and observe the temperature displayed on the radiant warmer begin to steadily increase. **(3.6)**
4. **Prewarming is critical to prevent rapid conductive heat loss in neonatal patients.** Always advise the clinical or nursing staff to allow bedding to warm while waiting for the baby to arrive in the nursery, be transferred to the radiant warmer, or be delivered in the labour ward.



3.4 Plug in the temperature probe.



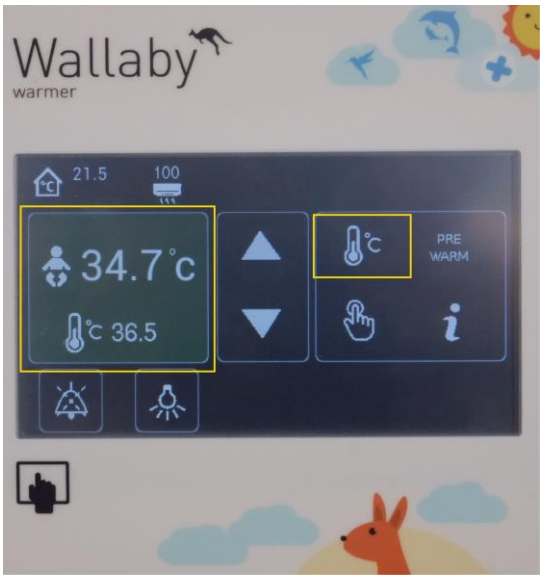
3.5 Pass the temperature probe underneath the heating elements.



3.6 Feel heat emitted from elements.

STARTING A PATIENT

1. Ensure radiant heater has been prewarmed. If the radiant warmer has not been prewarmed, then take steps to do so. Prewarming is essential in order to prevent infant from conductively losing heat to the mattress when initially placed on the warmer.
2. Change the radiant warmer from **Pre-Warm** to **Servo/Automatic** mode. **(3.7)**
3. Position infant in middle of radiant warmer cot, maintaining additional treatment tubing (e.g., CPAP tubing, IV lines) in place. **(3.8)**
4. Use gauze and 70% alcohol to clean temperature probe.
5. Place temperature probe directly above infant's liver and secure with tape or elastic bandage. **(3.9)** If a child needs to be cared for in a prone position, then place the probe over the infant's flank. The probe should be secured firmly enough that it will not fall off the patient, but not so firmly that it is pressing into the infant's skin.



3.7 Switch to servo mode.

3.8 Place the patient in the centre of the cot.

3.9 Place & secure temperature probe.

6. If used in servo mode, the **set temperature** for the baby is usually set to a default 36.5°C. The user may change the set temperature depending on patient's clinical status.
7. If the radiant heater is used in manual mode, the baby must be constantly attended as there is a real danger of overheating. Some heaters will automatically shut off after a certain amount of time in manual mode and will need to be restarted.

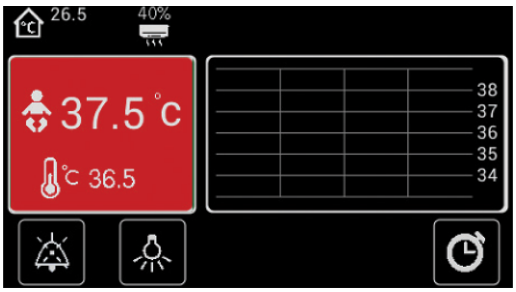
Alert 3.1

Each radiant warmer should be used for one baby with a temperature probe dedicated for that patient. **Sharing of a radiant warmer and temperature probe poses a risk for inaccurate temperature regulation and poor infection control.** If multiple patients are sharing one warmer, regular temperature monitoring must be conducted using a temperature probe or thermometer.

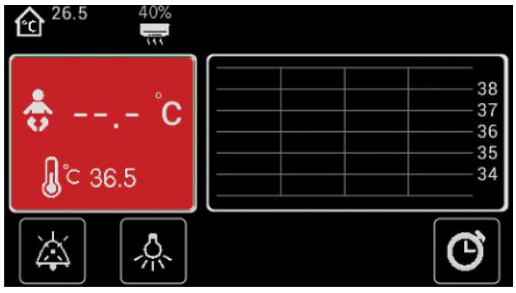
CARING FOR A PATIENT

1. Clinical or nursing staff should monitor the patient's temperature 5 minutes after starting on radiant warmer, and then 4 hourly (if in **servo** mode) or every 30 minutes (if in **manual** mode). **(Alert 3.2)** At each monitoring point, probe placement should be checked to ensure the patient has not become tangled in the probe cable and that the probe sensor has not detached.
2. Alarms should be immediately addressed by the medical or technical staff when possible:
    - **Temperature:** the infant temperature probe has recorded temperatures below **(3.10)** or above **(3.11)** the safe range for the patient. Assess if the patient is too hot or cold and change the radiant warmer settings accordingly. Check probe is not dislodged from the baby.
    - **Probe:** the temperature probe is not secured in the radiant warmer appropriately or the probe has malfunctioned. **(3.12)** Make sure the probe is plugged in; if the alarm continues, replace the probe or contact your maintenance department.
    - **Power:** the mains power has failed. **(3.13)** Turn off the power button on the radiant warmer control and move the patient to a working warmer.
    - **System:** the radiant warmer has recorded a problem with its system. **(3.14)** This may result in the radiant warmer no longer providing heat or no longer monitoring the patient. The patient should be moved to a working warmer and the malfunctioning device removed for service.

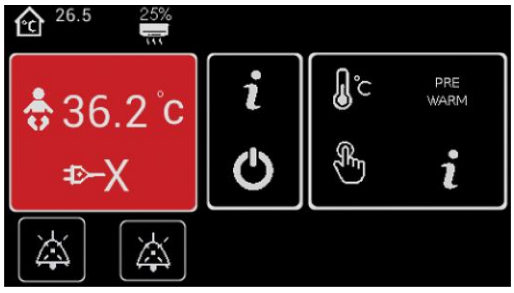
3.10 Low Patient Temperature alarm.



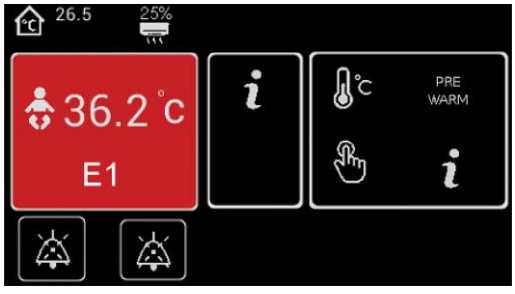
3.11 High Patient Temperature alarm.



3.12 Probe Failure alarm.



3.13 Power Failure alarm.



3.14 System Failure alarm.

Alert 3.2

In some devices, the microprocessor is programmed to reduce heater output to 60% and activate an alarm when it has been in manual mode without adjustment for more than 15 minutes. The microprocessor is also programmed to cut heater output to 0% and trigger an alarm if the patient's measured temperature reaches 40°C or above.

REMOVING A PATIENT

1. Collect:
   - Gauze
   - 70% alcohol
2. Gently remove tape/bandage holding temperature probe from patient.
3. Disinfect probe site on patient and temperature probe with gauze and alcohol. Remove patient to appropriate level of care (i.e., KMC, swaddled in bassinet, etc.).
4. Turn off warmer using switch and unplug.
5. After the patient has been off the warmer for 30 minutes, check the patient's temperature to ensure normal body temperature is maintained.

4 Infection Prevention

Routine and adequate cleaning of medical devices is critical to prevent hospital-acquired infections in newborn care units.

CLINICAL INFECTION PREVENTION

1. Clean hands with soap and water or 70% alcohol before and after placing a patient in a radiant warmer or handling any consumables that will be used on a patient (e.g., temperature probe).
2. Ensure that all patient-related consumables (including probes) are new or have been cleaned thoroughly before use. **(Alert 4.1)** Any patient-related consumables must be cleaned before they are used to assess another patient on the radiant warmer.
3. All patient-related consumables should be stored in a clean, dry location. Any cables should be loosely wrapped and secured, preventing sharp bends or kinks which will decrease the lifetime of the cables. Do not pinch or bend the cables.
4. As mentioned in **Radiant Warmer: Management**, each radiant warmer should be used for one baby with a temperature probe dedicated for that patient. Sharing of a radiant warmer and temperature probe poses a high risk for infection transmission between patients. If the

patient probe and surfaces are not cleaned thoroughly before using, infection can also be transmitted.

DISINFECTION AFTER USE

1. Turn off and unplug the radiant warmer, if not using with another patient. Allow to cool.
2. Immediately after every use, use gauze and 70% alcohol to thoroughly wipe:
    a. Temperature probe, including cable and plug head
    b. Control panel
    c. Power button
    d. Mattress
    e. Bassinet walls & floor
3. Housing of the radiant warmer should be cleaned according to ward guidelines for disinfecting surfaces. **(Alert 4.1)**

BMET INFECTION PREVENTION

1. Any piece of equipment used in providing patient care must be handled carefully, as it may be contaminated and have the potential to spread infection.
2. Clean and disinfect radiant warmer housing and components whilst wearing PPE as appropriate (e.g., rubber gloves, apron, face protection, etc.) **before any repairs or maintenance are made.**
3. Avoid any contact between used piece of equipment and skin, mucosa or clothing.
4. Post-maintenance, decontaminate all tools and surfaces used with 70% alcohol or according to manufacturer guidelines. Do not use equipment until it has fully dried following decontamination.

? Alert 4.1 Disinfecting Equipment

Disinfection of equipment should always comply with manufacturer guidelines. WHO recommends 0.5% dilution of chlorine (0.5% or > 100ppm available sodium hypochlorite) as the standard disinfectant for materials and surfaces contaminated by blood or body fluids.[6] For metal and rubber surfaces, which may be corroded by chlorine, 70% alcohol is also commonly utilised for low level disinfection.

Other appropriate low-level disinfectants include quaternary ammonium, improved hydrogen peroxide and Iodophor germicidal detergent.[7] Phenolic germicidal detergent is also listed in this category but should not be used in neonatal wards since affordable, effective alternatives are available; and, there are concerns it may cause hyperbilirubinemia and/or neurotoxicity in neonates.[8]

Please see dedicated NEST module on Infection Prevention and Control for further details on risks, benefits and utilisation of chemical disinfectants. For comprehensive guidance on infection prevention and control we recommend utilising Reference Manual for Health Care Facilities with Limited Resources Infection Prevention and Control (Caston-Gaa & Ruparelia, 2018).

5 Complications

Equipment in newborn care units are highly specialised. Without proper knowledge and skills, this equipment can be potentially dangerous for the infants, families and care providers.

CLINICAL COMPLICATIONS

- **Hypothermia & cold stress:** if the device is not prepared correctly, is malfunctioning, or the baby is left exposed for a long period of time, there is a risk of hypothermia. This is associated with a significant increase in mortality and morbidity.
- **Hyperthermia & heat stress:** hyperthermia can occur in patients whilst on manual mode who are not monitored regularly or on servo mode if the temperature probe falls off as they may become overheated. Hyperthermia increases morbidity and mortality. [9–13]
- **Pressure sores:** pressure sores may develop if the patient is incorrectly positioned, is lying on additional tubing/equipment, or the temperature probe is not positioned correctly.
- **Falls:** the cot sides of the radiant warmer must be in place to prevent the baby falling off the mattress on to the floor.
- **Infection:** if the temperature probe or infant warmer are not cleaned thoroughly before use, infection can be transmitted. Care should be taken particularly for consumables that are marked as single-use but are reused in practice (such as temperature probes).

DEVICE COMPLICATIONS

- **Hyperthermia due to probe mismanagement:** if the device is set to automatically adjust its temperature based on the patient's temperature (servo mode) and the patient temperature probe falls off the patient or is not well secured **(5.1)**, the radiant warmer may overheat in an attempt to compensate for what it observes as a low body temperature. This puts the patient at risk for a body temperature > 40°C and clinical harm.

5.1 An unsecured temperature probe may cause the radiant warmer to overheat.

- **Alarms:** radiant warmers have in-built alarms that should sound if the patient's temperature is above or below a set normothermic range. If this range is not appropriately set, alarms may sound inappropriately.
- **Fire:** if linen is placed on the radiant heater head, heat and dust may build up and pose a fire hazard. Linen should never be stored on top of the device or close to the heating elements. Although treatment devices (e.g., phototherapy units, oxygen concentrators) can be used with a radiant warmer, care should be taken to ensure that the direct line of heat to the patient from the radiant warmer heating elements is not obstructed.

6 Care & Maintenance

Biomedical engineers and technicians are responsible for second-line care and maintenance to ensure equipment lasts to their potential lifetime.

POWER SOURCE

Radiant warmers are powered with mains/socket power. Radiant warmers are typically the largest consumers of power in a nursery and should be plugged into **their own socket and surge protector** if available. **(6.1 & 6.2)** Radiant warmers typically draw too much power to be used with small-scale solar systems. In most cases, the cost (both financially and energetically) to run radiant warmers during a power cut prevents them from being used with backup power.

6.1 Radiant warmers should be plugged into their own socket.

6.2 Radiant warmers should be plugged into a surge protector if possible.

WARD LOCATION

Radiant warmers should be placed against a wall with the power cable/stand facing the wall and control panel facing the middle of the nursery room. **(6.3)** Warmers should be away from any windows to avoid air currents providing the potential for additional convective heat loss. Windows are preferably kept closed.

6.3 Appropriate placement with the power cable port facing the wall and display LCD facing away from the wall.

DEVICE CALIBRATION

Manufacturers do not typically recommend calibration for any radiant warmer components. Should the radiant warmer begin to provide temperature readings inaccurate to patient condition

or respond incorrectly to user feedback, the manufacturer may be contacted to recommend a firmware update or other repair.

DECOMMISSIONING

Assuming appropriate use and consistent maintenance, a radiant warmer may last 3 or more years. Generally, it is more fiscally responsible to repair radiant warmers when necessary, although there are some low-cost models that may be cheaper to replace rather than repair. When decommissioning a radiant warmer, heating elements, control and heating circuit board components and housing components should be taken apart and stored for further use. If the LCD, heating elements or various PCBs are still in good condition, these parts may be repurposed for other devices. Typically, the control PCB should only be repurposed for devices of the same manufacturer and model, although components from the circuit board may be desoldered and repurposed independently. **(Alert 7.3)**

PREVENTIVE MAINTENANCE

After Each Use

- [ ] Turn off, unplug and allow the radiant warmer to cool. Use gauze & 70% alcohol to wipe:
    - Temperature probe, including cable and plug head
    - Control panel
    - Power button
    - Mattress
    - Bassinet walls & floor

  See **Radiant Warmer: Disinfection After Use** and **Alert 4.1** for more information.
- [ ] Visually inspect radiant warmer components.

Weekly

- [ ] Test the heating elements and temperature probe:
    - Plug in the machine. Connect the temperature probe. Turn the power switch to ON. Leave the machine on for 1 minute.
    - Hold the temperature probe in the palm of your hand and hold your hand near the overhead heating elements. Slowly move it from the part of the heating element closest to the stand, moving towards the outside end of the heating element. You should feel your hand progressively heat as it moves and see the temperature reading on the machine steadily increase.
- [ ] Document cumulative hours and preventive maintenance actions taken.

Monthly

- [ ] Perform **Weekly** preventive maintenance steps.
- [ ] **Test the power loss alarm:** while the radiant warmer is plugged in and turned on, turn off the power at the wall socket. An alarm should sound.
- [ ] Check the operation of the baby cot, tilting mechanism and drawers.
- [ ] Document cumulative hours and preventive maintenance actions taken.

Quarterly

- [ ] Perform **Monthly** preventive maintenance steps.
- [ ] Check functionality of device in Information page or test the device in self-diagnosis mode. Observe general functionality and safety checks.
- [ ] Measure ground resistance and leakage currents. Inspect electrical components for signs of excessive heat or deterioration.
- [ ] Document cumulative hours and preventive maintenance actions taken.

Annually

- [ ] Perform **Quarterly** preventive maintenance steps.
- [ ] Confirm supply of spare heating elements, temperature probes, control PCBs, LCDs and power cables are adequate to support estimated replacement for next year.
- [ ] Document cumulative hours and preventive maintenance actions taken.

7 Troubleshooting & Repair

Biomedical engineers & technicians are responsible for providing rapid maintenance, troubleshooting & repair support for users.

PREPARE FOR REPAIR

ACCESSIBLE TOOLS	SPARE PARTS	DEVICE CHECKLIST
Digital multimeter Phillips, star & flat head screw drivers Allen keys Adjustable wrench Spanner (various sizes) Needle nose pliers Wire strippers Phase tester	Heating element Power cable Temperature probe Temperature probe port Control PCB LCD	☐ Radiant warmer ☐ Patient temperature probe ☐ Power cable (if detachable) ☐ Bassinet walls ☐ Bassinet mattress

TROUBLESHOOTING FAILURES

The radiant warmer does not turn on.

Probable Cause: Faulty power supply

Components to Check:
Power cable and switch physical integrity & continuity
Power entry module fuse(s) physical integrity & continuity
PSU continuity & voltage

The radiant warmer turns on but is not heating, or the system failure alarm sounds.

Probable Cause: Faulty heating element or microcontroller

Components to Check:
Heater terminal wires physical integrity & continuity
Heating element resistance
Heater PCB (if pertinent) voltage
Firmware edition
Control PCB & associated components continuity

The radiant warmer turns on, but the temperature probe does not read the patient's temperature and the probe alarm sounds.

Probable Cause: Faulty temperature probe

Components to Check: Probe & probe port physical integrity
Control PCB & associated components continuity

The power failure alarm does not sound when there is a power cut.

Probable Cause: Low alarm battery voltage

Components to Check: Alarm battery voltage
Battery wiring continuity

Discoloured or black spots obstruct view of the display.

Probable Cause: Damaged LCD

Components to Check: LCD physical integrity

REPAIR & REPLACE

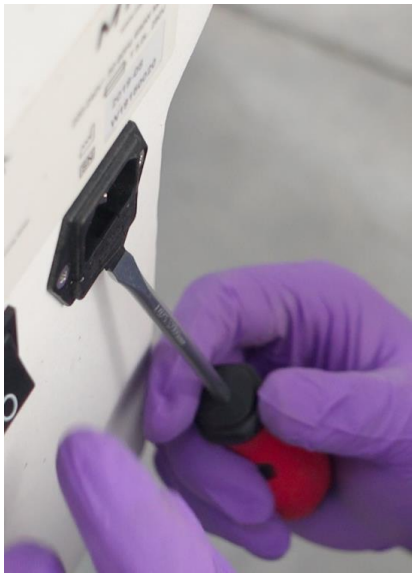
Where technically possible and not likely to obstruct clinical care, repairs may be made within the newborn care ward. Use discretion to determine if this is appropriate or if the device should be removed to the biomedical workshop for more testing or repair.

Alert 7.1

All testing, repair and replacement steps should be conducted with the power to the device switched off and the power cable removed from mains power, unless otherwise stated.

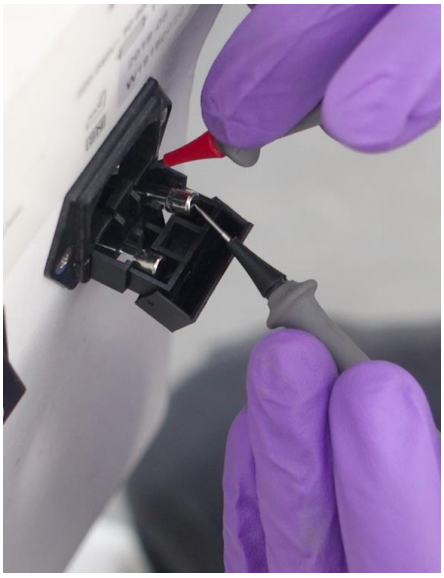
Testing & replacing the power supply fuses

Fuses may be located both on the radiant warmer housing and on the power supply cable. Fuse integrity may be visually assessed or evaluated by testing the continuity across the fuse. **(7.1 – 7.6)** Always refer to the manufacturer specifications for replacement fuses to ensure that the device remains electrically sound in standard operation.

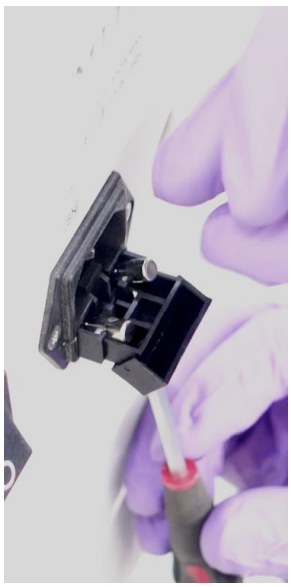


7.1 Use a screwdriver to open the fuse drawer.

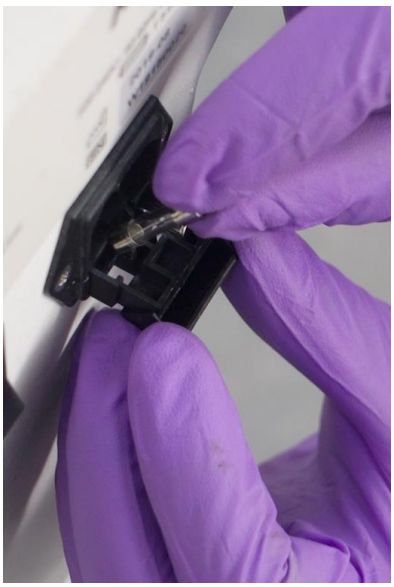
7.2 Pull out the fuse drawer to view the fuses.



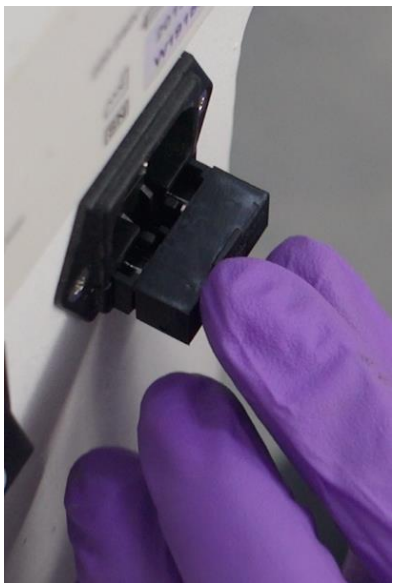
7.3 Test the fuses with a multimeter.



7.4 If replacement is needed, remove the faulty fuse.



7.5 Replace with fuse of comparable specifications.



7.6 Close the fuse drawer.

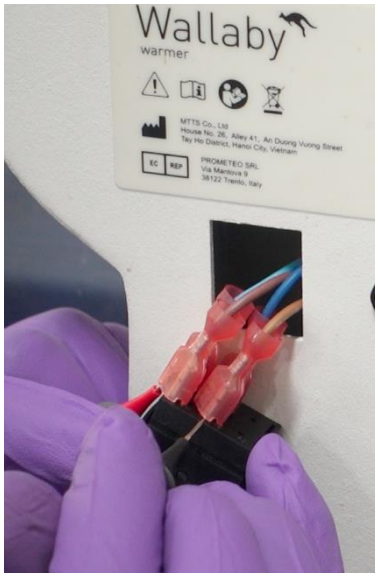
Testing & replacing the power switch

Power switches should be tested in both the off and on positions to confirm functionality. In the **On** position, the switch terminals should be continuous. In the **Off** position, the switch terminals should show a high resistance, or **OL** in most multimeters. **(7.7 – 7.9)** Although the switch may be tested whilst in circuit to preliminarily check the switch, best practice is to then remove it completely from the circuit and retest to confirm.

If the switch shows continuity or discontinuity inappropriately, assess the switch for visible physical or electrical damage. If the switch is visibly damaged or dislodged, assess whether it can be repaired with glue or solder. If it cannot be easily repaired, replace the switch. Refer to manufacturer specifications for replacement switches to ensure the device remains electrically sound in standard operation.

7.7 Remove the power switch from the housing.

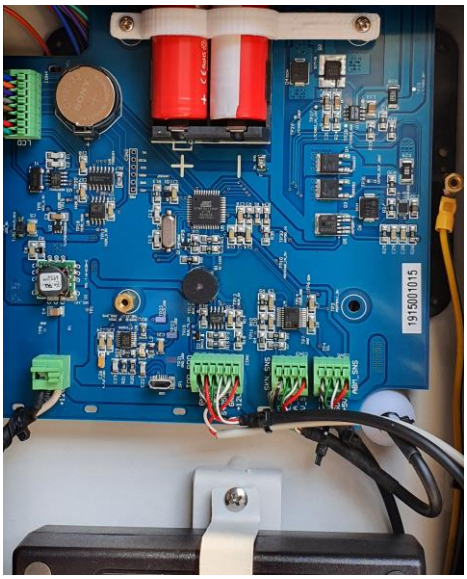
7.8 Pull out the power switch to access switch terminals.



7.9 Test the power switches in Off & On positions.

Testing & replacing control PCB and associated components

In most cases, if one element of the control PCB has malfunctioned, the entire control PCB should be replaced. Visually assess the PCB for burnt or damaged components. **(Alert 7.2)** Internal wiring continuity leading from the power supply to the control PCB and from the control PCB to the heating element may also be assessed for replacement. **(7.10 – 7.12)**



7.10 Visually assess the control board.

7.11 Remove the PCB power supply covers.

7.12 Confirm voltage at the PCB power supply with specifications.

! Alert 7.2

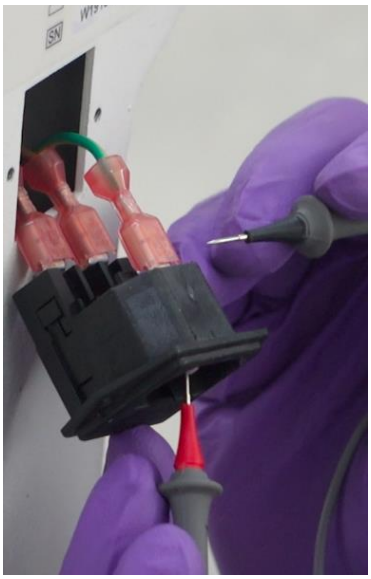
Printed Circuit Boards (PCBs) contain components that are sensitive to electrostatic discharge (ESD) and can damage the board if not handled properly. As when handling any ESD-sensitive PCB, observe standard ESD safety procedures.

Testing & replacing the power supply unit and module

Test the power supply module's continuity without the device connected to power. **(7.13 – 7.14)** Testing the power supply unit and module cannot always be completed appropriately without checking the alternating voltage at the power supply unit. **This should be completed with caution**, as the power to the device must be switched on to accurately measure the voltage delivered. If the power supply unit or module is damaged, contact the manufacturer to request a replacement part.

7.13 Unscrew power supply module from housing.

7.14 Pull the module from the housing.



7.15 Confirm continuity across the module.

Testing & replacing heating elements & element components

Testing the heating elements and associated components involves checking for loose or physically damaged wiring, terminals and heating elements. A visual check can be conducted for these components to assess basic physical damage (e.g., cracked elements, melted or loose terminal wires).

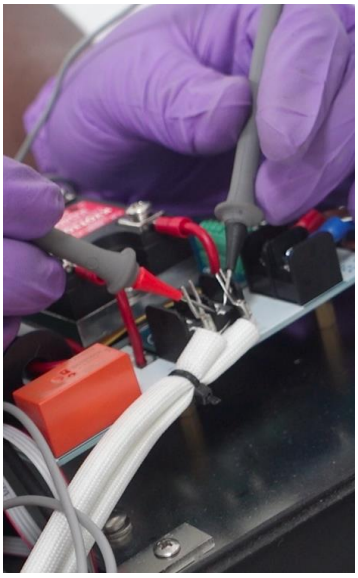
Electrically, heating elements and wiring should be assessed for continuity or resistance. The alternating voltage at the heating elements can also be measured: **this should be completed with caution**, as the power to the device must be switched on to accurately measure the power supply to the heating elements. Damage to heating elements will display as very high resistance or no continuity. **(7.16 – 7.18)**

If the heating elements are physically or electrically damaged, contact the manufacturer to request a replacement part and replace. **(7.19 – 7.21)** In some cases, the heating element may be replaced with repurposed parts from other nonfunctioning radiant warmers. This is generally not advisable as replacement parts from varying models or manufacturers may not be compatible with device microcontroller or firmware (causing incorrect temperature readings or system errors) or the system specifications for the heating element (creating the potential for further damage to other parts of the device or electrical fire).

If repurposing, replacement parts should be checked with the manufacturer to ensure specifications are within standard for the device.

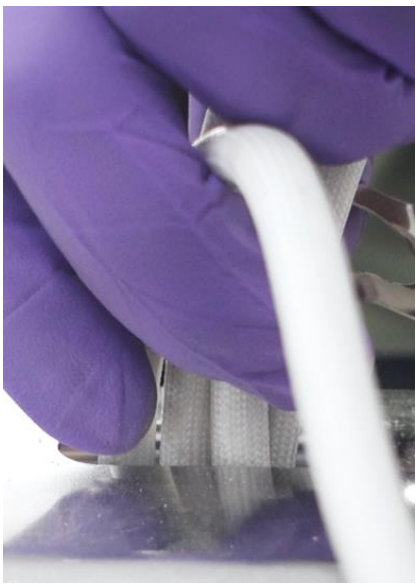
7.16 Use a screwdriver to open the heater housing.

7.17 Remove housing and set aside.

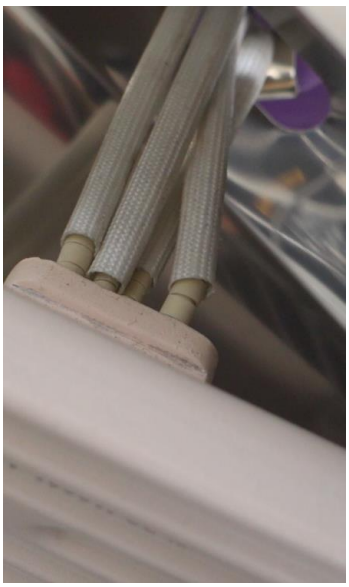


7.18 Test heating element terminals with a multimeter.

7.19 If replacing, remove clip securing the element.



7.20 Pass faulty element through hole in element housing.



7.21 Withdraw the faulty element from below the element housing.

Repairing & replacing the temperature probe or probe port

The radiant warmer temperature feedback system relies on the temperature probe and the temperature probe port being physically and electrically sound. If the temperature probe is visibly damaged, replace with a spare probe.

The temperature probe port should also be assessed externally and internally for physical damage. If the patient temperature probe port is visibly damaged or dislodged, assess whether the part can be repaired with glue or solder. If it cannot be easily repaired, contact the manufacturer to request a replacement part. In some cases, the probe port may be replaced with repurposed parts from other non-functioning radiant warmers. This is generally not advisable:

- If the radiant warmer from which the replacement probe port is taken is a defunct model, the concomitant temperature probe may be difficult to find.
- Replacement parts from varying models or manufacturers may not be compatible with the microcontroller or firmware of the radiant warmer, causing incorrect temperature readings or system errors.

After providing any maintenance on the probe or probe port, confirm the probe's accuracy by measuring different temperatures that are within the expected range of the system using a thermocouple.

Updating the radiant warmer firmware

If the radiant warmer has malfunctioning firmware, communication may be lost between the microcontroller and temperature probe or heating element. Contact the manufacturer to confirm that a firmware update is needed and coordinate the update, if possible.

Testing & replacing the alarm battery

The alarm battery is typically responsible for powering basic display functions and alarms in the event of a power outage. The specifications for battery voltage should be available in the manufacturer's service manual, but are typically 9V. Both the voltage across the battery terminals and the continuity of the wires from the battery to the control board should be tested and the battery or wires replaced if necessary.

Testing & replacing the LCD

The LCD is typically damaged by incorrect use, particularly when the user pushes with too much force on the screen. If the damaged areas do not hinder viewing or use of the display, the radiant warmer may be used without significant issues. However, if the damaged areas prevent easy use, the LCD should be replaced. Contact the manufacturer to request a replacement part specific to the radiant warmer model.

? Alert 7.3 Repurposing Parts

In some cases, parts on the unit may be replaced with a repurposed or recycled part from another piece of equipment being used for parts. **Repurposed parts should be considered with caution and guidance from the manufacturer to ensure specifications of the repurposed part is compatible with the equipment.** This includes spare parts and accessories that may not be compatible with multiple systems.

8 References

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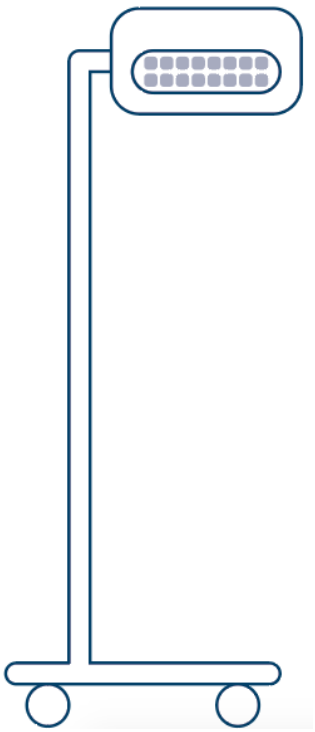
Jaundice Management

Phototherapy Light



1 Clinical Problem

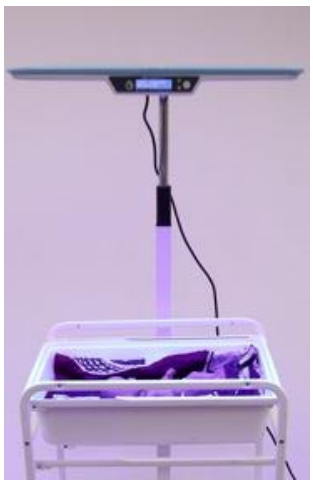
Phototherapy lights are used exclusively within the newborn care ward for newborn patients displaying symptoms of high bilirubin levels (jaundice).

Jaundice is symptomatically shown by the yellowing of skin and whites of the eyes. Phototherapy may be considered for neonates with jaundice based on the age at which they show symptoms, measured or estimated blood bilirubin concentrations or with specific complications with which they present.

2 Assessment

Infants have a large volume of bilirubin in the bloodstream because they have a high red cell mass (haemoglobin) and rapid red blood cell breakdown in the first days of life. Unconjugated bilirubin released by red blood cell breakdown cannot be rapidly removed by a newborn's immature liver, leading to an excess of unconjugated bilirubin and jaundice.

Phototherapy uses blue light transmitted on the patient's skin within the wavelengths of 425 to 475 nm[1] to break down unconjugated bilirubin to a water-soluble, non-toxic form that can be easily excreted.[2] Phototherapy lights may be integrated into units with overhead **(2.1)**, over- and under-body **(2.2)**, or flexible blanket lights. **(2.3)** Most phototherapy units can be used in tandem with other devices (e.g., radiant warmers, incubators, and oxygen therapy).



2.1 Overhead phototherapy unit.

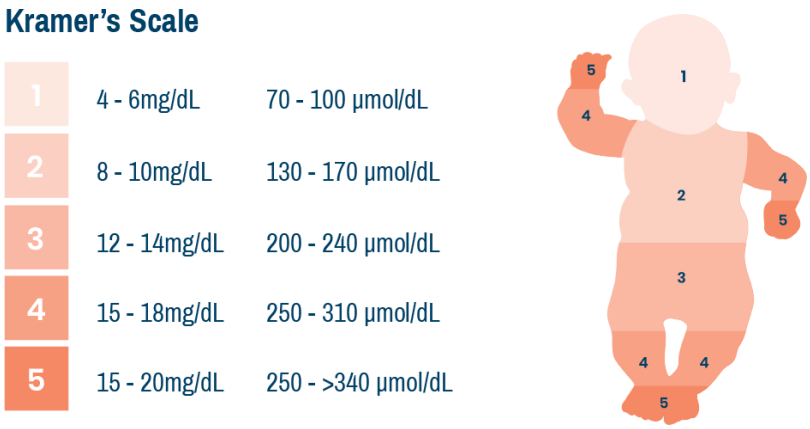
2.2 Over & under the body phototherapy unit.

2.3 Flexible phototherapy blanket.

Phototherapy lights are most effective when providing blue or green light within 425 to 475 nm via LEDs. Other types of bulbs providing blue light within 425 to 475 nm (e.g., halogen or fluorescent) are less effective for treating jaundice, have a shorter lifetime, and are not as sustainable for long term use. Halogen and fluorescent bulbs are less energy efficient than LEDs; as they lose energy in the form of heat, they may also create a potential risk for hyperthermia or evaporative water loss.[3,4] Other types of phototherapy are also used, but are typically not recommended:

- **UV lights:** not recommended for neonatal therapy due to increased melanoma risk associated with childhood UV exposure.
- **Natural sunlight:** historically used prior to wide availability of phototherapy devices; natural sunlight is not ideal due to increased challenges with temperature control of the patient and UV radiation risks.
- **Filtered sunlight:** there is emerging evidence that devices that filter sunlight, while requiring close monitoring in order to prevent temperature instability, can be used in babies > 2.2 kg in tropical climates to treat neonatal jaundice.[5–8]

There are different methods to determine need for phototherapy, all of which rely on measuring or estimating the bilirubin levels in the blood. Bilirubin levels can be measured using a blood test or transcutaneous devices.[9,10] Levels can also be estimated through visual assessment using the Kramer's scale. **(2.4)**



2.4 Kramer's Scale visual assessment areas.

Physical assessment for jaundice should be made in natural or white light to ensure results are accurate. Blood serum measurement of bilirubin levels is the gold standard for jaundice assessment. Both transcutaneous bilirubin and the Kramer's scale are less accurate approximations of serum bilirubin levels, particularly after phototherapy has begun.[11]

Most jaundiced patients require treatment for 24 to 48 hours, and typically do not require treatment for any longer than seven days. If jaundice persists, further investigation into the cause of the jaundice should be advised.

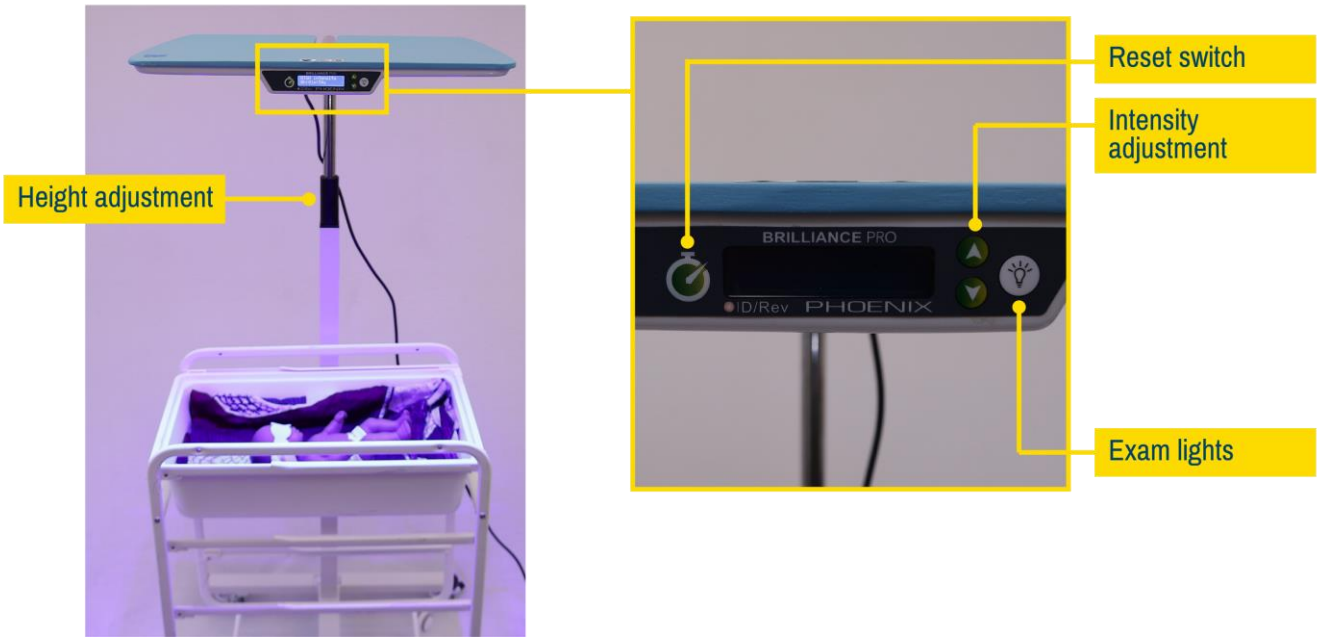
HOW IT WORKS

A phototherapy unit is a light. Phototherapy lamps emit a spectral irradiance (µW/cm^2), which is optimised when the light source is set to the recommended distance (height) from the patient. Most phototherapy lights' output can be adjusted to a **standard** or **intensive** mode depending on patient needs:

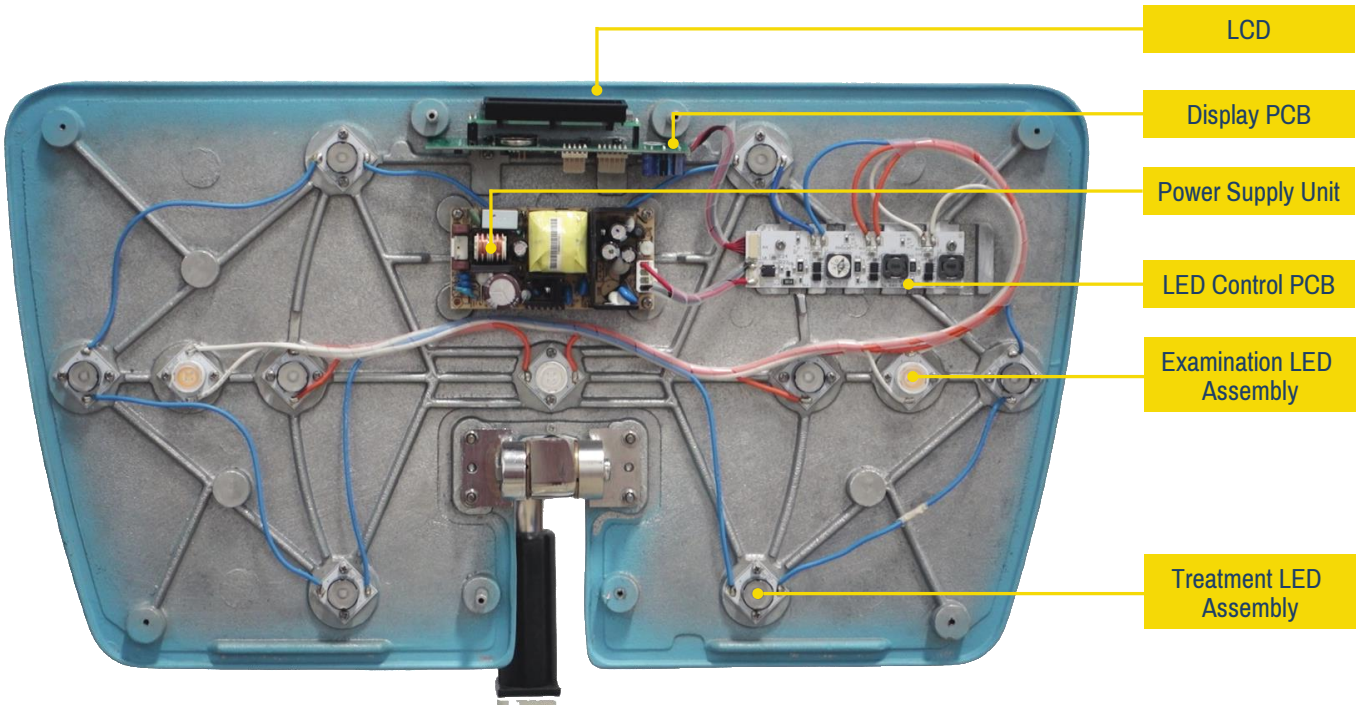
- **Standard:** provides normal-range spectral irradiances for conventional phototherapy (25-30µW/cm^2) at recommended distance from the patient.
- **Intensive:** provides higher spectral irradiances for intensive phototherapy (30-35 µW/cm^2) at recommended distance from the patient).

Standard external and internal device components are annotated below in **Figures 2.5** and **2.6**. Components should be similar regardless of model. However, specific locations, visual setup and

component type may vary by brand and device model. Refer to service and user manuals if model in use is different from the displayed version.

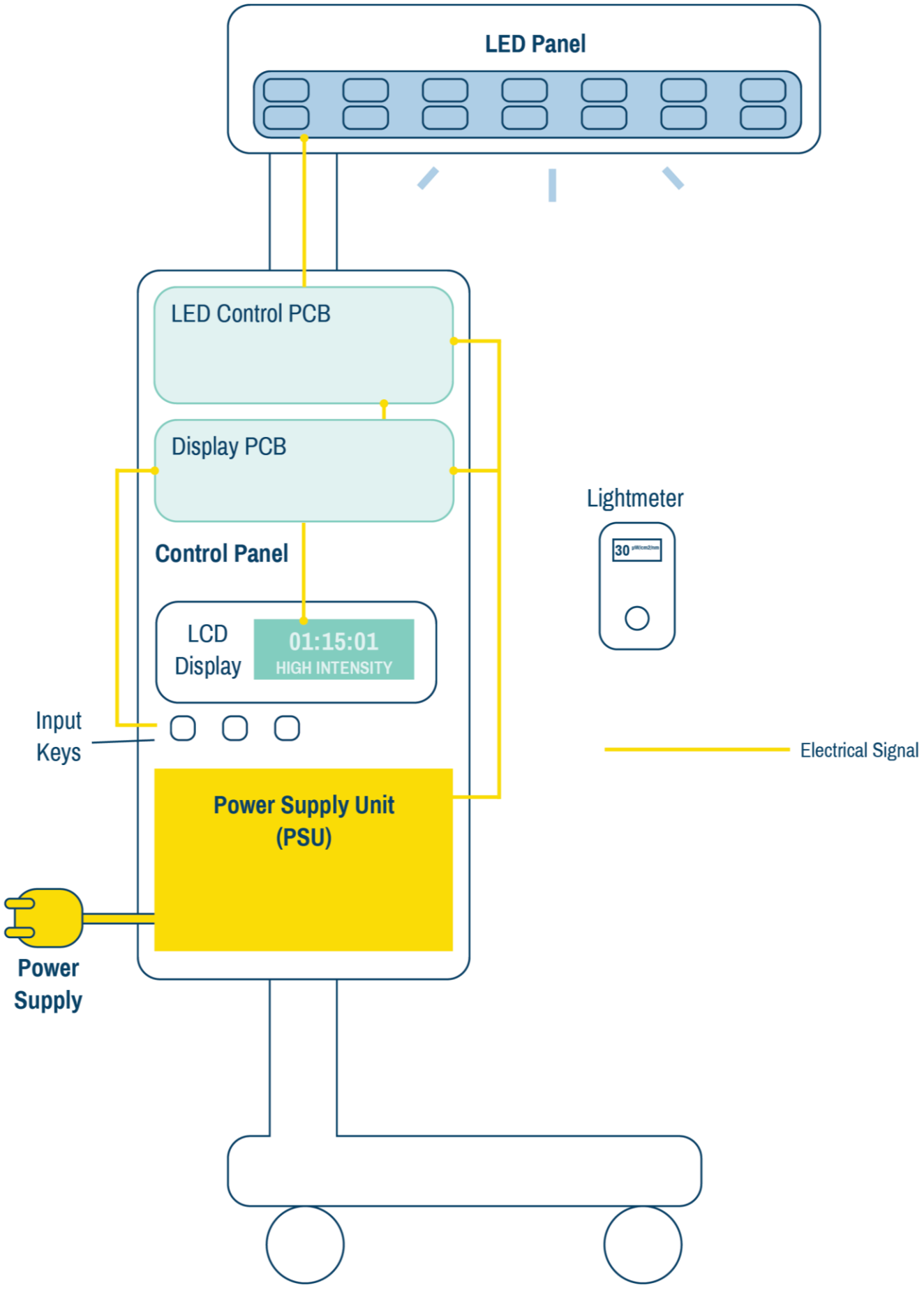


2.5 External components of a phototherapy light.



2.6 Internal components of a phototherapy light.

TYPICAL DEVICE FLOW



MAIN COMPONENTS

The following device components should be similar regardless of model. However, specific locations, visual setup and component type may vary by brand and device model. Refer to service & user manuals if model is different from the displayed model.

On/Off button

The On/Off button is located on the control panel or at the back of the unit and turns the device on and off.

Control panel

The control panel, located in the front of the phototherapy light, includes an LCD that usually displays treatment time and mode. Some models may show intensity value indicators and total device hours (the total number of hours the light has been used).

The control panel also houses buttons to control the settings like light intensity and type selection (e.g., Standard vs Intensive mode and Therapeutic vs Examination lights).

Power Supply Unit (PSU)

The PSU is located internally within the phototherapy light. Its main function is to convert AC mains power (110 or 220 V) to lower voltage regulated DC power (typically 24 V). The basic components within a power supply are a transformer, rectifier, voltage regulator and filters.

Control PCB

The control PCB executes all operations of the machine, controls the display, interfaces with the input keys, controls the LEDs' intensity, and sets the timer. It also monitors the system and collects errors for diagnosis and troubleshooting.

Lighting panel

The lighting panel is mounted internally and houses lightbulb or LED assemblies. These may be connected in series or parallel depending on the model. The lighting panel emits blue light (425 to 475 nm), which is the appropriate wavelength to break down excess bilirubin in the bloodstream.

Lightmeter

The lightmeter may be a separate measurement device or attached to phototherapy light. The lightmeter is typically a simple device, with a digital readout and photosensor to measure effective 425 to 475 nm irradiance delivered in $\mu W/cm^2/nm$. **A lightmeter (if available) should always be used to ensure the phototherapy light is providing therapeutic levels of irradiance. (Alert 2.1)** If irradiance is low, the phototherapy light will not effectively lower patient bilirubin levels.

Alert 2.1

Lightmeters may be both device-specific or sold separately and independently calibrated. If lightmeters are device-specific, they will be calibrated to read for one device and may show variation if used for a different brand or model device. In this instance, the readings may be used as an estimate but will not be completely accurate.

3 Management

Management covers how to use the phototherapy light, including set up for a patient, patient commencement, care whilst on the device, and removal of the patient from the device. These instructions are helpful for a biomedical engineer or technician both in user training and in assessing the appropriate functionality of the device.

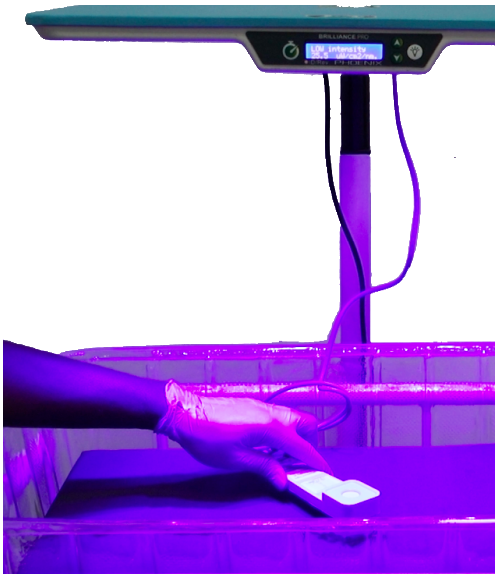
SETTING UP FOR A PATIENT

1 Collect:

- Phototherapy device
- Power cable
- Phototherapy lightmeter (if available)

2 Plug in phototherapy device. Turn on and check for **blue light** from the overhead light elements. Some phototherapy lights may have white examination lights. In most models, if light emitting from this type of device is white, it is **not therapeutic**.

3 Turn on lightmeter if available. Hold lightmeter just above the mattress where the patient needing phototherapy will be placed. **(3.1)**



3.1 Ideal lightmeter reading location.

3.2 Adjust height if necessary.

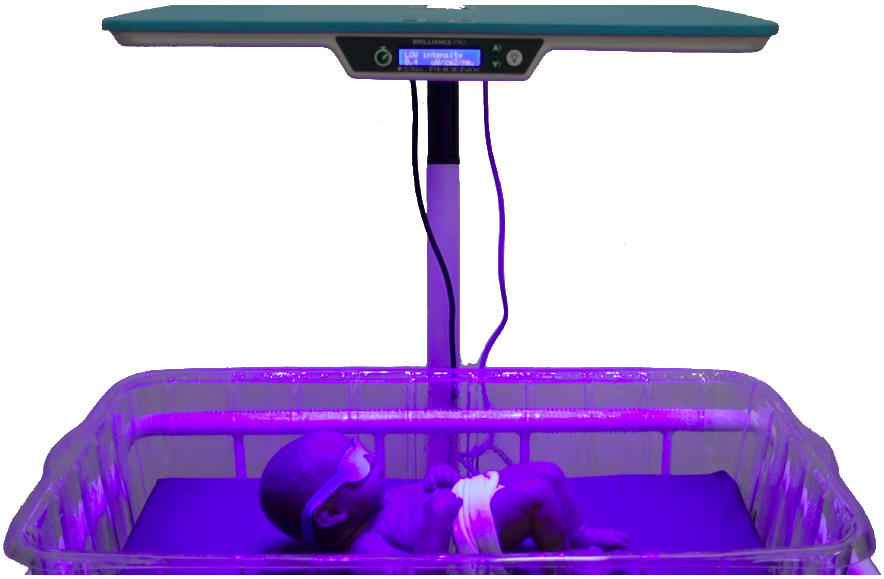
4 The phototherapy unit is typically set so the overhead lights are approximately 30 – 40 cm above the cot. Light should cover the entire surface where the patient will be treated. Check that irradiance provided at this height is within therapeutic ranges; adjust height up or down if necessary. **(3.2)**

- If irradiance is too low, lower the height of the light until therapeutic ranges are reached without obstructing care. If there is less than 15 cm between the light and the patient to reach therapeutic levels, the device should be removed for maintenance.
- If irradiance is too high, raise the height of the light until therapeutic ranges are reached.

PREPARING A PATIENT

1 Clinical or nursing staff or guardian should remove all the patient's clothes, leaving the diaper to cover the minimum necessary to keep the baby clean.

2 An eye mask should be placed so that it fully covers the patient's eyes. **(3.3)** The mask should be tight enough that it will remain in place should the patient be active, but not so tight that it is visibly uncomfortable or cutting into the patient's skin. If a ready-made eye mask is not available, ward staff may use gauze to cover the eyes and tape to secure. Avoid putting tape on the eyebrows and hair.



3.3 Fully cover the eyes and place the patient in centre of prepared cot with the phototherapy light on.

STARTING A PATIENT

1 Ward staff should place the patient directly under phototherapy lights that are switched on in a prepared cot or warming device **(3.3)** and the date and time of phototherapy initiation documented.

CARING FOR A PATIENT

1. Ward staff should monitor vital signs (especially temperature), skin rotation, daily bilirubin levels, signs of dehydration, and daily weight every 4 hours. **Phototherapy lights are not heaters**. Any heat provided by the phototherapy light is minimal. If the baby's temperature lowers, they should be initiated on thermal support whilst maintaining phototherapy treatment.

! Alert 3.1

Phototherapy lights are **not heaters**. Any heat provided by the phototherapy light is minimal and due to energy loss from the efficiency of the lighting assemblies within the unit. This heat emission is not typically strong enough to provide sufficient heat to prevent a neonatal patient from becoming hypothermic. Although visually similar to radiant warmers, the purpose of the phototherapy light is solely to provide therapeutic light to treat jaundice.

2. At every monitoring point, they should also confirm that:
    - The eye mask fully covers the patient's eyes and is still secure. **(Alert 3.2)**
    - The baby is feeding well and weight is not decreasing.
    - There are no abnormal movements and any underlying conditions are being treated.
    - Serum bilirubin levels or jaundice areas are not increasing. **Blue lights must be switched off to accurately assess visible jaundice.** Some phototherapy lights may have white examination lights that can be used to better assess the patient.

! Alert 3.2

When feeding and not under the blue light, ward staff should remove the patient's eye mask and check for any signs of infection. The baby can be swaddled, removed from the phototherapy unit and fed in mother's arms to facilitate mother-child bonding.

REMOVING A PATIENT

1. Turn off the phototherapy light. Gently remove the eye covering from the patient and discard. **(3.5)**

3.5 Gently remove and dispose of eye covering.

4 Infection Prevention

Routine and adequate cleaning of medical devices is critical to prevent hospital-acquired infections in newborn care units.

CLINICAL INFECTION PREVENTION

1. Clean hands with soap and water or 70% alcohol before and after placing a patient under phototherapy or handling any materials that will be used on a patient (e.g., eye covers).
2. Ensure that all patient-related equipment (including eye coverings) are new or have been cleaned thoroughly before use. Any patient-related materials, including cot linen, must be cleaned before they are placed on a patient under a phototherapy device.
3. All patient-related equipment should be stored in a clean, dry location. Any cables should be loosely wrapped and secured, preventing sharp bends or kinks, which will decrease the lifetime of the cables. Do not pinch or bend the cables.
4. Only one baby should be under each phototherapy unit at any time. **Sharing a phototherapy light in one cot poses a high risk for infection transmission between patients.** Some phototherapy units may be able to provide therapeutic light to multiple patients in several cots at once; this inevitably means that cots are close to each other and increases the likelihood of infection transmission.

DISINFECTION AFTER USE

1. Turn off phototherapy light and unplug. Disinfect handle of phototherapy lightmeter and LCD controls using alcohol. **(Alert 4.1)**
2. Housing of the phototherapy unit (including the casing on the LEDs or lightbulbs) should be cleaned thoroughly according to ward guidelines for disinfecting surfaces.

BMET INFECTION PREVENTION

1. Any piece of equipment used in providing patient care must be handled carefully, as it may be contaminated and have the potential to spread infection.
2. Clean and disinfect phototherapy light housing and components whilst wearing PPE as appropriate (e.g., rubber gloves, apron, face protection, etc.) **before any repairs or maintenance are made. (Alert 4.1)**
3. Avoid any contact between used piece of equipment and skin, mucosa or clothing.

4 Post-maintenance, decontaminate all tools and surfaces used with 70% alcohol or according to manufacturer guidelines. Do not use equipment until it has fully dried following decontamination.

? Alert 4.1 Disinfecting Equipment

Disinfection of equipment should always comply with manufacturer guidelines. WHO recommends 0.5% dilution of chlorine (0.5% or > 100ppm available sodium hypochlorite) as the standard disinfectant for materials and surfaces contaminated by blood or body fluids.[12] For metal and rubber surfaces, which may be corroded by chlorine, 70% alcohol is also commonly utilised for low level disinfection.

Other appropriate low-level disinfectants include quaternary ammonium, improved hydrogen peroxide and Iodophor germicidal detergent.[13] Phenolic germicidal detergent is also listed in this category but should not be used in neonatal wards since affordable, effective alternatives are available; and, there are concerns it may cause hyperbilirubinemia and/or neurotoxicity in neonates.[14]

Please see dedicated NEST module on Infection Prevention and Control for further details on risks, benefits and utilisation of chemical disinfectants. For comprehensive guidance on infection prevention and control we recommend utilising Reference Manual for Health Care Facilities with Limited Resources Infection Prevention and Control (Caston-Gaa & Ruparelia, 2018).

5 Complications

Equipment in newborn care units are highly specialised. Without proper knowledge and skills, this equipment can be potentially dangerous for the infants, families and care providers.

CLINICAL COMPLICATIONS

- **Dehydration:** neonatal patients under phototherapy with lights other than LEDs may require more fluid than maintenance volumes.[15]
- **Hypo- or hyperthermia:** temperature should be carefully monitored as patients are nearly naked under phototherapy. Phototherapy devices are not intended to be heating devices. LED bulbs used in modern devices are very efficient and generate minimal heat; thermal support may be required to avoid hypothermia. Fluorescent or halogen bulbs may generate some heat through energy loss, which should be monitored to prevent hyperthermia.
- **Retinal damage:** consistent exposure of the eyes to strong light has been shown to cause retinal damage in adults. Although this has not been tested in neonates, care should be taken to keep the eyes covered at all times during treatment. **(5.1)**

5.1 Uncovered eyes during phototherapy can lead to retinal damage.

- **Eye coverings:** eye coverings have the potential for several areas of complication.
  - **Attachment:** if eye coverings are too tight, they may uncomfortably constrict the patient's head or even lead to intracranial bleeding. If eye coverings are secured using ties or strings, care should be taken to make sure the fit is comfortable and ties are not in an area that could put the patient at risk of strangulation.
  - **Eye infections:** eye coverings are kept on the patient for the duration of phototherapy treatment. Eyes should be checked regularly for redness, swelling or discharge, and the skin under the eye pads should be cleaned daily with warm sterile water to prevent infection.
  - **Infection prevention: if** eye coverings are not cleaned thoroughly before use, infection can be transmitted. Care should be taken particularly for eye coverings that are marked as single-use but are reused, or improvised eye coverings (e.g., gauze).
- **Bronze baby syndrome:** some babies develop a greyish colour to their skin, urine, and plasma during phototherapy. This is self-limiting and resolves after phototherapy is stopped.[16–18]
- **Acute bilirubin encephalopathy (Kernicterus):** if phototherapy settings are too low or the light is nearing the end of its bulb lifetime, bilirubin may not be effectively broken down during treatment. Extremely high levels of bilirubin can cross the blood brain barrier and cause permanent brain damage. In addition to phototherapy, exchange blood transfusions are required for serious jaundice.[15]

DEVICE COMPLICATIONS

- **Inadequate light:** after a set period of use (20,000-50,000 hours, depending on manufacturer recommendations), phototherapy devices may lose their ability to provide therapeutic light. It is important to test the capacity of the phototherapy regularly to ensure that the phototherapy light is still providing a therapeutic range (25-35 μW/cm^2).

6 Care & Maintenance

Biomedical engineers and technicians are responsible for second-line care and maintenance to ensure equipment lasts to their potential lifetime.

POWER SOURCE

Phototherapy units may be powered via mains or grid power with a rechargeable battery.

WARD LOCATION

Phototherapy devices are usually rolling units on caster wheels with brakes. Devices may be rolled from patient bed to patient bed as needed. Phototherapy lights may be used with other devices, such as radiant warmers, although they should be placed in such a way that they do not hinder or obstruct care. **(6.1)**

6.1 Appropriate placement for a phototherapy unit used in conjunction with a radiant warmer and oxygen splitter.

DEVICE CALIBRATION

Manufacturers do not typically recommend calibration for any phototherapy light components. Phototherapy light and lightmeter components degrade over time but typically require replacement rather than calibration.

DECOMMISSIONING

Assuming appropriate use and consistent maintenance, a phototherapy light may last up to 5 years. LED light panels are intended to last the lifetime of the device and should not require replacement. Halogen or fluorescent bulbs may require replacement every 1-3000 hours or every 2-3 months until degradation. Models with these bulbs should be considered for replacement with a lower cost LED model where fiscally possible. When decommissioning a phototherapy light, intact light assemblies and circuit boards may be repurposed for other phototherapy lights or for fabricated phototherapy lights. Typically, the control PCB should only be repurposed for devices of the same manufacturer and model, although components from the circuit board may be desoldered and repurposed independently. **(Alert 7.3)**

PREVENTIVE MAINTENANCE

After Each Use

- [ ] Turn off and unplug phototherapy light. Use gauze and 70% alcohol or diluted chlorine to thoroughly wipe:
    - Phototherapy lightmeter, including cable and plug head if applicable
    - Control panel
    - Power button
    - Mattress and cot (if part of device)

  See **Phototherapy Light: Disinfection After Use** and **Alert 4.1** for more information.
- [ ] Visually inspect phototherapy light components.

Weekly

- [ ] Document cumulative hours run and preventive maintenance actions taken.
- [ ] Test the therapeutic irradiance of the phototherapy light:
    - Plug in phototherapy device. Turn on and check for blue light from the overhead light elements. NOTE: Some phototherapy lights may have white examination lights. In most models, if light emitting from this type of device is white, it is not therapeutic**. Check the device manual or research the device to determine if the device is meant for phototherapy.**
    - Turn on lightmeter if available. Read the irradiance in Standard Brilliance mode at 40 cm.

Monthly

- [ ] Perform **Weekly** preventive maintenance steps.
- [ ] Check the caster wheels for proper movement and brake functions.
- [ ] Document cumulative running hours and preventive maintenance actions taken.

Quarterly

- [ ] Perform **Monthly** preventive maintenance steps.
- [ ] Measure grounding integrity and earth and casing leakage current.
- [ ] Document cumulative running hours and preventive maintenance actions taken.

Annually

- [ ] Perform **Quarterly** preventive maintenance steps.
- [ ] Confirm supply of spare power supply units, lightmeters, control PCBs, LEDs and power cables are adequate to support estimated replacement for next year.
- [ ] Document cumulative running hours and preventive maintenance actions taken.

7 Troubleshooting & Repair

Biomedical engineers & technicians are responsible for providing rapid maintenance, troubleshooting & repair support for users.

PREPARE FOR REPAIR

ACCESSIBLE TOOLS	SPARE PARTS	DEVICE CHECKLIST
Digital multimeter Phillips, star & flat head screw drivers Allen keys Adjustable wrench Needle nose pliers Wire strippers Phase tester Lightmeter	Power supply unit Power cable Control PCB Lighting panel / assembly	☐ Phototherapy light ☐ Power cable (if detachable) ☐ Lightmeter

TROUBLESHOOTING FAILURES

The phototherapy light is not turning on.

Probable Cause: Faulty power supply

Components to Check:
Power cable continuity
Power switch physical integrity & continuity
Power entry module fuse(s) physical integrity & continuity
Power supply unit continuity & voltage

The phototherapy light turns on but light intensity will not change.

Probable Cause: Faulty key or wiring

Components to Check:
Membrane or LCD key physical integrity & continuity
Control PCB & associated wiring / component continuity

The phototherapy light turns on, but only some of the bulbs are alight.

Probable Cause: Burnt out light assembly

Components to Check:
Irradiance delivery
Light assembly physical integrity & continuity

REPAIR & REPLACE

Where technically possible and not likely to obstruct clinical care, repairs may be made within the newborn care ward. Use discretion to determine if this is appropriate or if the device should be removed to the biomedical workshop for more testing or repair. **(Alert 7.1)**

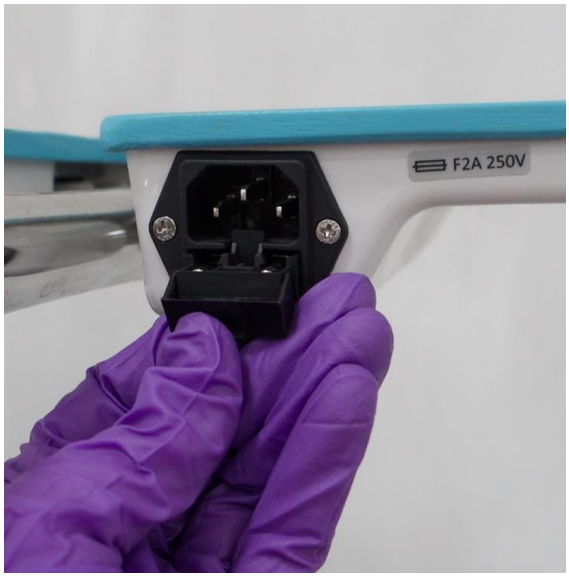
Alert 7.1

All testing, repair and replacement steps should be conducted with the power to the device switched off and the power cable removed from mains power, unless otherwise stated.

Testing & replacing the power supply fuses

Fuses may be located both on the phototherapy light housing and on the power supply cable. **(7.1, 7.2)** Fuse integrity may be visually assessed or evaluated by testing the continuity across the fuse. Always refer to the manufacturer specifications for replacement fuses to ensure that the device remains electrically sound in standard operation.

7.1 Assess the housing for fuses.

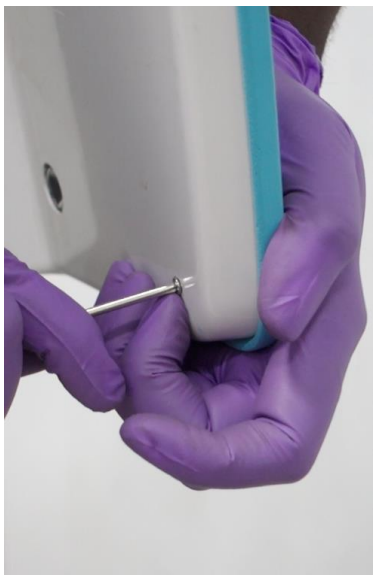


7.2 Open the fuse drawer and inspect the fuses. Test with a multimeter.

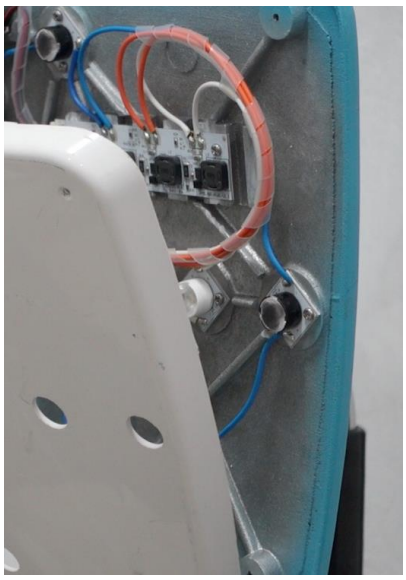
Testing & replacing the power switch

Power switches should be tested in both the off and on positions to confirm functionality. In the **On** position, the switch terminals should be continuous. In the **Off** position, the switch terminals should show a high resistance, or **OL** in most multimeters. **(7.3 – 7.5)**

If the switch shows continuity or discontinuity inappropriately, assess the switch for visible physical or electrical damage. If the switch is visibly damaged or dislodged, assess whether the part can be repaired with glue or solder. If it cannot be easily repaired, replace the switch. Always refer to the manufacturer specifications for replacement switches to ensure that the device remains electrically sound in standard operation.



7.3 Unscrew housing to access circuitry.

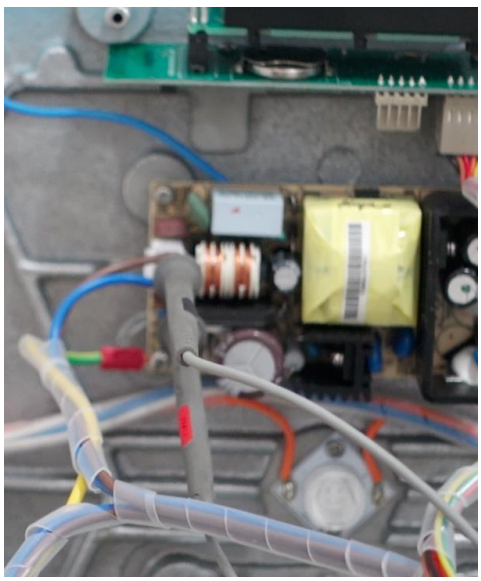


7.4 Pull housing away carefully to prevent damaging wires.

7.5 Test the continuity across the switch in **On / Off** positions.

Testing & replacing the power supply unit or module

Testing the power supply unit cannot be completed appropriately without checking the alternating voltage at the power supply unit. **(7.6, 7.7) This should be completed with caution**, as the power to the device must be switched on to accurately measure the voltage delivered. If the power supply unit or module is damaged, contact the manufacturer to request a replacement part.



7.6 Check the line voltage at the power supply unit.

7.7 Test known voltages along the power supply unit and throughout the wiring circuits.

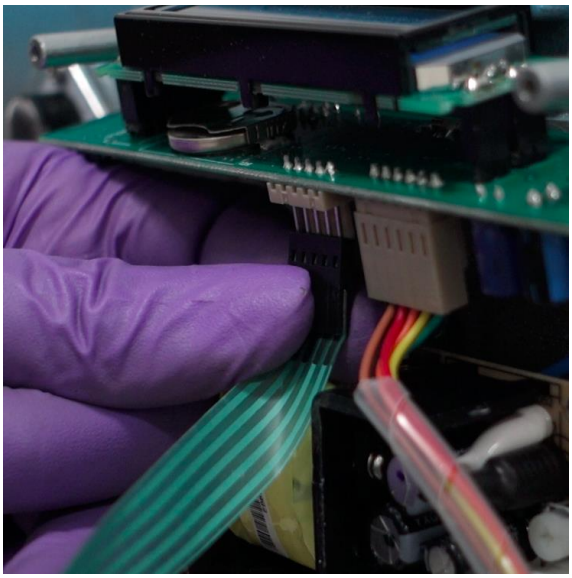
Testing & replacing the control panel membrane keys

Open the device and visually assess the membrane key or keys for damaged components. Verify the continuity across the membrane key. If the membrane key is not continuous, replace the key or display panel as needed.

Testing & replacing control PCB and associated components

In most cases, if one element of the control PCB has malfunctioned, the entire control PCB should be replaced. Visually assess the PCB for burnt or damaged components. **(7.8, 7.9)** Internal wiring continuity leading from the power supply to the control PCB and from the control PCB to the lighting assemblies may also be assessed for replacement. **(Alert 7.2)**

7.8 Check that components are securely connected to the PCBs.



7.9 Gently disconnect wiring and replace PCBs as needed.

Alert 7.2

Printed Circuit Boards (PCBs) contain components that are sensitive to electrostatic discharge (ESD) and can damage the board if not handled properly. As when handling any ESD-sensitive PCB, observe standard ESD safety procedures.

Testing & replacing the lighting panel or assemblies

If the irradiance delivered by the phototherapy light assemblies at a standard height (20 to 40 cm from the treatment location) is low, the lighting panels may need replacement. Lighting panels may be replaced in full or bulb/LED assemblies replaced individually. **(7.10)** Physical damage to the lighting panel should also be assessed and the entire panel replaced as needed.

7.10 Desolder and replace treatment LED assemblies as needed.

? **Alert 7.3** Repurposing Parts

In some cases, parts on the phototherapy unit may be replaced with a repurposed or recycled part from another piece of equipment being used for parts. **Repurposed parts should be considered with caution and guidance from the manufacturer to ensure specifications of the repurposed part are compatible with the equipment.** This includes probes and accessories that may not be compatible with multiple systems.

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