INSTRUCTIONS FOR USE

VO200 - NeurOs Cerebral Oximetry

ENGLISH

Mespere LIFE SCIENCES

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Section 1: Introduction

About this Manual

Paper Copy

If a paper copy of this manual is needed, please contact your distributor or Mespere LifeSciences directly. Paper copy will be provided to all CE customers.

Download

The electronic version of this manual is available at http://www.mespere.com/resources.html. Please contact your distributor or Mespere LifeSciences directly to obtain the login information to download this manual.

Previous Versions

Please contact Mespere LifeSciences directly to obtain previous versions of this manual.

Description

The Mespere LifeSciences Inc. model VO200 - NeurOs Cerebral Oximetry displays regional hemoglobin oxygen saturation of blood in the brain tissue beneath the sensor (StO_2) value (in percentage, %), Blood Volume Index (BVI) value (in milliliter of blood per liter of tissue, %), and the corresponding trends. The StO_2 and BVI are monitored using non-invasive near infrared and proprietary signal-processing technologies. The measured StO_2 number and BVI are displayed at a refresh rate of approximately one (1) second.

The saturation (StO2) is calculated through the ratio of the amplitude attenuation of two different near-infrared wavelengths. Blood Volume Index (BVI) is calculated through the sum of the amplitude attenuation of the two wavelengths.

Indications for Use

The VO200 – NeurOs Cerebral Oximetry is intended for use as an adjunct monitor of regional hemoglobin oxygen saturation in the brain tissue and relative level of blood volume in the tissue beneath the sensor. The prospective clinical value of data from the VO200 - NeurOs Cerebral Oximetry has not been demonstrated in disease states. The VO200 - NeurOs Cerebral Oximetry should not be used as the sole basis for diagnosis or therapy.

Contraindications

- Do NOT use the VO200 - NeurOs Cerebral Oximetry on patients:
    - Undergoing photodynamic therapy (PDT).
    - Known to have allergic reactions to medical-grade adhesive tape

Section 2: Safety Information

Warnings

WARNING

- *The clinical value of the data obtained by the VO200 – NeurOs Cerebral Oximetry has not been demonstrated in all diseased states. Currently, the protocol for cerebral oximetry validation is by following the FDA Guidance document, Pulse Oximeters – Premarket Notification Submissions [510(k)s] – Guidance for Industry and Food and Drug Administration Staff. This guidance states to perform the validation on healthy volunteers, however the intended use is for diseased states.

- The VO200 – NeurOs Cerebral Oximetry is intended to be used for adult patients in order to ensure safety and effectiveness
- Do NOT use the VO200 - NeurOs Cerebral Oximetry unless on the order of a physician.
- The VO200 - NeurOs Cerebral Oximetry is intended for use by healthcare professionals only.
- As per Standard IEC 60601-1 Section 11, it has been disclosed that the maximum temperature of the applied parts for the VO200 - NeurOs Cerebral Oximetry is 43.2 degrees Celsius. It is recommended that the VO200 - NeurOs Cerebral Oximetry is not left running on the patient when it is not in use so that the applied parts will not reach the maximum temperature. Caution must be taken for patients who are taking medication that would make their skin more susceptible to damage from sun or light.
- The VO200 - NeurOs Cerebral Oximetry may cause radio interference or may disrupt the operation of nearby equipment. It may be necessary to take mitigation measures, such as reorienting or relocating the VO200 - NeurOs Cerebral Oximetry or shielding the location.
- To avoid the risk of electric shock, grounded power supplies must be connected to an AC outlet with protective earth.
- To avoid the risk of electric shock, the sensor must be connected to Isolator (IS-01) in order to connect to monitor.
- Do NOT re-use sensor adhesives. Doing so may increase the risk of infection or cross-contamination.
- Always unplug the system before cleaning. Refer to **Section 5: Cleaning, Disinfection, Maintenance, and Disposal** for more information.
- Any changes or modification to this equipment not expressly approved by Mespere LifeSciences Inc. may cause bodily harm and void your authority to use this equipment.

- The use of accessories and cables other than those specified, with the exception of accessories and cables qualified and sold by Mespere LifeSciences Inc. may result in increased emissions or decreased immunity of the equipment and may cause the VO200 - NeurOs Cerebral Oximetry to be non-compliant with the requirements of IEC 60601-1-2:2014.

- Pins of connectors should not be touched and that connections should not be made to these connectors unless ESD precautionary procedures are used.

- The operator should NOT touch the monitor and the patient at the same time.

- The VO200 - NeurOs Cerebral Oximetry should not be used adjacent to or stacked with other equipment and that if adjacent or stacked use is necessary, the equipment should be observed to verify normal operation in the configuration in which it will be used.

Cautions

CAUTION

- Read and understand this entire manual carefully before using the VO200 - NeurOs Cerebral Oximetry.

- Inaccurate StO2 readings with the VO200 – NeurOs Cerebral Oximetry may occur by:
    - Anemia or low hemoglobin concentrations
    - Hemoglobinopathies and synthesis disorders such as thalassemias, Hb s, Hb c, sickle cell, etc.
    - Elevated levels of COHb, MetHb, or other dyshemoblobins
    - Elevated level of total bilirubin
    - Non-normocapnic conditions or other conditions that affect blood volume
    - Hypotension, severe vasoconstriction, or hypothermia
    - Cardiac arrest
    - Venous congestion, venous pulsations and pooled blood under the skin
    - Intravascular dyes or externally applied coloring (such as indelible ink)
    - Birthmark(s) or skin discolorations in sensor path
    - Moisture on the skin
    - Excessive motion
    - Metal plate or other foreign object in sensor path
    - Excessive light or direct sunlight
    - Electrosurgical interference
    - Improper sensor application

- The VO200 - NeurOs Cerebral Oximetry needs precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in **Section 7: Specifications**.

- Portable and mobile RF communications equipment may affect the VO200 - NeurOs Cerebral Oximetry.

- Do NOT sterilize any part of the VO200 - NeurOs Cerebral Oximetry using any process.
  No part of the VO200 - NeurOs Cerebral Oximetry is to be sterilized. Cleaning must be performed as described in **Section 5: Cleaning, Disinfection, Maintenance, and Disposal**.
- A cable connects the VO200 - NeurOs Cerebral Oximetry sensor to the monitor.
  Do NOT twist or pull on this connection.
  Do NOT allow this cable to become tangled in other equipment such as bed frames.

Section 3: Setup

Installation

Before the VO200 - NeurOs Cerebral Oximetry can be used in a clinical setting, it should be inspected and properly setup.

Display Software Setup

The display software can be pre-loaded by distributor or Mespere LifeSciences to a monitor. If the display software is not preloaded, please refer to the Display Software Installation document.

Procedure

1. Download NeurOs Installer file provided to you via Dropbox or by a Mespere LifeSciences representative.
2. Plug an external hard drive, thumb drive, or USB drive into your computer.
3. Place the NeurOs Installer file onto the external hard drive, thumb drive, or USB stick.
4. Plug external hard drive, thumb drive, or USB drive into the Display Monitor. A pop-up window should appear showing the contents of this drive.
5. Open the NeurOs Installer file.
6. Allow the NeurOs Installer file to make changes to your computer by clicking “Yes”.
7. Click “Install” on the NeurOs Installer Setup Wizard.
8. Once the NeurOs Installation is complete press “Finish”. The NeurOs Display Software is now installed on the display monitor.

Turning the Monitor On and Off:

The display software can be pre-loaded by distributor or Mespere LifeSciences to a monitor. Once the monitor is turned on the Mespere home screen will appear. If the display software is not pre-loaded please refer to the Display Software Installation document.

Procedure

9. Turn the monitor on by pushing the power button.
10. Once the Mespere home screen appears, the system is ready for use.
11. Turn the monitor off by pushing the virtual power button on the home screen

Monitor Display

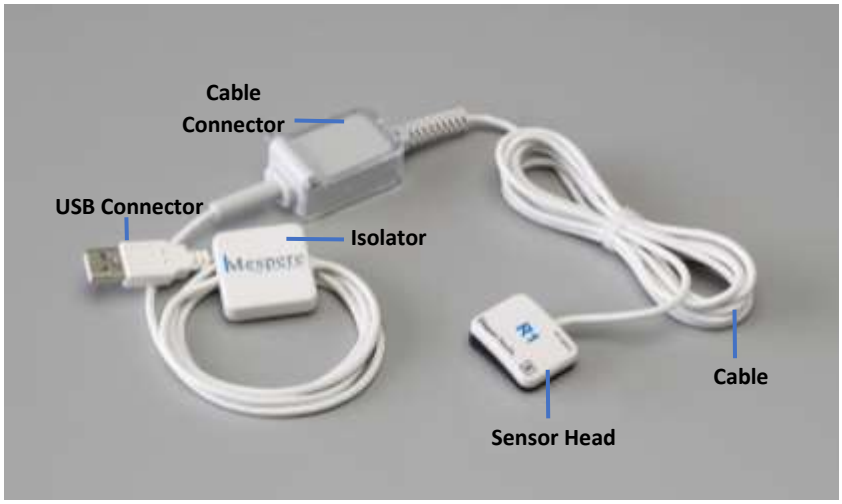
The VO200 - NeurOs Cerebral Oximetry displays the StO_2 and BVI values in real time.

Control/Indicator	Description
Regional Saturation (StO_2)	Regional hemoglobin oxygen saturation of blood oxygenation in the brain or in other tissue beneath the sensor
StO_2 Baseline	User determined baseline for regional hemoglobin oxygen saturation
Variation from StO_2 baseline	Change in StO_2 measurement from the user determined baseline
Blood Volume Index (BVI)	Index of the regional blood volume in the tissue beneath the sensor
BVI Baseline	User determined set baseline for blood volume index
Variation from BVI Baseline	Percent change in BVI reading from the user determined baseline
Trend Plot	The StO_2 and BVI data trends
ID – Patient Folder	Once a patient ID is entered, a patient folder will be created using this ID and all patient data will be saved in this folder. If a patient ID is not entered the files will be saved in the temp folder using the current time stamp as the file name.
New Measurement	Pressing this button will clear the stopped data on the screen
Start	Pressing this button will start a new monitoring session
Stop – Auto Save	Press this button to stop the current monitoring session. Once the monitoring session is stopped an excel file, screenshot, and summary pdf will automatically be saved to the patient's folder.
Set Baseline	Set the baseline to the current values
Event Marker	Mark an event by displaying a vertical line on the trend window. Enter event details and/or press OK once complete. Marked events can be reviewed at any time under the Review – Trend window.
Trend Toggle	Change the displayed data trend (StO_2 and BVI)
Review	**Trend:** view the complete StO_2 and BVI trend summary and marked events from the entire monitoring session. Press Save Review on the top toolbar to save a pdf summary and screenshot to the patient's folder **Compare Snap Shot:** Select two Snap Shot files to compare the data and create a comparison report. Press Save Comparison on the top toolbar to save a pdf summary to the patient's folder.
Snap Shot	Create a report based on the average of the last 30 seconds of data. An excel file and pdf summary will automatically be saved to the patient's folder.

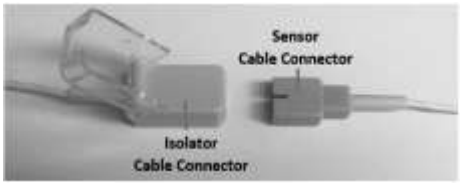
Export Data	Export previously saved patient files such as Snap Shots, Review Summaries, Excel Files, and Screenshots to a removable drive. Patient data is saved by patient ID. Locate the patient's folder and copy desired files to removable drive. If a patient ID was not entered, the patient's data files will be located in the temp folder and can be identified using the time stamps as the file name.
Help	Help Center
Settings	**Trend Display Duration:** Select the duration of the displayed trend, 5 or 30 minutes **Displayed Channels:** Select the number of displayed channels, 2 or 4. If 2 is selected, select which two sensors will be displayed. **Sensitivity:** Select the displayed sensitivity, default or depth resolved **StO2 Baseline Variation:** select whether the StO2 variation from baseline is the relative or absolute change from the baseline. **Alarms:** adjust the alarm bounds based on level or by fractional change from baseline (baseline must be set in order to create alarms by fraction of baseline), or turn the alarms off. **Data Recovery Frequency:** Select whether data is stored every 1 or 30 seconds in the excel and trend files
Minimize	Minimize the NeurOs application to return to the homescreen
Exit	Exit the NeurOs application and return to the homescreen

VO200/VO200S - NeurOs Cerebral Oximetry Sensor and Isolator

The VO200/VO200S - NeurOs Cerebral Oximetry Sensor consists of a sensor cable and sensor head. The sensor head contains the LEDs and PDs. The isolator consists of a cable connector, an isolator, flexible cable, and USB connector. The isolator connects the VO200/VO200S – NeurOs Cerebral Venous Oximetry sensor to the computer or USB hub.



Procedure



1. Open the clear case on the isolator cable connector.
2. Plug the cable connector from the VO200/VO200S NeurOs Cerebral Oximetry sensor into the cable connector of the isolator.
3. Close the clear case on the cable connector.

Sensor Adhesive

The VO200/VO200SS – NeurOs Cerebral Oximetry sensor adhesives are single-use, and use a medical-grade adhesive and foam.

The sensor adhesive clips onto the VO200/VO200S – NeurOs Cerebral Oximetry sensor head and is used to adhere the VO200/VO200S – NeurOs Cerebral Oximetry sensor to the patient.

WARNING

- The VO200/VO200S - NeurOs Cerebral Oximetry sensor adhesives are intended for single-use only.
- Do NOT re-use the VO200/VO200S - NeurOs Cerebral Oximetry sensor adhesives. Doing so may increase the risk of infection or cross-contamination.

Section 4: System Operation

Setup for Non-Invasive and Continuous Monitoring of Cerebral Oximetry

Monitor Setup

1. Choose the $rStO_2$/BVI application from the homescreen.
2. Plug the VO200/VO200S - NeurOs Cerebral Oximetry sensor into the monitor.

Sensor Setup

3. Snap a disposable adhesive onto the sensor head.

Sensor Placement

Cerebral Saturation Readings

4. Place sensor(s) so that the cable is towards the top of the patient's head.
5. Position the right sensor (R1 or R2) so that the clip from the sensor adhesive is centered over the patient's temple region before the contour change. Ensure that there is no hair beneath the PDs and LEDs.
6. Remove paper liner and adhere the sensor to the patient.
7. Press down on the adhesive to ensure strong adhesion has been made. Do not reuse adhesives, if not positioned correctly use a new adhesive.
8. Repeat with the left sensor (L1 or L2) if conducting bilateral readings.

Tissue Saturation Readings

4. Place sensor(s) so that there is no tension on the cables.
5. Place the right sensor (R1 or R2) on the targeted tissue.
6. Repeat with the left side (L1 or L2) if conducting bilateral readings.
7. Remove the paper liner and adhere the sensor to the patient.
8. Press down on the adhesive to ensure strong adhesion has been made.

Settings

9. Press the Settings button on the monitor.
    - **Trend Duration:** Select the duration of the displayed trend, 5 or 30 minutes.
    - **Displayed Channels:** Select the number of displayed channels, 2 or 4.
    - **Sensitivity:** Select the displayed sensitivity, default or depth resolved.
    - **Alarms:** Adjust the alarm bounds and volume, or turn off the alarms.
10. Press OK.

Monitoring

11. Press the Start button on the monitor.

- **Trend:** change the displayed data trend (StO_2 or BVI)
- **Set Baseline:** set the baseline to the current values.
- **Event Marker:** mark an event on the trend window. Enter event details and/or press OK once complete.
- **Review:** view previous data and marked events from the entire monitoring session.

12. Press OK.

Computer Functions

ID – Enter Patient ID

1. Enter a patient ID into the white input box anytime throughout the monitoring session.

2. A patient folder will be created using this ID and all patient data will be saved in this folder. If a patient ID is not entered the file will be saved in the temp folder using the current time stamp as the file name.

New Measurement (New Meas.)

1. Press New Meas. to clear the previously stopped data showing on the screen.

Start

1. Press Start to begin a new monitoring session.

Stop – Auto Save

1. Press Stop to stop the current monitoring session.

2. Once the monitoring session is stopped an excel file, screenshot, and summary pdf will automatically be saved to the patient's folder.

Set the Baseline

1. Press the Set Baseline button.

2. A horizontal line will appear in the trend window showing the baseline value (for StO_2 and BVI values only). The baseline value will appear to below the current reading. Below the baseline value, the variation from the baseline and current reading will appear.

Event Marker

1. Press the Event Marker button.

2. Enter event details and press OK.

3. A vertical line will appear in the trend window marking an event.

Change Event Description

1. Press the Review button and select Trend.

2. The Review – Trend screen will appear. Press View Events from the top toolbar.

3. A pop-up window will appear with the marked events.

4. Click the event box and enter the appropriate description.

Review - Trend

1. Press the Review button on the monitor. A dropdown menu will appear and select Trend.

2. A window will appear with a complete StO_2 and BVI trend summary and marked events from the entire monitoring session.

3. Press Save Review on the top toolbar to save a pdf summary and screenshot to the patient's folder.

Review – Compare Snap Shot

1. Press the Review button on the monitor. A dropdown menu will appear and select Compare Snap Shot.

2. A pop-up window will appear. Select two Snap Shot files to compare the data and create a comparison report.

3. Press Save Comparison on the top toolbar to save a pdf summary to the patient's folder.

Stop – Auto Save

3. Press the Stop button located on the top toolbar once the monitoring session is complete.

4. A pop-up window will appear showing that an excel file, screenshot, and summary pdf will automatically be saved to the patient's folder.

Snap Shot

1. Press the Snap Shot button located on the top toolbar.

2. A report will be created based on the average of the last 30 seconds of data. An excel file and pdf summary will automatically be saved to the patient's folder.

Export Data – Snap Shots, Review Summaries, Excel Files, and Screenshots

1. Press the Export Data button on the top toolbar.

2. Locate the patient's folder. If a patient ID was entered, a folder was created using this ID and all patient data will be saved in this folder. If a patient ID is not entered the file will be saved in the temp folder using the current time stamp as the file name.

3. Plug in an external memory source to the USB port on the right side of the computer.

4. Click the file until a menu appears. Select Copy

5. Open the external memory source and hold the screen until a menu appears. Select Paste. The copied files will be transferred to the connected removable drive.

Deleting saved files

1. Press Export Data button on the top toolbar.
2. Locate the patient folder.
3. Click the file until a menu appears.
4. Select delete from the menu.

Checking Sensor Life

1. Plug the sensor into the USB port on the right side of the computer.
2. Press the Help button.
3. Press the sensor life button.
4. A pop-up window will appear indicating the number of hours remaining for that specific sensor.

System Messages

The guidance messages on the Display are shown in Table 1:

Table 1: Informative system messages

Message	Cause and Resolution
"Disconnected"	The Mespere NeurOs is detecting that the VO200/VO200S sensor is not connected to the computer. - Ensure that the VO200/VO200S sensor is correctly connected to the isolator. - Ensure that the isolator is correctly connected to the computer.
"Standing By…"	The Mespere NeurOs is detecting that the VO200/VO200S sensor is disconnected from the computer. - Ensure that the VO200/VO200S sensor is correctly connected to the isolator. - Ensure that the isolator is correctly connected to the computer.
"Sensor Expired"	The Mespere NeurOs is detecting that the attached VO200 sensor has expired. - Replace the connected VO200/VO200S sensor with a new one or one that hasn't expired
"Check Sensor Patch"	The sensor has loose adhesion to the patient's skin. - Ensure that the sensor is adhered to the patient's skin.
"Demo Mode"	The Mespere NeurOs is running in demo mode. - Press "Exit Demo Mode" or connect a sensor to exit the demo application.
"Please wait"	The Mespere NeurOs is loading. Please wait until this message has closed, before continuing.
"__ hours of usage has elapsed"	The attached VO200 sensor has been used for this many hours.

Patient Environment

The sensor adhesives are the applied parts of the VO200/VO200S - NeurOs Cerebral Oximetry that will come in contact with the patient during normal use.

The sensor and sensor adhesive are components of the VO200 - NeurOs Cerebral Oximetry that will be in the patient environment.

NOTE

☞ The patient environment is defined as the area that is 1.5m from the patient in their bed or chair.

CAUTION

The isolator chip and the monitor should be kept away from the patient environment.

System Trend Display

The history of the StO_2 and BVI trend is displayed on the monitor.

Reading the Trend Data Display

The StO_2 and BVI trend data is displayed on the monitor, with the x axis representing number of data points and the y axis displaying the history StO_2 and BVI data. The current version of the VO200 - NeurOs Cerebral Oximetry does not allow the user to display the StO_2 and BVI trend data in another unit.

Clearing Trend Information

All history VO200 - NeurOs Cerebral Oximetry data is erased when a new measurement is started by pressing the Start button.

Essential Performance

The VO 200 – NeurOs Cerebral Oximetry has no essential performance characteristics.

Sensor Performance Considerations

CAUTION

Patients must not move excessively during measurements. Excessive talking and motions such as yawning, deep-breathing and the like should be discouraged while measurements are being taken.

Factory Default Settings

Operating System

The display software will include the software version NeurOs.EN.00.01.00.046

Section 5: Cleaning, Disinfection, Maintenance, and Disposal

Cleaning and Disinfection

The VO200 - NeurOs Cerebral Oximetry requires no preventive maintenance. Only regular cleaning and disinfection based on the institutional or jurisdictional guidelines is required. In the absence of guidelines, it is recommended that cleaning is performed after each use of the VO200 - NeurOs Cerebral Oximetry.

WARNING

- Always unplug the VO200 - NeurOs Cerebral Oximetry before cleaning.
- Allow the VO200 - NeurOs Cerebral Oximetry to dry completely before re-connecting power.

CAUTION

- Do NOT immerse any part of the VO200 - NeurOs Cerebral Oximetry in any liquid for any reason.
- Cleaning should be performed using institutional or jurisdictional guidelines.
- Do NOT subject any component of the system to sterilization (e.g. ETO, steam). Doing so may damage the components of the VO200 - NeurOs Cerebral Oximetry.

Maintenance

The VO200 - NeurOs Cerebral Oximetry requires no preventive maintenance.

Inspecting the Equipment and Accessories

Prior to each use of the VO200 - NeurOs Cerebral Oximetry, it is suggested that the user checks that all connections to the monitor, isolator, and sensor are correct and secure. For instructions on how to make these connections, please refer to **Section 3: Setup**.

Returning the System for Repairs and/or Service

Contact your distributor for information on repairs and/or services for the VO200 - NeurOs Cerebral Oximetry.

Disposal

Comply with local laws for disposal of VO200 - NeurOs Cerebral Oximetry.

CAUTION

Product is to be taken too separate collection at end of product life. Do NOT dispose of the product as unsorted municipal waste.

Section 6: Troubleshooting

The following table provides basic guidance in the event of a problem with the VO200 - NeurOs Cerebral Oximetry.

Table 2: List of Problems for Troubleshooting

Problem	Possible Causes	Possible Remedies
Computer will not power on	- No power	- Check connection of the power supply to the computer. - Check connection of Power Supply to AC power (wall outlet). - Try alternate outlet.
Computer cannot communicate sensor	- Connection of sensor	- Ensure sensors are connected correctly to the isolator and computer. - Try re-starting software by powering down the computer, then turn the computer on.
Mespere NeurOs does not display the StO_2 or BVI values	- Patient status - sensor placement	- Be sure to follow the on-screen instructions for adjusting the patient angle. Refer to Section 3: Setup. - Check the sensor placement and orientation.
"Disconnected"	The Mespere NeurOs is detecting that the VO200/VO200S sensor is not connected to the computer.	- Ensure that the VO200/VO200S sensor is correctly connected to the isolator. - Ensure that the isolator is correctly connected to the computer.
"Standing By…"	The Mespere NeurOs is detecting that either the VO200/VO200S sensor is disconnect from the computer.	- Ensure that the VO200/VO200S sensor is correctly connected to the isolator. - Ensure that the isolator is correctly connected to the computer.
"Sensor Expired"	The Mespere NeurOs is detecting that the attached VO200/VO200S sensor has expired.	- Replace the connected VO200/VO200S sensor with a new one or one that hasn't expired
"Check Sensor Patch"	This may if the sensor has loose adhesion to the patient's skin.	- Ensure that the sensor is adhered to the patient's skin.

For Technical Assistance

In the event that your problem is not resolved with the help of Table or if you have additional problems to report, contact your distributor or Mespere LifeSciences directly.

Section 7: Specifications

Performance

Table 3: Performance specifications

Parameter	Specification	Notes
StO_2 Measurement Range	0 – 100%	
Trending Accuracy of StO_2	± 1.5%	1,2
Resolution of StO_2	1%	
Trending Accuracy of BVI	4.3 mL of blood per L of tissue	3
Resolution of BVI	0.1%	

NOTES:

1 Measurement range is 40% - 90%

2 Accuracy is based on a validation study comparison with venous jugular bulb and radial arterial blood samples and a Co-Oximeter on healthy volunteers. In the StO2 range of 40-90%, the trending accuracy was ± 1.5% in the study STP-9200001 at the University of California San Francisco, UCSF (San Francisco, California, USA).

3 Accuracy is based on a validation study performed through the comparison of BVI with an ultrasound measurement of the cross section of the jugular vein through a body inclination protocol. The trending accuracy was ±4.3 mL/L in the study STP-9200002 at Wayne State University (Detroit, Michigan, USA).

Electrical

Table 4: Electrical specifications

Parameter	Specification		Notes
Monitor Specifications	CPU: Quad Core Intel® Atom™x7-Z8700 processor (2MB Cache, 1.6GHz with Intel Burst™ technology up to 2.4GHz) or faster RAM: 2G or more Storage: 64GB or more USB: 5Vdc, 500mA, USB 2.0 port OS: WIN 10 IEC 60950-1 compliant		
Power Supply	IEC 60950-1 compliant		
Measurement NIR wavelength	905±5 and 660±3nm		
Base Sampling Modulation Rate	2 kHz		
NIR LED duty cycle	7.5 ms		
NIR power	Peak	14 mw	3,4
	Average	0.9 mw	

NOTES:

3 Peak power indicates instantaneous electrical power dissipated by one NIR LED when 'on'. Average power reflects the time-averaged electrical power dissipated by one NIR LED when the system is running normally at a sampling rate of 2kHz and an NIR LED duty cycle of 9.1%.

4 Power figures are given for one NIR LED. Only one of the two NIR LEDs is active at any given time.

NOTE

☞ The Monitor and the device form a ME system.

Environmental

Table 5: Environmental specifications

Parameter		Specification
Temperature	Operating	10 °C – 38 °C
	Transportation/Storage	-20 °C – 50 °C
Humidity	Operating	30% – 70%
	Transportation/Storage	20% – 80%
Air Pressure	Operating	86 – 106 kPa
	Transportation/Storage	86 – 106 kPa

Physical Characteristics

Table 6: Physical characteristics specifications

Parameter		Specification
Dimensions of VO200 - NeurOs Cerebral Oximetry Sensor	L × W × D	50mm × 30mm × 10mm
Dimensions of VO200S – NeurOs Cerebral Oximetry Sensor	L x W x D	33mm x 25mm x 10mm
Dimensions of Isolator	L × W × D	33mm × 33mm × 9mm
Data Display		StO_2 (%) and BVI number, and trend
Display update rate		1 second

Compliance

Table 7: Compliance

Parameter	Specification
Safety Standard for Medical Equipment	IEC 60601-1 edition 3 Amendment 1
EMC Standard	IEC 60601-1-2 Class A
Degree of protection	Type BF-Applied part
Mode of Operation	Continuous

Warranty

Mespere LifeSciences Inc. warrants to the Purchaser for a period of one (1) year from the date of purchase for the monitor, and six (6) months or 200 hour operation hours for the sensor, whichever comes first. Mespere warrants that the Product delivered is free from defects in workmanship or materials and the Product will perform as labelled in the directions for use. Mespere LifeSciences will work with the end-users distributor, or directly with the end user to determine warranty coverage for issues, should they arise, and if the issue is not covered by warranty, will provide a quote with respect to the repair costs to rectify the issue.

EXCLUSIONS

The warranty does not apply in the following conditions:

1) The product is modified without authorization from Mespere LifeSciences Inc.
2) Used with devices not supplied or authorized by Mespere LifeSciences Inc.
3) Used with sensor not supplied by or approved by Mespere LifeSciences Inc.
4) Used in conditions other than mentioned in the Instructions For Use
5) Products used for testing or demonstration purposes
6) Mishandling of equipment
7) Accident, fire, water, vandalism, weather or any act of God

Lifetime

Product Code	Description	Lifetime
SEN-NeurOs	VO200 - NeurOs Cerebral Oximetry Sensor	1 year
SEN-NeurOs S	VO200S - NeurOs Cerebral Oximetry Sensor	1 year
SA-NeurOs	VO200 - NeurOs Cerebral Oximetry Sensor Adhesive (Single use)	1 year
SA-NeurOs S	VO200S - NeurOs Cerebral Oximetry Sensor Adhesive (Single use)	1 year
IS-01	Mespere Isolator	3 years

Manufacturer's Declaration

WARNING

The use of accessories and cables other than those specified with the exception of accessories and cables qualified and sold by Mespere LifeSciences Inc. may result in increased emissions or decreased immunity of the equipment and may cause the system to be non-compliant with the requirements of IEC 60601-1-2:2014.

Table 8: Electromagnetic Emissions

The VO200 - NeurOs Cerebral Oximetry is intended for use in the electromagnetic environment specified below. The customer or the user of the VO200 - NeurOs Cerebral Oximetry should assure that it is used in such an environment.

Emissions Test	Compliance	Electromagnetic Environment Guidance
RF emissions CISPR 11	Group 1	The equipment uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class A	The equipment is suitable for use in all establishments other than domestic, and may be used in domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes, provided the following warning is heeded: Warning: This equipment/system is intended for use by healthcare professionals only. This equipment/ system may cause radio interference or may disrupt the operation of nearby equipment. It may be necessary to take mitigation measures, such as re-orienting or relocating the equipment or shielding the location.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

Table 9: Electromagnetic Immunity

The VO200 - NeurOs Cerebral Oximetry is intended for use in the electromagnetic environment specified below. The customer or the user of the VO200 - NeurOs Cerebral Oximetry 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	±6 kV contact ±8 kV air	±4 kV contact ±4 kV air	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/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	±2 kV for power supply lines Input/output lines are exempted because none are more and 3 meter in length	Mains power quality should be that of a typical commercial/residential or hospital environment.

Surge IEC 61000-4-5	±1 kV line(s) to line(s) ±2 kV line(s) to earth	±1 kV line(s) to line(s) ±2 kV line(s) to earth	Mains power quality should be that of a typical commercial/residential or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11 U_T = 240 Vac and 120Vac	<5 % U_T (>95 % dip in U_T) for 0.5 cycle 40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) for 25 cycles <5 % U_T (>95 % dip in U_T) for 5 sec	<5 % U_T (>95 % dip in U_T) for 0.5 cycle 40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) for 25 cycles <5 % U_T (>95 % dip in U_T) for 5 sec	Mains power quality should be that of a typical commercial/residential or hospital environment. If the user of the equipment requires continued operation during power mains interruptions, it is recommended that the equipment be powered from an uninterruptible power supply or a battery.
Power frequency (50 Hz/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial/residential or hospital environment.

Table 10: Electronic Immunity for Portable and Mobile RF Equipment

The VO200 - NeurOs Cerebral Oximetry is intended for use in the electromagnetic environment specified below. The customer or the user of the VO200 - NeurOs Cerebral Oximetry 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	3 Vrms	Portable and mobile RF communications equipment should be used no closer to any part of the equipment including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = \frac{3.5}{v_1}\sqrt{P}$ $d = \frac{3.5}{v_1}\sqrt{P}$ $80\ MHz\ to\ 800\ MHz$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	

			$d = \frac{3.5}{v_1}\sqrt{P}$ 800 MH *to* 2.5 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m).

NOTE ☞ At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE ☞ These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey[1] should be less than the compliance level in each frequency range[2].

Interference may occur in the vicinity of known RF transmitting devices and equipment marked with the following symbol:

Table 11: Recommended Separation Distances

The ME equipment is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the ME equipment can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the ME equipment as recommended below, according to the maximum output power of the communications equipment.

Rated Maximum Output Power of Transmitter W	**Separation Distance According to Frequency of Transmitter** m		
	150 kHz to 80 MHz $\boldsymbol{d = \frac{3.5}{v_1}\sqrt{P}}$	**80 MHz to 800 MHz** $\boldsymbol{d = \frac{3.5}{E_1}\sqrt{P}}$	**800 MHz to 2.5 GHz** $\boldsymbol{d = \frac{7}{E_1}\sqrt{P}}$
0.01	0.12	0.12	0.24

[1] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the equipment is used exceeds the applicable RF compliance level above, the equipment should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the equipment.

[2] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m

0.1	0.37	0.37	0.74
1	1.17	1.17	2.34
10	3.69	3.69	7.38
100	11.7	11.7	23.4

For transmitters rated at a maximum output power not listed above, the recommended separation distance *d* in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE

☞ At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE

☞ These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Table 12: Cable Compliance

The following cables comply with:

- RF emissions, CISPR 11, Class A/Group 1
- Electrostatic discharge (ESD), IEC 61000-4-2
- Radiated RF, IEC 61000-4-3
- Electric fast transient/burst, IEC 61000-4-4
- Conducted RF IEC 61000-4-6

Cables and Accessories	Maximum Length
Cable of the VO200 - NeurOs Cerebral Oximetry (SEN-NeurOs)	1.5m
Cable of the VO200S - NeurOs Cerebral Oximetry (SEN-NeurOs S)	1.5m
Cable of isolator (IS-01)	1.5m

Section 8: Appendices

Appendix 1: List of Abbreviations

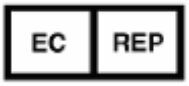
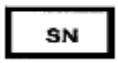
Table 13: Glossary of Abbreviations

Acronym	Meaning
StO_2	Cerebral Blood Oxygenation Regional hemoglobin oxygen saturation of blood oxygenation in the brain or in other tissue beneath the sensor.
BVI	Blood Volume Index Regional blood volume of blood in the tissue beneath the sensor.
NIR	Near-Infra-Red Light having a wavelength between 0.7- and 5-microns (700nm to 5000nm).

Appendix 2: List of Symbols

Table 14: Glossary of Symbols

Symbol	Meaning
	"Note" message used to convey tips, helpful information and instructive statements.
	"Caution" message used to call attention to installations, practices, and operations that, if not properly performed or adhered to, could result in damage to the equipment.
	"Warning" message used to call attention to installations, practices, and operations that, if not properly performed or adhered to, could result in personal injury to the patient and/or user.
	Mark of conformity to European Union Medical Device Directive.
	Federal law (U.S.) restricts this device to sale by or on the order of a physician.
	Direct current (DC)
	Power indicator, located onto or near power switches.
	ESD sensitivity. This symbol may appear adjacent ports on the equipment that have heightened sensitivity to static discharge.
	Type BF applied part. This symbol indicates that the applied part is suitable for connection to the patient and that it delivers Type BF isolation.

Symbol	Meaning
	Consult Manual
	Class II Symbol
	European Authorized Representative
	Lot Number
	Reference/Model Number
	Serial Number
PN	Part number (re-order number)
	Manufacturer
	Consult Instructions For Use
	Single Use Only
	Product is to be taken too separate collection at end of product life. Do NOT dispose of the product as unsorted municipal waste.
	Date of Manufacture
	Storage temperature range: -20°C to 50°C

NOTE 	Not all symbols shown in Table may appear on the equipment or in this manual.

Appendix 3: List of VO200 - NeurOs Cerebral Oximetry Components

Table 15: List of VO200 - NeurOs Cerebral Oximetry Components

Description	Component Part Number
Main Components	
VO200 - NeurOs Cerebral Oximetry Sensor	SEN-NeurOs
VO200S - NeurOs Cerebral Oximetry Sensor	SEN-NeurOs S
VO200 - NeurOs Cerebral Oximetry Adhesives (Single use)	SA-NeurOs
VO200S NeurOs Cerebral Oximetry Adhesives (Single use)	SA-NeurOs S
Operating System	OS-NeurOs
Mespere Isolator	IS-01
Instructions for Use – English	IFU-NeurOs
Quickstart Guide – English	QG-NeurOs

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