iSyncWave PBM Technical Specifications

Photobiomodulation User Manual

iMediSync

Photobiomodulation User Manual

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Photobiomodulation User Manual

Introduction

This user manual is a reference for iSyncWave users.
It includes information about components, instructions for use, and safety precautions for iSyncWave. It will explain the features and functionality of iSyncWave's transcranial Photobiomodulation (tPBM) capabilities or Near- Infrared Light Emitting Diode (NIR-LED) Care. Please read the user manual before using the iSyncWave. It is recommended to store the manual in a safe place near the device.

iMediSync does not provide tPBM protocols. Providers are responsible for choosing protocols themselves based on their understanding of the QEEG. Please contact **cs@imedisync.com** if you would like information on mentors who provide QEEG interpretation and protocol generation training.

1 Company Information

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Device Overview

1 How the device works

iSyncWave is a comprehensive device designed for EEG (Electroencephalogram) measurement and digital therapeutics intervention using transcranial Photobiomodulation therapy. iSyncWave measures 19 channel EEG in real time and transfers the data through Bluetooth Low Energy (BLE) wireless connection to the iSyncWave App. The data is displayed and recorded via the iSyncWave App. iSyncWave uses dry-electrode technology, which doesn't require a preparation process (e.g., applying conductive gel), to obtain high quality EEG signals. Before measuring the EEG, you can check the impedance of each electrode under the impedance check screen in the iSyncWave app. An EEG amplifier, analog-to-digital converter and Bluetooth are built in the device. All EEG signal is sampled at 250 Hz and then converted to digital data at 24-bit resolution.

This device measures EEG using 19 EEG dry-electrodes, 1 reference cable, and 1 ground electrode. The measured data can be digitally converted to common average, longitudinal, and transverse montage. The measured data is stored at tablet and can be uploaded automatically or manually to a secure cloud server via wi-fi connection and saved securely. The data saved in the cloud server can be seen on the iSyncWave app.

iSyncWave can be only used by professional and/or medical personnel with product training and experience in EEG measurement. The professional and/or medical personnel can check the signal quality in real time and refer to the measured data in clinical practice.

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Digital Therapeutics Intervention through transcranial Photobiomodulation:

A. Integration of NIR-LEDs: iSyncWave incorporates NIR-LEDs, which emit near-infrared light. This technology is used for the Photobiomodulation feature “NIR-LED Care” on the iSyncWave App.

B. Treatment Customization: Based on the EEG data and the specific therapeutic goals, professionals using the iSyncWave App can customize the photobiomodulation therapy. This may involve defining the frequency, duration, prescription mode, and target areas for the light therapy.

C. Therapeutic Application: After the EEG measurement, the NIR-LEDs are activated according to the customised prescription plan. The near-infrared light is applied to the patient’s scalp, where it penetrates the tissue and interacts with the cells. This interaction may stimulate cellular energy production and promote modulation of neural activity or blood circulation.

D. Monitoring and Adjustment: The professional can closely monitor the patient's response to the therapy in real-time through the iSyncWave App. Adjustments to the therapy parameters can be made as needed based on the patient's progress and feedback.

iSyncWave combines EEG measurement capabilities with digital therapeutics through Photobiomodulation therapy. It offers professionals a tool for both monitoring brain activity and delivering targeted, non-invasive therapeutic interventions. The integration of advanced technology and therapy makes it a versatile device for medical and research applications in the field of brain health.

Technical Specifications

1 Device Information

Product Name	Electroencephalograph (iSyncWave)
Model Name	ISW-MUS101(US)
Intended Use	· Acquire electroencephalogram (EEG) and wirelessly transfer data to tablet · Transcranial Photobiomodulation (tPBM) or Photostimulation
How to Use	Refer to user manual
Type of Protection against Electric Shock	Internally powered ME equipment
Degree of Protection against Electric Shock	Type BF applied part
Degree of Harmful Ingress of Water	IPX0
Degree of Safety in the Presence of Flammable Anesthetic Mixture with Air, Oxygen or Nitrous Oxide	Not suitable for case
Weight	1.59 kg

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② Device Specification

Number of Electrodes	19 EEG electrodes + 1 Reference Cable + 1 Ground electrode
Reference Cable	A1
Channel Position	International 10-20 System
Battery	Rechargeable Li-ion
Rated Input Voltage	3.6 V, 2, 950 mAh (Li-ion Polymer Battery)
Sampling Rate	250 Hz
Digital Signal Resolution	24 Bit
Wireless Connection	Bluetooth Low Energy (BLE) V 5.0
Accuracy of Signal Reproduction	Within 10 %
Input Dynamic Range	± 1 mV
Maximum Offset Voltage	± 300 mV
Noise	4 μV peak to peak
Frequency Range and Bandwidth	0.5 ~ 50 Hz
Common Mode Rejection	89 dB
Description of all Functions	Impedance Check, Signal Check, EEG Recording and Review
Description of Waveform Displays	Tablet Application (Real-time display)

③ Recommended Tablet Specifications

Processor	CPU Speed	2.3 GHz, 1.7 GHz (Octa-Core)
Display	Resolution (Main)	2000 × 1200 (WUXGA+)
Memory	RAM Size (GB)	4
	ROM Size (GB)	128
Wi-Fi	802.11 a/b/g/n/ac 2.4G+5 GHz, VHT80 MIMO	
Bluetooth	Bluetooth V5.0 (LE up to 2 Mbps)	
System	Android 8 (Oreo)	

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4 iSyncWave tPBM Technical Specifications

Irradiance Source	19 LED Bulbs (Built in the center of each electrode)
Wavelength	Near-infrared 850 nm
Pulse Rate	1 ~ 45 Hz (Adjustable in 1 Hz increments)
Injection Current	10 mA/LED

Safety and Considerations

1 Safety Requirements (PBM): IEC 60601-1

A. ES60601-1:2005/(R)2012 and A1:2012, C1:2009/(R)2012 and A2:2010/(R)2012 (Consolidated Text) Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005, MOD)

B. IEC 60601-1-2 Edition 4.0 2014-02 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests

C. IEC 80601-2-26:2019 Medical electrical equipment - Part 2-26: Particular requirements for the basic safety and essential performance of electroencephalographs

D. IEC 60601-1-6 Edition 3.1 2013-10 Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability

E. IEC 62304:2006/A1:2015 Medical device software - Software life-cycle processes (IEC 62304 :2006)

F. 10993-1 Fifth edition 2018-08 Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process

G. 10993-5 Third edition 2009-06-01 Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicit

H. 10993-10 Third Edition 2010-08-01 Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization

I. 10993-23 First edition 2021-01 Biological evaluation of medical devices - Part 23: Tests for irritation

2 Precautions:

A. Read all instructions and labels, including this manual before starting to use the device system.

B. Do not attach or detach any device components while the device is on to prevent any damage to the system or components. Turn off the device when attaching or detaching any components to the device

C. Do not use acetone or any other cleaning solvents to clean the device.

D. The battery life of the device may be shortened if the device is used frequently and/or for a prolonged period of time.

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E. The battery life of the device is affected by how often you charge and discharge the battery.

F. The battery life and capacity may decrease when the device is stored in a high-temperature environment.

G. The battery may self-discharge when the device is in storage.

H. Keep the battery charged. If the battery is discharged, it may take a longer time to fully charge.

I. Do not immerse the device into any liquid.

J. Do not expose the device to direct sunlight, heat sources of thermal radiation, moisture, vibration, mechanical shock, excessive dust, or humidity.

K. The warranty will be void if the device is opened, disassembled, or altered by any unauthorized personnel.

L. Do not use when the device is damaged.

M. Do not use when the device is wet. If any moisture penetrates the device, have the device checked by the manufacturer.

N. Do not use caustic or abrasive cleaning agents to clean the device or electrodes.

O. Do not charge when the patient/subject is wearing the device.

P. Always clean the electrodes after each measurement according to the cleaning instructions.

Q. For electrode channels that have persistent problems with signal quality, check the wear of the electrode coating.

R. The battery used in this device may present a fire or chemical burn hazard if mistreated.

S. Do not excessively pull or overstress the device as it may break the device.

T. Do not sit or place a heavy object on the device.

U. Do not use the device under the environment with strong electromagnetic Interference.

V. If used in environments such as high-frequency surgical equipment, magnetic resonance imaging equipment, or other equipment that generates high levels of electromagnetic interference, the device's product performance may be affected. In this case, unexpected high-frequency or environmental artificial waveforms and the recorded EEG waveform may be recorded. However, it does not cause any harm to the patient or operator.

W. Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the iSyncWave. Otherwise, degradation of the performance of this equipment could result.

X. Use of the device in an unsupported environment would not harm the patient or operator.

Y. Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

Z. Avoid exposing the eyes to NIR-LED light during tPBM sessions, as direct exposure to this light can be hazardous. This precaution is essential to mitigate the risk of eye injury or damage.

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③ Known Side Effects:

Transcranial photobiomodulation (tPBM) is generally considered safe.
when administered correctly and within recommended parameters. However, like any medical or therapeutic intervention, it may have side effects or adverse reactions, although they are typically mild and infrequent. Some potential side effects and considerations associated with tPBM include:

A. Headache: Some individuals may experience mild headaches after tPBM sessions, which typically subside within a short time. Adjusting the treatment parameters or session duration may help alleviate this side effect.

B. Scalp Sensitivity: A sensation of warmth or tingling on the scalp or skin under the device during treatment is possible but usually not uncomfortable.

C. Fatigue: Some users report temporary fatigue or drowsiness following tPBM sessions, which can be attributed to the relaxation effects of the treatment.

D. Nausea: Although rare, some individuals may experience mild nausea or gastrointestinal discomfort during or after tPBM. If this occurs, it is advisable to discontinue treatment and consult a healthcare professional.

E. Skin Irritation: Prolonged or repeated tPBM sessions may, in some cases, lead to skin irritation or redness at the treatment site.

F. Unknown Long-Term Effects: While short-term studies have not identified significant adverse effects, the long-term safety of tPBM is still being researched, and potential risks may become more apparent with further investigation.

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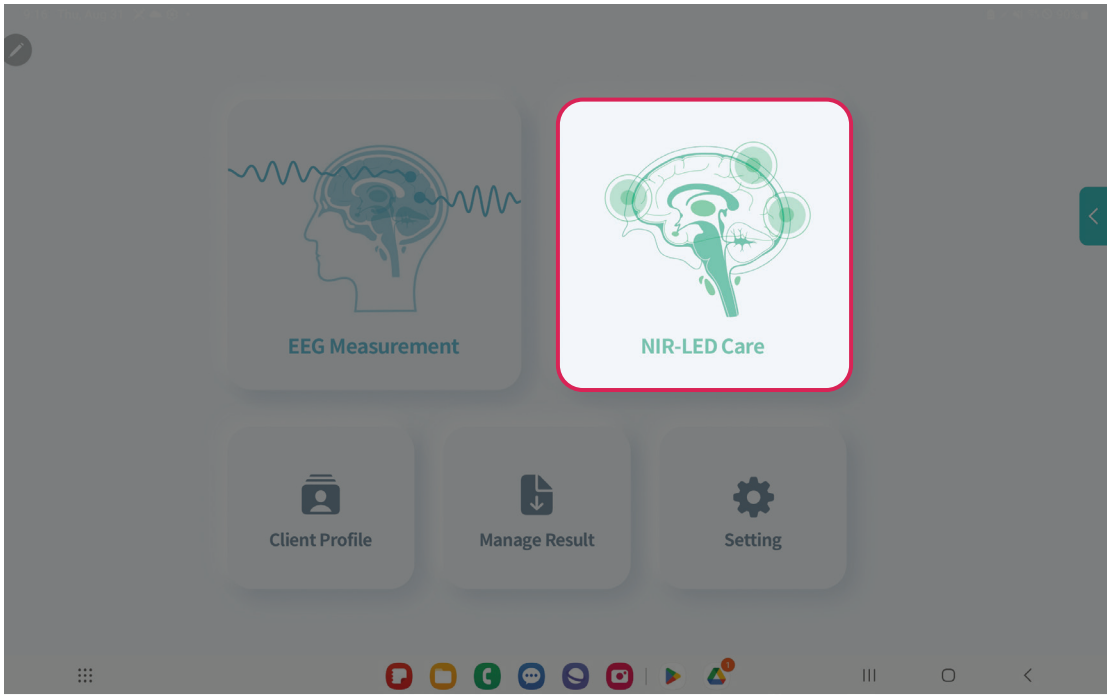
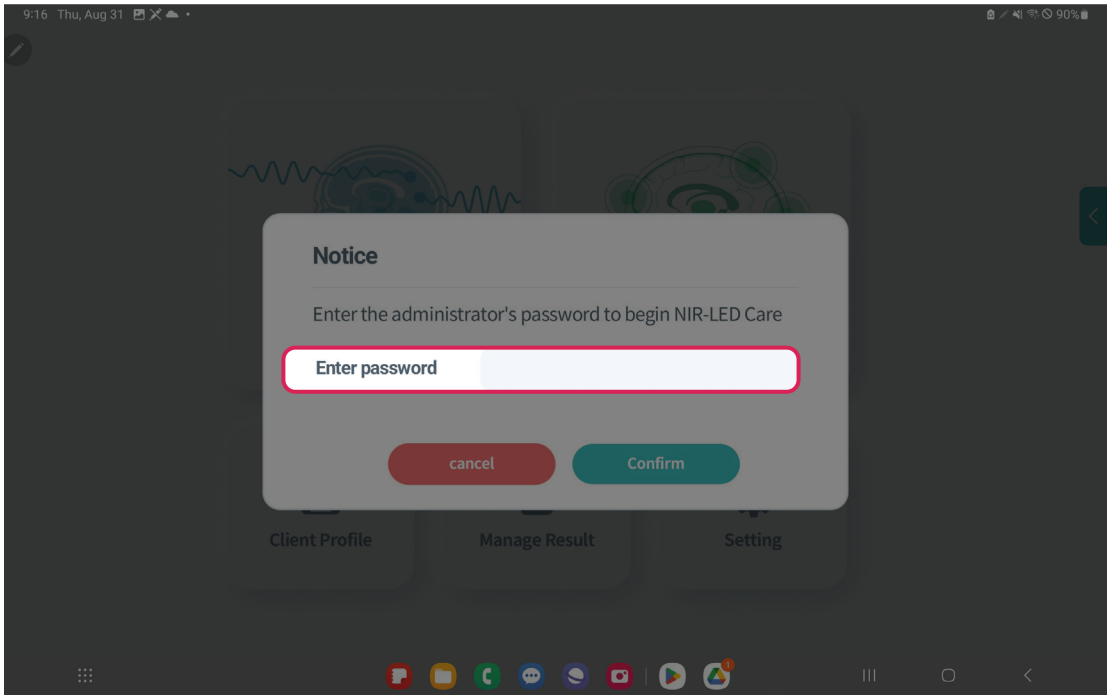
Procedure

1. Once logged in, on the main screen select NIR-LED Care



2. Type in your administrator's password for NIR-LED Care Feature. This password will be provided to you once you have purchased the PBM feature. Press the confirm button after entering the password.



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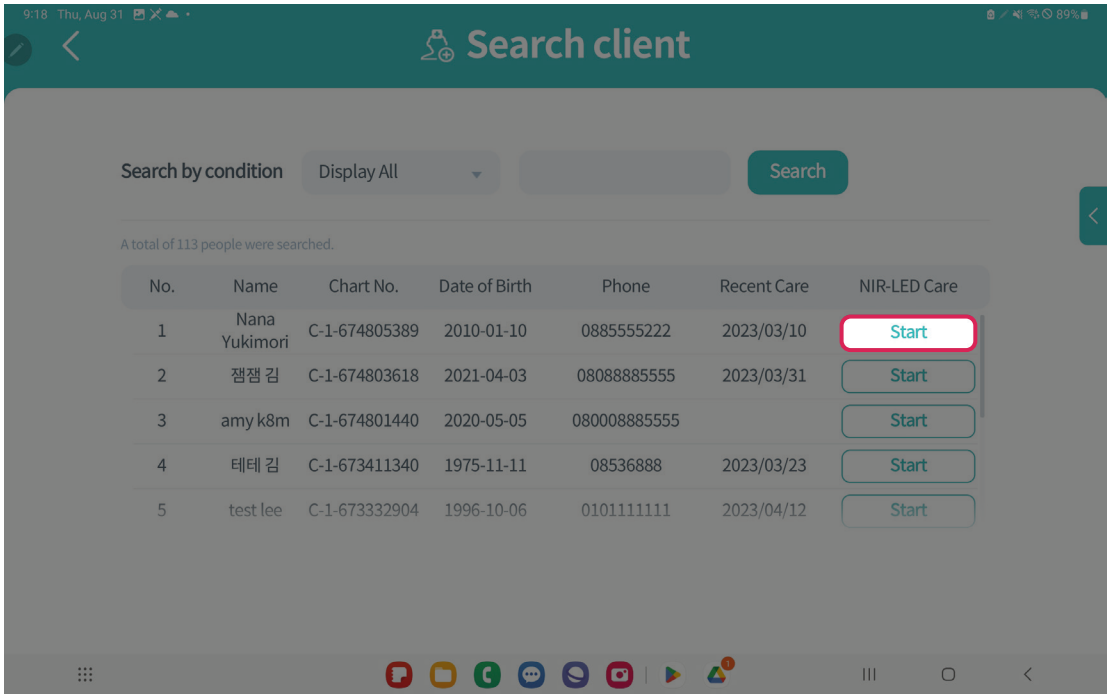
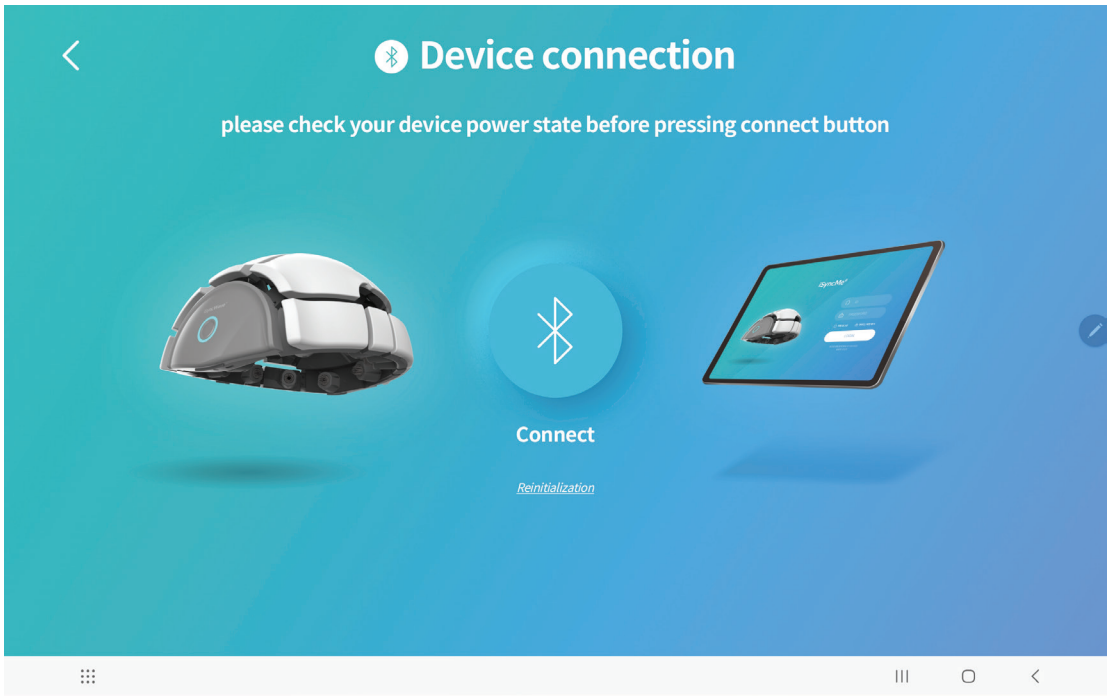
3 After clicking the “Confirm” button, your “Search client” screen will appear. Search for the desired client and click the “**Start**” button to continue.



4 Connect your iSyncWave App to your iSyncWave helmet. Make sure your iSyncWave helmet is turned on.



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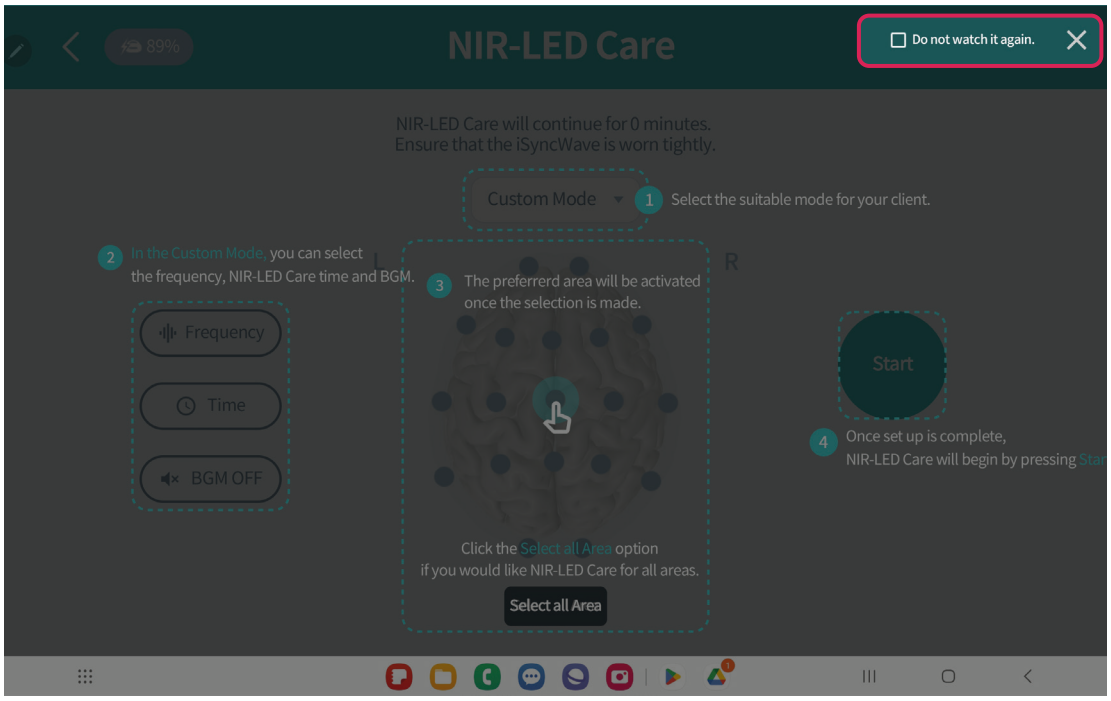
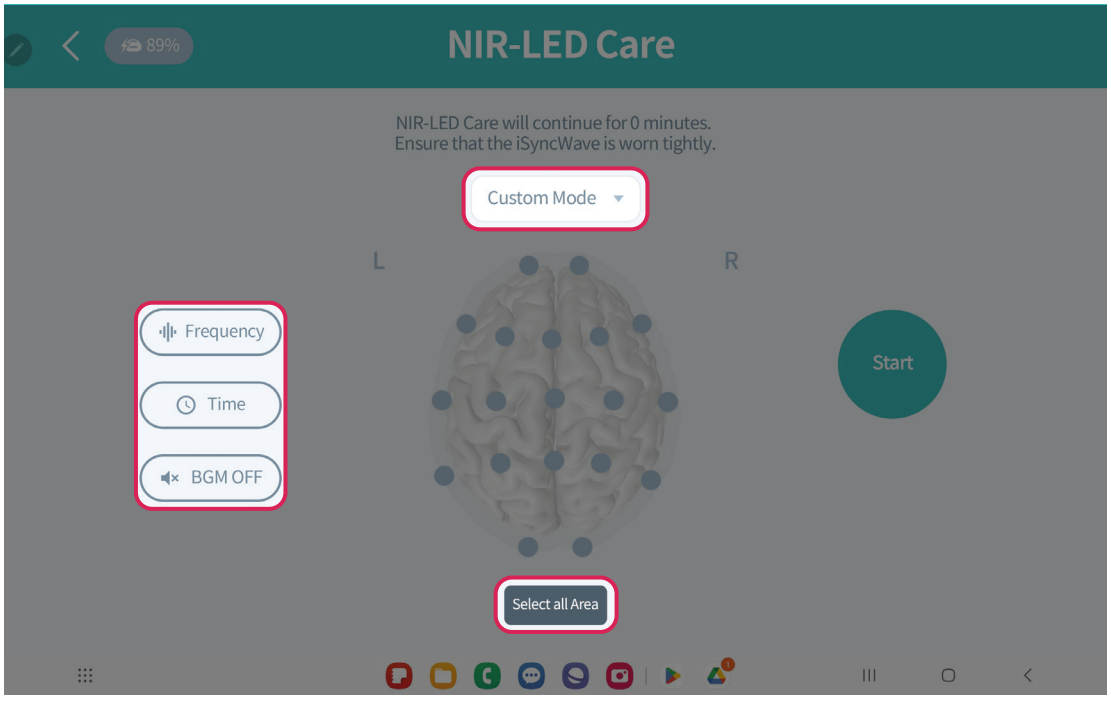
5 Once your iSyncWave has been successfully connected to the App, the NIR-LED Care Feature screen will appear. A pre-screen will show the characteristics of your Photobiomodulation (PBM) Therapy that are tunable (Frequency, Time, Background Music (BGM), Custom / Prescription Mode, Area). If you don't want this pre-screen to show up again, make sure to click on the "**Do not watch it again**" box at the upper corner. To proceed, press the "**X**" in the upper corner.



6 Before you start with the desired PBM Therapy session, you'll need to set up the desired parameters for **Mode, Frequency, Time, Area and BGM** (on/off).



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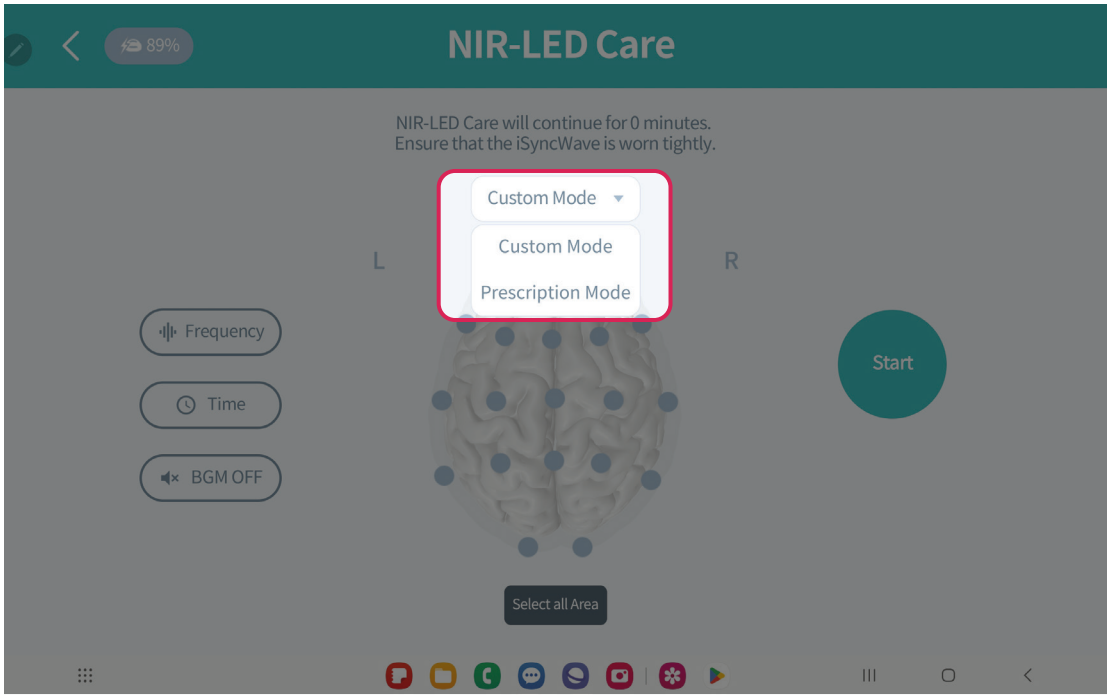
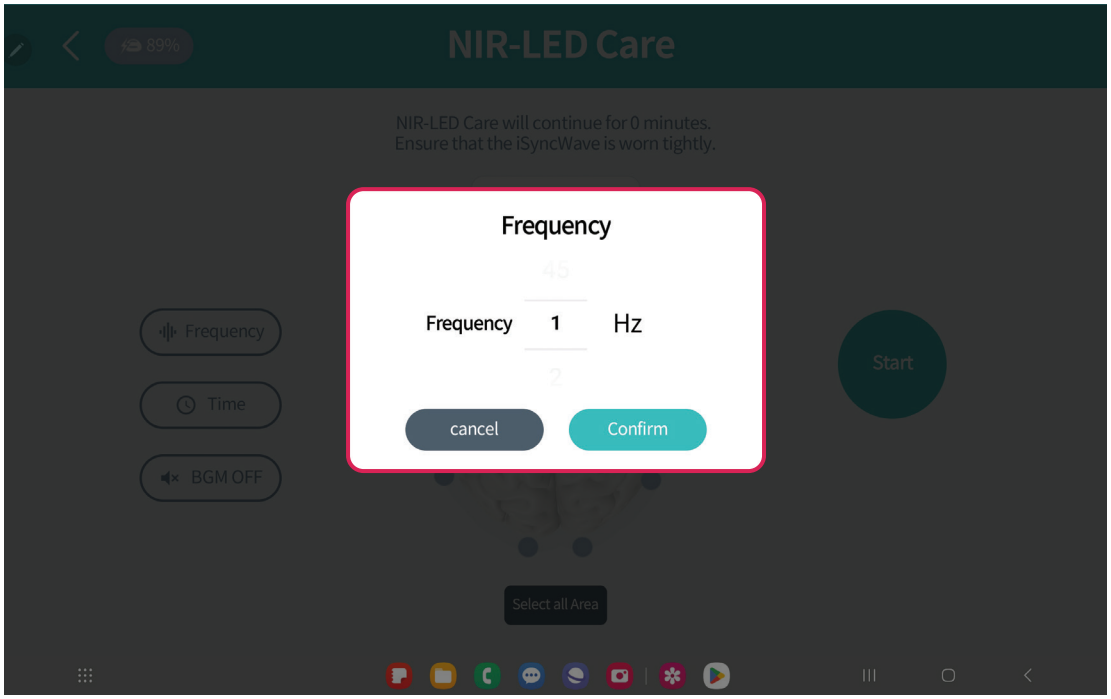
7 Select the desired Mode. Click the “Custom Mode” button. You may choose between “Custom” or “Prescription” . Prescription is only used if your physician already prescribed your therapy session on the platform.



8 Select the desired Frequency. Select the “Frequency” button and the frequency box will pop-up. The available frequency range goes from 1-45 Hz. Select the desired frequency and press the “Confirm” button.



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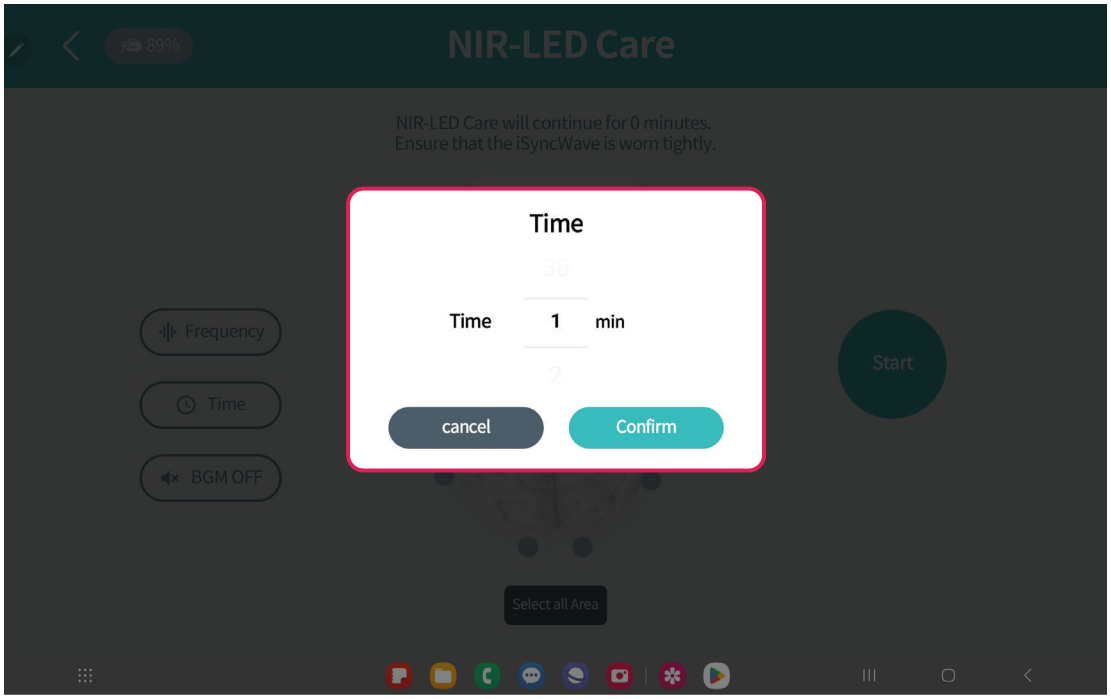
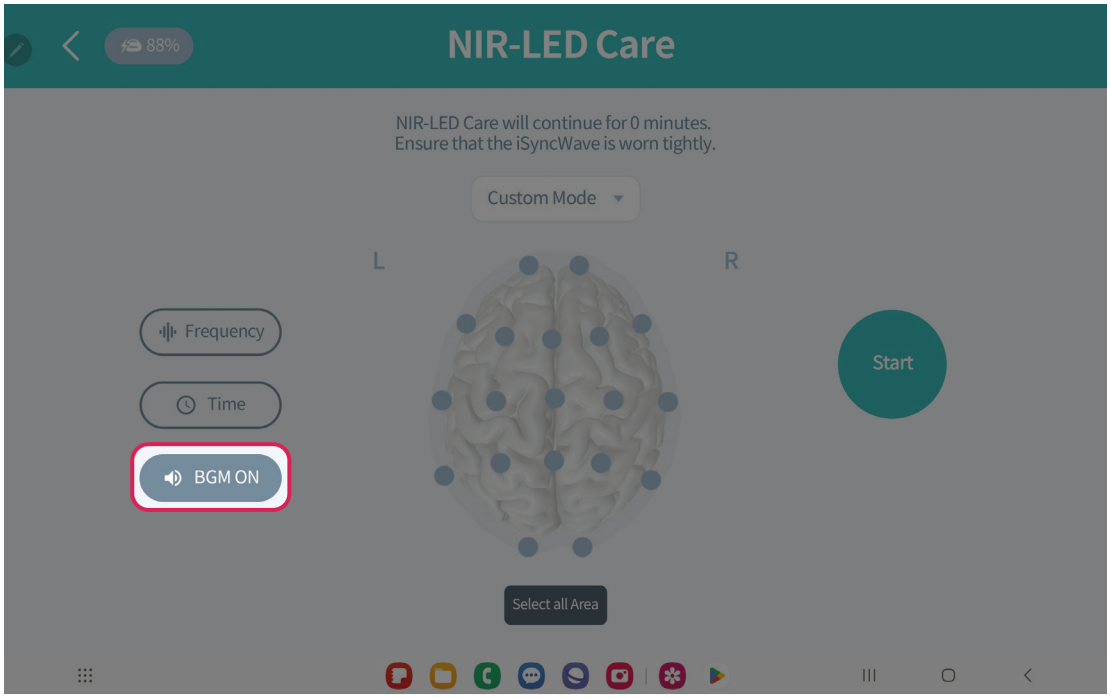
9 Select the time for your PBM session. Click the “Time” button and a window will pop up as below. In your Time window you may select any value ranging from 1-30 minutes. After you’re done with your selection press the “Confirm” button to proceed.



10 You may turn on the “Background Music (BGM)” feature by clicking on the Sound icon if music is desired for the Therapy session. If not, just leave “BGM OFF”.



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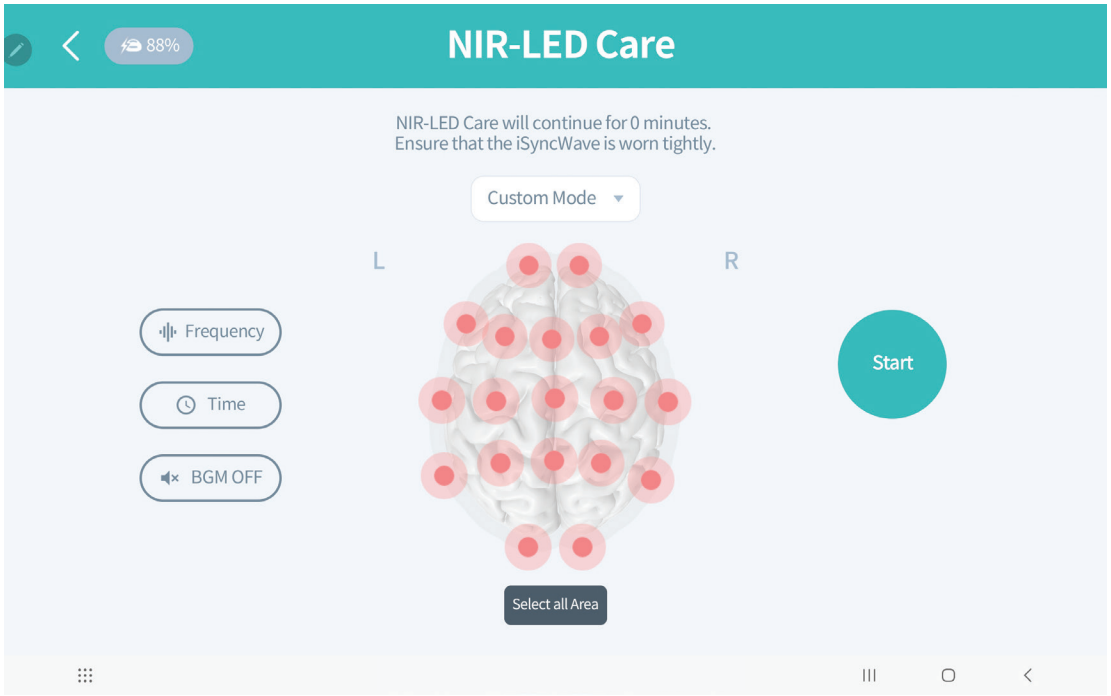
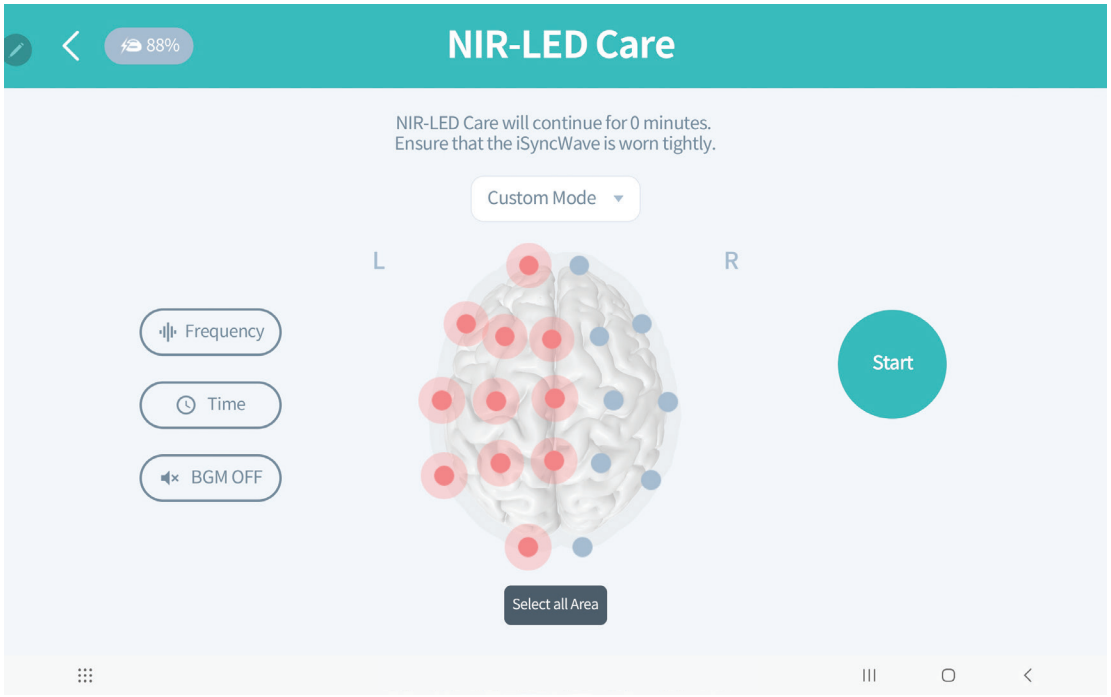
Example: Select ALL AREAS:

11 Select the targeted area to stimulate. If you go for a generalized protocol, select “Select all Area”.



Example: Select ALL AREAS:

12 If not, select manually the desired positions that will be trained with the protocol.



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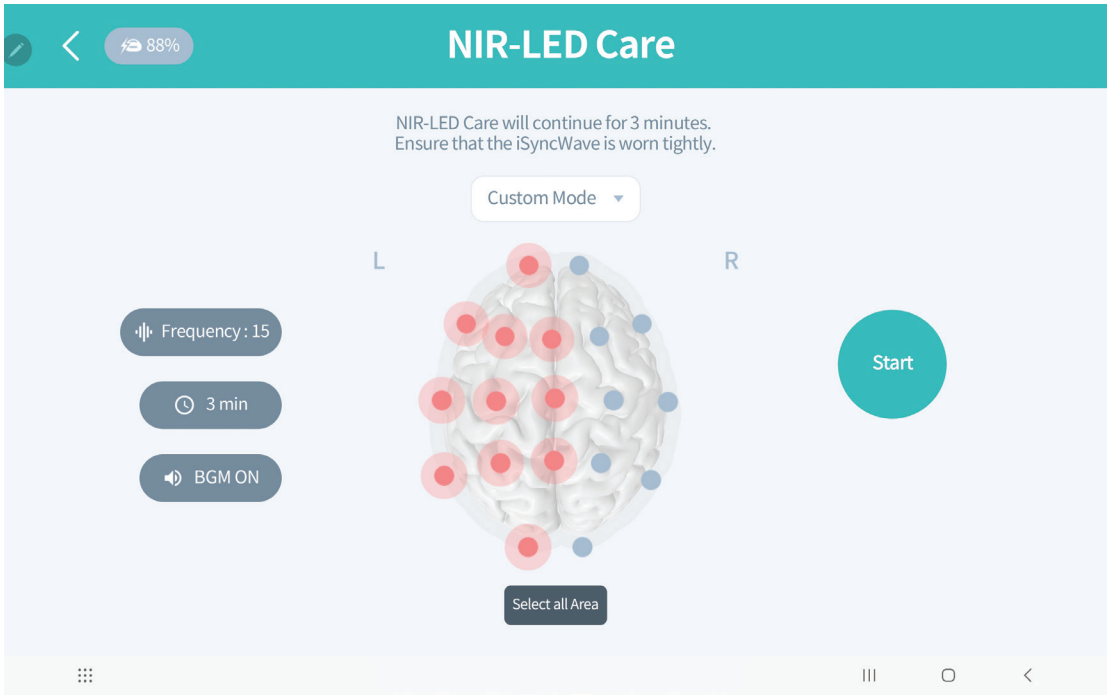
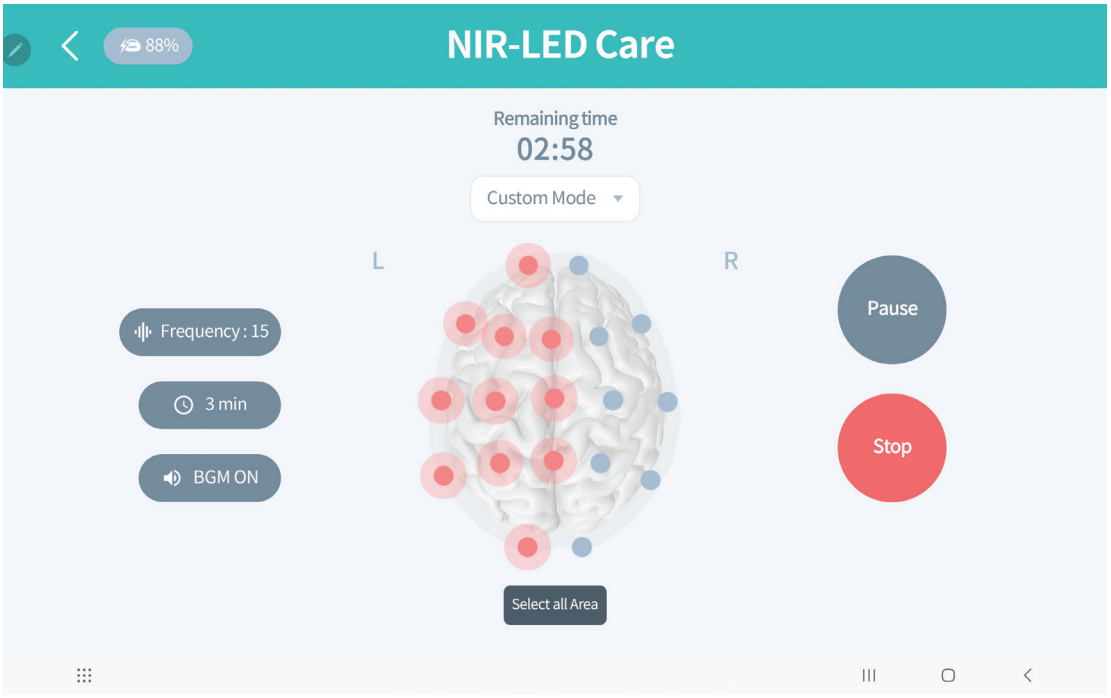
13 Once all the tunables features have been chosen (e.g. Frequency = 3 Hz, Time= 3 minutes, BGM ON, Custom Mode, Manual Selection of Area) proceed to select the “Start” button. During the session, you may pause or stop the PBM.





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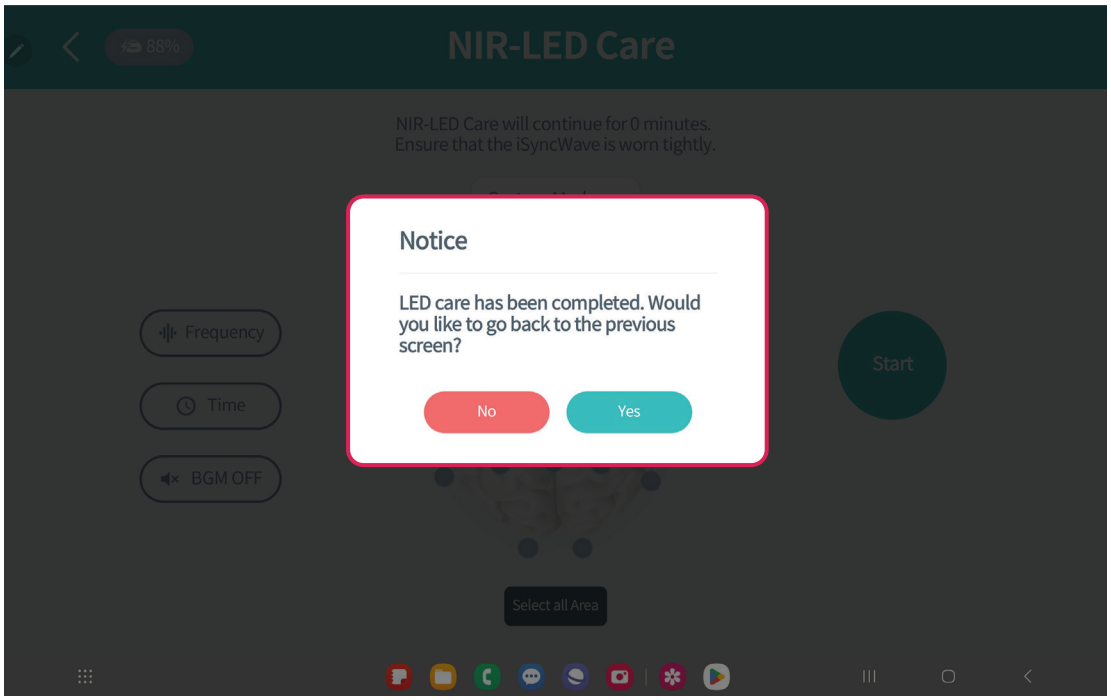
14 Once your session is over a window will appear as shown below. You can choose "**No**" to return to your "**Search client**" screen or "**Yes**" to continue with a different session and/or protocol.



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