SLE1500

Non-Invasive Respiratory Therapy System

Instructions for use

Software V6

OxyGenie®
Inspired Oxygen Control

SLE
Innovate | Create | Inspire

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WARNING: A WARNING statement provides important information about a potentially hazardous situation which, if not avoided, could result in death or serious injury.

CAUTION: A CAUTION statement provides important information about a potentially hazardous situation which, if not avoided, could result in minor or moderate injury.

NOTE: Emphasises information of importance.

This manual is only to be used with the SLE1500.

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Document ref: RA-IFU-000020 Issue 9

REF RA-IFU-000020

Contents

1. Intended use

The SLE1500 is intended to drive an air/oxygen blend at controlled flow and pressure to the required device for the chosen therapy. The SLE1500 is intended for use with neonatal, infant and paediatric patients.

The integrated Masimo SET® Pulse Oximeter is indicated for the continuous non-invasive monitoring of functional oxygen saturation of arterial haemoglobin (SpO_2) and pulse rate (measured by an SpO_2 sensor).

The Masimo SET® Pulse Oximeter is indicated for use with neonatal, infant and paediatric patients during both motion and no-motion conditions, and for patients who are well or poorly perfused in hospitals and hospital-type facilities.

The incorporated OxyGenie® system is intended to control the inspired oxygen delivery, to keep the SpO_2 of the patient within a predefined range of SpO_2, during mechanical ventilation, nCPAP and non-invasive respiratory support administered to neonatal, infant and paediatric patients.

1.1 Operating principle

The SLE1500 will deliver a continuous flow of blended oxygen and medical air in order to provide respiratory support for spontaneously breathing patients.

The SLE1500 is intended to run on mains power and with high-pressure oxygen and air from wall supplies or cylinders.

The SLE1500 offers a range of therapy modes. The parameter settings and alarms in these modes are customised to the intended patient size and therapy type. A full description of the therapy modes is included later in the Instructions for Use.

The SLE1500 contains an internal memory and, on device restart, will revert to the last used mode and reset to the lowest parameter settings for that mode.

The SLE1500 does not contact the patient but the user interacts with the device during set up.

The user interface and therapy display are navigated using the 4.2” colour touchscreen. A separate power on/off button is located below the touchscreen.

The button will illuminate green when the device is switched on.

The SLE1500 monitors the O_2%, flow rate and pressure of the gas delivered to the patient. The monitored parameters are displayed numerically on the therapy screen and can also be displayed graphically via a configurable real-time waveform.

In neonatal nCPAP mode the therapy screen will display a calculated breaths per minute value. The breaths per minute calculation uses a Schmitt trigger, which adjusts its threshold values, based on an average patient pressure. The mid-point average is calculated from 100 samples, so has a response time of 0.53s. The upper and lower thresholds are defined as 8% either side of the average patient pressure. Each time the patient pressure (85ms response time) crosses these thresholds, the time is noted. The reciprocal of this time gives the breaths per minute value.

The SLE1500 is supplied with an internal thermal mass flow sensor and a paramagnetic oxygen sensor. Both sensors are maintenance free and intended to last the lifetime of the device. The sensors are calibrated using the in-built calibration function within the device settings. The patient respiratory pressure is measured via the 6% female Luer proximal pressure port on the front of the device and/or the internal pressure sensor in the respiratory gas outlet.

The SLE1500 contains a number of audible and visual text alarms to help ensure patient safety. A log of alarm incidents is saved to an internal memory.

The SLE1500 contains a rechargeable Li-ion battery, intended to provide limited backup power in the event of mains failure.

The Masimo SET® SpO_2 sensor can be connected to the device to continuously monitor the patient’s blood oxygen saturation and pulse. The patient’s perfusion index and real-time plethysmograph waveform can also be displayed.

See “Pulse Oximetry–Masimo SET®” on page 68 for more details.

In the event of a mains failure, the battery backup will continue to power the device with no change to the pulse oximeter equipment. Once the battery backup has run out, the device will turn off.

NOTE: *Leaks or internal venting of sample gas will have no effect on performance. If a leak is significant, the device will alarm or compensate.*

1.2 OxyGenie®

The OxyGenie® system is integrated into the SLE1500 and is intended to control the inspired oxygen delivery, to keep the SpO_2 of the patient within a predefined range of SpO_2, during nCPAP, non-invasive respiratory support and High Flow Oxygen Therapy administered to neonatal, infant and paediatric patients.

The OxyGenie® algorithm is a closed loop proportional-integral-derivative (PID) controller. Once a second, this algorithm uses the patient's SpO_2 (measured using Masimo SET® sensors) to calculate the appropriate O_2 setting to maintain SpO_2 within a target range.

WARNING: *Use of OxyGenie® is contraindicated on patients whose target SpO_2 is outside the available pre-set target ranges.*

WARNING: *Use of OxyGenie® is contraindicated on cardiac patients.*

2. Intended user

To be used by clinical staff with an appropriate level of training in a hospital environment.

3. Operational notes

- For use in hospital and hospital-type facilities only.
- For use with spontaneously breathing patients only.
- Only for use with tubing and breathing sets compliant with ISO 5367:2000.
- Only for use with respiratory humidifiers compliant with ISO 8185:2007 or ISO 80601-2-74: 2020.
- For use with SLE-recommended breathing system and accessories only.
- Only for use with the supplied power supply.
- For use with medical air and/or medical oxygen only.
- Intended for use with the operator positioned directly in front of the device and with the display in full view.

WARNING: *Use of non-SLE recommended accessories or consumables could cause device malfunction, breakage or patient injury.*

4. Limitations of use

- Not for use in homecare environment.
- Not for use in a hyperbaric chamber.
- The materials used in the SLE1500 and related equipment may not be compatible with anaesthetic or respirable gases, solutions/suspensions/emulsions that have not been evaluated.
- Not for use with helium or gas mixtures including helium.
- Not for use with antistatic or electrically conductive hoses or tubing.
- Use of OxyGenie® is contraindicated on cardiac patients.
- Not for use during magnetic resonance imaging (MRI) or in an MRI environment.

5. Warnings and Cautions

5.1 SLE1500 warnings and cautions

WARNINGS:

- Operators should familiarise themselves with this manual before using the SLE1500 on a patient.
- The functioning of this device may be adversely affected by the operation of equipment such as high frequency surgical (diathermy) equipment, defibrillators, mobile phones or short-wave therapy equipment. If this occurs, the SLE1500 should be removed from the vicinity of such devices. Ensure normal operation of devices prior to use.
- Do not use the SLE1500 in the presence of flammable anaesthetic agents or other ignition sources.
- Unauthorised modification of the SLE1500 is not to be carried out by the end user.
- Visually inspect the SLE1500 and accessories for damage before use.
- Every component of the breathing system must be visually inspected and checked for function, leakage and occlusions, immediately before use on each patient. Ensure that connections are secure.
- Check the condition of the gas supply hoses to the SLE1500. Do not use any hose that shows signs of cracking, abrasion, kinking, splits, excessive wear or ageing. Make sure that the Air and O_2 hose have not come into contact with oil or grease.
- Do not use the SLE1500 if it is subjected to a significant force or impact. Remove the SLE1500 from use and contact SLE for technical assistance.
- Prior to use, consult the respective documentation and Instructions for Use of all connected devices, or combination of devices.
- The materials used in the SLE1500 and related equipment may not be compatible with anaesthetic or respirable gases, solutions/ suspensions/emulsions that have not been evaluated.
- If an alarm condition cannot be identified, the SLE1500 should be turned off immediately and removed from service.
- Monitor the clinical parameters of the patient during the treatment. The device alarms should not be the only method of detecting faults.
- Flow accuracy can be affected by use of a gas-driven nebuliser.
- On activation of an adaptive alarm, check supply of gas to the patient.
- Only to be used by suitably qualified clinicians.
- Check the SLE1500 settings and alarm status before starting and during treatment.
- Do not occlude or tamper with any of the SLE1500 ports.
- Ensure red dust caps are removed from device prior to use.
- Do not reuse single-use accessories. Reuse poses a threat to patient safety in terms of cross infection and device malfunction and breakage. Cleaning can lead to device malfunction and breakage.
- Ensure SLE1500 display screen is visible at all times.
- The SLE1500 is a high flow device and should only be connected to a pipeline installation that allows for the indicated flow.
- Should device software malfunction, display an unrecoverable error screen, or perform any unexpected action, remove from service and contact SLE for technical support.
- Output cannot exceed the concentration of the input.
- No alarms are present to indicate patient disconnection in flow mode using nFlow™ Generator with extra small prongs and small prongs.
- For low set pressure (up to 4 mbar), the only alarm to state leak may be the “Unexpected flow high” with:
  nFlow™ Generator with extra small prongs.
- The patient circuit should be checked at regular intervals for condensate / rain out at intervals.
- No alarms are present to highlight disconnection when in **Neonatal, infant and paediatric HFOT Mode, Neonatal, infant and paediatric nCPAP – Flow Mode and Manual Flow Mode.**

CAUTIONS:

- When connecting or disconnecting the breathing system, use a push and twist action.
- Mount the SLE1500 in an upright orientation.
- Ensure that screen touches are correctly registered.
- Ensure that gas supply is connected prior to starting treatment. Do not connect gas supply if treatment is already running without pausing the treatment first.
- If the SLE1500 is operating on battery power and is allowed to completely discharge the battery, the unit should be recharged as soon as possible. This is to avoid damaging the battery by allowing them to remain in a deep discharged state for any period of time. Allowing the battery to remain in the deep discharged state will shorten the life of the battery and the amount of time the SLE1500 can remain on battery power.

- The SLE1500 contains temperature dependent devices which perform normally in controlled environments in hospitals. If the SLE1500 has been stored at a temperature different to that in which it will be used, allow the unit to acclimatise before powering up.
- The SLE1500 requires calibration after every software update.

5.2 Masimo® SpO_2 warnings and cautions

NOTE: *These cautions and warnings refer to use of Masimo® Pulse Oximetry.*

GENERAL:

- The pulse oximeter is to be operated by, or under the supervision of, qualified personnel only. The manual, accessories, directions for use, all precautionary information, and specifications should be read before use.

WARNINGS:

- As with all medical equipment, carefully route patient cabling to reduce the possibility of patient entanglement or strangulation.
- Do not place the pulse oximeter or accessories in any position that might cause it to fall on the patient.
- Do not start or operate the pulse oximeter unless the set-up was verified to be correct.
- Do not use the pulse oximeter during magnetic resonance imaging (MRI) or in an MRI environment.
- Do not use the pulse oximeter if it appears or is suspected to be damaged.
- Explosion hazard: Do not use the pulse oximeter in the presence of flammable anaesthetics or other flammable substance in combination with air, or oxygen-enriched environments, or nitrous oxide.
- To ensure safety, avoid stacking multiple devices or placing anything on the device during operation.
- To protect against injury, follow the directions below:
  - Avoid placing the device on surfaces with visible liquid spills.
  - Do not soak or immerse the device in liquids.
  - Do not attempt to sterilise the device.
  - Use cleaning solutions only as instructed in this operator's manual.
  - Do not attempt to clean the device while monitoring a patient.
  - To protect from electric shock, always remove the sensor and completely disconnect the pulse oximeter before bathing the patient.
  - If any measurement seems questionable, first check the patient’s vital signs by alternate means and then check the pulse oximeter for proper functioning.

- Inaccurate SpO_2 readings may be caused by:
  - Improper sensor application and placement.
  - Elevated levels of COHb or MetHb: High levels of COHb or MetHb may occur with a seemingly normal SpO_2. When elevated levels of COHb or MetHb are suspected, laboratory analysis (CO-Oximetry) of a blood sample should be performed.
  - Elevated levels of bilirubin.
  - Elevated levels of dyshemoglobin.
  - Vasospastic disease, such as Raynaud's, and peripheral vascular disease.
  - Hemoglobinopathies and synthesis disorders such as thalassemia, Hb s, Hb c, sickle cell, etc.
  - Hypocapnic or hypercapnic conditions.
  - Severe anaemia.
  - Very low arterial perfusion.
  - Extreme motion artefact.
  - Abnormal venous pulsation or venous constriction.
  - Severe vasoconstriction or hypothermia.
  - Arterial catheters and intra-aortic balloon.
  - Intravascular dyes, such as indocyanine green or methylene blue.
  - Externally applied colouring and texture, such as nail polish, acrylic nails, glitter, etc.
  - Birthmark(s), tattoos, skin discolorations, moisture on skin, deformed or abnormal fingers, etc.
  - Skin colour disorders.
- Interfering substances: Dyes or any substance containing dyes that change usual blood pigmentation may cause erroneous readings.
- The pulse oximeter should not be used as the sole basis for medical decisions. It must be used in conjunction with clinical signs and symptoms.
- The pulse oximeter is not an apnoea monitor.
- The pulse oximeter may be used during defibrillation, but this may affect the accuracy or availability of the parameters and measurements.
- The pulse oximeter may be used during electrocautery, but this may affect the accuracy or availability of the parameters and measurements.
- The pulse oximeter should not be used for arrhythmia analysis.
- SpO_2 is empirically calibrated in healthy adult volunteers with normal levels of carboxyhemoglobin (COHb) and methaemoglobin (MetHb).
- Do not adjust, repair, open, disassemble, or modify the pulse oximeter or accessories. Injury to personnel or equipment damage could occur. Return the pulse oximeter for servicing if necessary.
- Misapplication of a pulse oximeter sensor with excessive pressure for prolonged periods can induce pressure injury.

CAUTIONS:

- Do not place the pulse oximeter where the controls can be changed by the patient.
- Electrical shock and flammability hazard: Before cleaning, always turn off the device and disconnect from any power source.
- When patients are undergoing photodynamic therapy, they may be sensitive to light sources. Pulse oximetry may be used only under careful clinical supervision for short time periods to minimise interference with photodynamic therapy.
- Do not place the pulse oximeter on electrical equipment that may affect the device, preventing it from working properly.
- If SpO_2 values indicate hypoxemia, a laboratory blood sample should be taken to confirm the patient's condition.
- If the Low Perfusion message is frequently displayed, find a better perfused monitoring site. In the interim, assess the patient and, if indicated, verify oxygenation status through other means.
- Change the application site or replace the sensor and/or patient cable when a "Replace sensor" and/or "Replace patient cable", or a persistent poor signal quality message (such as "Low SIQ") is displayed on the host monitor. These messages may indicate that patient monitoring time is exhausted on the patient cable or sensor.
- If using pulse oximetry during full body irradiation, keep the sensor out of the radiation field. If the sensor is exposed to the radiation, the reading might be inaccurate, or the device might read zero for the duration of the active irradiation period.
- To ensure that alarm limits are appropriate for the patient being monitored, check the limits each time the pulse oximeter is used.
- Variation in measurements may be profound and may be affected by sampling technique as well as the patient's physiological conditions. Any results exhibiting inconsistency with the patient's clinical status should be repeated and/or supplemented with additional test data. Blood samples should be analysed by laboratory instruments prior to clinical decision making to completely understand the patient's condition.
- Do not submerge the pulse oximeter in any cleaning solution or attempt to sterilise by autoclave, irradiation, steam, gas, ethylene oxide or any other method. This will seriously damage the pulse oximeter.
- Electrical Shock Hazard: Carry out periodic tests to verify that leakage currents of patient-applied circuits and the system are within acceptable

limits as specified by the applicable safety standards. The summation of leakage currents must be checked and in compliance with IEC 60601-1 and UL60601-1. The system leakage current must be checked when connecting external equipment to the system. When an event such as a component drop of approximately 1 metre or greater or a spillage of blood or other liquids occurs, retest before further use. Injury to personnel could occur.

- Disposal of product - Comply with local laws in the disposal of the device and/or its accessories.
- To minimize radio interference, other electrical equipment that emits radio frequency transmissions should not be in close proximity to the pulse oximeter.
- Replace the cable or sensor when a Replace Sensor or when a Low SIQ message is consistently displayed while monitoring consecutive patients after completing troubleshooting steps listed in this manual.

NOTES:

- A functional tester cannot be used to assess the accuracy of the pulse oximeter.
- High-intensity extreme lights (such as pulsating strobe lights) directed on the sensor, may not allow the pulse oximeter to obtain vital sign readings.
- When using the Maximum Sensitivity setting, performance of the "Sensor Off" detection may be compromised. If the device is in this setting and the sensor becomes dislodged from the patient, the potential for false readings may occur due to environmental "noise" such as light, vibration, and excessive air movement.
- Do not loop the patient cabling into a tight coil or wrap around the device, as this can damage the patient cabling.
- Additional information specific to the Masimo® sensors compatible with the pulse oximeter, including information about parameter/ measurement performance during motion and low perfusion, may be found in the sensor's Directions for Use (DFU).
- Cables and sensors are provided with X-Cal™ technology to minimize the risk of inaccurate readings and unanticipated loss of patient monitoring. Refer to the Cable or Sensor DFU for the specified duration of the patient monitoring time.

5.3 OxyGenie® warnings and cautions

NOTES:

These cautions and warnings refer to use of OxyGenie®.

The "Reference O_2" value is an average of the patient's oxygen requirement for every 30 minutes.

OxyGenie® is only available when the SpO_2 sensor is connected and SpO_2 monitoring is turned on.

GENERAL:

- OxyGenie® is to be operated by, or under the supervision of, qualified personnel only. The manual, accessories, Directions for Use, all precautionary information, and specifications should be read before use.
- Before initiating (or reinitiating) OxyGenie®, check that the O_2 setting reflects the patient's current clinical condition to ensure that the control algorithm responds appropriately. Failure to do so can affect the response time of the algorithm.

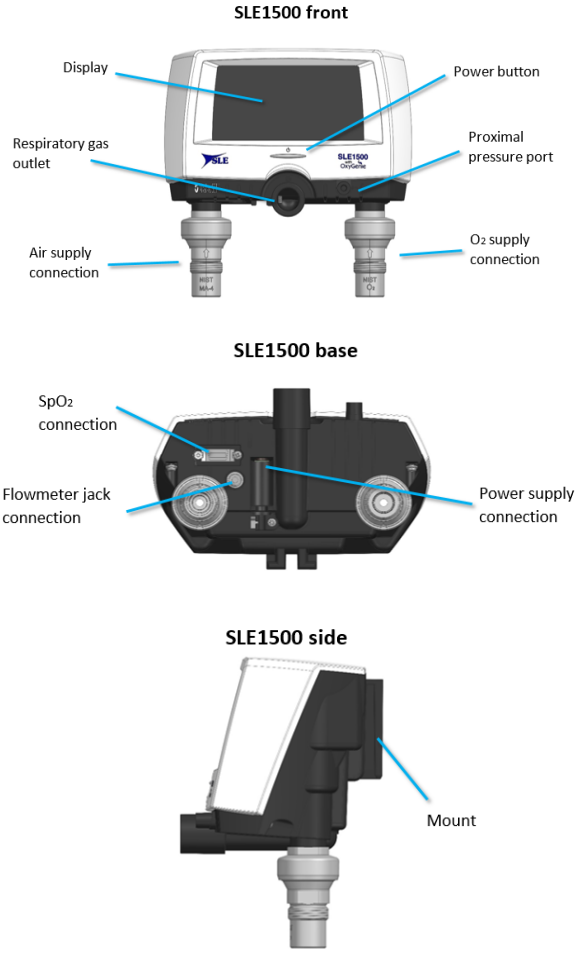
WARNINGS:

- SpO_2 monitoring is via Masimo® sensor. High and low SpO_2 alarms are automatically set to 1% above the upper end of the target range and 1% below the lower end of the target range. These limits are user adjustable.
- See SLE SpO_2 Pulse Oximetry Cable (Masimo® SET®) IFU for details of conditions which may affect the accuracy of SpO_2 readings.
- Do not use OxyGenie® if the difference between SpO_2 and SaO_2 is greater than 5%.
- Time base for the OxyGenie® graph is selectable by the user between 10, 30, 60 & 120 minutes, graph axis displays duration of time.
- The boost function (+5%) is not recommended to be used when the set O_2 is equal or higher than 60, since it may not provide the desired oxygen output.

CAUTIONS:

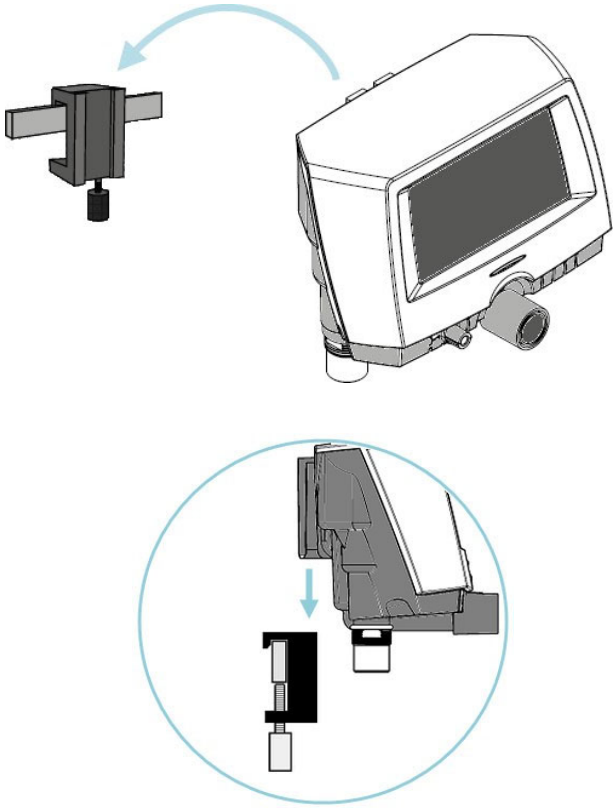
- Additional ventilator independent patient monitoring (bedside vital-monitoring blood-gas analyser) should be performed.
- An increasing requirement for oxygen while using OxyGenie® may be indicative of an underlying condition which has to be addressed, even if SpO_2 is within the target range.

6. SLE1500 Assembly schematic



6.1 Installation

- Remove and dispose of the red dust caps from the device prior to first use.



1) Mount the SLE1500

- Attach the mounting bracket to the medi-rail, drip pole, cart or other secure location.
- Mount the SLE1500 on to the bracket.

WARNING: *Ensure that the SLE1500 is mounted securely to the bracket before the gas supplies, power supply, sensor cable or breathing system are connected.*

2) Connect supply

- Connect the air supply to the SLE1500, ensure the supply is between 2 and 6 bar.
- Connect the O_2 supply to the SLE1500, ensure the supply is between 2 and 6 bar.
- Connect the power supply to the SLE1500 and ensure the plug is safely connected to the mains.

WARNING: *Ensure that gas supply connections are hand tightened to avoid damage to the SLE1500. Do not use a spanner.*

3) Calibrate

- Calibrate the SLE1500 prior to first use. See Section 6.2.4 O2 Calibration for further details.

4) Connect the breathing system

- Connect the breathing system machine connection to the SLE1500 respiratory gas outlet (see breathing system IFU for details).
- Connect the breathing system proximal gas monitoring line to the Proximal Pressure Port using a push and twist action (if applicable - see breathing system IFU for details).

5) Connect the SpO_2 sensor (optional)

- Connect the SpO_2 sensor to the SpO_2 connection on the SLE1500 (see SpO_2 sensor IFU for details).

WARNING: *Ensure the following checks are performed before first use (refer to the SLE1500 IFU or service manual for further details):*

- Electrical safety check
- Flow calibration
- O_2 calibration
- Functionality checks

WARNING: *Ensure that pre-use checks are carried out on both the SLE1500, breathing system and other accessories prior to each use.*

WARNING: *If a malfunction is detected, do not use the SLE1500 and contact SLE for assistance.*

6.2 Installation Checks

- Ensure that the following checks are performed during installation and before first use of the SLE1500. See Section '22.6 Initial Installation/ relocation check sheet' to assist with documenting a record of this check'.

WARNING: *Prior to first use, the InterFlow must be connected to a mains power source for 24 hours to ensure that the battery is fully charged. Failure to do this will shorten the service life of the battery which will result in reduced battery life in a mains power failure situation.*

6.2.1 Visual inspection

Visual inspection of the SLE1500 and accessories should be performed monthly.

- Inspect for any defects such as:

- Damage, eg. cracks, breaks, cuts any to wiring

- Wrong connections

- Any obstructions to the inlet or outlet

Damaged accessories should be replaced as necessary. If the SLE1500 is damaged, remove the SLE1500 from use. The device should be serviced, repaired or replaced as necessary.

6.2.2 Electrical Safety Check

- Test to local medical electrical device standards. A ground connection test of the SLE1500 is not required. The SLE1500 is an IEC 60601-1 Class II BF Device.

6.2.3 Functionality check: Software relief valve (Simple)

NOTE: Ensure that the following check takes place in an environment where there is no significant surrounding noise.

Ensure that the SLE1500 is connected to mains. Power on the SLE1500 and during boot-up, check that a “click” can be heard. This will be the Software Relief Valve self-check completing.

NOTE: **If a click is not heard, contact technical support.**

6.2.4 O2 Calibration

NOTE: After O2 Calibration, functionality check O2 Accuracy Test must be carried out. (Section 6.2.5)

Equipment

Tools/Equipment	
Name	**Part No**
22mm Outlet Tube	5005000
Filter	N3688
NIST/DISS Medical Air Supply (2-6Bar, capable of 85L/min)	N/A
NIST/DISS Oxygen Supply (2-6Bar, capable of 20L/min, 99%+)	N/A

Process

Step 1

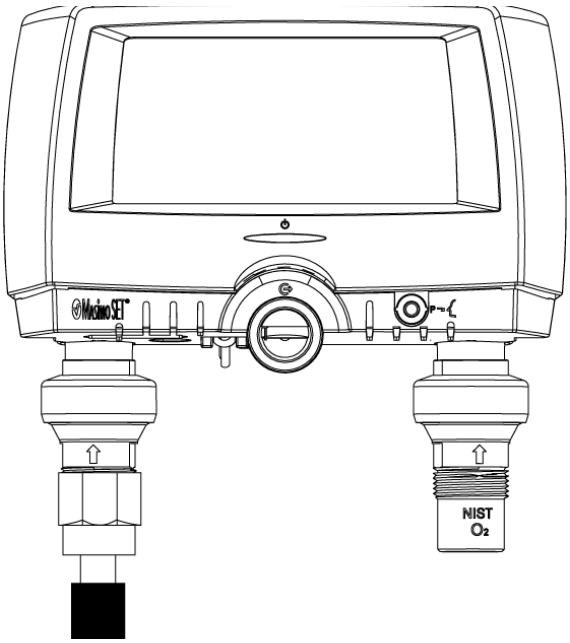
Connect SLE1500 Power Supply to a Mains power source.

Step 2

Connect the Medical Air Supply (usually black outer hose) to the Air Connector (left) on the SLE1500. Once connected, turn the Medical Air Supply on and check that there are no audible leaks.

WARNING: Minimum supply pressure: 2bar, Maximum supply pressure: 6bar

WARNING: Ensure that gas supply connections are hand tightened to avoid damage to the SLE1500. Do not use a spanner.



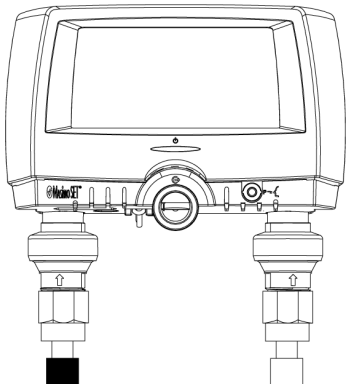
Step 3

Connect the Oxygen Supply (usually white outer hose) to the O_2 Connector (right) on the SLE1500.

Once connected, turn the O_2 Supply on and check that there are no audible leaks.

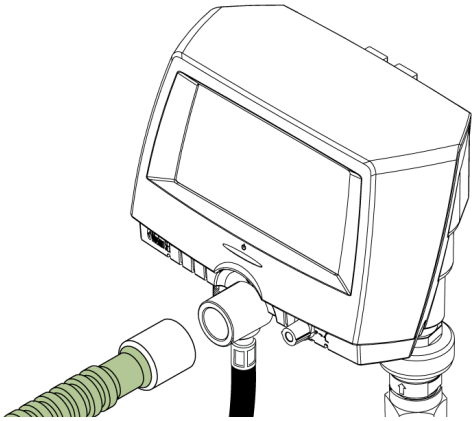
WARNING: Minimum supply pressure: 2bar, Maximum supply pressure: 6bar

WARNING: Ensure that gas supply connections are hand tightened to avoid damage to the SLE1500. Do not use a spanner.



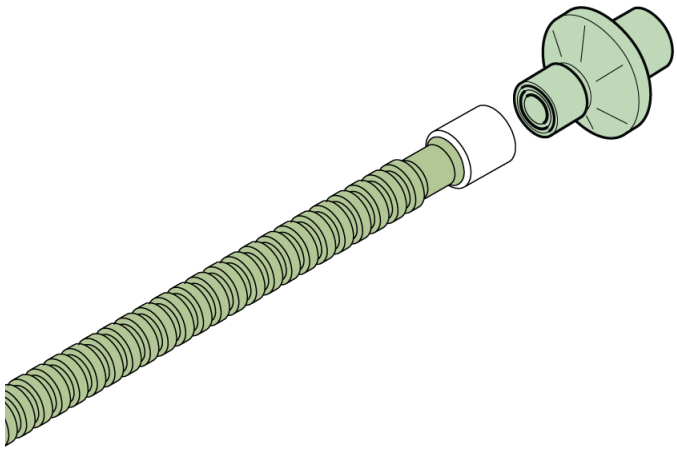
Step 4

Connect 22mm Outlet Tube to the Patient Gas Outlet of the SLE1500 securely using the 'push and twist' method.



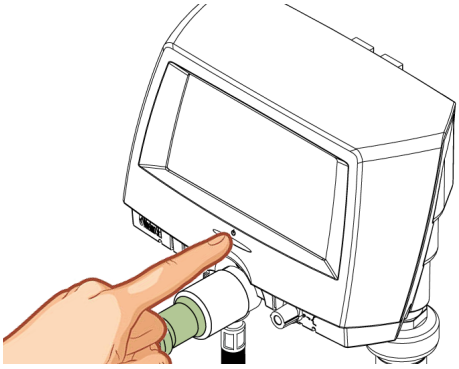
Step 5

Connect the Filter to the end of the 22mm Outlet Tube using 'push and twist' method.



Step 6

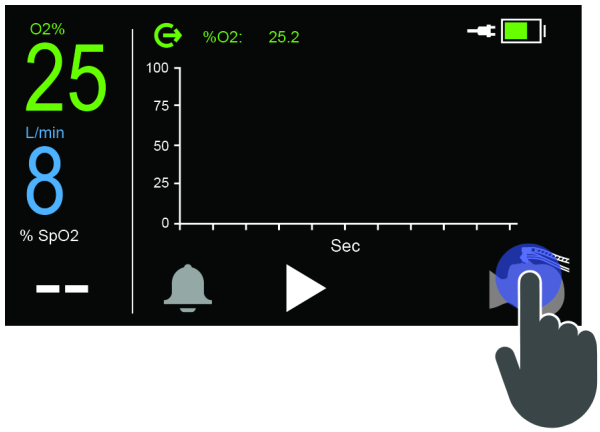
Power on the SLE1500 by Pressing and Holding the Power Button.



Step 7

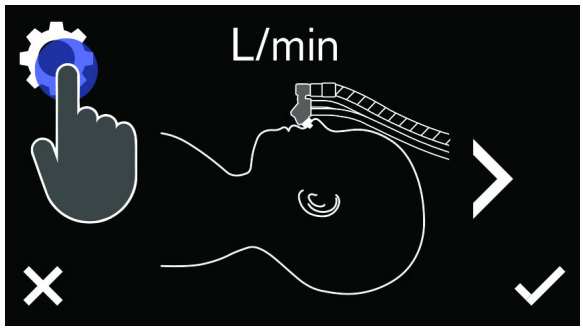
Tap on the symbol in the bottom right corner to enter the Mode Selection Menu.

***NOTE:* This symbol will be different depending on which 'mode' the device was last used in, but tapping it will always bring up the same menu.**



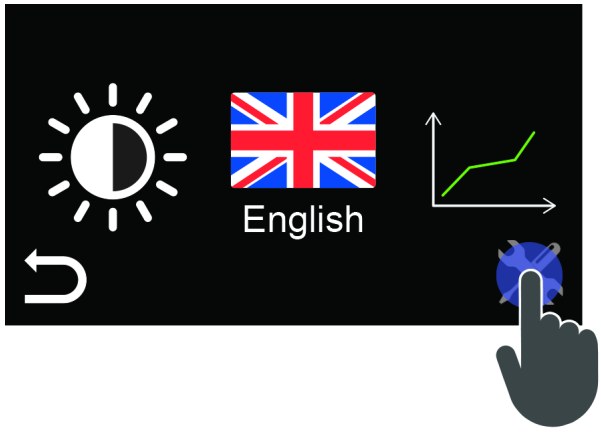
Step 8

Tap on the 'Settings' icon in the top left hand corner of the screen.



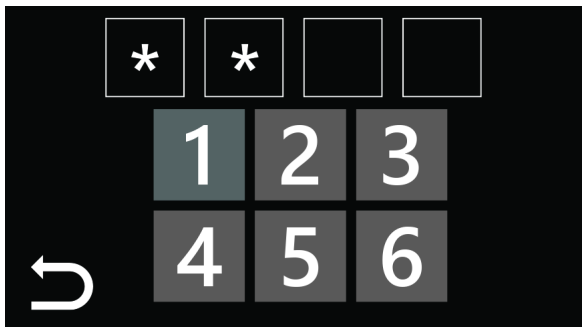
Step 9

Tap the Protected Menu icon in the bottom right-hand corner of the screen.



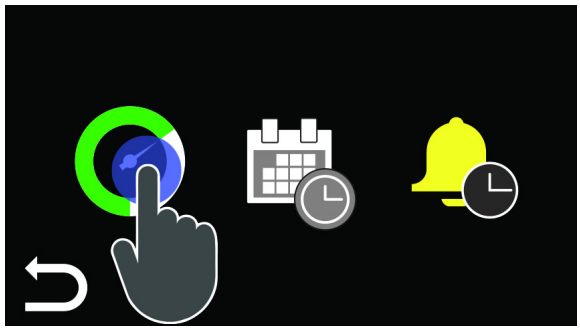
Step 10

Enter the passcode: **6563.** The screen will automatically transition to the next screen once the correct password has been entered



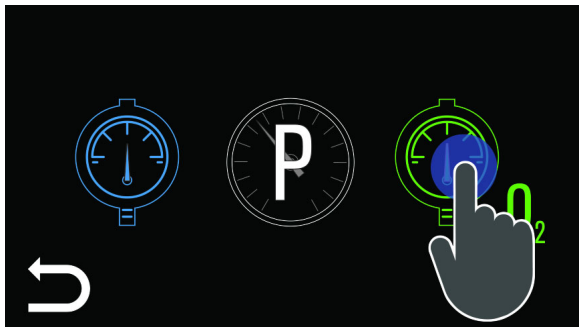
Step 11

Tap the dial symbol to enter the Calibration Menu.



Step 12

Tap the GREEN O_2 dial symbol to initiate the Oxygen Calibration.

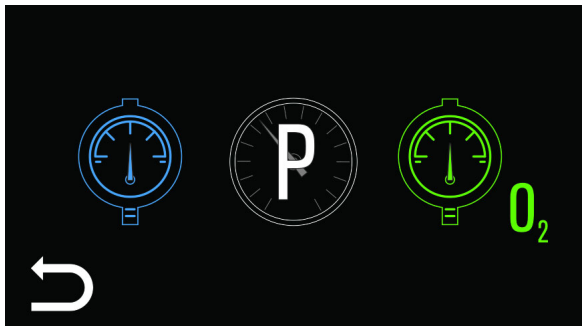


Step 13

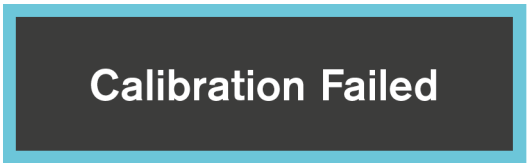
Wait for the calibration to complete, this takes roughly around 1 minute.

Step 14

Once complete, the device will show a Calibration Successful screen. Tap the screen to return to the Calibration menu.



NOTE: Should you see a “Calibration Failed” screen, please refer to the Troubleshooting section (Section 9) for further information



6.2.5 Functionality Check: O2 Accuracy

NOTE: After O2 Calibration, a functionality check of O2 Accuracy must be carried out.

Equipment

Tools/Equipment	
Name	**Part No**
22mm Outlet Tube	5005000
Filter	N3688
NIST/DISS Medical Air Supply (2-6Bar, capable of 85L/min)	N/A
NIST/DISS Oxygen Supply (2-6Bar, capable of 20L/min, 99%+)	N/A

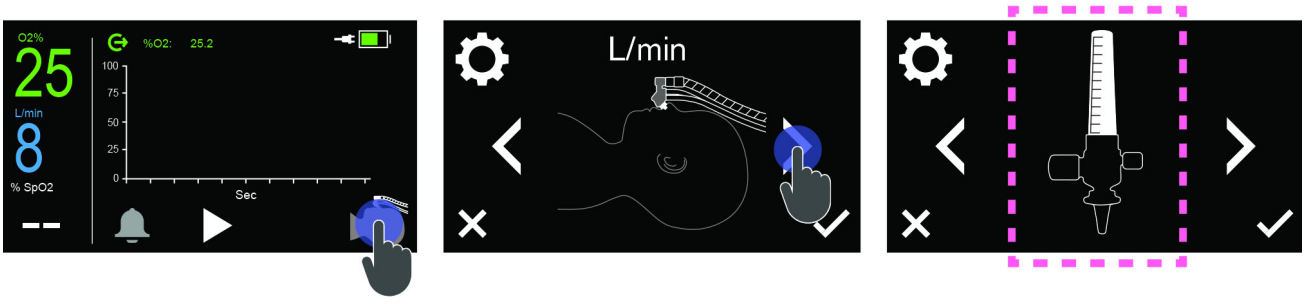
Process

Step 1

Set the SLE1500 up as per Steps 1-7 of O2 Calibration, if not already done so.

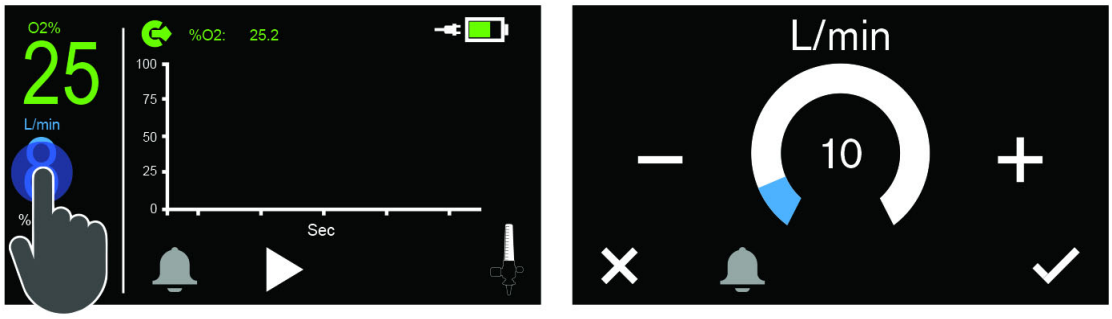
Step 2

Set SLE1500 to ‘Manual Flow’ mode, if not already done so.



Step 3

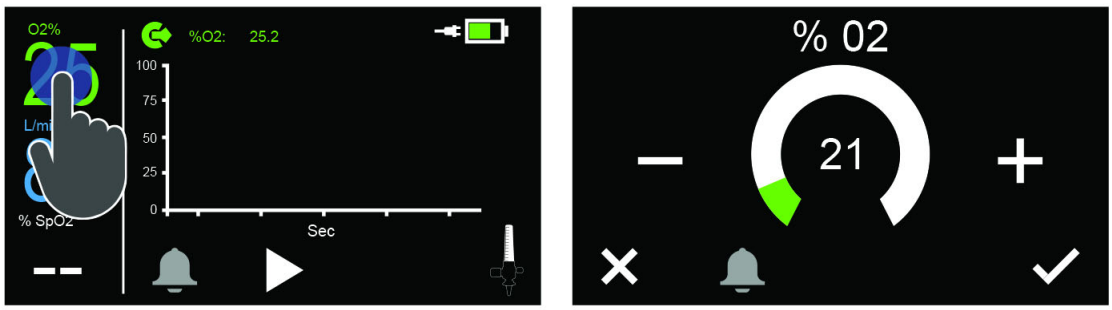
Set Flow to **10L/min.**



Step 4

Test SLE1500 at the following Oxygen concentrations:

- 21%
- 40%
- 60%
- 80%
- 100%

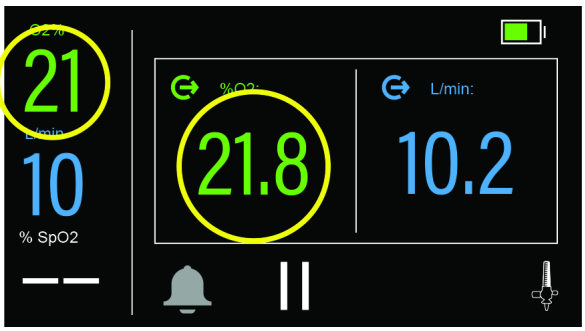


Step 5

When each percentage is set, press play to start treatment.

Step 6

Check that the device shows as reaching those limits. To see the limits, tap on the graph until you reach the following screen below. The numbers on the left show the set values, and the numbers in the middle show the reached values. Ensure that the reached value for O2% matches the set value for O2% +/- 3%.



NOTE: **If any alarms occur during testing, please refer to Section 9 'Alarms' for support.**

6.3 Using device with SLE1500 Cart

The SLE1500 is verified for use with the recommended SLE Cart.

The SLE1500 Cart is provided with an extendable pole with 4 bag holders, adjustable upper and lower mounting brackets and an accessories basket.

The SLE Cart should be adjusted for maximum stability. Limit the height of the bag holders to the minimum required for water to flow unimpeded up to a maximum of 1.8 metres/ 6 feet.

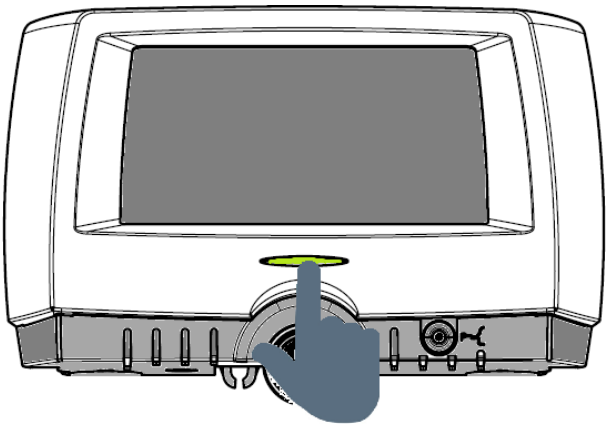
Use a maximum of 2kg (1 x 2 litre or 2 x 1 litre) water bags on the holders.

WARNING: *Prior to first use, the SLE1500 must be connected to a mains power source for 24 hours to ensure that the battery is fully charged. Failure to do this will shorten the service life of the battery which will result in reduced battery life in a mains power failure situation.*

7. User interface

7.1 SLE1500 start-up

- To switch on the SLE1500, press and hold the power on/off button.



- A ‘splash screen’ will be displayed.
- A system test is initiated automatically, and the SLE1500 alarms will beep twice.
- During the system test the performance of the following components are checked:

  Software

  Electronic controls

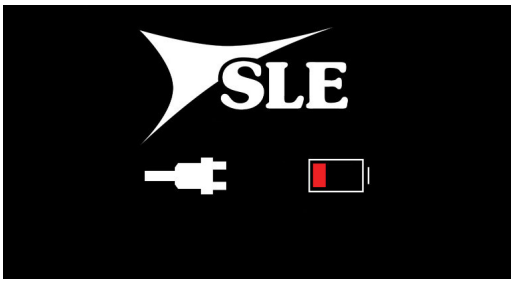
  Audible alarms

  Power supply

NOTE: The SLE1500 contains a rechargeable Li-ion battery intended to provide limited backup power in the event of mains failure. The battery is intended for short-term use only. The SLE1500 functionality may be limited when running on backup power.

The SLE1500 should be plugged into the mains for as long as possible. The SLE1500 should be checked, calibrated and serviced before putting back into operation if it has been in storage for over 6 months.

- If the power detected is too low to start the SLE1500, the Low Power splash screen will be displayed.



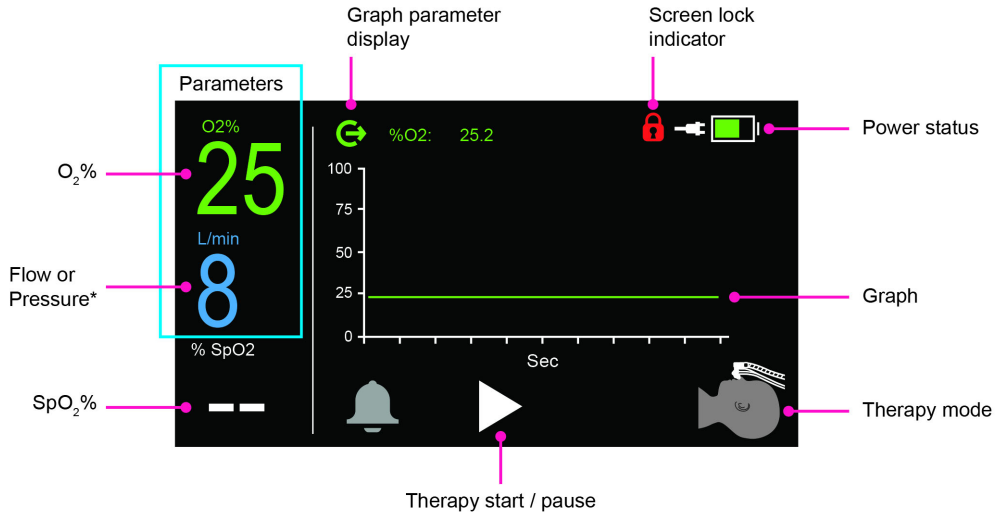
Low Power splash screen

- If the Low Power screen is displayed, the SLE1500 will turn off after 5 seconds.
- Check the SLE1500 is connected to mains power and press and hold the power on/off button.
- If the power splash screen is still displayed, remove the SLE1500 and contact SLE for assistance.
- If a malfunction is detected, the following message is displayed:

WARNING: If a malfunction is detected or the device does not beep twice, remove the SLE1500 from use and contact SLE for assistance.

7.2 Therapy screen

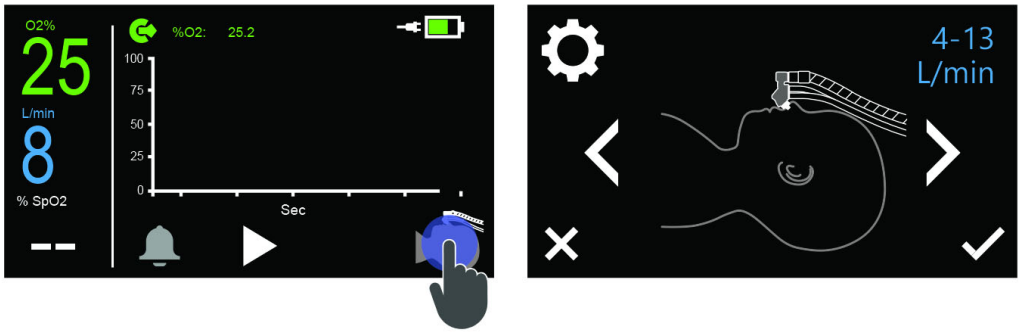
- On successful completion of the system test, the therapy screen will be displayed.



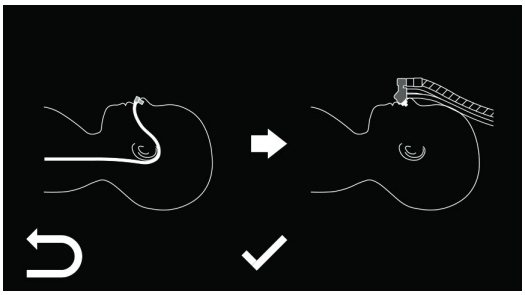
Initial therapy screen

* The parameter displayed is mode dependent.

7.3 Therapy mode selection



- Press the mode symbol on the therapy display screen to change the selected therapy mode.
- Use the navigation arrows ◀ ▶ to cycle through the therapy mode options.
- Press ☑ or the central mode symbol to select the mode.
- Alternatively, press ☒ to return to the therapy screen without making changes to the mode.
- Once a new mode is selected, the mode confirmation screen is entered.



- The current mode is shown on the left of the screen and the new mode on the right.
- Press the ☑ to confirm new mode selection.
- Alternatively, press ⮌ to return to the Therapy Mode selection screen without making changes to the mode.

NOTE: *The mode selection screen will time out after 10 seconds of inactivity. On activation of time out, the alarm will sound once, and the display will return to the therapy screen without making a change to the mode.*

NOTE: *A mode change will pause the current treatment.*

NOTE: *A mode change will reset the pressure or flow settings to the minimum selectable values.*

7.4 Therapy Modes

7.4.1 Neonatal, infant and paediatric HFOT Mode

Flow control mode intended to deliver HFOT (High Flow Oxygen Therapy) to neonatal, infant and paediatric patients via a High Flow nasal cannula.

Therapy information:

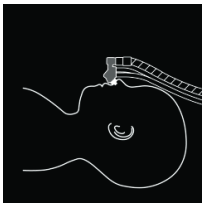
Patient Parameter	Setting range	Alarm limits
O_2 %:	21 – 100 %	High priority alarm: ±3 % set
Flow:	2 – 25 L/min	Adaptive alarm: ±20 %
Patient Pressure	Measured value	Adaptive alarm: ±20 % High priority alarm: < 0 mbar or > 100 mbar

Recommended accessories: F&P Optiflow breathing circuit, F&P Optiflow Junior circuit and interface.

7.4.2 Neonatal, infant and paediatric nCPAP – Flow Mode

Flow control mode intended to deliver nCPAP (nasal Continuous Positive Airway Pressure) to neonatal, infant and paediatric patients via a nCPAP generator.

Therapy information:



Patient Parameter	Setting range	Alarm limits
O_2 %:	21 – 100 %	High priority alarm: ±3 % set
Flow:	4 – 13 L/min	Adaptive alarm: ±20 %
Patient Pressure:	Measured value	Adaptive alarm: ±20 % High priority alarm: < 0.3 mbar or > 20 mbar
Breaths per minute:	Measured value	No alarm

Recommended accessories: Intersurgical nFlow® breathing systems.

7.4.3 Neonatal, infant and paediatric nCPAP – Pressure Mode

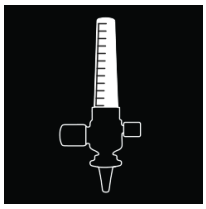
Pressure control mode intended to deliver nCPAP (nasal Continuous Positive Airway Pressure) to neonatal, infant and paediatric patients via a nCPAP generator.

Therapy information:

Patient Parameter	Setting range	Alarm limits
O_2 %:	21 – 100 %	High priority alarm: ±3% set
Flow:	Measured value	Adaptive alarm: ±20 %
Patient Pressure:	2 – 12 mbar (cmH_2O)	Adaptive alarm: ±20 % High priority alarm: < 2 mbar (cmH_2O) or 12 mbar (cmH_2O)
Breaths per minute:	Measured value	No alarm

Recommended accessories: Intersurgical nFlow® breathing systems.

7.4.4 Manual Flow Mode



Adjustable flow mode intended to allow the user maximum control of supplied flows.

Therapy information:

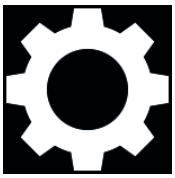
Parameter	Setting range	Alarm limits
O_2 %:	21 – 100 %	High priority alarm: ±3% set
Flow:	1 – 30 L/min	Adaptive alarm: ±20 %
Outlet Pressure:	Measured value	Adaptive alarm: ±20% High priority alarm: > 150 mbar

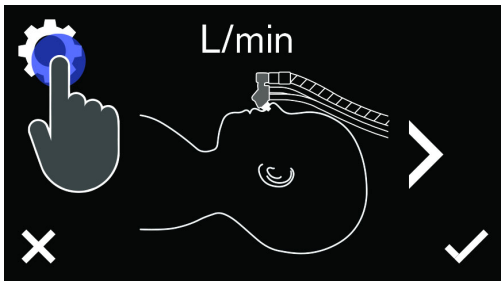
NOTE: *The maximum flow and O_2 % levels achievable may be dependent. The SLE1500 will automatically limit the allowed flow or O_2 % based on the supply pressure and parameter settings.*

Recommended accessory: Bubble CPAP can be found in "Accessories" section on page 11.

7.4.5 Settings Mode

The Settings mode is entered by pressing  symbol within the Therapy Mode selection menu.





See “Settings” on page 52 for further information.

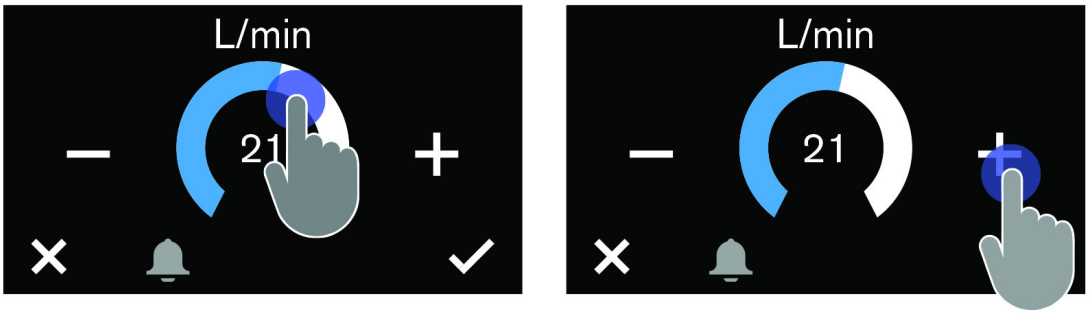
7.4.6 Mode Warnings

- The patient circuit should be checked at regular intervals for condensate / rain out at intervals.
- No alarms are present to highlight disconnection when in **Neonatal, infant and paediatric HFOT Mode, Neonatal, infant and paediatric nCPAP – Flow Mode and Manual Flow Mode.**

7.5 Therapy parameter adjustment

- To change the therapy parameter setting, press the parameter value on the therapy screen.

NOTE: *The allowed range is mode dependent. See 'Therapy Mode selection' above for more details.*

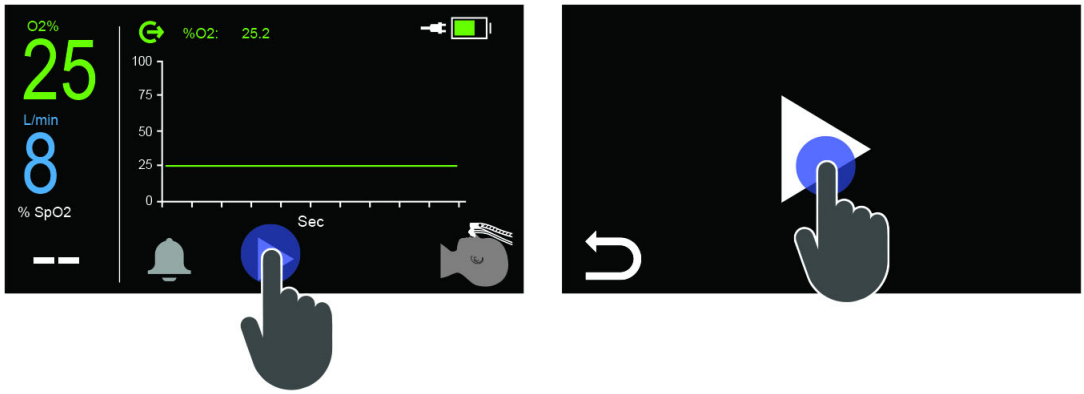


- Press + or − to adjust the value or, alternatively, tap on the gauge to jump to a desired value.
- Press ✓ to confirm selection and return to the therapy screen.
- Alternatively, press ✕ to return to the therapy screen without making changes.

NOTE: *The parameter adjustment screen will time out after 10 seconds of inactivity. On activation of time out, the alarm will sound once, and the display will return to the therapy screen without making a change to the parameter value.*

7.6 Start/pause treatment

- To start treatment, press the start treatment symbol ▶ on the therapy screen.
- To pause treatment, press the pause treatment symbol ⏸ on the therapy screen.

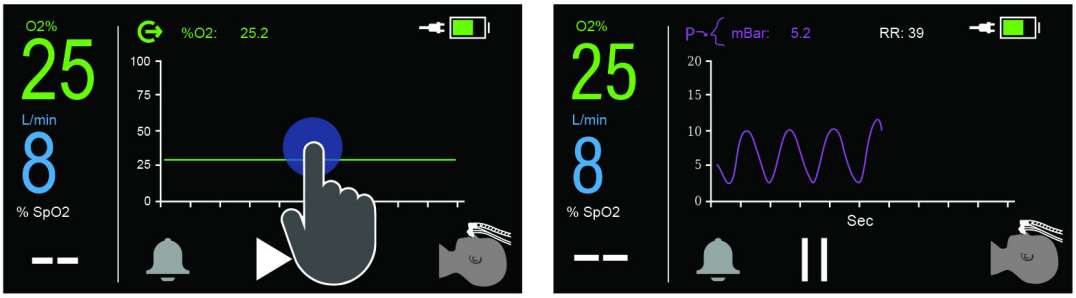


- Press the ▶ or ⏸ again to confirm selection.
- Alternatively, press ⮌ to return to the therapy screen without making any changes to the treatment.

NOTE: *When treatment is paused, therapy will temporarily stop until the therapy is restarted by pressing the start treatment symbol. When the treatment is restarted, all settings will remain the same prior to the treatment being paused.*

NOTE: *The confirmation screen will time out after 10 seconds of inactivity. On activation of time out, the alarm will sound once, and the display will return to the therapy screen without making a change to the treatment.*

7.7 Therapy graph display

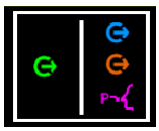


- To change the graph information displayed, press the graph on the therapy screen to cycle through the available options.

NOTE: *The graph colour corresponds to the parameter displayed (see below).*
InterActive maintains Essential Performance.

NOTE:

	**Outlet Oxygen** Waveform display of the delivered gas oxygen percentage over time. Units: % oxygen
	**Outlet Pressure** Waveform display of the gas pressure at the SLE1500 outlet over time. Units: cmH_20 or mBar
	**Patient Pressure** Waveform display of the gas pressure at the patient over time (small bore proximal monitoring line required). Units: cmH20 or mBar **Respiratory Rate:** When this graph is selected and a compatible mode is selected, the respiratory rate (RR) is also displayed as per the right hand image above. Units: Breaths per minute.*The graph colour corresponds to the parameter displayed (see below).* RR compatible modes: Neonatal nCPAP - Pressure modes Neonatal nCPAP - Flow mode
	**Outlet Flow** Waveform of the delivered gas flow over time. Units: L/min
	**SpO_2** Plethysmograph waveform that displays the change in volume of the arterial blood over time (where applicable).

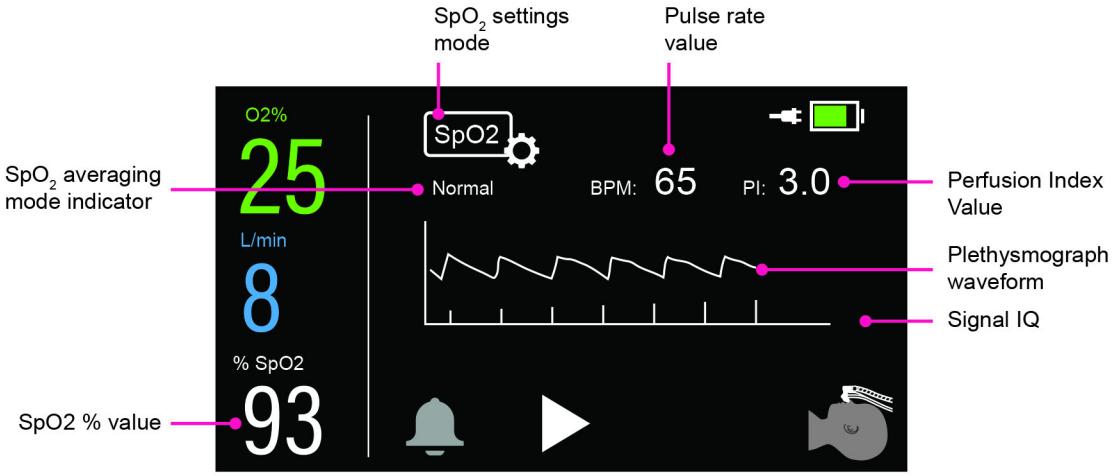


Large Readings

- To display large readings in place of the display.

7.8 SpO_2 display

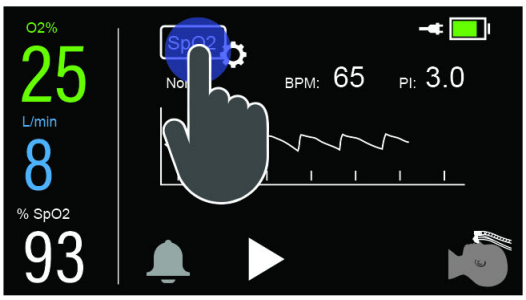
- The SpO_2 % value is shown in the bottom left corner of the therapy display screen.
- The plethysmograph waveform, pulse rate value, perfusion index value and the SpO_2 averaging mode can be displayed either by pressing the SpO_2 % value in the bottom left corner of the therapy display screen, or by cycling through the graph options (See “Therapy graph display” on page 25).

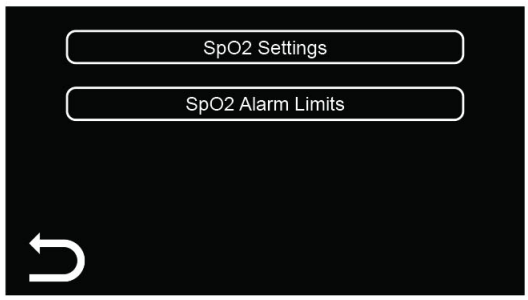


SpO_2 %	• The SpO_2 % is an indirect measurement of the oxygen saturation in the blood. • It is measured by the SpO_2 sensor and displayed as a percentage.
Pulse rate value (BPM)	• The pulse rate value indicates the pulse rate of the patient measured by the SpO_2 sensor. • The rate is shown in beats per minute (BPM).
Perfusion index (PI)	• The perfusion index (PI) indicates pulse strength at the sensor’s location.
Plethysmograph waveform	• The plethysmograph waveform displays the change in volume of the arterial blood over time.
Signal IQ (SIQ)	• The signal IQ or signal inadequacy indicator is displayed as vertical lines underneath the waveform. • The height of the SIQ line indicates how much confidence to have in the displayed measurement. • The value received is between 0-128. This is scaled to between 1-8 so it can be displayed on the graph.
• *If a parameter value is not available, the display will read ‘--'.* • *Refer to SpO_2 sensor IFU for full details.* • *To exit the SpO_2 display, press the graph to cycle through the available graph display options.*	

7.8.1 SpO_2 settings and alarm limits

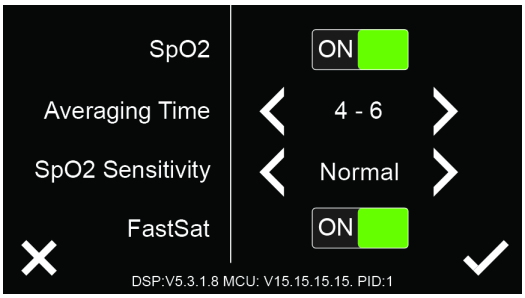
- To adjust the SpO_2 settings, press the SpO_2 settings menu symbol:

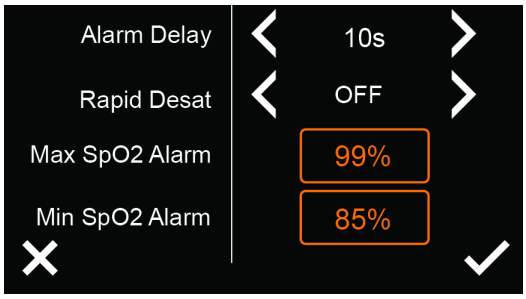




Press button SpO2 Settings to change the SpO_2 settings.

Press button SpO2 Alarm Limits to change the SpO_2 alarm limits.

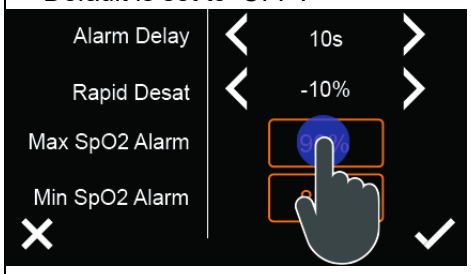
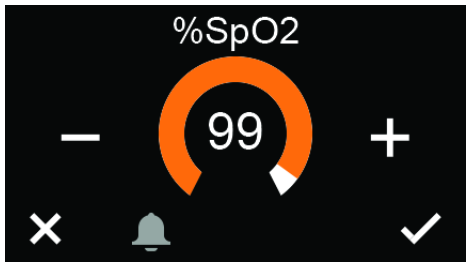
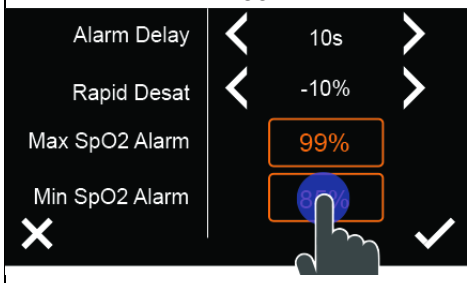
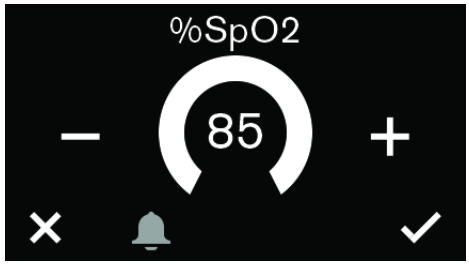




- Alternatively, press ↩ to return to the SpO_2 display without making changes.

SpO2 Settings	
SpO_2	• Select SpO_2 measurement display. • Press to toggle on ON and off OFF. • Default set to ON.
Averaging Mode	• Set how many SpO_2 readings will be used to calculate the final value to display. A higher averaging time provides a more accurate value, but takes longer. • Use the navigation arrows ‹ › to cycle through options (2–4, 4–6, 8,10,12,14,16). • Default is set to '8'.
Sensitivity Mode	• Set the sensor sensitivity. See SpO_2 sensor IFU for guidance on settings. • Use the navigation arrows ‹ › to cycle through options (Normal, Maximum, APOD). • Default is set to 'Normal'.
FastSat®	• Select fast SpO_2 sampling and display. FastSat® enables rapid tracking of arterial oxygen saturation changes by minimising averaging. • Press to toggle on ON and off OFF. • Default set to 'OFF'.

- Press ✓ to confirm SpO_2 selections and return to the SpO_2 settings menu.
- Alternatively, press ✗ to return to the SpO_2 settings menu without making changes.

SpO2 Alarm Limits	
Alarm Delay	• Set the SpO_2 alarm delay time after an alarm condition has been activated. • Use the navigation arrows to cycle through options (0s, 5s, 10s, 15s). • Default is set to '10s'.
Rapid Desat	• Set SpO_2 Rapid Desat limit. • The Rapid Desat limit is designed to detect rapid desaturation of 5%, 10% or 0% below the Min SpO_2 alarm limit. The Alarm Delay feature is overridden when activated. • Use the navigation arrows to cycle through options (OFF, -5%, -10%). • Default is set to 'OFF'
Max SpO_2 alarm	• Set the Maximum SpO_2 alarm limit. • If the SpO_2 level exceeds this limit, the SpO_2 alarm will be activated. • To change the limit setting, press the limit value. • Default is set to 'OFF'.   • Press + or − to adjust the value. • To turn off the alarm limit, press + until 'OFF' is shown and press ✓ to confirm. • Press ✓ to confirm selection and return to the SpO_2 settings menu. • Alternatively, press ✗ to return to the SpO_2 settings menu without making changes.
Min SpO_2 alarm	• Set the Minimum SpO_2 alarm limit. • If the SpO_2 level falls below this limit, the SpO_2 alarm will be activated. • To change the limit setting, press the limit value. • Default is set to '85%'.   • Press + or − to adjust the value. • To turn off the alarm limit, press + until 'OFF' is shown and press ✓ to confirm. • Press the ✓ to confirm selection and return to the SpO_2 settings menu. • Alternatively, press ✗ to return to the SpO_2 settings menu without making changes.

Refer to SpO_2 sensor IFU for full details.

NOTE: *The maximum and minimum SpO_2 alarm limits are interdependent. The minimum limit must always be lower than the maximum. If a limit is changed so that the minimum is above the maximum, the other limit will automatically adjust.*

NOTE: *The SpO_2 settings menu, SpO_2 settings screen and SpO_2 alarm limits screen will time out after 10 seconds of inactivity. On activation of timeout, the alarm will sound once and the display will return to the therapy screen without making a change to the settings.*

7.9 OxyGenie®

OxyGenie® can be used in any mode of therapy.

NOTE: *The OxyGenie® algorithm is a closed loop proportional-integral-derivative (PID) controller. Once a second this algorithm uses the patient's SpO_2 (measured using Masimo SET®) to calculate the appropriate O_2 setting to maintain SpO_2 within the target range.*

NOTE: *Before initiating (or reinitiating) OxyGenie®, check that the O_2 setting reflects the patient's current clinical condition to ensure that the control algorithm responds appropriately. Failure to do so can affect the response time of the algorithm.*

NOTE: *OxyGenie® calculates the average amount of oxygen required to keep the patient within the target range.This is calculated using 1 hour's data. This is called the Reference O_2.*

NOTE: *OxyGenie® will not set the O_2 to more than 40% above or below the Reference O_2. This is to avoid large swings in delivered oxygen.*

NOTE: *The Reference O_2 is capped at 60% so that OxyGenie® can always reduce the O_2 to 21%.*

NOTE: *During OxyGenie® use the O_2 control button shows the instantaneous O_2 value being sent to the SLE1500. The monitored O_2 will show the O_2 measured by the oxygen sensor. A slight difference in these values is normal.*

NOTE: *An increasing requirement for oxygen while using OxyGenie® may be indicative of an underlying condition which has to be addressed, even if the SpO_2 is within the target range.*

NOTE: *See SLE SpO_2 Pulse Oximetry Cable (Masimo SET®) IFU for details of conditions which may affect the accuracy of SpO_2 readings.*

NOTE: *Additional ventilator independent patient monitoring (bedside vital monitoring blood gas analyser) should be performed.*

WARNING: *Do not use OxyGenie® if the difference between SpO_2 and SaO_2 is greater than 5%.*

7.10 OxyGenie® modes of operation

- Auto: OxyGenie® calculates the patient's oxygen requirement from the current and previous SpO_2 values every second and adjusts the SLE1500 setting accordingly.
- Fall-back mode: see below.
- Manual override: at any time during OxyGenie® the user may deliver +5% to the set FiO2. The override will be delivered for 30 seconds.

When OxyGenie® is in "Auto" mode, the status indication box and the O_2 Control shows "Auto".

When OxyGenie® is in "Fall-back" mode, the status indication box shows "waiting for signal" and the O_2 Control shows "- - -"

When OxyGenie® is in "manual override" mode, the status indication box shows "manual override" and the O_2 Control shows "- - - "

When OxyGenie® is not active, the status indication box will not be visible.

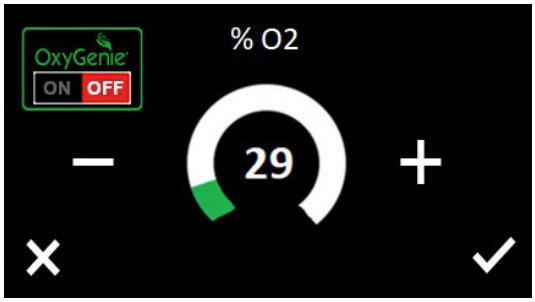
7.10.1 Accessing OxyGenie®

OxyGenie® is turned on/off from within the oxygen value change screen. There is an OxyGenie® icon in the top left corner as shown below (in the OFF position).

No changes will be made until the user confirms the new settings by pressing ☑.

NOTE: OxyGenie® can only be accessed when an SpO_2 sensor is connected and the device is not standby. SpO_2 must also be switched on.

NOTE: SpO_2 defaults to ON; if it has been switched off manually, the OxyGenie® ON/OFF button will not be visible;

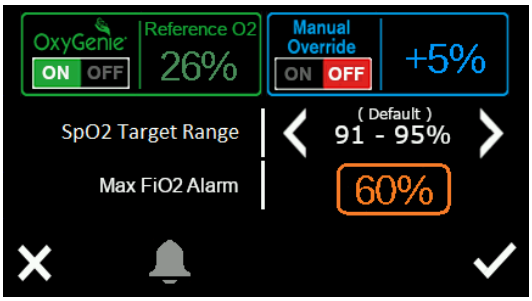


OxyGenie® ON/OFF

When Oxygenie is turned on the O_2 value at that time will become the initial Reference O_2, unless it is over 60%, in which case it will be capped at 60%.

The display will then change to show the OxyGenie® settings, rather than the settable O_2 value.

This is shown below.



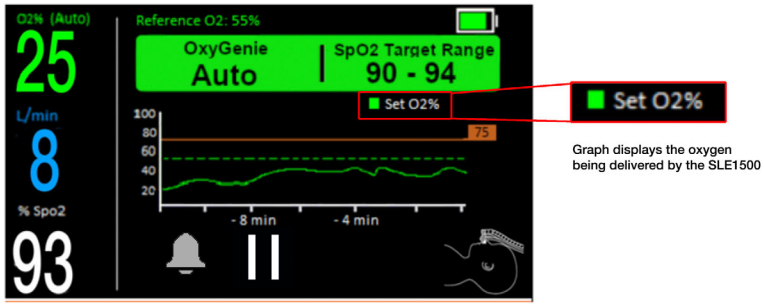
OxyGenie® Treatment Settings

7.10.2 Treatment screens

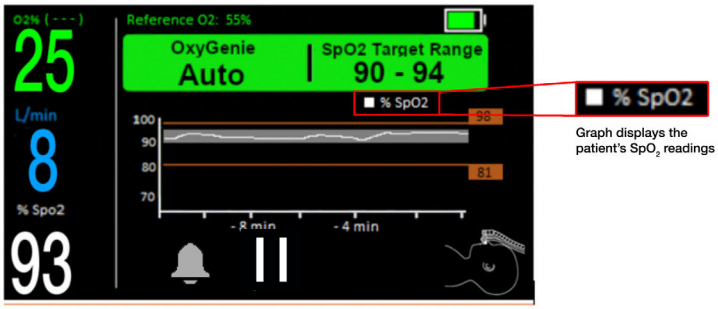
The response of OxyGenie® to changes in SpO_2 can be seen in the set O_2 shown in the O_2 control button and also in the O_2 trend.

When OxyGenie® mode is enabled, two additional graphs become selectable. These show the target SpO_2 range/actual SpO_2 on one graph and the set O_2% value on the other. See “Therapy mode selection” on page 21 on how to select the additional graphs.

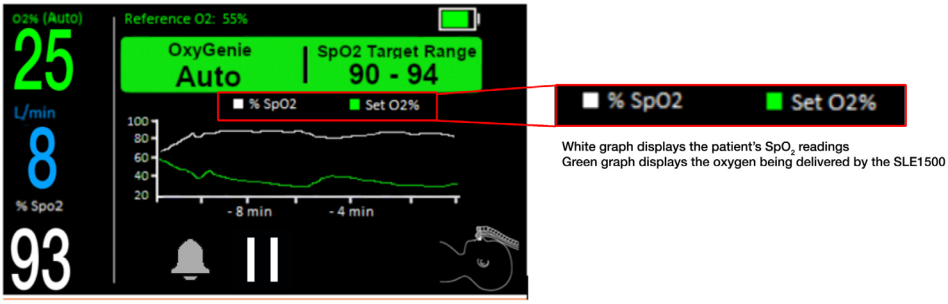
See below.



Treatment Screen Set O_2% graph



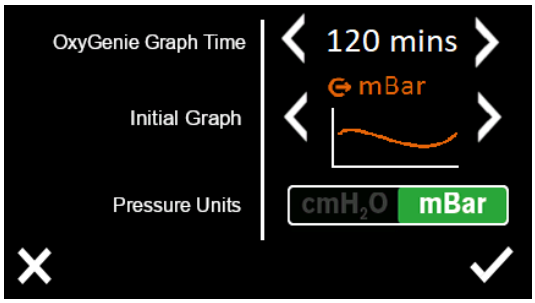
Treatment screen SpO_2% graph



Treatment screen Dual OxyGenie® graph

7.10.3 Graph preferences

The graph preferences screen now includes an adjustable time interval for the OxyGenie® screen graph. See “SpO_2 settings and alarm limits” on page 28.

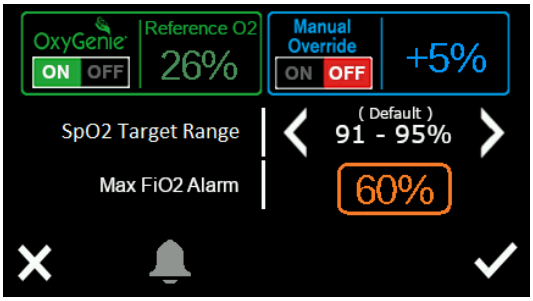


Graph Preferences Screen

7.10.4 Manual override

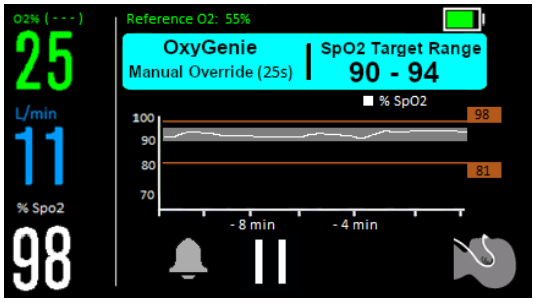
When OxyGenie® is on, the user can boost the Reference O2 by +5% for 30 seconds.

The Manual Override ON/OFF button needs to be set to On and will only be activated when the user presses ☑



OxyGenie® Manual Override

During manual override, the OxyGenie® status box on the treatment screen also turns blue and displays Manual Override, with the remaining time left. The treatment O_2 value is updated to the manual override value, and Auto is replaced with - - -. (See below).

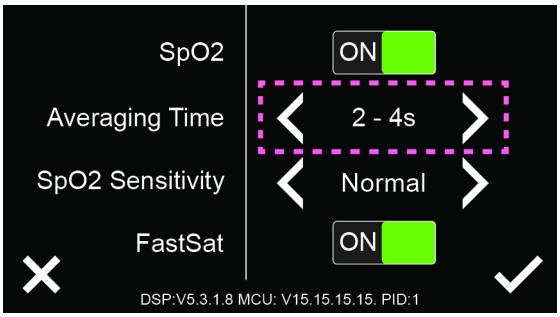


Manual Override treatment screen

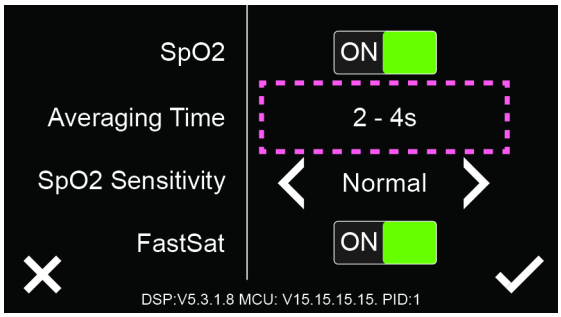
7.10.5 SpO_2 Settings with OxyGenie®

The SpO_2 settings menu allows the user to modify the averaging time, sensitivity mode and FastSat® state. In this menu SpO_2 monitoring can also be turned on or off. SpO_2 monitoring must be turned on when Oxygenie is activated. (See “SpO_2 settings and alarm limits” on page 28.)

When OxyGenie® is turned on, the averaging time is pre-set to 2 – 4s and is not adjustable. The left and right arrows will not be shown in this case. (See below, right).



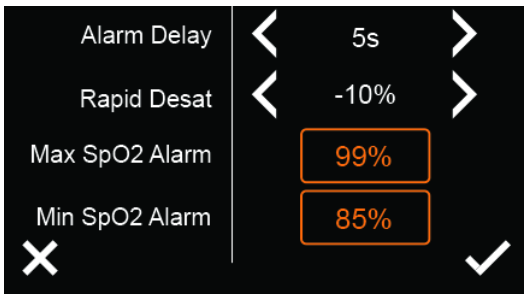
Standard SpO_2 Settings Screen



SpO_2 Settings Screen with OxyGenie® on

7.10.6 SpO_2 Alarm Limits with OxyGenie®

The SpO_2 alarm settings screen provides menu items to select the alarm delay time, rapid desaturation level along with max and min SpO_2 alarm values.



SpO_2 Alarm Settings Screen

SpO_2 monitoring is via a Masimo® sensor. High and low SpO_2 alarms are automatically set to 1% above the upper end of the target range and 1% below the lower end of the target range. These limits are user adjustable.

7.10.7 Fall-back Mode

OxyGenie® will go into fall-back mode when no valid SpO_2 signal is received. This can occur if the SpO_2 sensor gets detached from the patient or does not make good contact with the skin, or if a low SIQ is reported by the Masimo® system:

First 60 seconds of no valid SpO_2 signal:

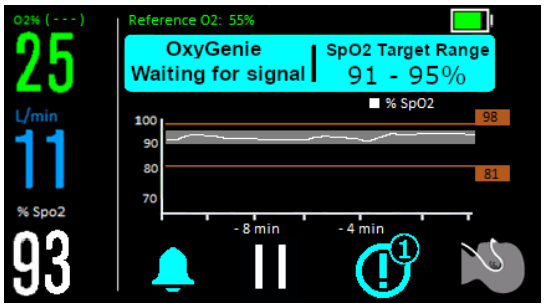
- OxyGenie® will deliver the last O_2 setting.

After 60 seconds of no valid SpO_2 setting:

- If the last valid SpO_2 reading was above the target range, OxyGenie® will slowly decrease the delivered oxygen towards the Reference O_2 Value
- If the last valid SpO_2 reading was below the target range, OxyGenie® will slowly increase the delivered oxygen towards the Reference O_2 Value

As soon as a valid SpO_2 signal is received, the OxyGenie® will calculate and set the oxygen requirement based on that SpO_2 value.

NOTE: *The Reference O_2 value is an average of the patient's oxygen requirement for the last hour.*



'Waiting for Signal' screen in fall-back mode

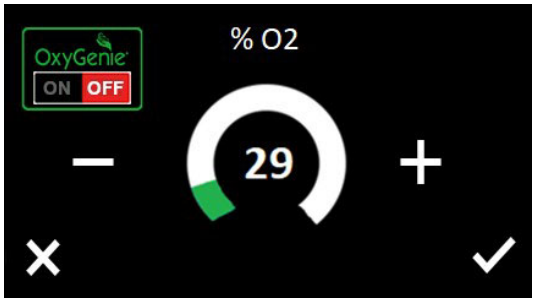
During fall-back mode, the O_2 control button will show "---" in place of "Auto" and the OxyGenie® status indication will show "waiting for signal".

SpO_2 alarms and exception messages will show in the alarms section.

7.10.8 Turning off OxyGenie®

OxyGenie® is turned off from within the oxygen value change screen. There is an OxyGenie® icon in the top left corner - see below. Press the ON/OFF button until the OFF side is illuminated in red.

No changes will be made until the user confirms the new settings by pressing ✔



OxyGenie® ON/OFF screen

7.11 Power status display

The power status display is located in the top right-hand corner of the therapy screen (see Section 8.2 – Therapy screen).

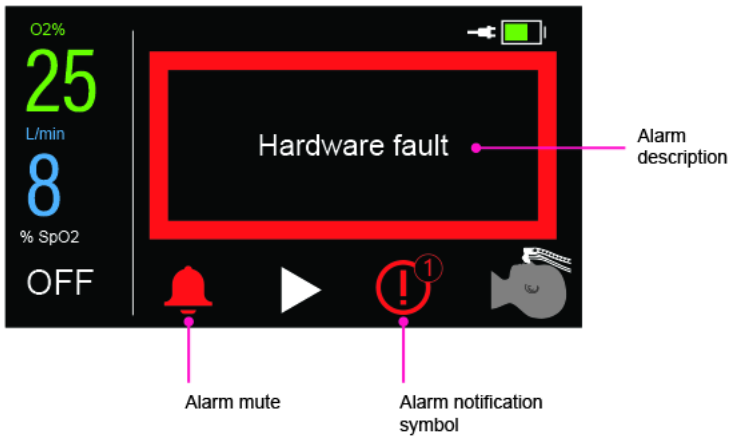
The symbol is intended to indicate the power status of the SLE1500.

	Indicates that the SLE1500 is connected to mains.
	Indicates the battery is fully charged.
	Indicates mains is not connected, the battery power level is good.
	Indicates battery power is low.

NOTE: *When the SLE1500 is connected to mains power, the battery will be charged with or without the device being switched on.*

7.12 Alarm display

During an alarm fault condition, the therapy screen will display a description of the alarm. For priority alarms, an audible alarm will also sound. See “Alarms” on page 38 for more information.



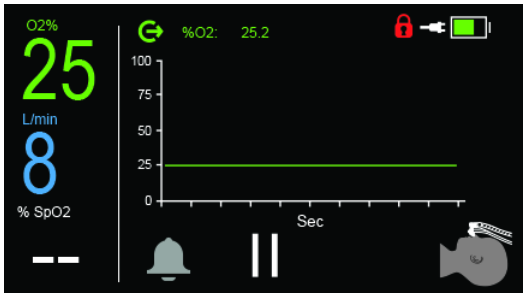
Example shown: High priority, Hardware fault alarm.

	Press to acknowledge the alarm.
	Press to mute the alarm.
	Press to transition to ‘Alarm information display’.

7.13 Locking/unlocking the screen

-  Screen is unlocked. Press to lock the screen.
-  Screen is locked. Press to unlock the screen.

NOTE: *When locked, the therapy screen will show a locked symbol*  *next to the battery indicator.*



Locked screen, with red padlock

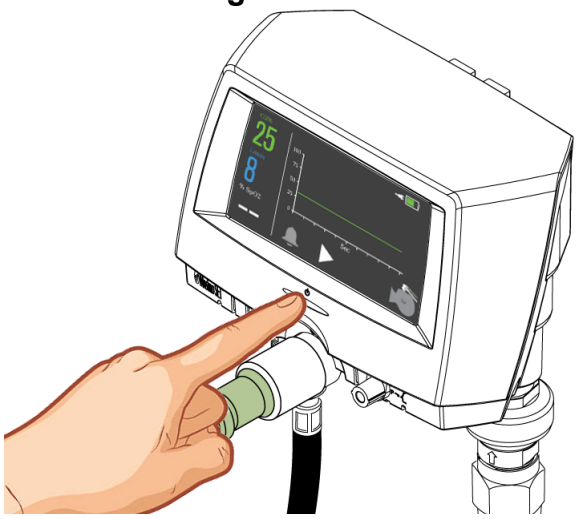
To unlock the screen, press and hold anywhere on the display screen for 3 seconds.

NOTE: *The switch off screen will time out after 10 seconds of inactivity. On activation of time out, the alarm will sound once, and the display will return to the therapy screen.*

NOTE: *The SLE1500 will revert to the last used mode and settings on device restart.*

NOTE: *When the SLE1500 is powered down, the time of power down is captured in the log. All existing alarm conditions raised or dropped prior to power down are recorded and retained, regardless of the duration of power down.*

7.14 Switching off the SLE1500



- To switch off the device, press the power ON/OFF button.

- To confirm selection, press the power ON/OFF symbol  .
- To cancel the power off, press the power ON/OFF button again.

NOTE: *Treatment will end when the device is switched off.*

8. Alarms

NOTE: *If any alarm continues after troubleshooting, remove and replace the SLE1500 and breathing system and contact SLE for technical assistance.*

8.1 Adaptive alarms

During treatment, adaptive alarms shall monitor the output flow, patient pressure and outlet pressure for unexpected variances.

The alarm limits are continuously updated unless a fault is detected. If a fault is detected, the reading will either return to acceptable limits, or the alarm can be acknowledged, and the adaptive alarm will re-adapt to the new readings.

The alarm system will engage within 2 minutes of a change to treatment such as mode or flow, once it has collected enough data to establish a baseline and calculate the alarm limits. After an alarm has been acknowledged, any further alarms shall not be raised for another 2 minutes whilst the limits are recalculated.

See “User interface” on page 20 for details of adaptive alarm limits.

Adaptive alarms are low priority alarms. See “General low priority alarms” on page 40 for further details.

8.2 Technical alarms

- When a ‘For information’ alarm is raised, a message box is displayed in place of the therapy graph and an audible alarm will sound once.
- When a technical alarm is raised, a message box is displayed in place of the therapy graph and a repeating audible alarm will sound.
- An alarm information symbol is also displayed. A superscript number denotes how many other alarms of the same priority are raised at the same time (up to 3, after which 3+ is shown).
- Press the message box to acknowledge and dismiss the message and return to the therapy graph.
- Press the alarm information symbol to transition to the alarm information screen (See “Alarm information screen” on page 48 below).
- Monitoring System Communication Lost.

  Alarm delay time: 5s
  Cause of alarm: Communication with Patient Monitoring System lost
  Actions/Troubleshooting: Check connection of Patient Monitoring System to the SLE1500.

For information alarms			
Message box alarm	**Alarm Delay time (Max)**	**Cause of alarm**	**Actions/Troubleshooting**
None	Typical 10s ± 1s	Screen selection time out.	Reselect change if still required.
None	3s	Screen unlocked.	Ensure unlocking of screen is intended. If not, relock screen, See “Locking/unlocking the screen” on page 37.
External power removed	2s	External power removed.	Check connection of power supply to the SLE1500 and mains supply.

Technical alarms			
Message box alarm	**Alarm Delay time (Max)**	**Cause of alarm**	**Actions / Troubleshooting**
Calibration failed	Typical: 8s ±1s when motors fail to close Typical: 1s ±1s if calibration values not accepted	Calibration failure.	Re-run calibration. If the alarm continues, remove and replace the SLE1500 and contact SLE for assistance.
Calibration failed: No external power	2s	Calibration failed as external power source is not connected.	Check connection of power supply and re-run calibration. If the alarm continues, remove and replace the SLE1500 and contact SLE for assistance.
Calibration failed: Flow meter error	3s	Calibration failed due to an error communication with the flow meter.	Check connection of the flow meter and re-run calibration. If the alarm continues, remove and replace the SLE1500 and contact SLE for assistance. Restart meter if communication stops.
Calibration failed: Gas error	Typical: 10s ± 20s	Calibration failed due to error with the gas supply.	Check connection of gas supply and re-run calibration. If the alarm continues, remove and replace the SLE1500 and contact SLE for assistance.
Calibration Successful	Less than 1s	Calibration has successfully completed.	Information only, no actions required.
Flow Calibration Required	5s	Flow Calibration is recommended. Duration since previous calibration has elapsed.	Perform Flow Calibration.
O2 Calibration Required	5s	O_2 Calibration is recommended. Duration since previous calibration has elapsed.	Perform O_2 Calibration.
SpO2 board fault	4s	Loss of communication or fault with SpO_2 board.	Remove and replace the SLE1500 and contact SLE service for assistance.
System fault	5s	Non-critical fault eg: ambient light sensor or real time clock failure.	Remove and replace the SLE1500 and contact SLE for assistance.

8.3 Low priority alarms

- When a low priority alarm is raised, a message box with a yellow border is displayed in place of the therapy graph and a repeating audible alarm will sound.
- An alarm information symbol is also displayed. A superscript number denotes how many other alarms of the same priority are raised at the same time (up to 3, after which 3+ is shown).
- Press the message box to acknowledge, dismiss the message, and return to the therapy graph.
- Press the alarm information symbol to transition to the alarm information screen (see Section 9.6 below).
- Low and medium priority alarms can be muted for 2 minutes by pressing .
- Muted alarms continue to be shown on the display screen and the mute alarm symbol is displayed .

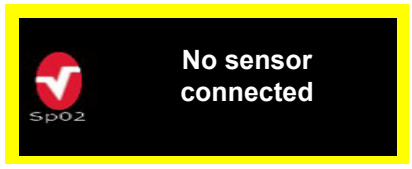
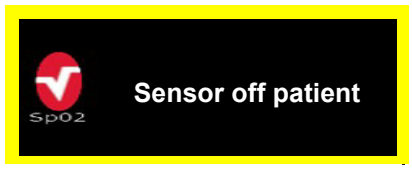
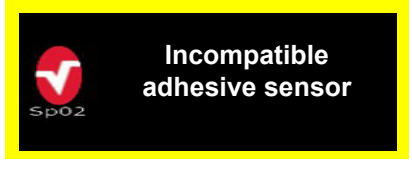
8.3.1 General low priority alarms

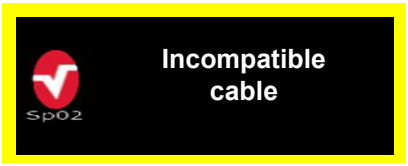
General low priority alarms			
Message box alarm	**Alarm Delay time (Max)**	**Cause of alarm**	**Actions / Troubleshooting**
Battery low	3s	Battery low.	CAUTION: The SLE1500 will not allow treatment to be started when the battery low alarm has been activated. Connect the SLE1500 to mains supply.
Possible output leak	±1s NOTE: Additional 2 minutes delay after target change	When the adaptive alarms detect a low pressure or a high flow reading, a possible output leak is reported.	Check patient condition. Check breathing system and patient interface for disconnection or leaks.
Possible output occlusion	Typical: 120s ±1s NOTE: Additional 2 minutes delay after target change	When the adaptive alarms detect a high pressure or a low flow reading, a possible output occlusion is reported.	Check patient condition. Check breathing system and patient interface for occlusion.
Unexpected Flow: Low	Typical: 5 ±1s NOTE: Additional 2 minutes delay after target change	When an out of expected range flow is needed to achieve the target pressure during Infant nCPAP Pressure Mode.	Check patient condition. For information only. See section 22.8 for Appendix B (AB) Nomogram for CPAP and Flow.

General low priority alarms			
Message box alarm	**Alarm Delay time (Max)**	**Cause of alarm**	**Actions / Troubleshooting**
Unexpected Flow: High	Typical: 5 ±1s NOTE: Additional 2 minutes delay after target change	When an out of expected range flow is needed to achieve the target pressure during Infant nCPAP Pressure Mode.	Check patient condition. For information only. See section 22.8 Appendix B (AB) Nomogram for CPAP and Flow.
OxyGenie Waiting For Signal	-	OxyGenie has lost signal with the SpO_2 sensor.	Check connection of the SpO_2 cable and sensor to the SLE1500. Assess patient.
OxyGenie Delta FiO2 Max	-	OxyGenie has increased the FiO_2 to over 40% away from the reference O_2.	Assess patient.

8.3.2 Masimo® SpO_2 low priority alarms

- When a Masimo® SpO_2 alarm is dismissed, the alarm message will remain displayed below the therapy graph.

Masimo® SpO_2 low priority alarms			
Message box alarm	**Alarm Delay time (Max)**	**Cause of alarm**	**Actions/Troubleshooting**
	3s	No SpO_2 sensor connected to the SLE1500. ***Note:*** *Once this alarm is acknowledged, the alarm will be removed until raised again.*	Check connection of the SpO_2 sensor to the SLE1500.
	3s	No adhesive SpO_2 sensor. ***Note:*** *Once this alarm is acknowledged, the alarm will be removed until raised again.*	Check connection of the adhesive SpO_2 sensor to the SLE1500.
	3s	SpO_2 sensor not connected to the patient. ***Note:*** *Once this alarm is acknowledged, the alarm will be removed until raised again.*	Check connection of the sensor to the patient.
	3s	No SpO_2 cable connected to the SLE1500. ***Note:*** *Once this alarm is acknowledged, the alarm will be removed until raised again.*	Connect cables.
	3s	The SpO_2 sensor connected to the SLE1500 has expired. Faulty or damaged SpO_2 sensor.	Replace the SpO_2 sensor.
	3s	Incompatible SpO_2 sensor connected to the SLE1500.	Check make and model of the connected sensor is compatible with the SLE1500. Replace as required.
	3s	The SpO_2 sensor connected to the SLE1500 has expired. Faulty or damaged adhesive SpO_2 sensor.	Replace the adhesive SpO_2 sensor.
	3s	Incompatible adhesive SpO_2 sensor connected to the SLE1500.	Check make and model of the connected sensor is compatible with the SLE1500. Replace as required.
	3s	The SpO_2 cable connected to the SLE1500 has expired.	Replace cable.

Masimo® SpO_2 low priority alarms			
Message box alarm	**Alarm Delay time (Max)**	**Cause of alarm**	**Actions/Troubleshooting**
	3s	Incompatible cable connected to the SpO_2 sensor.	Replace with a compatible cable.

8.3.3 Masimo® SpO_2 low priority text messages

- When a Masimo® SpO_2 text message is raised, the message is displayed below the therapy graph. No audible alarm will sound.

Message	Cause of message	Actions/Troubleshooting
Sensor near expiration	The SpO_2 sensor connected to the SLE1500 is near expiration.	Be prepared to replace SpO_2 sensor soon.
Adhesive near expiration	The adhesive SpO_2 sensor connected to the SLE1500 is near expiration.	Be prepared to replace adhesive SpO_2 sensor soon.
Cable near expiration	The SpO_2 cable connected to the SLE1500 is near expiration.	Be prepared to replace cable soon.
Low perfusion index	Low perfusion index.	Check patient and sensor. Adjust the sensor position if required.
Low signal IQ	Low IQ signal.	Check patient and sensor. Adjust the sensor position if required.
Interference detected	Interference with the SpO_2 sensor.	Check patient and sensor. Adjust the sensor position if required.
Pulse search	The device is searching for a pulse.	Check patient and sensor. Adjust the sensor position if required.
Too much ambient light	Too much ambient light for the SpO_2 sensor to work correctly.	Check the patient and sensor. Adjust the sensor position if required.
Sensor initializing	SpO_2 sensor initializing.	SpO_2 sensing unavailable during initialisation. Initialisation should complete within a few seconds.
SpO_2 only mode	The SpO_2 sensor is operating in SpO_2 % only mode as it failed to calibrate correctly.	Re-connect the cable to the SLE1500. Remove the SpO_2 sensor from the patient and reapply.

8.4 Medium priority alarms

- When a medium priority alarm is raised, a flashing message box with a yellow border is displayed in place of the therapy graph and a repeating audible alarm will sound.
- An alarm information symbol is also displayed. A superscript number denotes how many other alarms of the same priority are raised at the same time (up to 3, after which 3+ is shown).
- Press the message box to acknowledge, dismiss the message, and return to the therapy graph.
- Press the alarm information symbol to transition to the alarm information screen (see section 9.6 below).
- Low and medium priority alarms can be muted for 2 minutes by pressing .
- Muted alarms continue to be shown on the display screen and the mute alarm symbol is displayed .

8.4.1 General medium priority alarms

General medium priority alarms			
Message box alarm	**Alarm Delay time (Max)**	**Cause of alarm**	**Actions/Troubleshooting**
Outlet pressure low	2s	When the pressure from the outlet port is detected as low, an Outlet pressure low alarm is reported. (Mode specific limits – see section 8).	Check patient condition. Check breathing system and patient interface for disconnection.
Sensor fault	20s ± 1s	A sensor within the SLE1500 is determined to be faulty. Sensor reading is not within expected range.	Remove device from service. Replace faulty sensor.
OxyGenie: Max FiO2	-	OxyGenie has increased beyond the FiO_2 to beyond the set alarm level.	Assess patient and alarm limit.

NOTE: *If the alarm continues after troubleshooting, remove and replace the SLE1500 and breathing system and contact SLE for technical assistance.*

8.4.2 Masimo® SpO_2 limit medium priority alarms

- When an SpO_2 limit alarm is raised, the alarm message is displayed above the therapy graph.
- The alarm will start in a muted state and remain muted until the current set SpO2 Alarm Delay period has elapsed.

NOTE: *There is no Alarm Delay period if the SpO_2 % falls below the Rapid Desat limit. A repeating audible alarm will sound* immediately for technical assistance.

Masimo® SpO_2 medium priority alarms			
Message box alarm	**Alarm Delay time (Max)**	**Cause of alarm**	**Actions/ Troubleshooting**
	Typical: 0, 5, 10, 15 ±2s depending on configured value.	The set maximum SpO_2 alarm limit (XX) is exceeded.	Check the patient and sensor.
	Typical: 0, 5, 10, 15 ±2s depending on configured value.	The set minimum SpO_2 alarm limit (XX) is not met. The set minimum SpO_2 Alarm limit less than current Rapid Desat limit (XX) is not met.	Check the patient and sensor.

NOTE: *If the alarm continues after troubleshooting, remove and replace the SLE1500 and breathing system and contact SLE for technical assistance.*

8.5 High priority alarms

- When an alarm is raised, a message box with a flashing red border is displayed in place of the therapy graph and a repeating audible alarm will sound.
- An alarm information symbol is also displayed. The superscript number denotes how many other alarms of the same priority are raised at the same time (up to 3, after which 3+ is shown).
- Press the message box to acknowledge and dismiss the message.
- Press the alarm information symbol to transition to the alarm information screen (see section 9.6 below).
- High priority alarms can be muted for 2 minutes by pressing .
- Muted alarms continue to be shown on the display screen and the mute alarm symbol is displayed .

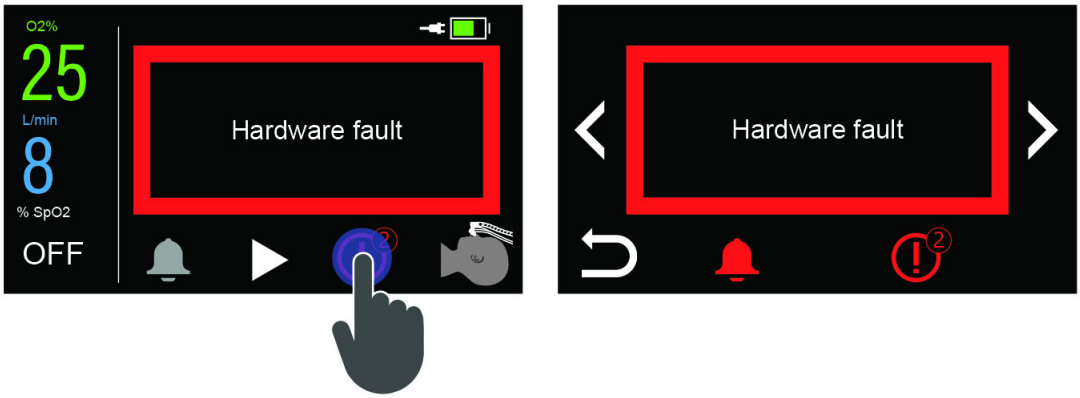
High priority alarms			
Message box alarm	**Alarm Delay time (Max)**	**Cause of alarm**	**Actions/Troubleshooting**
Patient pressure high	10s NOTE: Additional 2 minute delay after target change.	When the pressure from the proximal port is detected as high, a Patient pressure high alarm is reported. (Mode specific limits – see section 8).	Check patient condition. Check breathing system and patient interface for occlusion. Alarm only if in Neonatal nCPAP modes. In Neonatal nCPAP - Pressure mode, flow is reduced and solenoid opened if pressure is 5 mBar above set value.
Patient pressure low	15s NOTE: Additional 2 minute delay after target change.	When the pressure from the proximal port is detected as low, a Patient pressure low alarm is reported. (Mode specific limits - see section 8).	Check patient condition. Check breathing system and patient interface for disconnection. Alarm only if in Neonatal nCPAP modes.
O2 Sensor fault	Typical: 45s ± 1	O_2 sensor fault.	Perform O_2 sensor calibration.
Sensor fault	5s ± 1s SpO_2 sensor 2min ± 1s	A sensor within the SLE1500 is determined to be faulty. No sensor reading present.	Remove device from service. Replace faulty sensor.
Outlet pressure high	2s	When the pressure from the outlet port is detected as high, an Outlet pressure high alarm is reported. (Mode specific limits – see section 8).	Check patient condition. Check breathing system and patient interface for occlusion.

Air supply fault	Typical: 15s ±10s	If a fault is detected with the air supply, such as lack of supply or incorrect gas, an air supply fault is reported.	Check patient condition. Check air supply.
O2 supply fault	Typical: 15s ±10s	If a fault is detected with the O_2 supply, such as lack of supply or incorrect gas, an O_2 supply fault is reported.	Check patient condition. Check oxygen supply.
Output fault	Typical: 20s ±1s NOTE: Additional 2 minute delay after target change.	If a fault is detected with the output gas, such as failure to reach required treatment level, an output fault is reported.	Check patient condition. Remove and replace the SLE1500 and contact SLE for assistance. In flow control modes, if flow is 40% over set value, motors will be closed until flow reduces.
Hardware fault	4s	If a fault is detected with the hardware, such as failure of the flow meter or SD card, a hardware fault is raised.	Check patient condition. Remove and replace the SLE1500 and contact SLE for assistance.
Power button held	3s	If the power button is held for longer than 1 second, this alarm is raised.	Release power button.

NOTE: *If the alarm continues after troubleshooting, remove and replace the SLE1500 and breathing system and contact SLE for technical assistance.*

8.6 Alarm information screen

- Pressing the alarm information symbol / / during an active alarm, transitions the display to the alarm information screen.



Example shown: High priority, 'Hardware Fault' alarm

- Use the navigation arrows to cycle through the alarm messages.
- Press to return to the therapy screen.

8.7 Alarm pre-mute

- Alarms can be pre-muted for 2 minutes by tapping on the greyed out alarm symbol.
- When pre-mute is active, the greyed out alarm symbol will be shown with a cross. If any alarm lower than high priority is raised during these 2 minutes, the alarm will begin muted. When 2 minutes are exceeded, the alarm will no longer be muted and the pre-mute alarm will need to be activated again.
- If a high-level alarm is raised, the pre-mute is ignored.

8.8 Unrecoverable fault screen

- The unrecoverable fault screen (Error: 94 to 99) is displayed when either an unrecoverable fault is detected, or an error occurs during device start-up.

- Hold the power button to turn off and remove the SLE1500 from service. Contact SLE for technical assistance.

9. Patient Monitoring

9.1 Overview

The SLE1500 supports communication with Philips® Patient Monitoring Systems (PPMS) by using an IntelliBridge Interface.

Once the connection between the SLE1500 and the Philips® Patient Monitoring System (PPMS) is established, the SLE1500 transfers device settings, numeric measurements and alarms to the Philips® Patient Monitoring System.

NOTE 1: *The IntelliBridge® Interface Protocol is unidirectional, i.e. a Philips Patient Monitoring Systems can display data received from the SLE1500 but cannot remotely control the SLE1500.*

NOTE 2: *Due to the specific nature of the IntelliBridge® Open Interface Protocol, the display of data from the SLE1500 to the PPMS may be delayed by the following durations refer to table below:*

NOTE 3: *The SLE1500 has been validated with the English version of the IntelliBridge® Open Interface Protocol.*

If other languages are used on the Philips® Patient Monitoring Systems while connected to the SLE1500, conflicts may occur.

Maximum remote alarm generation delay	5s
Time taken from time of local alarm signal generation; to the time of the remote alarm signal generation	4s +/- 1s

9.2 Set-up

NOTE: *The instructions below refer to the Philips IntelliVue® MP50 Patient Monitor (PPMS). The procedure can slightly vary for other models.*

To set-up a connection from the SLE1500 to the Philips® Patient Monitoring System, proceed as follows:

Step 1. Switch the Philips monitor OFF.

Step 2. Find the module rack on your Philips® monitor.

Step 3. Insert the IntelliBridge EC10® module into the Philips® monitor module rack.

Step 4. Connect the Ethernet cable into the Ethernet port on the EC10 module.

Step 5. Connect the Male D-SUB 9 end of the SLE1500 Patient Monitoring cable to the EC5 #101 Philips® cable.

Step 6. Connect the EC5 cable to the Ethernet cable that is connected to the EC10 module.

Step 7. Connect the mini-jack end of the SLE1500 Patient Monitoring cable to the SLE1500 external port.

Step 8. Switch ON the Philips® monitor and the SLE1500.

Step 9. The communication between the SLE1500 and the Philips® Patient Monitoring System (PPMS) should be established within approximately 45 seconds. Once the communication is established, the SLE1500 will register as an available device on the Philips® Patient Monitoring System.

NOTE: *Communication status is shown on the LED as the following:*

Blinking green – Establishing connection.

Green – Running communication.

Blue – Communication error, check set-up (e.g. reconnect cable).

NOTE: *Contact a Philips® authorised technician if the module cannot be successfully configured.*

9.3 Patient Monitoring Display Information

Table 1 - Patient Monitoring: Displayed Settings			
Setting	**Label**	**Unit**	**Description**
Set O_2	sO_2	%	Target O_2 delivered to patient.
Set fresh gas flow	sfgFl	l/min	Target flow delivered to patient. In patient pressure modes, set flow will be displayed as 0.
Set patient pressure	sCPAP	mbar	In flow modes, set patient pressure will be displayed as 0.

Table 2 - Patient Monitoring: Displayed Measurements			
Measurement	**Label**	**Unit**	**Description**
SpO_2	SpO_2	%	Measured SpO_2.
Pulse rate	PULSE	bpm	Patient's pulse rate.
Perfusion Index	PERF	%	Patient's perfusion index.
Delivered O_2	inO_2	%	O_2 measured by SLE1500 at the outlet.
Total fresh gas flow	fgFlow	l/min	Flow measured by SLE1500 at the outlet.
Mean airway pressure	MnAwP	%	The mean airway pressure measured by the SLE1500 at the outlet.
Spontaneous Airway Respiration Rate	SpAWRR	rpm	Measured respiration rate.

Table 3 - Patient Monitoring: Inoperative Messages*		
Message	**Affected Data**	**Troubleshooting**
Inoperative	All data	Check patient condition. Remove and replace the SLE1500 and contact SLE for assistance.
SpO_2 SENSOR	SpO_2, pulse rate and perfusion index	Check connection of the SpO_2 sensor to the SLE1500 and patient. See specification alarm on SLE1500 for more information.
FLOW SENSOR	Measured Flow	Remove device from service. Replace faulty sensor.
O_2 SENSOR	Measured O_2	Perform O_2 sensor calibration.
PRESSURE SENSOR	Measured Airway Pressure	Remove device from service. Replace faulty sensor.

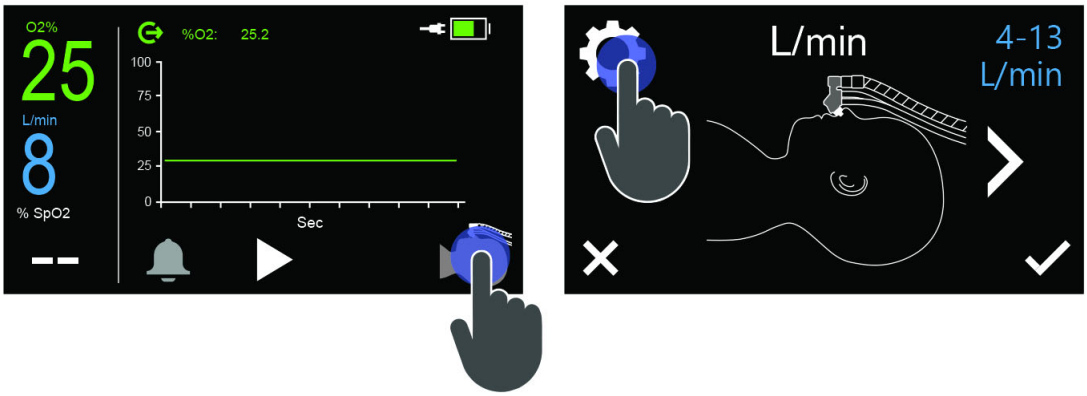
***NOTE:** Values will not be shown on patient monitor for all data within Table 3.*

Table 4 - Patient Monitoring: Alarms		
Message	**Priority**	**Equivalent Alarm(s)***
OUTPUT FAULT	High (Red)	Output Fault
GAS SUPPLY FAIL	High (Red)	O_2 supply fault Air supply fault
SENSOR FAULT	High (Red)	Sensor Fault (High Priority)
HIGH PRESSURE	High (Red)	Patient Pressure High Outlet Pressure High
LOW PRESSURE	High (Red)	Patient Pressure Low Outlet Pressure Low
O_2 SENSOR FAULT	High (Red)	O_2 Sensor Fault
HARDWARE FAULT	High (Red)	Hardware Fault
POWER BUTTON	High (Red)	Power Button Held
SENSOR FAULT	Medium (Yellow)	Sensor Fault (Medium Priority)
SPO_2 FAULT	Medium (Yellow)	No sensor connected No adhesive sensor Sensor off patient No cable connected Replace sensor Incompatible sensor Replace adhesive sensor Incompatible adhesive sensor Replace cable
POWER FAILURE	Medium (Yellow)	External Power Removed
SYSTEM FAULT	Medium (Yellow)	System Fault
PAT. CIRCUIT	Medium (Yellow)	Possible output leak Possible output occlusion Unexpected Flow: Low Unexpected Flow: High

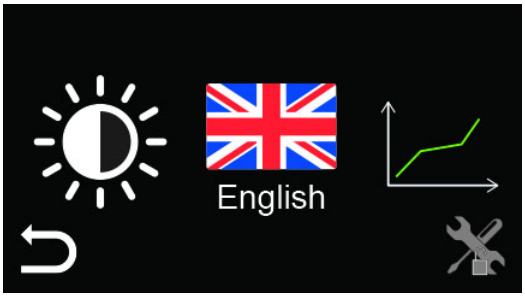
***NOTE:** See section 8 of this user manual for further alarm information/troubleshooting.*

10. Settings

- To access the SLE1500 settings, press the mode symbol on the therapy display screen to access the mode selection screen.
- Press the settings mode button.

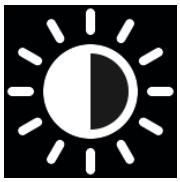


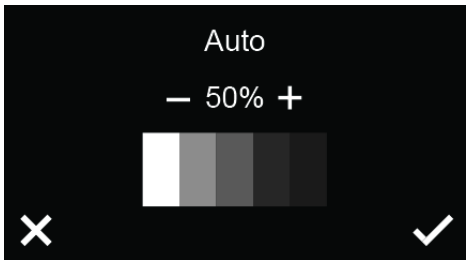
On selection of the settings mode, the SLE1500 will display the settings menu.



- The settings menu displays 3 options (detailed below). Press a symbol to select.
- Alternatively, press  to return to the therapy mode screen.

10.1 Adjusting screen brightness

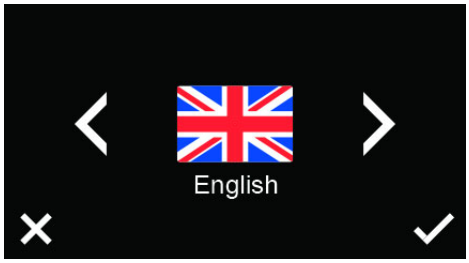




- Press + or – to adjust the display brightness.
- Press ✓ to confirm brightness selection and return to the settings screen.
- Alternatively, press ✗ to return to the settings screen without making changes.

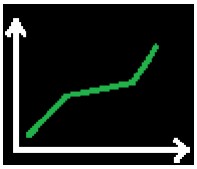
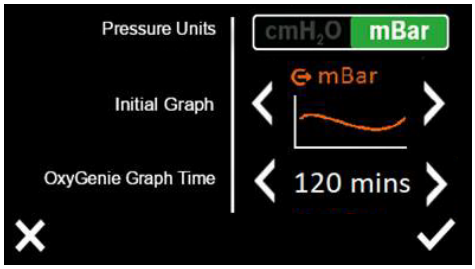
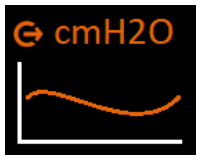
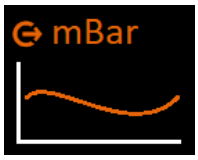
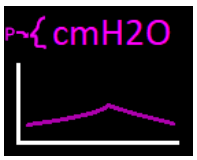
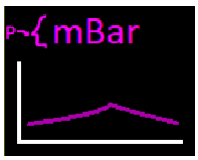
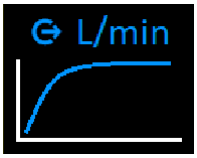
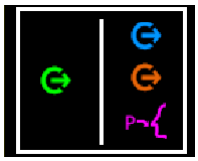
NOTE: *Select* Auto *to set the display brightness to adjust automatically to ambient conditions.*

10.2 Selecting language



- Use the navigation arrows ‹ › to cycle through the language options.
- Press ✓ to confirm language selection and return to the settings screen.
- Alternatively, press ✗ to return to the settings screen without making changes.

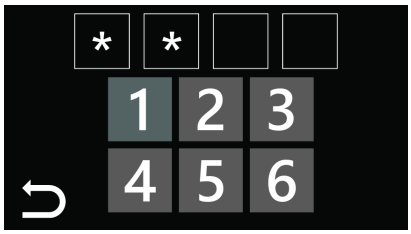
10.3 Selecting graph preferences

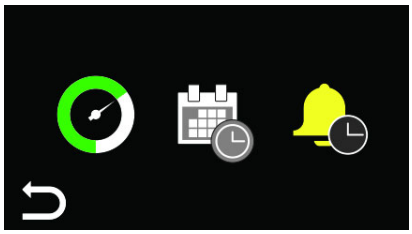
	• Press to toggle between cmH_2O and mbar. The green box indicates the selected pressure unit. • Press ☑ to confirm selection and return to the Settings menu. • Alternatively, press ☒ to return to the settings screen without making changes.
	 • Use the navigation arrows ◀ ▶ to select the graph that will display on start-up.
	 O2 selected
	  Outlet pressure selected.
	  Patient pressure selected.
	 Output flow selected.
	 SpO_2 selected.
	 Large readings selected.

10.4 Protected settings

NOTE: *The information in this section of the IFU is intended for personnel suitably qualified to perform maintenance and service on medical devices. Please refer to the SLE1500 service manual for information.*

- • On selection of the protected settings, the SLE1500 will display a password screen.

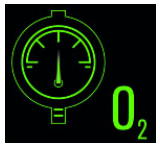




- Enter the 4-digit password (6563) to progress to protected settings.
- Alternatively, press to return to the settings menu.

10.4.1 Calibration menu

The motor calibration menu displays 3 options:

	Flow calibration
	O_2 sensor calibration
	Pressure calibration

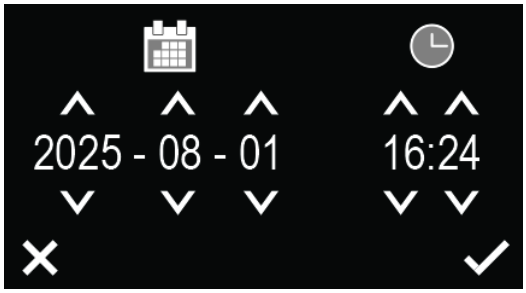
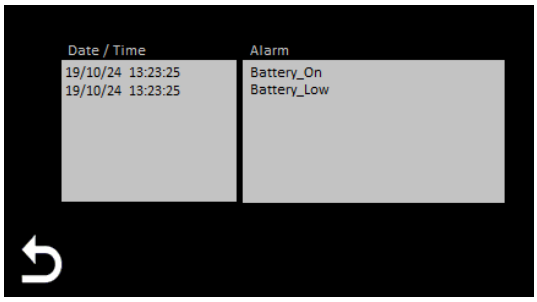
- If calibration is successful, "calibration successful" message is displayed.
- If calibration is unsuccessful, “calibration failed” message is displayed.

If calibration failure continues, remove the SLE1500 from service and contact SLE for assistance.

- Alternatively, press to return to the “Protected Settings” screen.

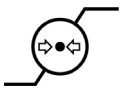
WARNING: *Ensure the SLE1500 is mounted upright during calibration.*

		**NOTE:** When the SLE1500 is delivering a treatment, the calibration settings button will be greyed out on the “Protected Settings” screen and the calibration menu cannot be accessed.

		**10.4.2 Adjusting time and date screen** • Press the  to change the date and time.  • Press  to confirm selections and return to the settings screen. • Alternatively, press  to return to the settings screen without making changes.
		**10.4.3 Alarm history screen** • The alarm history screen displays up to the last 6 alarms that have been raised.  • The screen displays the date and time and the source of each alarm raised. • Press  to return to the protected settings screen.
		**10.4.4 Software version number** • The software version number is displayed at the bottom of the Protected Settings screen.

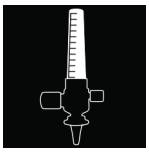
11. Symbols

Symbols used on device packaging and labelling

	Follow instructions for use
	Ingress protection IP22
~	Alternating current
	CAUTION Electrical shock
	Warning: Risk of harm
	Manufacturer
	Date of manufacture
	Temperature limitations during transport and storage
	Humidity limitations during transport and storage
	Atmospheric pressure limitations during transport and storage
	Do not discard
REF	Device reference
SN	Serial number
LOT	Lot number
UDI	Unique device identifier
MD	Medical device
	Recyclable carton
	This way up during transport and storage
	Fragile! Handle with care
	Keep dry during transport and storage

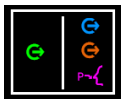
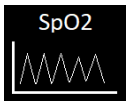
	Type BF applied part
	Intertek ETL mark indicates compliance to North American safety standards
	CE Marking of Conformity indicates compliance with MDD 93/42/EEC
	European authorised representative
	Swiss authorised representative

Symbols used on the device display:

	Power on/off
	Navigate left
	Navigate right
	Cancel selection
	Confirm selection
	Start treatment
	Pause treatment
	Return to previous screen
	Increase set value
	Decrease set value
	Infant HFOT mode
	Infant nCPAP mode
	Screen locked/unlocked button and indicator
	Indicates touch screen is locked
	Manual Flow mode
	Settings mode

	Brightness setting
	Access protected setting
	Auto brightness selection
	Edit display brightness and brightness indicator
	SpO_2 settings mode
	SpO_2 averaging mode indication
	Edit date and time
	Access calibration
	Change time and date value
	Perform Flow calibration

	Perform O_2 calibration
	Perform Pressure calibration
	Calibration Inaccessible
	Battery charge indicator
	Mains supply connected indicator
	Option activated/option deactivated
	Outlet Oxygen
	Outlet Pressure
	Patient Pressure
	Outlet Flow

	Pressure units button and indicator
	Large readings indicator
	SpO_2 selected
	Alarm history button

Alarm display symbols:

	Alarm: Low/Medium priority.
	Alarm mute: Low/Medium priority.
	Alarm: High priority.
	Alarm mute: High priority.
	Alarm information: Low/ Medium priority.
	Alarm information: High priority.
	Alarm information: Technical.

12. Maintenance

NOTE: *Maintenance of this device may only be performed by personnel suitably qualified to perform maintenance and service on medical devices. Please refer to the SLE1500 service manual for more information.*

WARNING: *Maintenance should not be performed while the SLE1500 is in use on a patient.*

12.1 Visual inspection

Visual inspection of the SLE1500 and accessories should be performed monthly.

Damaged items should be replaced as necessary.

12.2 Periodic maintenance

The following periodic maintenance is recommended **at least monthly**:

- Visual inspection
- Functionality Check*: Software relief valve

The following periodic maintenance is recommended **at least every six months, or when the unit has been first installed or relocated:**

- O_2 calibration
- Functionality Check: O_2 Accuracy*

The following periodic maintenance is recommended **at least once a year**:

- Flow and pressure calibration
- Functionality Check: Flow Accuracy*
- Functionality Check: Pressure Accuracy*
- Coin cell check
- Electrical Safety Check

NOTE: *Functionality Checks are mandatory to ensure that Servicing and Maintenance procedures have been carried out successfully and that the SLE1500 maintains Essential Performance.*

12.3 Servicing

Serviceable when required:

- Replace inline gas filters and nylon washers
- Replace rechargeable battery
- Replace SD card
- Replace the coin cell.

The following periodic checks are recommended after any of the above servicing is performed:

- O_2 & Pressure Sensor Calibration followed by:

  O_2 Accuracy Test

  Pressure Accuracy Test
- Flow Calibration followed by:

  Flow Accuracy Test
- Relief Valve Checks

NOTE: *Please refer to the SLE1500 service manual for full servicing instructions.*

13. Cleaning

13.1 Cleaning instructions

WARNING*: As a general safety precaution, the SLE1500 should be turned off, removed from the mains and gas supplies disconnected before performing any cleaning procedures.*

The following products have been tested on the device and have shown no adverse effects on the plastics or metals used in construction:

- Chlor-Clean/Biohazard wipes (e.g. Guest Medical Ltd.)
- 70% Isopropyl alcohol
- Benzalkonium chloride wipes (e.g. Clinell®, Klenzeen®)

13.2 Disinfection

Disinfect as per your hospital infection control guidelines.

If required, the SLE1500 and accessories can be disinfected using commercially available disinfectant wipes approved for use with medical equipment.

WARNING: *DO NOT IMMERSE, AUTOCLAVE or STERILISE the device.*

Clinell® is a registered trademark of GAMA Healthcare Ltd.

Klenzeen® is a registered trademark of Klenzeen Ltd.

14. Duration of use

The SLE1500 has an intended service life of 10 years.

15. Disposal

15.1 WEEE Compliance

This marking indicates that the product and all removed electronic parts should not be disposed of with other types of waste at the end of its working life. To prevent uncontrolled waste disposal causing possible harm to the environment or human health, please ensure proper disposal, reuse or the recycle of this product. Please contact your local authority or SLE for more information.

16. Storage, transport and operating conditions

		
Temperature limitations during transport and storage	Humidity limitations during transport and storage	Atmospheric pressure limitations during transport and storage
		
This way up during transport and storage	Fragile! Handle with care	Keep dry during transport and storage

16.1 Storage and transport conditions

Temperature: -18°C to 50°C

Relative Humidity: 10% to 80%

Altitude: 0 to 10,000 m

16.2 Operating conditions

Temperature: 18°C to 26°C

Relative Humidity: 10% to 80%

Atmospheric pressure: 0 to 2,000 m

17. Technical & performance data

17.1 Technical

General	
Size	H:155 mm x W:166 mm x D:111.4 mm
Weight	1.2 kg
Noise emissions	< 44 dB(A)

Gas Supply (STPD)	
O_2 supply	2 – 6 Bar (200 to 600 kPa); medical oxygen
O_2 connection	NIST or DISS
Air supply	2 – 6 Bar (200 to 600 kPa); medical air
Air connection	NIST or DISS

Performance (BTPS)	
O_2 %	21 – 100%*
Flow	0 – 30 L/min*
Pressure	0 – 210 cmH_2O
Total system response time	27 – 29s

Mechanical PRV	
Sustained pressure	< 200 mbar (~cmH_2O)
Peak pressure	< 260 mbar (~cmH_2O)

OxyGenie® PCLCS attributes

For normal use case	
Response time	19 seconds
Settling time	29 seconds
Overshoot	4%

For worst use case	
Response time	20 seconds
Settling time	38 seconds
Overshoot	4%

Electrical Rating**	
Supply voltage	5V DC 1500 mA
Supply frequency	50 – 60 Hz
Power rating	180 – 158 VA

Battery	
Type	Li-ion
Operating time	0.5 hours
Capacity	3500 mAh, 12.6 Wh
Voltage	3.6V

SD Card	
Type	Micro SD
Size	16 GB***
Read speed	> 10MB/s
Class	4

System Connections	
Gas outlet	22M/15F
Proximal pressure monitoring port	6% female Luer

Alarm volume	
High priority	56 – 72 dB
Medium priority	53 – 68 dB
Low priority	54 – 69 dB

** **NOTE:** The maximum flow and O_2 % levels achievable may be dependent. The SLE1500 will automatically limit the allowed flow or O_2 % based on the supply pressures and parameter settings.*

*** **NOTE:** Using approved power supply.*

**** **NOTE:** Log messages are recorded onto the SD card, which is not anticipated to reach capacity during the lifetime of the device. In the event of a logging failure, a hardware alarm will be raised.*

17.2 Measurements

O_2	
Range	0 - 100%
Resolution	0.1%
Accuracy	± 3%
Data sample rate	5 Hz

- The oxygen sensor is filtered for accuracy with a response time of 3.2s
- The maximum output response time from 21 to 90% oxygen is 90s

Flow	
Range	0 – 30 L/min (mode dependent)
Resolution	0.1 L/min
Accuracy	± 10% All flow values are in STPD Resolution is 0.1 L/min

Outlet pressure	
Range	0 – 250 cmH_2O
Resolution	0.1 cmH_2O
Accuracy	± 2 cmH_2O +4% of the actual reading

Patient pressure	
Range	0 – 35 cmH_2O
Resolution	0.1 cmH_2O
Accuracy	± 1 cmH_2O

SpO_2	
Range	1 – 100%
Resolution	1%
Accuracy	± 3 digits (70 – 100%); unspecified (0 – 69%)
Data update period	1s

Pulse	
Range	25 – 240 b/min
Resolution	1 b/min
Accuracy	± 3% ± 1 b/min
Data update period	1s

PI (Perfusion index)*	
Range	0.02 – 20.0%
Resolution	0.01 for < 10% 0.1 for >= 10%
Accuracy	--

*Refer to SpO2 sensor IFU and Section 21 ‘Pulse Oximetry – Masimo SET®’ for full details.

17.3 Classifications

Protection class, electrical hazard

IEC 60601-1 Class II Medical Electrical Equipment.

IP classification

IP22 - Protected from touch by fingers and objects greater than 12 millimetres.

Protected from water spray less than 15 degrees from vertical. 56 – 72 dB.

Mode of operation

Continuous use.

Sterilisation

Do not sterilise.

Applied Parts

This Device uses Type BF Applied Parts (Masimo SET® SpO_2 sensors).

Refer to SpO_2 sensor IFU and See “Pulse Oximetry–Masimo SET®” on page 68 for full details.

CAUTION: *To maintain specified performance and accuracy, only use the SLE1500 in an upright orientation with the recommended SLE accessories.*

CAUTION: *Measurement performance will deteriorate in the presence of humidity or condensation. Use only pure, dry medical grade gas supplies.*

NOTE: *The SLE1500 is not equipped with automatic barometric pressure compensation as there is no internal measurement of barometric pressure. Automatic compensation for pressure is internally applied for oxygen measurement; flow measurement is based on mass in SLPM and requires no compensation; pressure measurements are relative to atmospheric pressure at the time of last calibration.*

For further information contact SLE:
info@inspiration-healthcare.com

18. Regulatory

18.1 Product standards

The SLE1500 complies with the following relevant standards:

ISO 11195

ISO 80601-2-55

ISO 80601-2-12

ISO 60601-1

IEC 60601-1-6

IEC 60601-1-8

IEC 60601-1-10

ISO 80601-2-61

18.2 Essential Performance

ISO 11195:2018, Paragraph 4, Table 1.

Maintaining the set concentration of oxygen, or generation of a technical alarm condition

Maintaining the set flow, if applicable, or generation of a technical alarm condition

Prevention of a hypoxic mixture or generation of a technical alarm condition

Prevention of reverse gas flow from one inlet to the other

ISO 80601-2-61:2017 Clause 201.4.3

For Pulse Oximeter equipment provided with an alarm system that includes the capability to detect a physiological alarm condition: SpO_2 accuracy, pulse rate accuracy, and limit alarm conditions or generation of a technical alarm condition.

ISO 80601-2-55:2018 Clause 201.4.3.101

Measurement Accuracy of Readings. Technical Alarm Condition required when the measurement accuracy cannot be maintained (where detectable conditions allow). Where measurement accuracy cannot be detected and therefore not generate a Technical Alarm, warnings and cautions must be stated in the accompanying documents.

ISO 80601-2-12:2011 Clause 201.4.3.101

Delivery of ventilation at the patient-connection port within the alarm limits set by the operator or generation of an alarm condition.

Oxygen level alarm conditions

Airway pressure

Electrical supply failure

Internal electrical power source nears depletion

Gas supply failure

Gas failure cross flow

ISO 60601-1:2006+A12:2014 Clause 4.3

ISO 60601-1 describes Essential Performance to be identified by the Manufacturer during Risk Analysis, and to evaluate the performance limits and risks of going beyond these limits. Risk control measures are to be implemented to reduce the risk to an acceptable level.

NOTE: *Start-up to delivery of Essential Performance takes up to 10 seconds.*

WARNING: *The SLE1500 must remain properly serviced and maintained to ensure that Essential Performance is maintained. Please refer to the Service Manual.*

19. EMC Compliance

NOTE: *The emissions characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B I normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.*

The SLE1500 was tested to IEC 60601-1-2:2014 and complies to the following in relation to Electromagnetic disturbances with no deviations. Based on the stated intended environment, the SLE1500 has been classified as Group 1, Class A.

19.1 Emissions tests compliance levels

Mains terminal: CISPR16-2-1:2014 +A1:2017

230 Vac at 50Hz

Electromagnetic radiation disturbances – Electric Field: CISPR16-2-3:2016

30 MHz to 1 GHz – Vertical – 230Vac 50Hz

30 MHz to 1 GHz – Horizontal – 230Vac 50Hz

Harmonic Current Emissions: IEC61000-3-2:2014

230Vac at 50Hz

Voltage fluctuations and flicker: IEC61000-3-3:2013

230Vac at 50Hz

19.2 Immunity tests compliance levels

Electrostatic Discharge: IEC61000-4-2:2008

Air discharge at 2kV, 4kV, 8kV and 15kV

Contact discharge at 8kV

Indirect discharge at 8kV

Radiated RF Electromagnetic Fields: IEC61000-4-3:2006 +A1:2007 +A2:2010

80 – 2700MHz

Proximity Fields from RF Wireless Equipment: IEC61000-4-3:2006 +A1:2007 +A2:2010

TETRA 400 (380-390 MHz)

GMRS 460 and FRS460 (430-470 MHz)

LTE bands 13 and 17 (704-787 MHz)

GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5 (800-960 MHz)

GSM 1800, CDMA 1900, DECT, LTE Bands 1, 3, 4 & 15, UMTS (1700-1990 MHz) Bluetooth, WLAN 802.11b/g/n, RFID 2450, LTE Band 7 (2400-2570 MHz)

WLAN 802.11a/n (5100-5700 MHz)

Electrical Fast Transients and Bursts: IEC61000-4-4:2012

2kV AC input 230Vac 50Hz

Surges: IEC61000-4-5:2014 +A1:2017

AC input 230Vac 50Hz

Conducted disturbances induced by RF fields: IEC61000-4-6:2013

3 Vrms 230Vac 50Hz

Power Frequency Magnetic Fields: IEC61000-4-8:2009

30 A/m 230Vac 50Hz

Voltage dips and short interruptions: IEC61000-4-11:2004 +A1:2017

AC input 240Vac 50Hz

AC input 100Vac 50Hz

20. Warranty

THE WARRANTY DESCRIBED IN THIS AGREEMENT IS IN LIEU OF ANY AND ALL OTHER WARRANTIES, EXPRESS OR IMPLIED, INCLUDING IMPLIED WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE. HOWEVER, IMPLIED WARRANTIES ARE NOT DISCLAIMED DURING THE PERIOD OF THIS LIMITED WARRANTY.

SLE Ltd guarantees its Medical Equipment products to be shipped free from defects in material and workmanship for a period of twenty-four (24) months from the date of delivery of the product.

The warranty does not include disposable items. Disposable items and consumable products are considered to be of single or limited use only and must be replaced regularly as required for proper operation of the product in accordance with the Instructions for Use of the device.

SLE Ltd as the manufacturer shall have no obligations nor liabilities in connection with the product other than what is specified herein, including without limitation, obligations and/or liabilities for alleged negligence, or for strict liability.

In no event shall the company be liable for incidental or consequential damages, either direct or contingent. This Limited Warranty shall be void and not apply: -

1. If the product has not been installed by an authorised local representative of SLE Ltd in accordance with the instructions furnished by either SLE Ltd or by an SLE Ltd representative;
2. If replacements and/or repairs have not been performed by authorised or properly trained personnel;
3. If no evidence is present that the occurrence of damage/repair happened within the certified warranty period;
4. If the serial number has been altered, effaced or removed and there is no bill of sale or evidence to verify the product purchase date;
5. If the defects arise from misuse, negligence, or accidents or from repair, adjustment, modification or replacement made outside SLE Ltd factories or other authorised service or by an authorised service representative;
6. If the product has been modified, or in any nature altered without prior written authorisation from SLE Ltd;
7. If the maintenance schedule, as recommended in the Instructions for Use, has not been carried out.

Replacements and/or repairs furnished under this Limited Warranty do not carry a new warranty but carry only the unexpired portion of the original Limited Warranty. The warranty of repaired and/or replaced components does not exceed the Limited Warranty of the device. To obtain service under this Limited Warranty, claimant must promptly notify the country’s sales partner of SLE Ltd regarding the nature of the problem, serial number and the date of purchase of the product.

Except as stated above, SLE Ltd shall not be liable for any damages, claims or liabilities including, but not limited to, personal bodily injury, or incidental, consequential, or special damages.

21. Pulse Oximetry–Masimo SET®

21.1 Principles of Operation

Pulse Oximetry is governed by the following principles:

Oxyhaemoglobin (oxygenated blood), deoxyhaemoglobin (non-oxygenated blood), carboxyhaemoglobin (blood with carbon monoxide content), and methaemoglobin (blood with oxidised haemoglobin content) species differ in their absorption of visible and infrared light.

The amount of arterial blood in tissue changes with your pulse (photoplethysmography). Therefore, the amount of light absorbed by the varying quantities of arterial blood changes as well.

21.2 Product Description

The RD series patient cable are reusable, designed for use with systems incorporating Masimo® compatible or Masimo® approved pulse oximetry technology which are intended for continuous non-invasive monitoring of functional oxygen saturation of arterial haemoglobin (SpO_2) and pulse rate (measured by a SpO_2 sensor) for patients of the appropriate weight (see table below).

Masimo SET® performance specifications are met when the RD sensor is used with Masimo RD® patient cables and systems incorporating Masimo SET® Pulse Oximetry technology.

21.3 Method of Operation

The RD Sensor is attached to a patient's body at the appropriate site and one end of a patient cable is connected to the sensor and the other end connected to the Masimo SET® pulse oximeter on the SLE1500. Refer to 'Directions for Use' insert provided with the RD sensor and RD series patient cable for further information.

The monitor on the SLE1500 will begin continuously displaying the patient's pulse rate, and SpO_2 value.

The practitioner can use the information that is continuously displayed on the monitor to help assess the condition of the patient and as an aide in determining if any intervention is required by the practitioner.

21.4 SpO_2 Product Specifications

Range	
Saturation (% SpO_2)	1% – 100%
Pulse Rate (bpm)	25 – 240
Perfusion	0.02% – 20%

Accuracy

Saturation (% SpO_2) – During No Motion Conditions	
Paediatrics	70% – 100% ± 2 digits 0% – 69% unspecified
Neonates	70% – 100% ± 3 digits 0% – 69% unspecified

Saturation (% SpO_2) – During Motion Conditions	
Paediatrics	70% – 100% ± 3 digits 0% – 69% unspecified
Neonates	70% – 100% ± 3 digits 0% – 69% unspecified

Pulse Rate (bpm) – During No Motion Conditions	
Paediatric, Neonates	25 to 240 ± 3 digits

Pulse Rate (bpm) – During Motion Conditions	
Paediatric, Neonates	25 to 240 ± 5 digits

Resolution	
Saturation (%SpO_2)	1%
Pulse Rate (bpm)	1

Low Perfusion Performance

>0.02% Pulse Amplitude Saturation (% SpO_2) ± 2 digits and % Transmission>5% Pulse Rate ± 3 digits

Interfering Substances

Carboxyhaemoglobin may erroneously increase readings. The level of increase is approximately equal to the amount of carboxyhaemoglobin present. Dyes, or any substance containing dyes, that change usual arterial pigmentation may cause erroneous readings.

21.5 Sensor accuracy information

RD SET® Adhesives						SpO_2 Accuracy (%)		PR Accuracy (bpm)		Low Perfusion Accuracy (No Motion)	
P/N	Sensor	Description	Application Site	510K	Weight Range (kg)	No Motion	Motion	No Motion	Motion	SpO_2 (%)	PR (bpm)
4000	Adt	Adult	Finger or Toe	K042346	> 30	±2	±3	±3	±5	±2	±3
4001	Pdt	Paediatric	Finger or Toe	K042346	10 to 50	±2	±3	±3	±5	±2	±3
4002	Inf	Infant	Thumb or Great Toe	K042346	3 to 20	±2	±3	±3	±5	±2	±3
4003	Neo	Neonatal/Adult	Hand or Foot	K042346	<3	±3	±3	±3	±5	±3	±3
			Finger or Toe		> 40	±2				±2	
4004	Neo Pt	Neonatal	Hand or Foot	K042346	<1	±3	±3	±3	±5	±3	±3

Accuracy notes:

1. The Masimo SET® technology with Masimo® sensors has been validated for no motion accuracy in human blood studies on healthy adult male and female volunteers with light to dark skin pigmentation in induced hypoxia studies in the range of 70 – 100% SpO_2 against a laboratory CO-Oximeter and ECG monitor. This variation equals ±1 standard deviation. Plus or minus one standard deviation encompasses 68% of the population.

2. The Masimo SET® technology with Masimo® sensors has been validated for motion accuracy in human blood studies on healthy adult male and female volunteers with light to dark skin pigmentation in induced hypoxia studies while performing rubbing and tapping motions, at 2 to 4 Hz at an amplitude of 1 to 2 cm and a non-repetitive motion between 1 to 5 Hz at an amplitude of 2 to 3 cm in induced hypoxia studies in the range of 70 – 100% SpO_2 against a laboratory CO-Oximeter and ECG monitor. This variation equals ±1 standard deviation, which encompasses 68% of the population.

3. The Masimo SET® technology has been validated for low perfusion accuracy in bench top testing against a Biotek Index 2™ simulator and Masimo®'s simulator with signal strengths of greater than 0.02% and transmission of greater than 5% for saturations ranging from 70 to 100%. This variation equals ±1 standard deviation. Plus or minus one standard deviation encompasses 68% of the population.

4. The Masimo SET® Technology with Masimo® Neo sensors has been validated for neonatal motion accuracy in human blood studies on healthy adult male and female volunteers with light to dark skin pigmentation in induced hypoxia studies while performing rubbing and tapping motions, at 2 to 4 Hz at an amplitude of 1 to 2 cm and a non-repetitive motion between 1 to 5 Hz at an amplitude of 2 to 3 cm in induced hypoxia studies in the range of 70-100% SpO_2 against a laboratory CO-Oximeter and ECG monitor. This variation equals ±1 standard deviation. Plus or minus one standard deviation encompasses 68% of the population. 1% has been added to the results to account for the effects of foetal haemoglobin present in neonates.

5. The Masimo SET® technology with Masimo® sensors has been validated for pulse rate accuracy for the range of 25 – 240 bpm in bench top testing against a Biotek Index 2™ simulator. This variation equals ±1 standard deviation. Plus or minus one standard deviation encompasses 68% of the population.

6. See sensor Directions for Use (DFU) for complete application information. Unless otherwise indicated, reposition reusable sensors at least every 4 hours and adhesive sensors at least every 8 hours.

7. Sensor accuracy specified when used with Masimo® technology using a Masimo® patient cable for RD SET® sensors and RD sensors. Numbers represent Arms (RMS error compared to the reference). Because pulse oximeter measurements are statistically distributed, only about two-thirds of the measurements can be expected to fall within a range of ± Arms compared to the reference value. Unless otherwise noted, SpO_2 accuracy is specified from 70% to 100%. Pulse Rate accuracy is specified from 25 to 240 bpm.

8. Masimo® M-LNCS®, LNOP™, RD SET®, and LNCS™ sensors types have the same optical and electrical properties and may differ only in application type (adhesive/non-adhesive/hook & loop), cable lengths, optical component locations (top or bottom of sensor as aligned with cable), adhesive material type/size, and connector type (LNOP™ 8 pin modular plug, RD 15 pin modular plug, LNCS™ 9 pin, cable based, and M-LNCS® 15 pin, cable based). All sensor accuracy information and sensor application instructions are provided with the associated sensor Directions for Use.

21.6 Initial installation/relocation check sheet

Serial No.
SW Version:
Date & time:
Tested by:

Test	Criteria	Pass/Fail	Additional comments	Retest
Visual Inspection	Device is free of the following defects: - Damage, eg. cracks, breaks, cuts any to wiring - Wrong connections - Any obstructions to the inlet or outlet			
Electrical Check	SLE1500 passes relevant electrical safety checks			
Functionality check: Software relief valve (Simple)	When the device is connected to mains power, a “click” can be heard during boot-up.			
O2 calibration	Calibration successful			
Functionality check: O2 accuracy	At 10 L/min, measured value matches set value for O2% (+/-3%) at the following O2 concentrations:			
	21%			
	40%			
	60%			
	80%			
	100%			

Additional comments:

21.7 Masimo® Patent Information

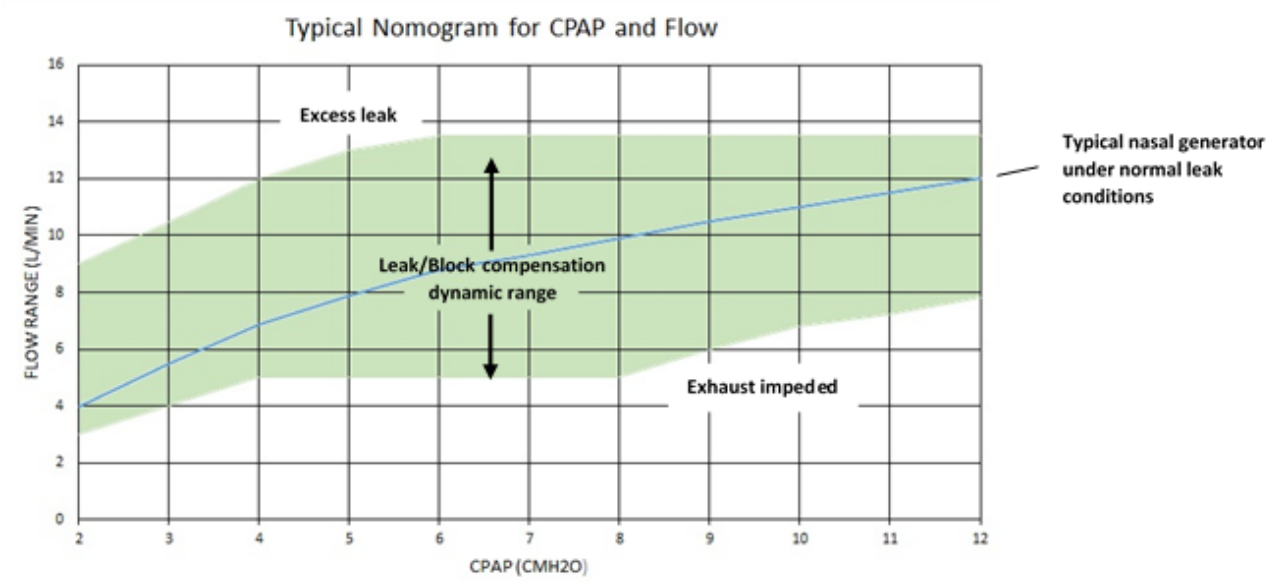
This device is covered under one or more patents as set forth at: http://masimo.com/patents.htm

21.8 No Implied Licence Statement

“Possession or purchase of this device does not convey any express or implied licence to use the device with unauthorised sensors or cables which would, alone or in combination with this device, fall within the scope of one or more of the patents relating to this device.”

21.9 Nomogram for CPAP and Flow

The graph below shows the expected flows for a given pressure for the SLE1500 as well as the upper and lower flow limits.



References

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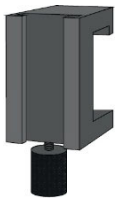
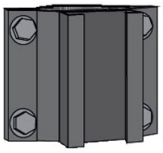
22. Accessories

22.1 Included accessories

Items	Image	Part No
SLE1500 Plug top power supply - 3m **Operating Voltage: 80 to 275 VAC, 47 to 63 Hz** **Max Power: 16.5W** • Double insulated, Class II Protection • IEC60601-1 Edition 3.1, • ES60601-1:2005(R2012), • CSAC22.2 NO.60601-1:14, • EN60601-1:2006/A1:2013		MBL2511
SLE1500 Desktop power supply - 3m **Operating Voltage: 80 to 275 VAC, 47 to 63 Hz** **Max Power: 13W** Class I Protection • IEC60601-1 Edition 3.1, • ES60601-1:2005(R2012), • CSAC22.2 NO.60601-1:14, • EN60601-1:2006/A1:2013		MBL2711
Masimo RD SET® MD14-05 patient cable REF: RD SET® MD14-05 (contact Masimo® for sales and support)		MBL2432B00
Masimo SET® LNC- 4 patient cable REF: LNC SET (contact Masimo® for sales and support)		LNC-4

22.2 Optional accessories

Items	Image	Part No
F&P Medi-rail mounting bracket		N6627/08
Fixed pole clamp		7601000
Cart		N6695

22.3 Accessories for patient monitoring

For use with Masimo® SpO2 Sensor		
Items	**Image**	**Part No**
SLE1500 patient monitoring cable D-SUB 9 to mini-jack (Order from SLE)		NBL9033
DCI Masimo RD SET® DCI adult reusable sensor (For test purposes)		MBL2432C00
Masimo RD SET® Inf		4002
Masimo RD SET® Neo		4003
Masimo RD SET® NeoPt		4004
Masimo RD SET® NeoPt-500		4005

For use with Philips IntelliBridge®		
Items	**Image**	**Philips® Part No**
Philips IntelliBridge EC10 Module®		865115 #A01,101
IntelliBridge EC5 ID-Module®		865114 #101DB9 male connector
Standard ethernet cable, CAT5, straight wired		1.5 m: 865114 #L21 3 m: 865114 #L02 10 m: 865114 #L03

All accessories for patient monitoring are to be ordered from Philips®; apart from SLE1500 patient monitoring lead.

- See section 10 of this User Manual for set-up and further information on patient monitoring with the SLE1500.
- For information on the full range of Philips IntelliBridge® options available, please contact Philips® for sales support.
- SLE assumes no liability for correctness of stated Philips® Product Codes.

22.4 High Flow mode accessories

Interface Description	Breathing Circuit and Interface Product Code
First Breath High Flow Breathing Circuit	C4330
First Breath High Flow Breathing Circuit with Autofeed Chamber	C4331
SLE Essential Cannula - Small	VINC-01
SLE Essential Cannula - Medium	VINC-02
SLE Essential Cannula - Large	VINC-03
SLE Essential Cannula - Extra Large	VINC-04
Fisher and Paykel Optiflow Ventilator Circuit	RT331

Interface Description	Breathing Circuit and Interface Product Code
Fisher and Paykel Optiflow Junior 2 Nasal Interface XS	OJR410
Fisher and Paykel Optiflow Junior 2 Nasal Interface S	OJR412
Fisher and Paykel Optiflow Junior 2 Nasal Interface M	OJR414
Fisher and Paykel Optiflow Junior 2 Nasal Interface L	OJR416
Fisher and Paykel Optiflow Junior 2 Nasal Interface XL	OJR418

Humidification Description*	Humidification Chamber Product Code
Fisher and Paykel MR290 Humidification Autofeed Chamber	N3290/01

***NOTE:** Any standard CE marked electronic humidifiers that are suitable and designed for use with infants and neonates shall be used with SLE1500.*

22.5 Manual mode accessories*

Interface Description	Breathing Circuit and Interface Product Code
Fisher and Paykel Bubble CPAP System with FlexiTrunk Interface	BC161-10
Fisher and Paykel Nasal Tubing 70 mm	BC191
Fisher and Paykel Nasal Prongs (3.0mm nare diameter/2.0mm septal width)	BC3020
Fisher and Paykel Nasal Prongs (3.5mm nare diameter/2.0mm septal width)	BC3520
Fisher and Paykel Nasal Prongs (4.0mm nare diameter/3.0mm septal width)	BC4030
Fisher and Paykel Nasal Prongs (4.5mm nare diameter/4.0mm septal width)	BC4540
Fisher and Paykel Nasal Prongs (5.0mm nare diameter/4.0mm septal width)	BC5040
Fisher and Paykel Nasal Prongs (5.0mm nare diameter/5.0mm septal width)	BC5050
Fisher and Paykel Nasal Prongs (5.5mm nare diameter/5.0mm septal width)	BC5550
Fisher and Paykel Nasal Prongs (5.5mm nare diameter/6.0mm septal width)	BC5560
Fisher and Paykel Nasal Prongs (6.0mm nare diameter/6.0mm septal width)	BC6060
Fisher and Paykel Nasal Prongs (6.0mm nare diameter/7.0mm septal width)	BC6070
Fisher and Paykel Nasal Prongs (6.5mm nare diameter/7.0mm septal width)	BC6570
Fisher and Paykel Infant Nasal Mask – Small	BC800
Fisher and Paykel Infant Nasal Mask – Medium	BC801
Fisher and Paykel Infant Nasal Mask – Large	BC802
Fisher and Paykel Infant Nasal Mask – Extra Large	BC803

NOTE: *Non SLE stock, contact F&P for purchase.*

22.6 Intersurgical accessories*

Interface Description Circuit	Breathing Circuit and Interface Product Code
nFlow™ CosyFit infant CPAP heated wire breathing system with detachable monitoring line ≥ 1.8m	4800016

Interface Description Modular System	Modular System Product Code
nFlow™ CosyFit Generator Adapter Kit with Nasal Prongs	4800004

Interface Description Bonnets	Bonnet Product Code
nFlow™ CosyFit, Infant Bonnet, Navy, size 9 (40 - 42 cm)	4907009
nFlow™ CosyFit, Infant Bonnet, Turquoise, size 8 (38 - 40 cm)	4907008
nFlow™ CosyFit, Infant Bonnet, Orange, size 7 (36 - 38 cm)	4907007
nFlow™ CosyFit, Infant Bonnet, Red, size 6 (34 - 36 cm)	4907006
nFlow™ CosyFit, Infant Bonnet, Green, size 5 (32 - 34 cm)	4907005
nFlow™ CosyFit, Infant Bonnet, Light Orange, size 4 (30 - 32 cm)	4907004
nFlow™ CosyFit, Infant Bonnet, Blue, size 3 (28 - 30 cm)	4907003
nFlow™ CosyFit, Infant Bonnet, Yellow, size 2 (26 - 28 cm)	4907002
nFlow™ CosyFit, Infant Bonnet, Dark Grey, size 1 (24 - 26 cm)	4907001
nFlow™ CosyFit, Infant Bonnet, Pink, size 0 (22 - 24 cm)	4907110
nFlow™ CosyFit, Infant Bonnet, Grey, size 00 (20 - 22 cm)	4907100
nFlow™ CosyFit, Infant Bonnet, White, size 000 (18 - 20 cm)	4907000

Interface Description Mask and Prongs	Mask and Prongs Product Code
nFlow™ Nasal Mask, Extra Large	4716000
nFlow™ Nasal Mask, Large	4706000
nFlow™ Nasal Mask, Medium	4705000
nFlow™ Nasal Mask, Small	4704000
nFlow™ Nasal Prong, Large	4703000
nFlow™ Nasal Prong, Medium	4702000

Interface Description	Mask and Prongs Product Code
Mask and Prongs	
nFlow™ Nasal Prong, Small	4701000
nFlow™ Nasal Prong, Extra Small	4711000

22.7 First Breath Accessories

Interface Description	Breathing Circuit and Interface Product Code
Circuit	
First Breath nCPAP with Breathing Circuit' (Pack of 20)	VX8001
First Breath nCPAP with Breathing Circuit and Humidifier Chamber' (Pack of 10)	VX8002

Interface Description	Bonnet Product Code
Headgear	
First Breath nCPAP Headgear Extra Small (XS) 18-22 cm – Grey (Cases of 10)	VX8011
First Breath nCPAP Headgear Small (S) 22-26 cm – Brown (Cases of 10)	VX8012
First Breath nCPAP Headgear Medium (M) 26-30 cm – Blue (Cases of 10)	VX8013
First Breath nCPAP Headgear Large (L) 30-36 cm – Burgundy (Cases of 10)	VX8014
First Breath nCPAP Headgear Extra Large (XL) 36-42 cm – Navy (Cases of 10)	VX8015
First Breath nCPAP Fixation Blocks (Case of 20)	VX8018

Interface Description	Mask and Prongs Product Code
Mask and Prongs	
First Breath nCPAP Generator with Nasal Sizer and S/M/L Nasal Prongs (Case of 10)	VX8000
First Breath nCPAP Silencer (Case of 20)	C4325
First Breath nCPAP Extra Small (XS) Nasal Prong – Green (Cases of 10)	VX8020
First Breath nCPAP Small (S) Nasal Prong – Red (Cases of 10)	VX8021
First Breath nCPAP Medium (M) Nasal Prong – Blue (Cases of 10)	VX80922
First Breath nCPAP Large (L) Nasal Prong – Purple (Cases of 10)	VX8023
First Breath nCPAP Small (S) Nasal Mask – Red (Cases of 10)	VX8030
First Breath nCPAP Medium (M) Nasal Mask – Blue (Cases of 10)	VX8031
First Breath nCPAP Large (L) Nasal Mask – Purple (Cases of 10)	VX8032
First Breath nCPAP Extra Large (XL) Nasal Mask – White (Cases of 10)	VX89033

22.8 SLE1000 nCPAP Accessories

Interface Description	Breathing Circuit and Interface Product Code
Circuit	
SLE1000 nCPAP - Generator only (including 3 prongs - S, M, L) (Pack of 10)	BH6000/600/010
SLE1000 nCPAP Generator with Fisher & Paykel RT124 spiral heated-wire circuit. (Pack of 10)	BH6300/605/010
SLE1000 nCPAP Generator with Fisher & Paykel RT324 spiral heated-wire patient circuit & MR290 auto-fill chamber (Pack of 10)	BH6400/605/010
SLE1000 nCPAP Silencer (Pack of 20)	BH6600/600/020

Interface Description	Bonnet Product Code
Headgear Bonnets	
SLE1000 nCPAP Bonnet - White, size 000 (Pack of 10)	BH1000/600/010
SLE1000 nCPAP Bonnet - Grey, size 00 (Pack of 10)	BH0100/600/010
SLE1000 nCPAP Bonnet - Pink, size 0 (Pack of 10)	BH0110/600/010
SLE1000 nCPAP Bonnet - Brown, size 1 (Pack of 10)	BH0001/600/010
SLE1000 nCPAP Bonnet - Yellow, size 2 (Pack of 10)	BH0002/600/010
SLE1000 nCPAP Bonnet - Blue, size 3 (Pack of 10)	BH0003/600/010
SLE1000 nCPAP Bonnet - Gold, size 4 (Pack of 10)	BH0004/600/010
SLE1000 nCPAP Bonnet - Green, size 5 (Pack of 10)	BH0005/600/010
SLE1000 nCPAP Bonnet - Burgundy, size 6 (Pack of 10)	BH0006/600/010
SLE1000 nCPAP Bonnet - Orange, size 7 (Pack of 10)	BH0007/600/010
SLE1000 nCPAP Bonnet - Dark Green, size 8 (Pack of 10)	BH0008/600/010
SLE1000 nCPAP Bonnet - Navy, size 9 (Pack of 10)	BH0009/600/010
SLE1000 nCPAP Bonnet Sample Pack. Pack includes 3 bonnets of each size, 10 x head measuring tapes (Pack of 36)	BH1000/STP/001

Interface Description	Mask and Prongs Product Code
Mask and Prongs	
SLE1000 nCPAP Nasal Mask - Small (Pack of 10)	BH4M00/600/010
SLE1000 nCPAP Nasal Mask - Medium (Pack of 10)	BH5M00/600/010
SLE1000 nCPAP Nasal Mask - Large (Pack of 10)	BH6M00/600/010
SLE1000 nCPAP Nasal Mask – X Large (Pack of 10)	BH7M00/600/010
SLE1000 nCPAP Nasal Prong - X Small (Pack of 10)	BH0P00/600/010
SLE1000 nCPAP Nasal Prong - Small (Pack of 10)	BH1P00/600/010

Interface Description	Mask and Prongs Product Code
Mask and Prongs	
SLE1000 nCPAP Nasal Prong - Medium (Pack of 10)	BH2P00/600/010
SLE1000 nCPAP Nasal Prong - Large (Pack of 10)	BH3P00/600/010

22.9 Inspire nCPAP Accessories

Interface Description	Breathing Circuit and Interface Product Code
Generator and Circuit	
Inspire nCPAP Generator with Nasal Sizer and S/M/L Nasal Prongs	IHC600/10
Inspire nCPAP Generator only	IHC616
Inspire nCPAP Generator & Cloverleaf Curly Wire Breathing Circuit inc Prongs	IHC4064/20N
Inspire nCPAP Generator & Cloverleaf Curly Wire Breathing Circuit	IHC4112/20
Inspire nCPAP Generator & Cloverleaf Curly Wire Breathing Circuit with Humdifier Chamber	IHC4113/10

Interface Description	Bonnet Product Code
Bonnets	
Inspire nCPAP Bonnet - White (16-18cm)	IHCWH000/10
Inspire nCPAP Bonnet - Grey (18-20cm)	IHCGY00/10
Inspire nCPAP Bonnet - Pink (20-22cm)	IHCPK0/10
Inspire nCPAP Bonnet - Brown (22-24cm)	IHCBR1/10
Inspire nCPAP Bonnet - Yellow (24-26cm)	IHCYE2/10
Inspire nCPAP Bonnet - Blue (26-28cm)	IHCBL3/10
Inspire nCPAP Bonnet - Gold (28-30cm)	IHCGO4/10
Inspire nCPAP Bonnet - Green (30-32cm)	IHCGR5/10
Inspire nCPAP Bonnet - Burgundy (32-34cm)	IHCBU6/10
Inspire nCPAP Bonnet - Orange (34-36cm	IHCOR7/10
Inspire nCPAP Bonnet - Dark Green (36-38cm)	IHCDG8/10
Inspire nCPAP Bonnet - Navy (38-40cm)	IHCNA9/10

Interface Description	Mask and Prongs Product Code
Mask and Prongs	
Inspire nCPAP Extra Small (XS) Nasal Prong - Green	IHC604/10

Interface Description	Mask and Prongs Product Code
Mask and Prongs	
Inspire nCPAP Small (S) Nasal Prong – Red	IHC605/10
Inspire nCPAP Medium (M) Nasal Prong – Blue	IHC606/10
Inspire nCPAP Large (L) Nasal Prong – Purple	IHC607/10
Inspire nCPAP Small (S) Nasal Mask – Red	IHC609/10
Inspire nCPAP Medium (M) Nasal Mask – Blue	IHC610/10
Inspire nCPAP Large (L) Nasal Mask – Purple	IHC611/10
Inspire nCPAP Extra Large (XL) Nasal Mask – White	IHC612/10

22.10 Support documentation

TS-SVM-000002 - SLE1500 Service Manual – English
RA-IFU-000031 - SLE1500 Quick Start Guide – English

Please contact SLE for further information and advice - info@inspiration-healthcare.com

SLE reserves the right to make changes without prior notice in equipment, publications and prices as may be deemed necessary or desirable.

Revision History

Rev.	Date	Change ref.
1	03/11/2020	Initial issue.
2	16/11/2020	CR 3047
3	20/11/2020	CR 3055
4	15/12/2020	CR 3100
5	15/11/2022	CR 3468 CR 3715
6	25/10/2023	GCC-00001 DP62
7	28/02/2024	CR-00052
8	01/12/2025	CR-00109 CR-00129 CR-00142 CR-00143 CN-005463 CN-006411 J-3556 J-3600 J-3873 DP62 V.6
9	24/12/2025	CR-00149

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