

nice Neötech Medical Systems Pvt. Ltd.

nice 5040 – Oxygen analyzer



OPERATING/INSTALLATION MANUAL

This operating manual provides all the information necessary for the user to safely set up and operate this equipment. It is the responsibility of the user to follow the instructions and recommendations provided.

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User Responsibility / Operator Profile

This Product will perform in conformity with the description thereof contained in this operating manual and accompanying labels and/or inserts, when assembled, operated, maintained and repaired in accordance with the instructions provided. This Product must be checked periodically. A defective Product should not be used. Parts that are broken, missing, plainly worn, distorted or contaminated should be replaced immediately. Should such repair or replacement become necessary, nice Neotech recommends that a telephone or written request for service advice be made to the nearest nice Neotech Regional Service Center.

This Product or any of its parts should not be repaired other than in accordance with written instructions provided by nice Neotech and by nice Neotech trained personnel. The Product must not be altered without the prior written approval of nice Neotech's Quality Assurance Department. The user of this Product shall have the sole responsibility for any malfunction which results from improper use, faulty maintenance, improper repair, damage, or alteration by anyone other than nice Neotech.



Warning

Warning: Before using the nice Neotech Oxygen Analyser, read this entire manual. Attempting to use this device without a thorough understanding of its operation may result in patient or user injury. This device should only be operated by personnel trained in its operation and under the direction of qualified medical personnel familiar with the benefits and risks of this type of device.

Declaration for Languages

User Manual and label will be provided in the appropriate language to ensure that the user understands. Language validation will be done for the language of the user manual, Label, Corresponding documents, when nice Neotech Medical Systems Private Limited supplies to EU countries.

Model Descriptions

nice 5040 Oxygen analyser.

Definitions

- a. **CAL:** Calibration.
- b. **Select:** choose the Audio and Visual Indication setting
- c. **Self-Test:** Booting the equipment to check the internal peripheral.
- d. **Sensor Fail:** Error message for Temperature sensor fail.

Definition of Warning indication

Three levels of warning indication are used throughout this manual and on the unit. They are defined as follows,

A **DANGER** notice indicates an immediately hazardous situation which, if not avoided, will result in death or serious injury, serious damage to property such as total loss of use of equipment, and a fire.

A **WARNING** notice indicates an indirectly (Potentially) hazardous situation which if not avoided, will result in Death or Serious injury, serious damage to property such as total loss of use of equipment, and a fire.

A notice indicates a hazardous situation which, if not avoided can result in minor or moderate injury, Partial damage to property and loss of data stored in computers.

Section A: Warnings














- Before using the nice Neotech oxygen analyser, read this entire manual. Attempting to use this device without a thorough understanding of its operation may result in patient or user injury. This device should only be operated by personnel trained in its operation and under the direction of qualified medical personnel familiar with the risks and benefits of this type of device.
- Do not use the oxygen analyser in the presence of flammable anesthetics; a possible explosion hazard exists under these conditions.
- In a dust free area, keep hands clean and then install the equipment.
- Do not perform the Checkout Procedures (Mechanical and Control Unit) with a patient.
- Complete the “Checkout Procedures” section of this manual before putting the unit into operation. If the oxygen analyser fails any portion of the checkout procedures it must be removed from use and repaired.
- There is a possibility of electromagnetic interference or other interference causes from other external equipment, the oxygen analyser may get in operation. Use EMC compliance Equipment to avoid the interference
- The oxygen analyser may cause radio interference, in which case adequate measure may be required to prevent interference
- even Small quantity of flammable agents such as ether and alcohol, left in the oxygen analyser it can cause fire in connection with oxygen.















Section B: Cautions

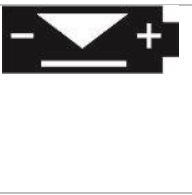


- Isolation from the supply mains is Detachable charger provided
- Use cleaning solution sparingly on a cloth when cleaning the oxygen analyser. Do not saturate the unit - excessive solution causes damage to internal components.
- Do not autoclave or gas sterilize the oxygen analyser & sensor. Do not immerse the device & sensor in liquid cleaner.
- Only competent individuals trained in the repair of this equipment should attempt to service it as detailed in the service manual. The Service Manual provides detailed information solely for use by individuals having proper knowledge, tools and test equipment, and for service representatives trained by nice Neotech.
- The equipment may affect while using the defebulator.
- **Use of nonstandard components:** Consult the manufacturer for repair and replacement of components. Use of incorrect component can adversely affect Safety, performance and/or damage the equipment performance.
- Clean surface using wet cloth dipped in mild soap water and squeeze dry excess water before use.
- Do not allow water to spill into equipment.
- Avoid using any solvent, spirits, alcohol to clean plastic parts.
- Do not use water or any other liquid to clean Electronics and Electrical par

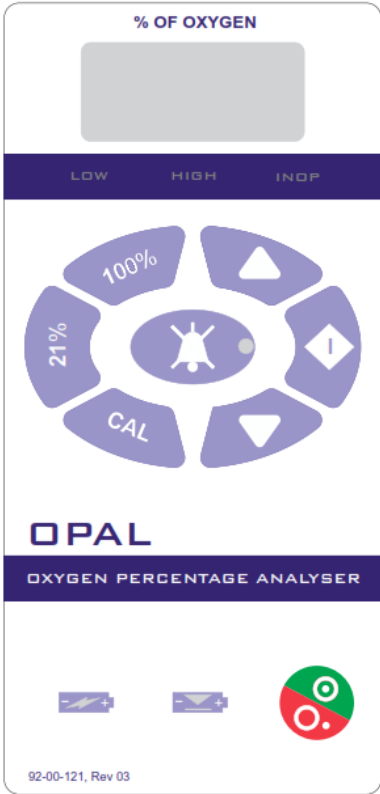
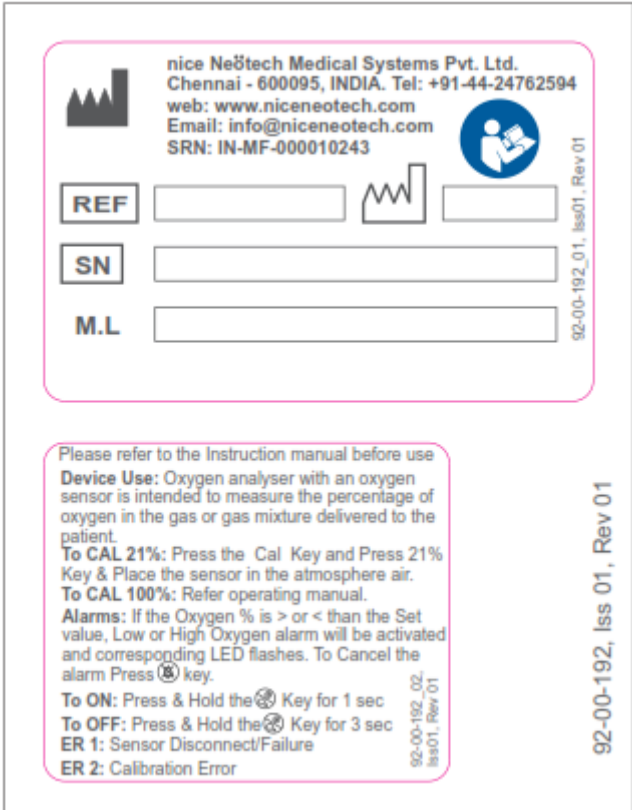
Section C: Symbols & Labels

| Mark | Indication |
|---|---|
|  | Caution |
|  | Caution, electric shock |
|  | Caution, ignition (Indicates possible ignition under certain condition) |
|  | Warning |
|  | Warning, Do not touch |
|  | Warning, Don't use fire |
|  | Protective Earth (ground) |
|  | Alternating current |
|  | Off (Power: disconnection from main) |
|  | On (Power: connection to the main) |
|  | "Off" (only for a part of Equipment) |

| | |
|---|---|
|  | “On” (only for a part of Equipment) |
|  | Audio and Visual Indicator |
|  | Audio Indication Silence |
|  | Serial Number |
|  | Authorised Representative in European Community |
|  | Date of Manufacture |
|  | Manufacturer |
|  | Catalogue Number |
|  | Refer Instruction for use |
|  | Drip proof protection to IPX1 |
|  | Type B Equipment |
|  | Mute Key |
|  | Select Key |
|  | ON/OFF Key |

| | |
|---|------------------------|
|  | Charging Indication |
|  | Low Battery Indication |

Labels

| Label | Description |
|---|---|
|  | <p>Label front panel 5040</p> |
|  | <p>Label 5040 – Oxygen analyzer instruction</p> |

Section 1: Description

1.1 Indication

Oxygen analyser can be used to measure oxygen in any condition which deals with oxygen.

1.2 Contraindication

There is no such contraindication associated with the use of oxygen percentage analyser

1.3 Intended Use

The oxygen analyser is a device with an oxygen sensor intended to measure the percentage of oxygen in the gas or gas mixture delivered to the patient.

1.4 General

Neotech oxygen analyser measures a oxygen percentage in the delivered gas to the patient. The control system uses a microprocessor. The audio and visual Audio and Visual Indication system is included on the front panel. The Audio and Visual Indication setting can be adjusted by the select key.

1.5 Control Unit

The mill volt output signal from the sensor is fed into the electronic signal processor, where it is used to calculate the oxygen gas concentration and display it on the LED screen. The data from the sensor is compared to the Audio and Visual Indication values set by the user, and activates the audible and visual Audio and Visual Indication if the oxygen level exceeds those values. Sensor fail/disconnect Audio and Visual Indication is incorporated in the oxygen analyser to warn the user of a sensor problem. The ER-1 indicator is illuminated on the LED and the audible and visual Audio and Visual Indication are activated whenever a sensor fault is detected.

Section 2: Installation

2.1 Setup

After removal from the shipping containers, inspect the oxygen analyser and all accessory items for any signs of damage which may have occurred during shipment. File a damage claim with the shipping carrier if damage has occurred. Also confirm the presence of all accessory items or factory installed options as listed on the packing slip.

2.2 Installation of battery



Picture 1

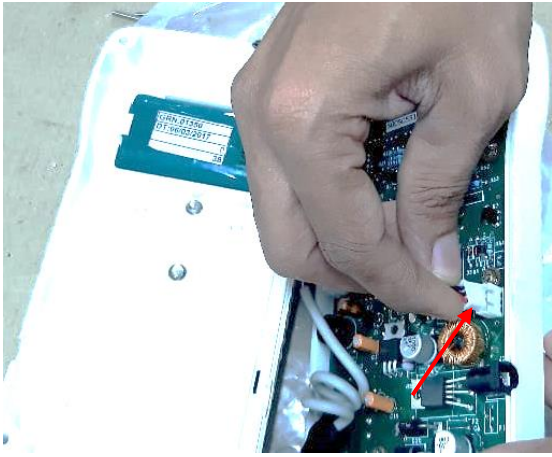
- Remove the rear housing by unthreading the screws using flat screwdriver.



Picture 2

- Then, place rechargeable battery provided in the rear housing.
- Use the screwdriver to place the battery in the groove/space provided for the battery.

Note: Ensure the flat side of the battery is facing upwards.



Picture 3

- Now, connect the 3 pin RMC connector from the battery to the PCB on the front housing.
- Then close the rear housing and put the screws.

Note: Ensure the battery and connector is placed properly before closing the lid.

2.3 Installation of Oxygen sensor



Picture 4

- Plug one end of the coiled cable into the jack receptacle on the back end of the sensor and secure in place with the capture nut located at the base of the connector.



Picture 5

- Plug the other end of the cable to the oxygen analyzer.

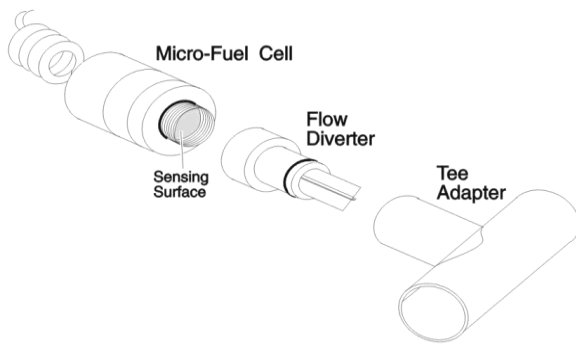
Note : Oxygen sensor must be installed before the oxygen analyzer/monitor can be operated



Warning

- Remove the new sensor from its protective bag. Inspect the sensor for damage or electrolyte leakage. If the sensor is damaged, obtain a replacement. Do not use the defective sensor as it may damage the unit.
- The sensor electrolyte is caustic. Do not let it come in contact with skin. If it does, flush affected area with water. Do not attempt to open or repair the sensor.
- The sensor also contains lead. Leaking or exhausted sensors should be handled and disposed of in accordance with local regulations.

2.4 Oxygen sensor mounting in Tee Adapter



Picture 6

- When the oxygen analyser is used for diffusion sampling (i.e., incubators, oxygen hood, oxygen tents, etc.), the plastic flow diverter must be removed from the sensor. If the sensor is used in breathing circuits, etc, the diverter must be used.

2.5 Charging of Oxygen Analyser



Picture 7

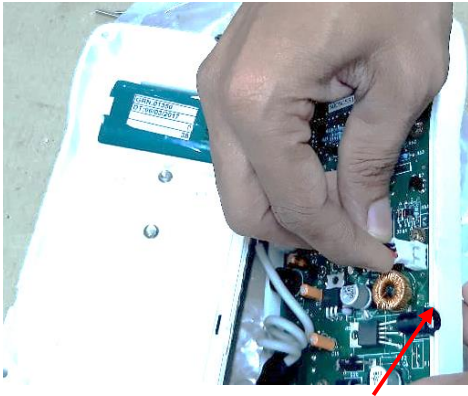
- For the initial charging keep the device for charging continuously 12 hours up to the green LED flashes

2.6 Removal of battery



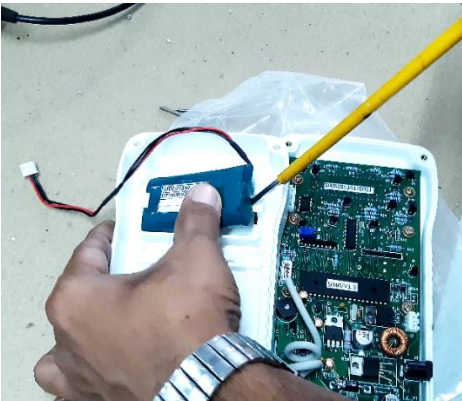
Picture 8

- Remove the rear housing by unthreading the screws using flat screwdriver.



Picture 9

- Now, unplug the 3 pin RMC connector from the PCB on the front housing.



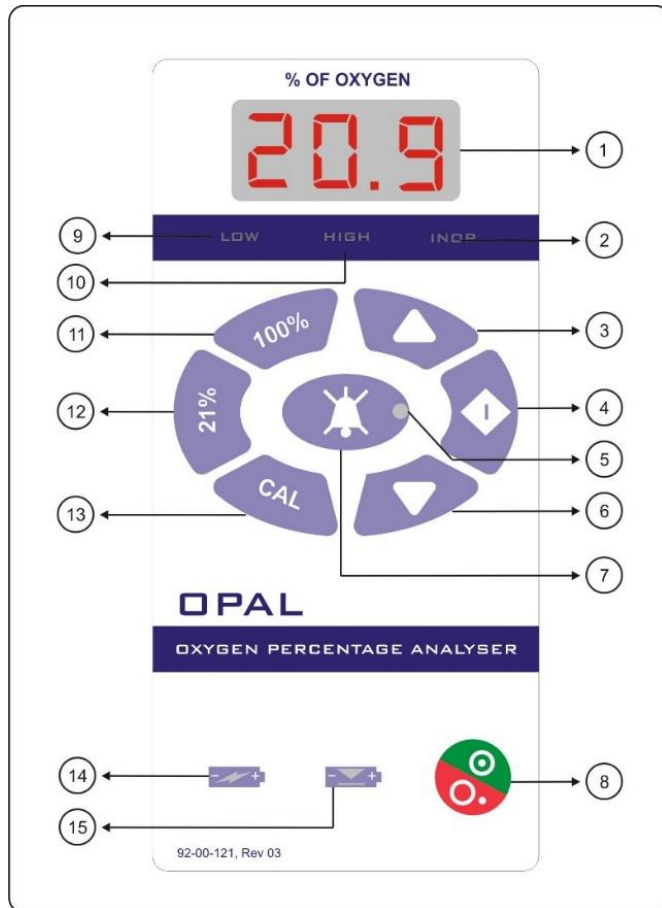
Picture 10

- remove rechargeable battery provided from the rear housing.
- Use the screwdriver to remove battery from the groove/space provided for the battery.
- Then close the rear housing and put screws.

To reinstall battery, refer section 2

Section 3: Operation

3.1 Control Panel Operation



Front Panel Button and Indicators

| | | | |
|---|------------------------------|----|------------------------|
| 1 | Percentage of Oxygen Display | 9 | LOW Indication |
| 2 | INOP Indication | 10 | High Indication |
| 3 | Increase Key | 11 | 100% Calibration Key |
| 4 | Select Key | 12 | 21% Calibration Key |
| 5 | Mute ON Indication | 13 | Calibration Key |
| 6 | Decrease Key | 14 | Charging Indication |
| 7 | Mute Key | 15 | Low Battery Indication |
| 8 | ON/OFF Key | | |

3.2 Calibration

The oxygen analyser should be calibrated before each use and every 8 hours to maintain accuracy for continuous use.

Whenever new batteries are installed or removed for any reason, the oxygen monitor defaults to the calibration mode with the LED display flashing CAL and 21. Only the 21% and ON/OFF keys are functional at this point.

Note: For first time and for routine maintenance calibrations, make sure the sensor and sensor cable are installed correctly before attempting to calibrate the instrument

3.2.1 21% Calibration:

3.2.1.1 Setup:

- Place the oxygen sensor in the open atmosphere air

3.2.1.2 Calibration:

- Turn the unit on by pressing the ON/OFF key, LED screen displays flashes CAL and 21%.
- Presses CAL key first then press 21% Key, LED screen flashes 21 wait for 30 second, ensure the oxygen sensor keep in the atmosphere air.
- After 21% calibration process completed the display screen shows the percentage of oxygen in the atmospheric air

Note: A single point air calibration is not recommended unless the sensor can be exposed to a known source of fresh outdoor air. Hospital room air is often enriched with excess oxygen, which will introduce errors into the calibration. Air calibration should only be used for monitoring oxygen levels between 21% and 40% and should never be used where a high degree of accuracy is needed.

Note: Never calibrate the unit in humidified gas, as water vapor makes the oxygen concentration appear lower than it really is. See Appendix: Humidity.

Note: The oxygen analyser can only be calibrated using 100% oxygen or room air 20.9%. Improper calibration or use of other gas concentrations will activate the calibration error (ER2). To repeat the calibration press the CAL key.

3.2.2 100% Calibration:

3.2.2.1 Setup:

- As with most oxygen analyzer(s) the highest level of accuracy is achieved when calibration is conducted using 100% oxygen. After installing the flow diverter as noted in Section 2.3, insert the sensor into the plastic tee and connect to a supply of pure dry oxygen flowing at 1-2 liters per minute

3.2.2.2 Calibration:

- Press CAL key, the LED screen flashes CAL
- Press 100% Key , LED screen flashes 100 wait for 60 second, ensure the oxygen sensor keep in the 100% oxygen gas source.
- After 100% calibration process completed the display screen shows the percentage of oxygen in the gas.

Note: An accessory 100% calibration kit is available as an option for use with the sensor.

Note: It is important to perform the calibration carefully and thoroughly, using calibration gases that are free

from contaminates. Wait for a stable reading before locking in calibration point. The accuracy of the instrument is only as good as the procedure used to calibrate it.

3.3 Audio and Visual Indication

3.3.1 O₂ % High Audio and Visual Indication:

- By using the Select key choose the high Audio and Visual Indication setting.
- By using the increase and decrease key until the desired value is displayed in the LED Screen.
- Press the select or wait for seven second to exit.

3.3.2 O₂ % Low Audio and Visual Indication:

- By using the Select key choose the low Audio and Visual Indication setting.
- By using the increase and decrease key until the desired value is displayed in the LED Screen.
- Press the select or wait for seven second to exit.

Note: The Oxygen analyser is designed to prevent crossing of HI/LO Audio and Visual Indication settings. If the user attempt to set the LO Audio and Visual Indication higher than the HI Audio and Visual Indication, it will not allow to the LO Audio and Visual Indication set point. This also applies when attempting to set the HI Audio and Visual Indication lower than the LO Audio and Visual Indication.

3.3.3 Sensor Error

- If the sensor defects or disconnect, the display screen shows ER1 with INOP LED will be activated

3.3.4 Calibration Error

- If the calibration fails, the display screen shows ER2 with INOP LED will be activated

3.3.5 Audio and Visual Indication Silence

- To silence the Audio and Visual Indication buzzer for 2 minutes press the mute key, the LED indicator will be ON.

3.4 Application

3.4.1 Procedure

Note: Prior to use, always test the batteries and Audio and Visual Indication. Also check calibration, the sensor for leaks and damage, and the Audio and Visual Indication settings.

The oxygen analyser can be used to measure a gas mixture for oxygen in two basic modes:

- In the inhalation side of breathing circuit ahead of antibacterial filters, humidifiers and medicating devices.
- In confined volumes such as incubators, oxygen hood or oxygen tents.

When monitoring for oxygen in breathing circuits, the flow diverter must be used. The diverter should be screwed onto the threaded front end of the sensor. A tee adapter should be placed into the circuit, and the above sensor assembly plugged into the tee adapter. See Figure 2.

**Caution**

- Check the breathing circuit for leaks. Be certain that the circuit downstream of the sensor does not produce any backpressure or restriction to flow. Errors in readings will result if this is not followed.
- The oxygen sensor is a non-sterile device and should be used in conjunction with an antibacterial filter. Always install the sensor on the inspired line ahead of filters, humidifiers and medicating devices. Never expose the sensor to patient's exhaled breath or secretions unless you intend to dispose of the sensor and flow adapter after use.
- When monitoring for oxygen in confined volumes such as incubators, hoods, etc., the flow diverter must be removed from the sensor so that it does not interfere with the rapid exchange of gases to and from the sensing surface of the sensor.
- Failure to remove the diverter in these application areas will result in a marked lowering of the response time of the sensor.
- The sensor can be placed or hung inside incubators, tents, etc. When it is necessary to thread the cable through a small hole in order to gain access to the inside of a chamber, the cable should be disconnected at the sensor, threaded through the hole, and reconnected inside the chamber.
- Note: Never calibrate the unit in humidified gas, as water vapor makes the oxygen concentration appear lower than it really is. See Appendix: Humidity.

3.5 Factors Influencing Calibration

The primary factors influencing the oxygen analyser are temperature, pressure, and humidity.

3.5.1 Effects of Humidity

Humidity does not directly affect the accuracy of the sensor's measurement. However, when a nebulizer or other device is used to increase moisture levels in gas mixtures, the moisture actually dilutes the mixture. This dilution effect decreases the oxygen concentration.

For example, if an 80% oxygen gas mixture is humidified to saturation at room temperature, the resulting gas mixture will contain only 77.5% oxygen. Your portable oxygen monitor accurately measures decreases in the oxygen concentration due to the dilution effects of moisture added to gas mixtures.

As with all oxygen sensors, excessive condensation on the sensing surface of the sensor will block the diffusion of oxygen to the sensor, rendering it inoperative. We recommend installing the sensor on the dry side of the breathing circuit at all times.

3.5.2 Effects of Temperature

The oxygen analyser will hold calibration and read correctly within $\pm 3\%$ when in thermal equilibrium within the operating temperature range. The device must be thermally stable when calibrated and allowed to thermally stabilize after experiencing temperature changes before readings are accurate. For these reasons, the following is recommended:

- Allow adequate time for the sensor to equilibrate to a new ambient temperature.
- When used in a breathing circuit, place the sensor upstream of the heater.
- For best results, perform the calibration procedure at a temperature close to the temperature where analysis will occur.

3.5.3 Effects of Pressure

Readings from the oxygen analyser are proportional to the partial pressure of oxygen. The partial pressure of Oxygen (PO₂) is equal to the percentage of oxygen (%O₂) times the absolute pressure (AP) at which the sample environment is measured. (PO₂=%O₂ x AP) (AP=0.11 atmosphere) Thus the readings are proportional to the concentration if the pressure is held constant. Flow rate of sample gas can affect pressure at the sensor in that back pressure at the sensing point may change. For these reasons, the following is recommended:

- Calibrate the oxygen analyser at the same pressure as the sample gas.
- If sample gases flow through tubing, use the same apparatus and flow rates when calibrating as when measuring.
- The oxygen analyser oxygen sensor has been validated at pressures up to 2 atmospheres absolute. Calibration or operation above this pressure is beyond the intended use.

3.6 Discrepancy in Readings

The oxygen analyser should be used to measure the oxygen concentration exiting another oxygen mixing device or life support system (i.e., a blender, incubator or anesthesia machine). The information obtained from the oxygen analyser should never be used to adjust a life-support system, but should only be used as an indication that the life support system or device may require service and/or calibration.

When a discrepancy in oxygen readings is detected, the oxygen analyzers readings should be verified by checking the oxygen analyser battery condition and calibration using 100% Oxygen. If the monitor can be calibrated, the unit can be assumed to be in good working order and capable of providing readings to specification. If, after reinstalling the unit, the discrepancy in oxygen readings persists, the problem is most likely elsewhere (i.e., flow blockage, primary device error, etc.). Further investigation should be made until the discrepancy in readings is resolved. The troubleshooting section of this manual may provide additional assistance in locating the problem.

3.7 Anaesthetic Gases

3.7.1 Gases that induce reading error

When using the oxygen sensor in the presence of anaesthetic gases such as Halothane, the oxygen reading may fall (see Table below). The magnitude of this error will depend upon the level of oxygen and the duration of exposure.

The anesthetic agents listed in the following table (Halothane, Enflurane, Isoflurane, Sevoflurane, and Desflurane) were vaporized into a stream of 30% oxygen / 70% nitrous oxide, and the resulting drops in oxygen level after an exposure of approximately two hours were noted.

Exposures in excess of two hours may produce slightly greater errors. The errors listed are typical for all oxygen sensors. Exposing the sensor to air or gases that do not contain anesthetic agents for a period of time equal to or greater than the exposure interval will eliminate the reading error in most cases.

Table 2-1: Oxygen Reading Error in a Mixture of Anesthetic Gas

| Gas or Vapor Level | | |
|--------------------|-----------------------------|----------------------|
| Gas or Vapor | Test Level | Oxygen Reading Error |
| Helium | 50%, balance O ₂ | 0% |
| Nitrous Oxide | 80%, balance O ₂ | 0% |

| | | |
|----------------|-----------------|-------------|
| Carbon Dioxide | 10%, balance O2 | 0% |
| Halothane | 4% | < 1.5% O2 * |
| Enflurane | 5% | < 1.5% O2 * |
| Isoflurane | 5% | < 1.5% O2 * |
| Sevoflurane | 5% | < 1.5% O2 * |
| Desflurane | 15% | < 1.5% O2 * |

* Errors are approximate and may vary based on exposure times and concentrations.

These performances meet or exceed the requirements of ISO 7767:1997 (E).



Caution

The oxygen analyser should not be used in the presence of flammable anesthetics such as diethyl ether or cyclopropane.

The Oxygen analyser, oxygen sensor and associated hardware are non-sterile devices Do not autoclave the instrument or sensor, as this will damage the equipment.

3.8 Care after use in nitrous oxide

Caution: The oxygen sensor should not be left in nitrous oxide mixtures any longer than absolutely necessary.

After exposure to nitrous oxide mixtures, the sensor should be left in 100% oxygen overnight (e.g., left in a breathing circuit that has been flushed with pure oxygen). If this is not practical, when using the Tee, remove the plastic flow diverter and leave the sensor in room air. If the oxygen reading continues to drop after each use in nitrous oxide the sensor should be removed from usages. If the sensor can no longer be calibrated or if there is any sign of electrolyte leakage, the sensor should be disposed of in accordance with local regulations.

Section 4: Cleaning & Maintenance



Warning

- Periodically check the insulation and the connection of the charger cable it may cause fire because of poor insulation and short circuits due to aging.
- Switch off the equipment and disconnect the Power cord from the mains before take in to cleaning
- Don't pour the water for cleaning it may enter into the electronics circuits it cause short circuit and get shock.



Caution

- Use the cleaning solution sparingly on a cloth when cleaning the oxygen analyser. Do not saturate the unit - excessive solution causes damage to internal components.
- **Use of nonstandard components:** Consult the manufacturer for repair and replacement of components. Use of incorrect component can adversely affect Safety, performance and/or damage the equipment performance

4.1 Cleaning and Disinfection of Oxygen Analyzer

During cleaning the Oxygen Analyzer, the processing shall comply with EN ISO 17664:2017 for reusable of the device

1. Clean the equipment with dampened cloth using soap (e.g. liquid dish soap) and clean water.
2. Rinse the equipment completely with water dampened cloth.
3. Disinfect the equipment by using 2% Glutaraldehyde to inactivate any remaining pathogens.
4. After every treatment, all approachable external surfaces should be cleaned daily with an antiseptic solution like 2% glutaraldehyde for **3 minutes**. All detachable assemblies, are to be treated similarly
5. Rinse with dampened cloth using sterile or clean water (i.e. water boiled for 5 minutes and cooled). Sterile water is preferred for rinsing off residual liquid chemical disinfectant from Oxygen Analyzer that has been chemically disinfected for reuse, because tap or distilled water may harbour microorganisms. However, when rinsing with sterile water is not feasible, instead, rinse with tap water or filtered water (i.e. water passed through a 0.2 µ filter).
6. Dry Oxygen Analyzer using dry towel or cloth.



Caution

- Use of cleaning/disinfecting solutions containing chemicals that are not listed above (i.e. alcohol, acetone, etc.), or chemicals in greater concentrations than those listed above, may damage the Fiber optic cable or other material being cleaned.
- Do not autoclave or gas sterilize oxygen analyser and oxygen sensor.
- The instruction below describes the methods to clean and disinfect the instrument, sensor and its accessories (e.g. diverter, tee adapter).

4.2 Cleaning and disinfection of Sensor, cable, diverter & tee adapter

1. Physically clean the Sensor, cable, diverter & tee adapter with soft cloth, removing all visible contaminants by wiping using water general cleaning.
2. When the equipment is not in use, Sensor, cable, diverter & tee adapter surfaces should be cleaned daily with an antiseptic solution like 2% glutaraldehyde and leave for 3 minutes.
3. Then rinse the Sensor, cable, diverter & tee adapter by wiping using water damped cloth
4. Dry Sensor, cable, diverter & tee adapter using dry towel or cloth

Note: Only the external surface of the sensor should be cleaned and disinfected.

4.3 Lifetime of product

Since the product is classified under programmable medical electrical system and in case of unavailability of microcontroller the life time of the product can be considered as minimum five years.

4.4 Do's and Don'ts

DO

- Read all of the directions before using for the first time.
- Calibrate every 8 hours or before every use.
- Visually inspect the sensor for leakage before each use.
- Calibrate using 100% oxygen and check in air.
- Check the HI and LO Audio and Visual Indication settings prior to each use.
- Test batteries regularly and charge the device when battery indicator shows low battery
- Keep the unit, sensor and connections dry, or on the dry side of the breathing circuit.
- Recalibrate after replacing the batteries.
- Recalibrate after replacing the sensor.
- Make sure the sensor is properly attached.
- Remove the plastic flow diverter only when using the tee adapter.
- Remove and save the plastic flow diverter when using the sensor in non-flowing applications (incubators, oxygen hood, tents, etc.)
- Clean the case with isopropyl alcohol or mild detergent only

DON'T

- Use this analyser if you suspect any malfunction.
- Use the device in the presence of flammable gases.
- Use alkaline batteries.
- Autoclave or freeze the sensor or device.
- Open or try to repair a leaking or broken sensor.
- Immerse the unit or sensor in any liquid.
- Pass hot or cold gas mixtures over the sensor.
- Expose the unit to devices that produce high levels of radio, short wave, microwave, x-ray, or high frequency interference.
- Use cleaning agents or liquids in the cable receptacles or around the battery compartment
- Place the unit itself in a water vapour-saturated environment.
- Expose the unit to a condensing water environment such as a mist tent.

Section 5: Specifications

| | |
|---|---|
| Monitoring Range | : 0-100% Oxygen |
| Display | : Hi-Bright LED Display |
| Resolution | : 0.1% |
| Accuracy | : $\pm 2\%$ |
| Response Time | : 90% of Final Value <15 seconds at 23° C |
| Warm-up Time | : not required |
| Cable length | : 10 ft. fully extended |
| Battery | : 7.2VDC Rechargeable |
| Operation | : Battery / Main Supply |
| Sensor Fail | : Sensor disconnects / defect |
| O2 High Audio and Visual Indication Range | : 19 to 100% |
| O2 Low Audio and Visual Indication Range | : 18 to 99% |
| Calibration and Diagnostics | : Auto |
| Sensor Life | : 18 months in air/Oxygen |
| Dimensions | |
| Weight | : 450 grams |
| Compliance | : ISO 80601-2-55:2018 |

Environment

| | |
|-----------------------------|-------------------------------|
| Operating Temperature | : 15°C to 35°C |
| Operating Relative Humidity | : 15 – 90% RH, non condensing |
| Storage Ambient Temperature | : -10°C to 60°C |
| Storage Relative Humidity | : 50 - 90% RH, non-condensing |
| Altitude | : Sea level to 1.9 miles 3 Km |
| Quality & Test Approval | |
| Quality | : 13485: 2016 |
| Electrical & Product Safety | : IEC 60601-1 |
| EMC Safety | : IEC 60601-1-2 |

Handling and Storage:

The label contains the following information and symbols:

- REF** -
- REF** -
- Module -
- HANDLE WITH CARE**
LIFE SAVING MEDICAL EQUIPMENT
- Temperature control icons: a thermometer with 40°C and -10°C, and a circular icon with 95% and 90%.
- Manufacturer: nice NeTech Medical Systems Pvt. Ltd., No 85, Krishna Industrial Estate, Vanagaram, Mettukuppam, Chennai - 600095, INDIA.
- Supplier: CMC Medical Devices & Drugs S.L., C/Horacio Lengo N°18, CP 29006, Málaga-Spain. Tel: +34951214054, mmateos@cmcmedicaldevices.com, www.cmcmedicaldevices.com.
- EC REP** logo.
- Information icon (i).
- Prohibited disposal icon (X).
- Stacking icon (4).
- Upright icon (↑↑).
- Wine glass icon (fragile).
- Umbrella icon (keep dry).
- Recycling icon.
- Hand icon (2).
- RoHS icon.
- STERILE icon.

Section 6: Warranty

1. The warranty is confined to the first purchaser of the product only and is not transferrable.
2. Repairs under warranty period shall be carried out by the company authorized personnel only
3. In the event of repairs of any part/s of the unit, this warranty will thereafter continue and remain in force only for the unexpired period of the warranty. The time taken for repair and in transit whether under the Warranty or otherwise shall not be excluded from the warranty period.
4. In case of any damage to the product/misuse detected by the Authorized service personnel the Warranty conditions are not applicable and repairs will be done subject to availability of parts and on a Chargeable basis only
5. Wear and Tear, and defects caused by manipulation or unsuitable treatment are not included under the Warranty.
6. Battery carries only 3 months warranty.
7. We warranty this unit for 12 months from the date of Installation. Warranty includes the repair and Replacement of faulty components.
8. Defects caused by improper use, and defects due to causes beyond control like lightning, abnormal Voltage, acts of god, and also defects caused by rats, cockroaches or any other insects will not be Covered under warranty.
9. Warranty is not applicable if the equipment is not purchased from Neötech/authorized Neotech Dealer
10. Warranty is not applicable if the warranty card is not filled and sent back to Neotech.
11. Equipment has an expected shelf life of 5 years and service life of 6 years.

Customer Details cum Warranty CardHospital Name & Address: _____

Contact Person & Telephone/Fax No _____

Email _____

Department: NICU / PICU / OT / Gynaecology / Causality / Others _____

Equipment Name: _____

Model No: _____ Sl. No. _____

Date of Purchase: _____ Date of Installation _____

Name of Authorized Dealer: _____

Customer Signature & Date Dealer Signature with seal

Date: _____

(I accept the terms & conditions of Warranty)

Kindly fill the above and send the sameFrom _____

To:

The Service In-charge
nice Neotech Medical Systems Pvt. Ltd.
No, 85. Krishna Industrial Estate,
Vanagaram, Mettukuppam,
Chennai-600095. Tamil Nadu, INDIA
Ph: 91-44-24762594, 24764608
Tele Fax: 91-44-24766920 – Ext: 203
Email: service@niceneotech.com,
info@niceneotech.com
Web: www.niceneotech.com
Toll Free No. 1800-425-2594 (India only)

Section 7: Trouble Shooting

7.1 General System Failure

| | |
|------------------------------------|--|
| No display on the control panel | Check A/C Supply Voltage |
| | Check if Power Cord is disconnected |
| | Check Fuse in the left side |
| | Otherwise, Contact nice Neötech |
| Weight error | Check whether the pan is fixed properly in the machine |
| | Check the pan if any damages in the 4 knob |
| | Otherwise, Contact nice Neötech |
| Bubble indicator not in the centre | Check the table where the machine is placed; Ensure that the table has no movements. |
| | Adjust the knob at down of the machine by using the 10 / 11 spanner |
| | Otherwise, Contact nice Neötech |

7.2 Maintenance levels

Always disinfect and clean the unit and accessories before any maintenance – even when returning the unit to the supplier for repair.

- Always disconnect power supply before any maintenance.
- Use only nice Neötech's original parts for maintenance.



Warning

- Periodically check the insulation and the connection of the cable it may cause fire because of poor Insulation and short circuits due to aging.
- Don't misalign the EMI Shielding and the beads it may cause the EMI interference to the equipment.
- To visually inspect the panels every day, whether it is properly fixed or breakages or lose.

Measurement specific to unit:

Inspection & Maintenance: Yearly by trained service personnel.

7.3 Disposing of the Unit

- At the end of its Service life Dispose of the equipment in accordance with National waste Disposal Regulations or ask a suitable Disposal contractor for disposal of the unit.
- The local Environmental agency can give further details.

Caution: Use of nonstandard components: Consult the manufacturer for repair and replacement of Components. Use of incorrect component can adversely affect Safety, performance and/or damage the Equipment performance

Section 8: Spare Parts List

| Sl. no | Part number | Part Name | Qty | UOM |
|--------|-------------|---------------------------------|-----|-----|
| 1 | 10-05-007 | PCB Control Assembly | 1 | NO |
| 2 | 96-00-004 | Weigh scale pan | 1 | NO |
| 3 | 91-00-023 | Fuse holder 5A small close | 1 | NO |
| 4 | 91-00-041 | Connector PG 7 | 1 | NO |
| 5 | 91-00-001 | Switch MRS -101 SPST | 1 | NO |
| 6 | 99-00-038 | Oxygen analyzer pan Bush Holder | 1 | NO |
| 7 | 91-00-147 | Transformer R5 12V , 0.5A | 1 | NO |
| 8 | 89-16-007 | 5A small Fuse | 1 | NO |

Service contact:



Niceneotech Medical Systems Pvt. Ltd.

No. 85, Krishna Industrial Estate, Vanagaram,
Mettukuppam Chennai-600095. Tamil Nadu, INDIA.
Ph: 91-44-2476 4608 Telefax: 91-44-2476 2594
E-mail: service@niceneotech.com / info@niceneotech.com
Web: www.niceneotech.com

EU Authorised Representative CMC Medical Devices

Located in C/Horacio Lengo N° 18
P 29006, Malaga – Spain
Mr. Manuel Mateos
Manager – Regulatory Affairs
Tel: +34951214054
Fax: +34952330100
mmateos@cmcmedicaldevices.com
www.cmcmedicaldevices.com

Section 9: Manufacturer's EMC Declaration

| Guidance and manufacturer's declaration – electromagnetic emissions | | |
|---|------------|--|
| The Oxygen analyzer is intended for use in the electromagnetic environment specified below. The customer or the user of the Oxygen analyzer should assure that it is used in such an environment. | | |
| Emissions test | Compliance | Electromagnetic environment – guidance |
| RF emissions CISPR 11 | Class A | Oxygen analyzer is used in professional hospital environment |
| Harmonic emissions IEC 61000-3-2 | Class A | |
| Voltage fluctuations/ flicker emissions IEC 61000-3-3 | Complies | |

| Guidance and manufacturer's declaration – electromagnetic immunity | | | |
|---|---|------------------|--|
| The Oxygen analyzer is intended for use in the electromagnetic environment specified below. The customer or the user of the Oxygen analyzer should assure that it is used in such an environment. | | | |
| IMMUNITY test | IEC 60601 test level | Compliance level | Electromagnetic environment – guidance |
| Electrostatic discharge (ESD) IEC 61000-4-2 | ± 8 kV contact ± 15 kV air | Criteria C | Floors should be wood, concrete or ceramic tile. If floors are covered with Synthetic material, the relative humidity should be at least 30 %. |
| Electrical fast transient. IEC 61000-4-4 | ± 2 kV for power supply lines | Criteria A | Mains power quality should be that of a typical commercial or hospital environment. |
| Surge IEC 61000-4-5 | ± 1 kV line(s) to line(s) ± 2 kV line(s) to earth | Criteria B | Mains power quality should be that of a typical commercial or hospital environment. |
| Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11 | 70% dips for 25 cycles 0% of dips for 0.5 0% short interruption for 5 Sec | Criteria B | Mains power quality should be that of a typical commercial or hospital environment. If the user of the Oxygen analyzer requires continued operation during power mains interruptions, it is recommended that the Oxygen analyzer be powered from an uninterruptible power supply or a battery. |
| Power frequency (50/60 Hz) magnetic field IEC 61000-4-8 | 30 A/m | Criteria A | Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment. |
| NOTE UT is the a.c. mains voltage prior to application of the test level. | | | |

Guidance and manufacturer's declaration – electromagnetic immunity

The Oxygen analyzer is intended for use in the electromagnetic environment specified below.
The customer or the user of the Oxygen analyzer should assure that it is used in such an environment.

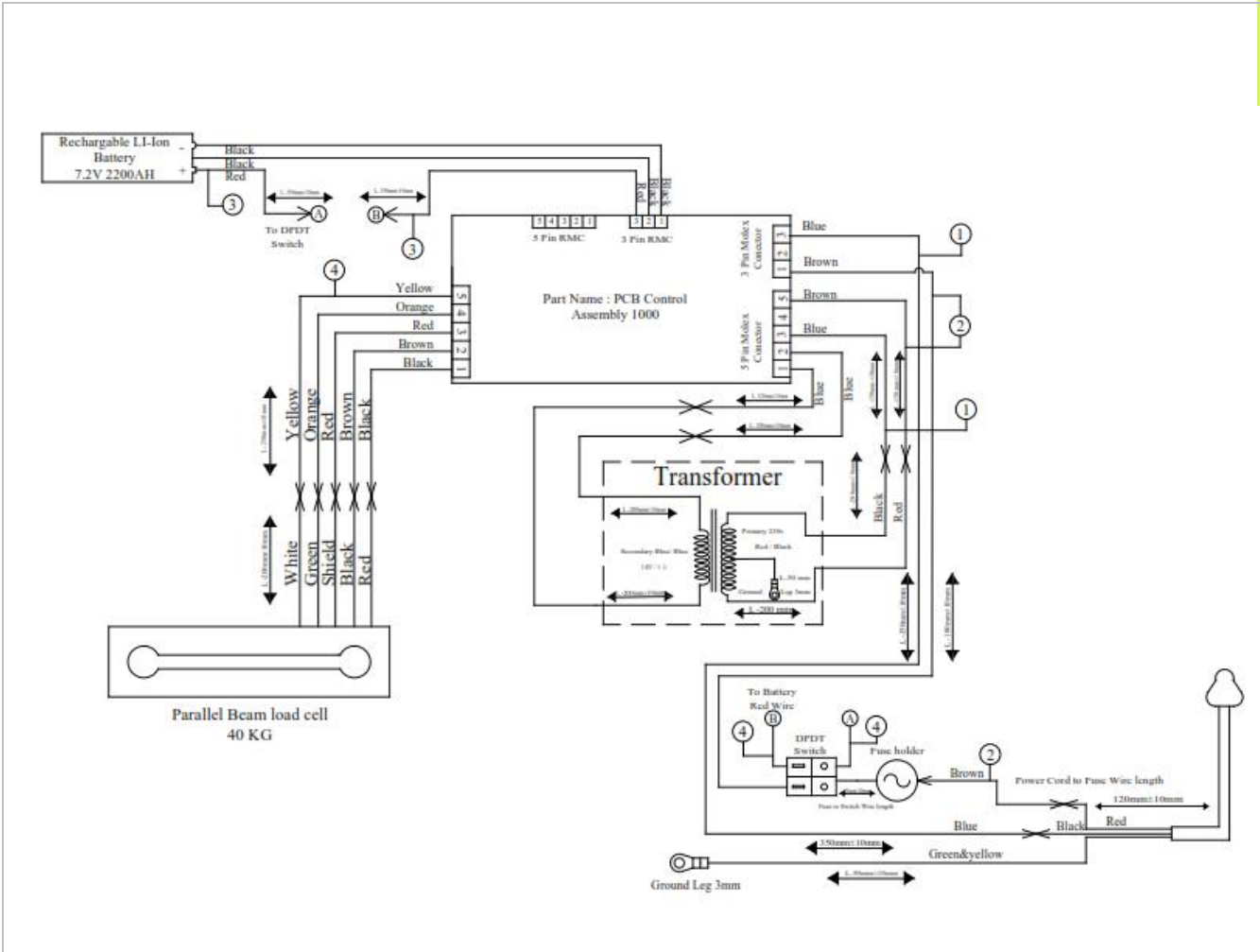
| Immunity test | IEC 60601 test level | Compliance level | Electromagnetic environment – guidance |
|-------------------------------|---|------------------|--|
| Conducted RF IEC 61000-4-6 | 3 Vrms 150 kHz to 80 MHz outside ISM bands 6 Vrms 150 kHz to 80 MHz in ISM bands | Criteria A | Floors should be wood, concrete or ceramic tile. If floors are covered with Synthetic material, the relative humidity should be at least 30 %. |

NOTE UT is the a.c. mains voltage prior to application of the test level.

Acceptance criteria:

| Performance criteria | Description |
|----------------------|--|
| A | Normal performance within limits specified by nice Neötech |
| B | Temporary loss of function or degradation of performance which ceases after the disturbance ceases, and from which the equipment under test recovers its normal performance, without operator intervention |
| C | Temporary loss of function or degradation of performance, the correction of which requires operator intervention |
| D | Loss of function or degradation, which is not recoverable, owing damage to hardware or software, or loss of data |

Section 10: Wiring Drawing



Section 11: For Complaints/Adverse Events/Comments/Feedback

| | | | | | |
|---------------------------------------|---|--|------------|-----------------------|--|
| | | | | Date: | |
| Hospital Name & Address: | | | | | |
| Contact Person & Contact No. & Email: | | | | | |
| Department: | | NICU / PICU / OT / Casualty / Others _____ | | | |
| Equipment name: | | | Model no.: | | |
| UDI / Serial No.: | | Date of purchase: | | Date of Installation: | |
| Pick one: | <input type="checkbox"/> Complaints <input type="checkbox"/> Adverse Events <input type="checkbox"/> Comments <input type="checkbox"/> Feedback | | | | |

In case of adverse events, fill the below details:

| | |
|---|--|
| Incident happened to: (Patient / User) | |
| Details of incident happened person: (Name/Age/type of incident) | |
| Severity of the event (Minor injury / Major injury / Death) | |
| Brief description of the event | |

For comments:

For Complaints:

For Feedbacks:

Kindly fill the above and send the same

From:

To:

The Marketing In-charge
 nice Neotech Medical Systems Pvt. Ltd.
 No, 85. Krishna Industrial Estate,
 Vanagaram, Mettukuppam,
 Chennai-600095. Tamil Nadu,
 INDIA.
 Ph: 91-44-24762594, 24764608
 Email: marketing@niceneotech.com
 Toll Free No. 1800-425-2594 (India only)

NOTE: In case of serious/adverse events, report the incident to nice Neotech, European Authorized Representative and the competent authority of the Member State by filling and sending the below form as letter post or email.

| Service Contact | EU Authorized Representative | Competent Authority |
|---|--|---|
| <p>nice Neotech Medical Systems Pvt. Ltd. No. 85, Krishna Industrial Estate, Vanagaram, Mettukuppam Chennai-600095. Tamil Nadu, INDIA. Ph: 91-44-2476 4608 Telefax: 91-44-2476 2594 E-mail: service@niceneotech.com /info@niceneotech.com Web: www.niceneotech.com</p> | <p>Amstermed B.V Located in Saturnusstraat 46-62, Unit 032, 2132 HB Hoofddorp, The Netherlands. Mr. Mike Vermin Tel: +31 23 565 6337 info@amstermed.nl www.amstermed.nl SRN: NL-AR-000001971</p> | <p>Ministerie van Volksgezondheid, Welzijn en Sport Address:P.O. Box, 20350, The Hague, Netherlands Country:Netherlands Email: medicaldevices@minvws.nl Tel:+31 70 340 79 11</p> |