# **OBELAB OBELAB**

# NIRSIT

User Manual

# **Before Using Our Product**

Thank you for purchasing NIRSIT-Lite Kids. NIRSIT-Lite Kids is functional Near-Infrared spectroscopy device made by OBELAB Inc. It is a device designed to measure variations in cerebral blood oxygen saturation by radiating a near-infrared light beam, at two wavelengths of 780 nm and 850 nm, into the cerebral cortex. The device radiates a LED light with a output of 1 mW or less which is harmless to the human body. The device comes with PC software you can use to monitor the distribution of cerebral oxygen saturation via multiple channels.

This user manual contains important information regarding the use of the device. Please read this manual carefully before using the device. Keep this manual within easy reach for future reference.

Please contact us if you have questions about this manual or the product purchased.

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# **Warranty and Liability**

### **Warranty**

OBELAB Inc. warrants the quality of this product as specified below

### **Warranty Service**

Free repair service is provided within warranty period (1 year from the date of purchase) to the damaged device due to component failure during proper operation.

### **Charged Service**

Service is charged when the following cases apply:

- 1 Out of warranty period
- 2 Within warranty period
  - a. repairs resulting from natural disasters (lightning, fire, earthquake, storm, flood, etc.)
  - b. repairs resulting from a device failure or damage caused by user mishandling (impact, dropping)
  - c. repairs resulting from old or worn out consumables (battery, cable, etc.) that need replacement
  - d. repairs resulting from a device failure due to unauthorized repair or modification
  - e. repairs resulting from the use of unauthorized components
  - f. repairs resulting from services performed by an unauthorized person or entity

### **Notice**

For matters that are not specified in this document, the Act on Consumer Protection of Korea and relevant regulations on compensation for consumers shall apply. For other repairs and questions, please contact your dealer or the OBELAB Customer Support Center.

Request for service on a functioning device will result in service charges. Please read the User Manual.

This warranty is only valid in the Republic of Korea, and not to be re-issued. Please store the warranty in a safe place or send a scanned copy to OBELAB (contact@obelab.com).

For other repairs and any service-related questions, please contact your dealer or the OBELAB Customer Support Center.

# **Copyrights**

This manual is the property of OBELAB Inc. and protected by copyright law. Unauthorized use or reproduction, in whole or part, is strictly forbidden.

Contents of this user manual are subject to change without notice, regarding changes to the performance or specifications of the device. For information on the device and user manual, please contact the OBELAB Customer Support Center.

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# **History of Revision**

Version	Revised date	Details	Remarks
1.0	2019/07/30	Initial edition	
-			
-			

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Overview **OBELAB** 

### 1. Overview

### 1.1 Safety Instructions

Safety instructions are provided to ensure user safety and prevent property damage. Please read the following safety instructions and warnings before using the device.

WARNING Symbol

### **^**WARNING

Indicates a potentially hazardous situation which, if not avoided, could result in death or serious injury. Failure to comply with a warning could result in severe damage to the device.

CAUTION Symbol

### **ACAUTION**

Indicates a potentially hazardous situation which, if not avoided, may result in minor or moderate injury. Failure to comply with a caution may result in damage to the device.

IMPORTANT Symbol

### **IMPORTANT**

Indicates instructions that users must observe or refer to. All users must check and follow the instructions.

### 1.1.1 User Qualification

To use the device, the user must

- Read and understand this user manual.
- Understand the basic structure and features of the device.
- **IMPORTANT**
- Be able to detect abnormal operation and take appropriate measures.
- Be at least 15 years old and have reading experience for at least five years.
- Be capable of understanding numbers and languages without difficulty, have knowledge of oxygen saturation measurement principles, and have experience using the device or previous training.

### 1.1.2 Electrical Safety Instructions

 $\triangle$ WARNING

- Always check the condition of the power supply, computer, tablet, and cable connections before using the device.
- Ensure that the battery is not replaced by an unauthorized user. There
  is risk of overheating, fire, and explosion.
- Do not disassemble the device for maintenance or repair when it is connected to a power supply.

**ACAUTION** 

Make sure to turn off the device when it is not in use.

### **1.1.3** General Safety Instructions

- Do not use the device in a place where there is a risk of explosion.
- Keep the device away from inflammables.
- Do not stare directly into the sensor unit or laser.

### **MARNING**

- Do not operate the device with wet hands.
- Do not arbitrarily disassemble, repair, or modify the device. Inspection and repair must only be performed by certified professionals. For technical support, please contact the nearest Customer Support Center.

# **⚠ CAUTION**

- Do not use the device on a patient who has a stab wound on the forehead or who is undergoing surgery.
- Keep the device away from water, humidity, and/or contaminants.
- To ensure safety, follow the instructions described in this user manual when using the device.
- Never let the device drop. Do not expose the device to excessive shock
- Always keep the device in the storage case when not in use.

This device is intended for research purposes only and must be used by researchers or personnel that have been sufficiently trained in its use.

### IMPORTANT

- Use the device with the dedicated software.
- Use the device under indoor lighting condition.
- Ensure that a fire extinguisher is within reach.
- Use the device at optimal temperature (15-35°C) to ensure safe operation.
- Store the device away from direct sunlight.

### 1.1.4 When cleaning the device

<b>≜</b> WARNING	Do not spray disinfectant on the device. Sprayed disinfectant can cause ignition.	
<b> ⚠</b> CAUTION	Do not use wet or damp clothes or spray cleaners. There is risk of electric shock and damage to the device.	

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Overview

# 1.2 Symbols Used

A list of symbols found in this manual and on the label on the device is shown below. It is important to understand these indications, and to follow the safety instructions.

**Table 1-1 Symbols Used** 

Symbol	Name	Description
<u>^</u> WARNING	WARNING	Indicates a potentially hazardous situation which, if not avoided, could result in death or serious injury. Failure to comply with a warning could result in severe damage to the device.
<b></b> CAUTION	CAUTION	Indicates a potentially hazardous situation which, if not avoided, may result in minor or moderate injury. Failure to comply with a caution may result in damage to the device.
IMPORTANT	IMPORTANT	Indicates instructions that users must observe or refer to. All users must check and follow the instructions.
NOTE	NOTE	Additional information that aids in device operation.

### 1.3 Guideline for equipment disposal



Figure 1-1 WEEE label (Directive 2002/96/EC)

Please dispose of the device according to your local regulations. The product contains components that can be recycled. Please recycle products to protect the environment. All of the product components, except for the battery, can be recycled. Plastic parts may be recycled, or burned in a controlled environment, depending on local laws.

NOTE

Please consult OBELAB, its resellers, or other disposal agencies for more information regarding disposal.

# 1.4 Notation

Notation is a series of special symbols or conventions used in this manual to denote different items

This manual uses the following notation for users' better understanding of the device:

**Table 1-2 Notation Used in the Manual** 

Notation	Decryption	
u 33	Used to denote a reference.  Example: See "Chapter 1. Overview."	
Bold	Used to denote GUI elements such as menus and buttons. Example: Click the <b>STOP</b> button.	
>	Used to list several menus or buttons in sequence.  Example: Click the <b>STOP</b> > <b>OPEN</b> buttons.	
<ul><li>ABC</li><li>ABC</li><li>ABC</li></ul>	Used to divide or list items of the same level in an organized way.	
1 ABC 2 ABC Used to describe a work procedure in order. 3 ABC		
<b>0</b> 2 3	Used to name or describe components of an image.	

### **FCC (Federal Communications Commission)**

This equipment has been tested and found to comply with limits for a Class B digital device, pursuant to Part 15 of the FCC Rules. These limits are residential installation.

This equipment generates uses and can radiate radio frequency energy and, if not install and use in accordance with the instructions, may cause harmful interference to radio communications.

However, there is no guarantee that interference will not occur in a particular installation. If this equipment dose cause harmful interference to radio or television reception , which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

Reorient or relocate the receiving antenna.

Increase the separation between the equipment and receiver.

Connect the equipment into an outlet in a circuit different

from that to which the receiver is connected.

Consult the dealer or an experienced radio/ TV technical for help.

WARNING: this equipment may generate or use radio frequency energy. Changes or modifications or this equipment may cause harmful interference unless the modifications are expressly approved in the instruction manual. The user could lose the authority to operate this equipment if an unauthorized change or modification is made.

This device complies with Par 15 of the FCC's Rules. Operation is subject to the following two Conditions:

- 1. This device may not cause harmful interference, and
- 2. This device must accept interference received, interference received, including interference that may cause undesirable operation.

Warning

To comply with FCC RF exposure requirements, a minimum separation distance of 25mm must be maintained between the human head and the radiator of device.

### **Canadian Compliance**

This device complies with Industry Canada license-exempt RSS standard(s).

Operation is subject to the following two conditions:

- (1) this device may not cause interference, and
- (2) this device must accept any interference, including interference that may cause undesired operation of the device.

Le présent appareil est conforme aux CNR d'Industrie Canada applicables aux appareils radio exempts de licence.

L'exploitation est autorisée aux deux conditions suivantes :

- (1) l'appareil ne doit pas produire de brouillage, et
- (2) l'utilisateur de l'appareil doit accepter tout brouillage radioélectrique subi, même si le brouillage est susceptible d'en compromettre le fonctionnement.

RF Exposure statement

This device complies with RF exposure requirement.

Déclaration d'exposition RF

Cet appareil est conforme à l'exigence d'exposition RF.

### Warning

To comply with IC RF exposure requirements, a minimum separation distance of 25mm must be maintained between the human head and the radiator of device.

### Warning

Pour se conformer aux exigences d'exposition RF de la IC, une distance de séparation minimale de 25 mm doit être respectée entre la tête humaine et le radiateur de l'appareil.

# 2. Using NIRSIT-Lite Kids System

# 2.1 Names and Locations of Components

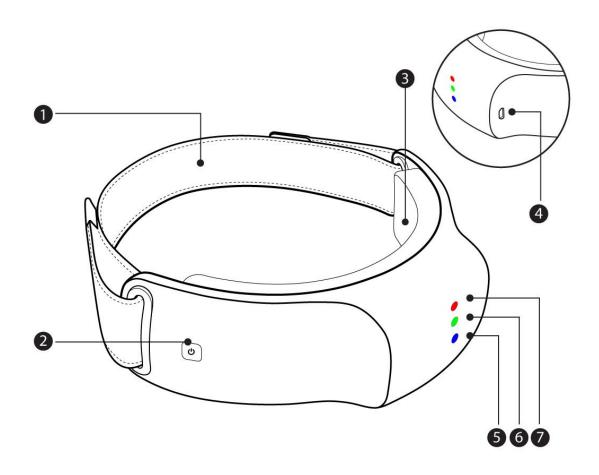


Figure 2-1 Components of the System Table 2-1 Components and Their Functions

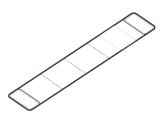
No.	설명	
1	Strap	
2	Power button	
3	Silicone padded Sensors	
4	5-pin micro connector	
5	Status Indicator (Charging)	
6	Status Indicator (Power)	
7	Status Indicator (Bluetooth)	

### 2.2 Basic Components

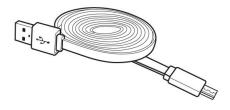
When opening the package, please make sure to check the components and inform the OBELAB Customer Support Center if there are any issues with the package.



NIRSIT LITE Main Unit



Replacement Strap



USB 2.0 Cable



Charger



**USB OTG Connecter** 



Storage and carry-on box for NIRSIT LITE



USB Memory stick with PC software and Manual

**NOTE** 

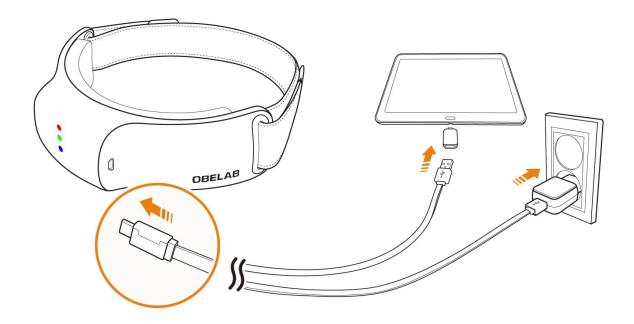
To purchase accessories, please contact OBELA or an authorized dealer.

### 2.3 Battery

NIRSIT is powered by a lithium-ion polymer battery. For prolonged use, charge the battery at least 1 hour and 30 minutes before operating the device. Regularly check the remaining battery level to ensure availability.

### 2.3.1 Charging the Battery

Charge the battery by connecting the NIRSIT-Lite to a battery charging pack or tablet via a USB cable.



NOTE

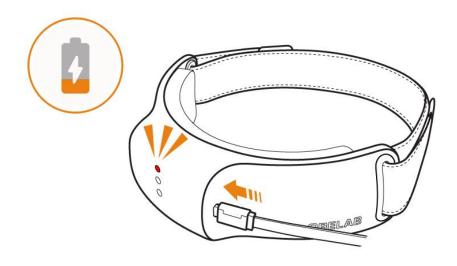
Charging adapter requirements

• Rated input: AC 100-240V 50-60Hz 0.50 A

• Rated output: DC 9.0 V 1.67 A or DC 5.0 V 2.0 A

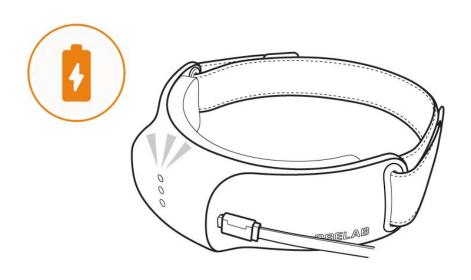
### 2.3.2 Checking Battery Level

### **Charging in Progress**



Red LED On

### **Fully Charged**



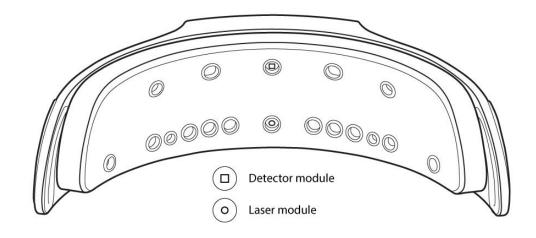
Red LED Off

### **Charging Mode**

Make sure that the device is off before you charge. Measurement cannot be performed while charging

### 2.4 Sensor Module Position

The below picture shows the difference between laser modules and detector modules in terms of external appearance.



**Optical Safety** 

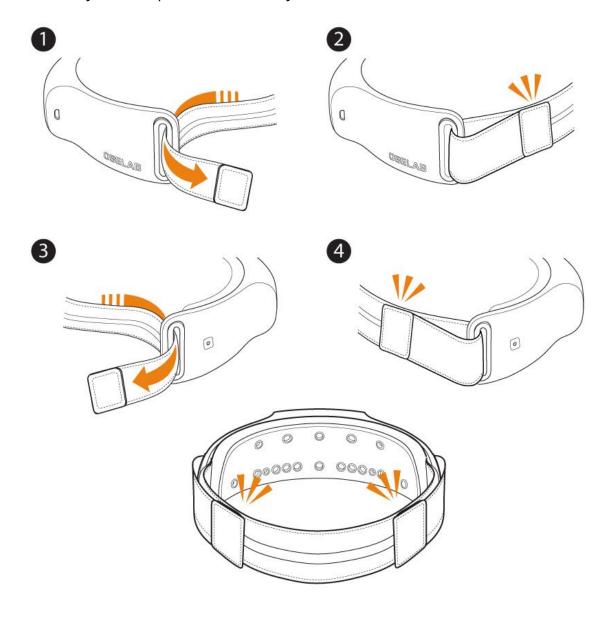
The device uses LED Light Sources which is harmless to human body.

# 3. Before Using NIRSIT-Lite Kids Software

# 3.1 Preparing to wear NIRSIT-Lite

### 3.1.1 Installing the Strap Holder

Adjust the strap holder to fit the subject's head.



### 3.1.2 Checking Operation Status



- 1 Press and hold the Power button for 3 seconds to turn on the device. Once powered on, the status indicator will illuminate in green, and a beep will be heard.
- 2 Press and hold the Power button for 3 seconds again to turn off the device. Once powered off, the status indicator will be off as well

### 3.2 Turning on the device

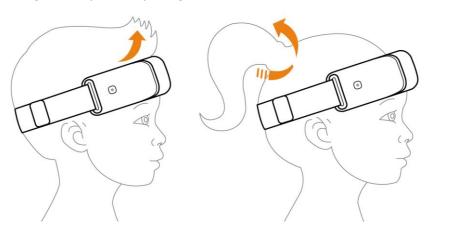


- 1 Turn on the NIRSIT device by pressing and holding the Power button for 3 seconds.
- 2 Check the green LED light from the status indicator in the middle of the device.
- 3 Run NIRSIT-Lite Kids software in PC.

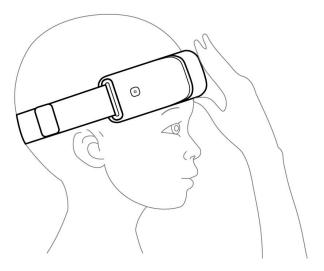
# 3.3 Putting on the device



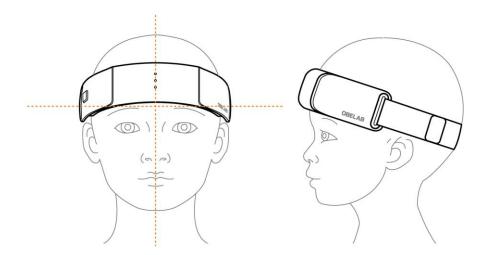
1 For the comfortable fitting, make enough space between subject's forehead and the device by loosening the strap before putting on the device.



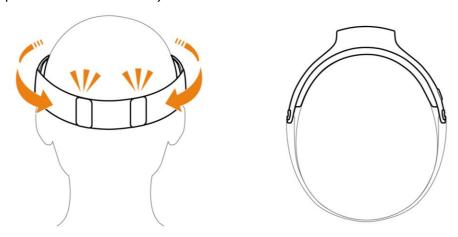
**2** As shown below, remove all hair from the forehead region and put the device on. Subject might need to hold a front side of the device with one hand for accurate fitting.



**3** Take extra care to align the green LED light with the subject's eyes, nose and eyebrows, so that the device is placed adequately on the middle of subject's forehead.



4 Attach the strap to the Velcro to ensure the device adequately comes into contact with the forehead of the subject. The closer the device is to the forehead, the better, but you can adjust the strength of the adhesion with a strap if necessary(e.g. the subject feels too much pressure around forehead)



### **Installing the Software** 3.4

Please install the PC software which is included inside the USB memory stick. Follow the instructions inside. If reinstallation or additional installation is needed, download the software from the OBELAB website after registering the device under www.obelab.com>JOIN US.

OBELAB website: www.obelab.com>SUPPORT>DOWNLOAD

### **Running the Software** 3.5

On the WINDOW PC screen, select **NIRSIT –Lite Kids PC** ( ) icon.



Software will run automatically.

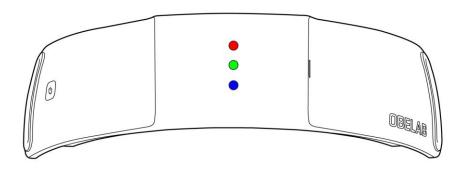
# 3.6 Connecting to the device

When you turn on the device, the device is connected to NIRSIT-Lite Kids PC software.

Power LED (Green Color) will be on after you turn on the NIRSIT LITE device initially,



BLE LED (Blue Color) will be on after pairing.



You can connect the device to the computer as shown below.

# 4. Using NIRSIT-Lite Kids Software

NIRSIT-Lite Kids PC software is designed to view real-time variations in cerebral oxygen saturation according to the subject's cognitive status, measured via the NIRSIT-Lite Kids device. This PC Software contains all functions for subjects and observers.

Subject

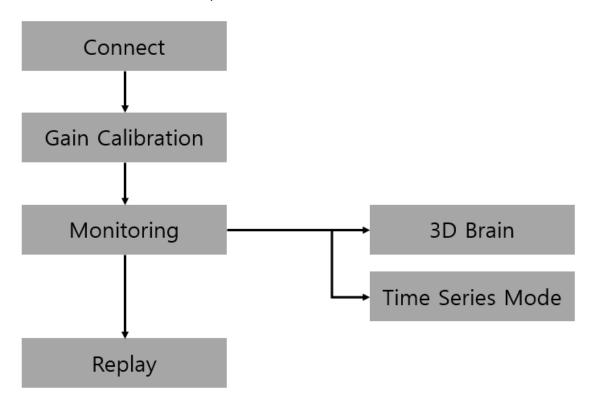
Wears the NIRSIT LITE device and performs tasks provided in the NIRSIT-Lite software.

Observer

Uses the NIRSIT LITE software to monitor the blood oxygen level of the subject's brain in **3D** mode or **TIME SERIES** mode in real-time.

### **4.1** PC Software Structure

Below chart briefly outlines the NIRSIT LITE software structure for Window OS. NIRSIT LITE software runs in Connect Mode by default to set serial.



# **4.2 Setting Serial Port**

### **4.2.1** Connecting to Serial Port

1 Select port in COM Port options and Click Open to connect.



### 4.3 Gain Calibration

1 Select Gain Cal Start. Sensor Gain calibration of NIRSIT-Lite Kids lasers and detectors allows the device to measure optimal signals from the subject. The subject will need to stay calm with minimal physical movement during the CALIBRATION process to avoid possible artifacts.



2 Once calibration is complete and the time bar at the bottom turns blue, active channels will be shown with yellow circles. In addition, signal to SNR (Signal Noise Ratio) will be shown as a graph.



Real-time Monitoring (MONITORING Mode)

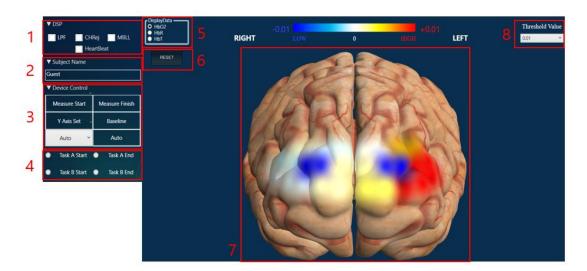
### 4.4 MONITORING

In MONITORING mode, two different modes are available for real time monitoring, both of which display the change in the cerebral oxygen saturation level of the subject.

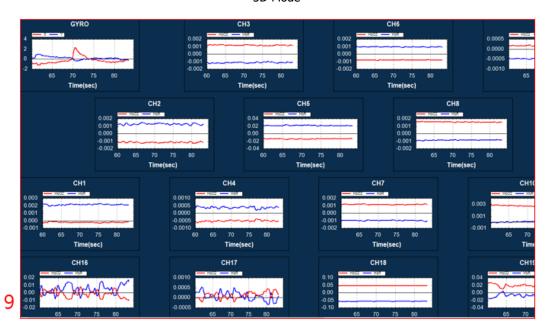
MONITORING comes with two sub-modes.

MONITORING Mode	설명
<b>3D</b> Mode	<b>3D</b> mode visualizes the changes in the hemoglobin level in real-time on a 3D brain model. Depending on the intended use, the user can choose to monitor among HbO2, HbR, or HbT changes.
Time Series Mode	<b>Time Series</b> mode shows HbO2 and HbR changes in a graph format in real-time on a channel by channel basis.

### 4.4.1 MONITORING Mode Screen Overview



3D Mode



**TIME SERIES Mode** 

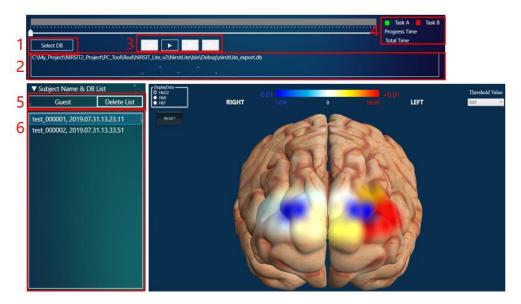
No.	Description
	Display on-screen filtering menu items as follows:
	■ LPF: Use a low-pass filter to remove high frequency noise.
1	■ CHANNEL REJECTION: that do not meet the default/set SNR value.
1	<ul> <li>MBLL: View changes in HbO2 and HbR levels calculated with the Modified Beer- Lambert Law.</li> </ul>
	HEART BEAT: Remove heartbeat effect.
2	Subject Name: Display subject's name.
3	Display on-screen function menu items as follows:

No.	Description		
	■ Measure Start: Start measurement of HbO2 Or HbR Or HbT		
	Measure Finish: Finish the measurement and save data		
	<ul><li>Y Axis Set: Set Y axis of Time</li></ul>	e Series graph	
	<ul><li>Baseline: Set the baseline of</li></ul>	finitial MBLL value to the current value.	
4		Save the task start point by selecting the <b>TASK A START</b> button. Save the task end point by selecting the <b>TASK A END</b> button. The same applies to the <b>Task B START</b> and <b>END</b> button.	
4	NOTE	You can manually save the task start point and end point in the NIRSIT database. It is possible to record two tasks (tasks A and B) simultaneously.	
	HbO2: Color-map change	es in HbO2 level	
5	HbR: Color-map changes	in HbR level	
	HbT: Color-map changes	in the sum of HbO2 and HbR levels	
6	Reset the position of the 3D bra	ain image.	
	3D brain image		
	RIGHT denotes Right Hemi	sphere.	
	LEFT denotes Left Hemisphere.		
	<ul><li>Measured signal is shown in mM, ranging from -0.010mM to 0.010mM.</li></ul>		
7		Measured signals are represented in multiple colors on 3D brain image, and each color indicates different states:	
	NOTE	■ White: Initial state of the brain (Baseline)	
		■ White < Yellow < Red: Increase in HbO2 level	
		■ White > Light Blue > Blue: Decrease in HbO2	
8	■ Threshold value: Update HbO2, HbR, HbT Display Color Map with changed value		
	Time series image		
9	Time Series Mode shows HbO2 and HbR changes in a graph format in real-time a channel by channel basis.		

# 4.5 REPLAY

REPLAY MODE plays measured data using saved database.

### 4.5.1 REPLAY Screen Overview



**REPLAY Mode** 

No.	설명
1	Select DB : Select database to play
2	Shows the path of database
3	Display on-screen function menu items as follows:  PLAY: Play saved data.  PAUSE: Pause playing.  STOP: Stop Playing.  BACKWARD: Move 5 seconds backward.  FORWARD: Move 5 seconds forward.
4	Display total time and progress time.
5	Reset the position of the 3D brain image.
6	Display the playlist of data in database.

Maintenance OBELAB

# 5. Maintenance

### **5.1** Replacing Accessories and Components

### 5.1.1 Replacing Straps

Replace with a new strap if the current strap is dirty, damaged or feels loose.

A strap can be removed by following the installation instructions in reverse order.

### 5.2 Cleaning

Make sure to turn off the NIRSIT device before cleaning. The device must be cleaned and stored after use. If not properly cleaned, or if exposed to direct sunlight, the device may become discolored.

### **5.2.1** Cleaning Silicone padded sensors

Wipe with an alcohol-moistened soft cloth.

Silicon caps are frequently in contact with subjects. Take extra care to maintain hygiene.

Use cotton buds to remove foreign substance in sensor holes.

### **5.2.2 Cleaning NIRSIT-Lite Kids**

1 Wipe with a soft cloth moistened with a non-abrasive cleaning solution mixed with water. .

 Make sure that liquid does not enter the device. This can cause device failure.



- Do not spray directly on the device.
- Do not use abrasive agents e.g. acetone as they can damage the surface.
- 1 Use a dry cloth to wipe off the moisture.
- **2** To remove foreign objects from the sensor, use a cotton ball soaked with alcohol.

**NOTE** NIRSIT-Lite Kids can be sterilized with ultraviolet rays.

# 6. Troubleshooting

Symptoms	Possible cause	Solution
The device will not turn on.	The battery is discharged.	Charge the battery
	The battery has expired.	Contact OBELAB or an authorized dealer.
The battery will not charge.	The cable is damaged or severed.	If you have a spare, replace the cable. If you do not have a spare, purchase a new cable.
	This environment is not suitable to store or operate the product.	Meet environmental requirements.
	The Wi-Fi feature is turned off.	Turn on the tablet Wi-Fi.
Cannot connect with the tablet.	Sometimes a wireless connection cannot be established due to environmental factors (e.g. congested area such as a big event venue).	Use a USB cable for a wired connection.

NOTE

Information related to after-sales services and other technical information on the device can be found in the service manual provided by OBELAB.

# 7. Product Specifications

# **7.1** Mechanical Characteristics

Item	Description
Size (Width x Depth x Height)	190 x 95 x 50 (mm)
Weight (including battery)	180 (g)

# 7.2 Technical Characteristics

	Item	Description
	Source Type	Dual wavelength LED
	Number of Sources	5
Source	Laser Output	Under 1 mW
	Wavelength	780 nm, 850 nm
	Operation Mode	Continuous-Wave
	Detector Type	Active detection sensor
Detector	Number of Detectors	13
	Number of channels	Up to 21 channels
	Source-Detector distance	2.5 cm, 0.8 cm, 1.6 cm 3.3 cm
Measurement	System Scan Rate	Up to 8.138 Hz
	Operation Mode	Continuous-Wave

# **7.3 Electrical Characteristics**

	Item	Description
Input Voltage (v	ia USB port)	5 V
Maximum Voltag	e (via USB port)	2.1 A
	Туре	Lithium ion polymer battery
Datten	Usage Time	Up to 5 hours(when fully charged)
Battery	Voltage	3.7 V
	Capacity	1000 mAh
Data Storage		Built-in memory in PC storage
Communication	Wireless	BLE 5.0 (2.4 GHz)
	Wired	Serial Communication

# **7.4** PC Requirements

Item	Description
Operating System	Windows 10 (64bit)
CPU	i5 core or higher
RAM	16 GB
Internal Memory	SSD (HDD not supported) 256 GB or higher

# **7.5 Environmental Requirements**

	Item	Description
Operating	Temperature	Operating Environment
Environment	Humidity	20%~80%
Storage	Temperature	Storage Environment
Environment	Humidity	20%~80%

		Warranty	nty
Serial Number			
Period			1 year from the date of purchase
Date of Purchase			
Place of Purchase	Sold at		TEL
	Name		
Cictoros Posistration	Address		
Custofflet Registration	Ħ	正	
	ĪĒ	Mobile	
■ Warranty Service			Notice
Free warranty service applies to repa failure during proper operation in the Charged Service	Free warranty service applies to repair services required for this device occurring as a result of failure during proper operation in the warranty period (1 year from the date of purchase).  Charged Service	curring as a result of te of purchase).	For matters that are not specified in this document, the Act on Consumer Protection of Korea and relevant regulations on compensation for consumers shall apply.  For other repairs and questions, please contact your dealer or the OBELAB Customer Support Center.
A service fee will be applied in the following cases.  1. Out of warranty period	ollowing cases.		Request for service on a functioning device will result in service charge. Please read the User Guide.
Within warranty period     I. repairs resulting from natura	n warranty period repairs resulting from natural disasters (lightning, fire, earthquake, storm, flood, etc.)	storm, flood, etc.)	Inis warranty is only effective in the Republic of Korea, and not to be re-Issued. Please store the warranty in a safe place or send a scanned copy to OBELAB (contact@obelab.com).
II. repairs resulting from a devidence (impact, dropping)	repairs resulting from a device failure or damage caused by the user's mishandling (impact, dropping)	ser's mishandling	Customer Service Center.
III. repairs resulting from old co  IV. repairs resulting from a device.	repairs resulting from old consumables (battery, cable, etc.) that need replacement repairs resulting from a device failure due to unauthorized repair and modification	eed replacement and modification	
V. repairs resulting from the us	repairs resulting from the use of unauthorized components		
VI. repairs resulting from service	repairs resulting from services performed by an unauthorized person	son	

# **OBELAB**