Oxy-Pro

Instruction Manual

Safety precautions

The precautions given here are for the safe and correct use of this product and to prevent from harming you and other people and causing damage to property. In order to clarify the magnitude of harm or damage and the degree of urgency, the contents that are expected to occur if mishandled are divided into "warning" and "caution". All of these are important safety issues, so make sure to read them carefully.

⚠ WARNING	Indicates a potentially hazardous situation which, if mishandled, could result in death or serious personal injury.

1. Keep batteries and products out of the reach of children. There is a risk of accidental ingestion. If swallowed, consult a doctor immediately.
2. Do not throw the battery in a fire. It may explode.
3. Do not allow the battery to get wet. It may heat the battery.

⚠ CAUTION	Indicates a potentially hazardous situation which, if mishandled, could result in moderate or minor personal injury, and/or property damage.

1. Do not disassemble. It will be the cause of the failure.
2. Do not subject it to excessive shock or vibration. It will be the cause of the failure.
3. Make sure that the batteries are correctly placed (+) and (-). It will be the cause of the failure.

It may cause liquid leakage, heat generation, rupture, etc. and damage the main body.

4. Do not replace the battery while the power is on.
5. Use the included fixing belt when using in direct sunlight.
6. Be careful not to hurt your skin with the hook-and-loop fastener.
7. Please attach it so that the hook-and-loop fastener does not stick to your clothes. It may cause fraying or transmission.
8. The shade is made of elastomer (chemical rubber), and its elasticity deteriorates if it is pulled unnecessarily.
9. Do not spray rubbing alcohol directly on the device.
10. Wipe dry the device with a soft cloth.
11. The shade is a water-resistant material, so it can be washed with water.

Do not use organic solvents (benzine thinner).

12. Wireless is Bluetooth-BLE. The range of radio waves is within a range of 5 meters.
13. The device is not a medical device. When using it for medical treatment, please use it after obtaining the approval of the ethics committee of the university or hospital.

Instruction Manual for Oxy-Pro (Model: Hb141)

This is the instruction manual for the measurement display program of the tissue oximeter Oxy-Pro ©.

Oxy-Pro is registered as a trademark, and the measurement algorithm is protected by the patent laws of Japan, the United States, and the United Kingdom. In addition, we have applied for and registered Japanese patents and utility models for the shape and fixing belt of Oxy-Pro.

Table of contents

Features of Oxy-Pro

Oxy-Pro has two measurement modes and a correction function for the influence of subcutaneous fat.

- Real-time mode

The measured values of Oxy-Pro are measured and displayed in real time on smartphones, tablets, and computers via Bluetooth.

- Storage mode

This mode can take measurement apart from smartphones, tablets, and computers without using Bluetooth that has a finite reach. The measured values are recorded and saved in the built-in flash memory, and the data can be downloaded via Bluetooth afterwards by bringing it closer to a smartphone, tablet, or computer.

- Correction mode

In biometric measurements using near-infrared light, the thickness of subcutaneous fat has a large effect as an error factor. Oxy-Pro corrects and outputs the oxygen saturation value by inputting the thickness of subcutaneous fat in advance.

1. Preparation

1-1. Install the application

Compatible devices and OS for smartphone apps: Smartphone, Tablet

<Supported OS>

iOS: 11.0 or newer (At Japanese store only at this moment)

Android: 7.0 or newer

Even if the OS version is compatible, it may not work depending on the device model.

Install the required application:

For Android smartphones and tablets

1. Open "Play Store".

2. Search for "Oxy-Pro" in the search window.

3. Tap “Install”.

4. The app icon of Oxy-Pro will be added in the home screen.

* The screen design and operation procedure may differ depending on the Android version and mobile device type, so follow the instructions on the screen.

* The application can be installed from our website.

For iPhones and iPads (At Japanese store only at this moment)

1. Open “App store”.

2. Tap “Search” icon in the right bottom.

3. Search for “Oxy-Pro”.

4. Tap “GET”.

5. Tap “INSTALL” and the installation begins.

6. The app icon of Oxy-Pro will be added in the home screen.

1-2. Preparation for measurement

Battery installation

Open the battery cover located on the front side of the device using a coin. Make sure to place the battery as the side marked (+) faced up. Place back the battery cover.

Install the main device (Oxy-Pro) into the shade.

Turn on Bluetooth of the smartphone or tablet if it is turned off.

1-3. Add a device

The following screen will be displayed when the application opens. Turn on the Oxy-Pro and confirm that the display light flashes. Tap “Monitoring” tab on the application.

(* For iPhone/iPad, tabs are located on the bottom side of screen.)

Serial number will be displayed in the device number column. Select the device and tap “Entry/Delete”. If two devices are used at the same time, register both devices.

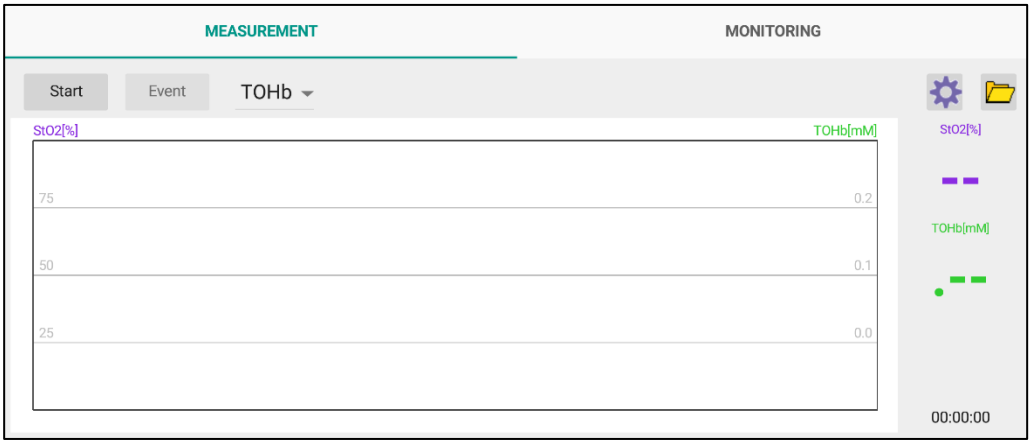


Figure 1. Android display

Figure 2. iPhone display

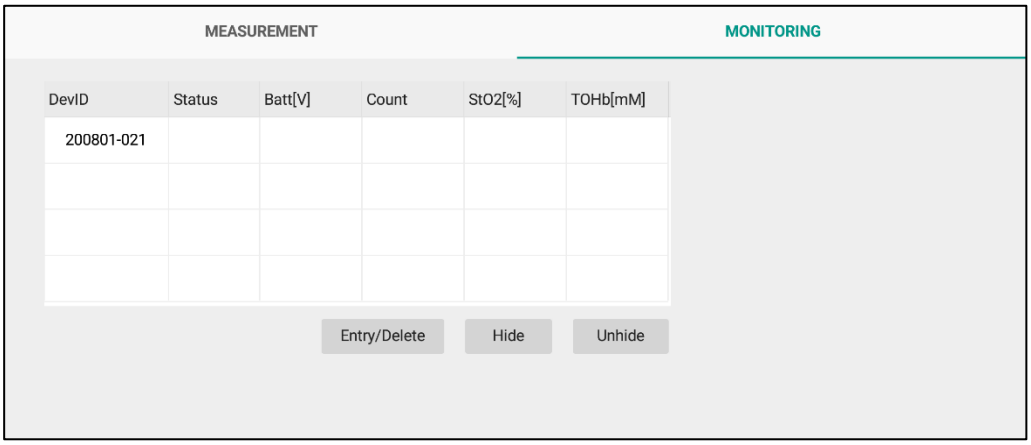


Figure 3. Android display

Figure 4. iPhone display

2. Setting screen

Tap the "Measurement" tab, and the following screen will be displayed.

Tap "Start" in the upper left corner (For iPhone/iPad, the tab is located at the bottom of the screen).

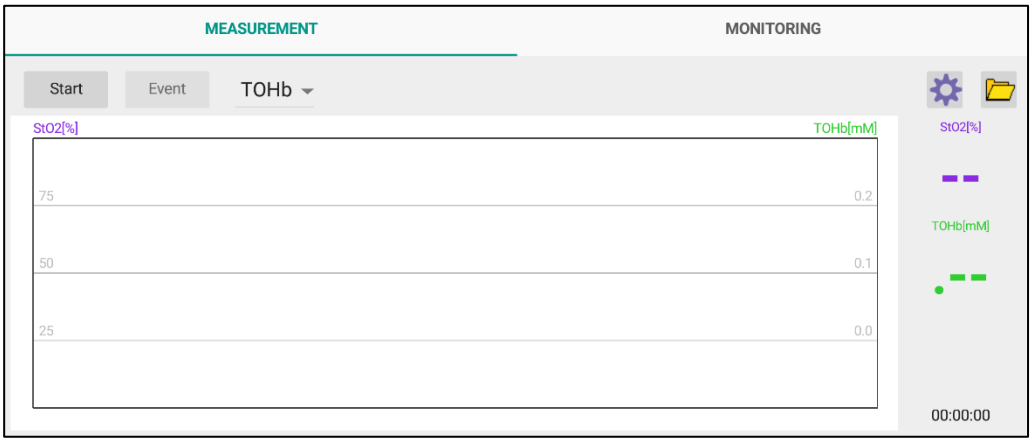


Figure 5. Android screen

A description of each item is explained below. Set the value for each.

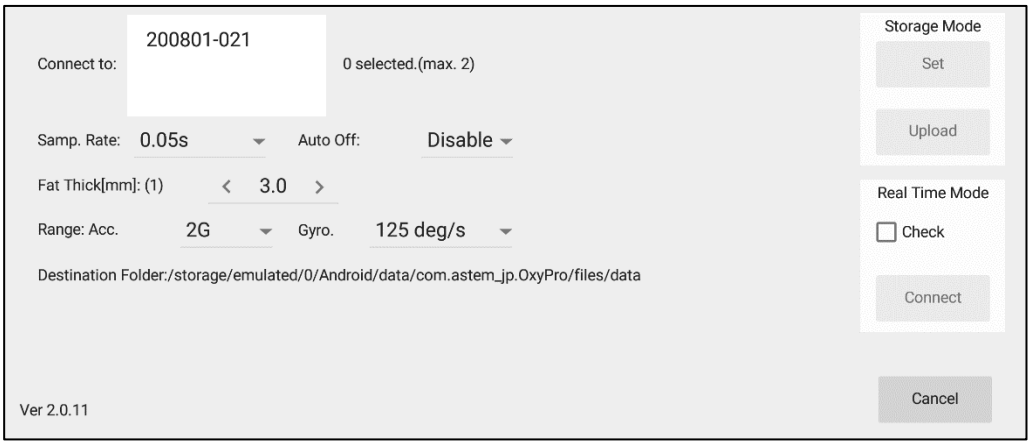


Figure 6. Android screen

2-1. Connect to

The serial number (registered device number) of the Oxy-Pro that is currently available for communication will be listed. Tap and select the serial number to be connected. When using two Oxy-Pro units simultaneously, turn on the power of those. The serial numbers of them will be listed. Tap and select their serial numbers.

2-2. Sampling rate

Set the sampling interval.

The sampling interval can be set to 0.05 sec, 0.1 sec, 0.2 sec, 0.5 sec, 1.0 sec, or 5.0 sec. When using two devices in real-time mode simultaneously, some smartphones and tablets cannot support sampling rate of as fast as 0.05 sec due to their capabilities. Please check it before taking measurement. There is also a possibility of being affected by the radio wave environment such as Bluetooth.

2-3. Thickness of intervening tissue

The algorithm used in Oxy-Pro corrects the measured value of oxygen saturation by setting the subcutaneous fat thickness, and displays and outputs a value closer to the actual measurement value. The intervening tissue thickness (thickness of fat) can be set from 1 to 11 mm.

Pinch the skin of the measuring area and set the value of 1/2 of the thickness of the area (For example, if the thickness is 8 mm, set the value of 4 mm).

The thickness can be set individually for each of the two units for the simultaneously use.

Measuring the thickness of the subcutaneous fat layer with an ultrasound tomography system and inputting the fat thickness will output more accurate oxygen saturation measurement values.

2-4. Accelerometer and gyroscope range

Set the range of the mounted 6-axis sensor (3-axis accelerometer, 3-axis gyroscope).

Accelerometer: ±2G, ±4G, ±8G, ±16G

Gyroscope: ±125 °/S, ±250 °/S, ±500 °/S, ±1000 °/S, ±2000 °/S

2-5. Auto-off

Set the time until the power is automatically turned off when the device is in standby mode (not in real-time or storage mode measurement).

Options: Disable, 10 minutes, 30 minutes, 1 hour

When "Disable" is selected, the power will not be turned off automatically.

2-6. Storage mode operation

For details, please refer to section 4, Measurement (Storage Mode).

By tapping "Set" button, the settings will be applied to the Oxy-Pro. If the Bluetooth connection is not established at this time, the message "ID is set" will not be displayed.

2-7. Readout

Download the data measured in storage mode to your smartphone or tablet. The data will be saved in the internal storage.

※ Only one record can be saved on storage mode. The previously saved record will be overwritten every time when a new measurement starts on the storage mode. Please refer to 4. Measurement (Storage mode) for details.

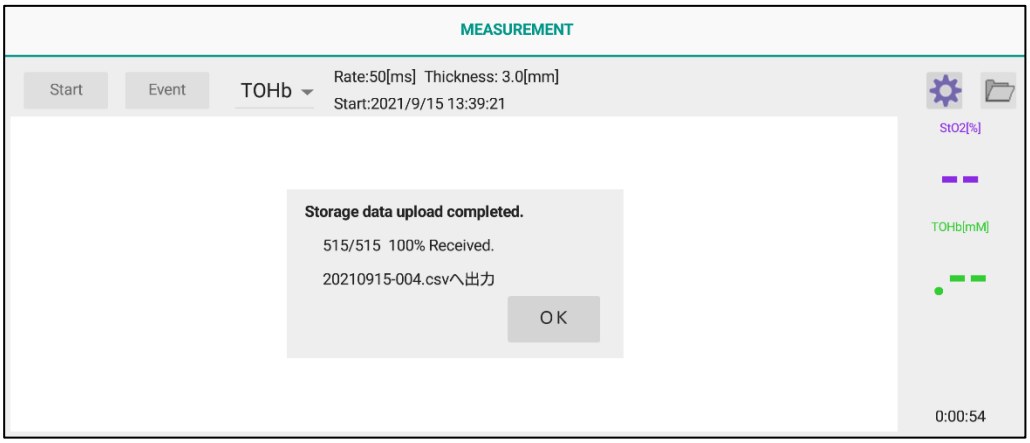


Figure 7. Display during readout (in storage mode)

When the measurement is finished, the measured value is displayed as a trend graph as shown on the next page.

For the explanation of each item, please refer to the next section 3, Measurement.

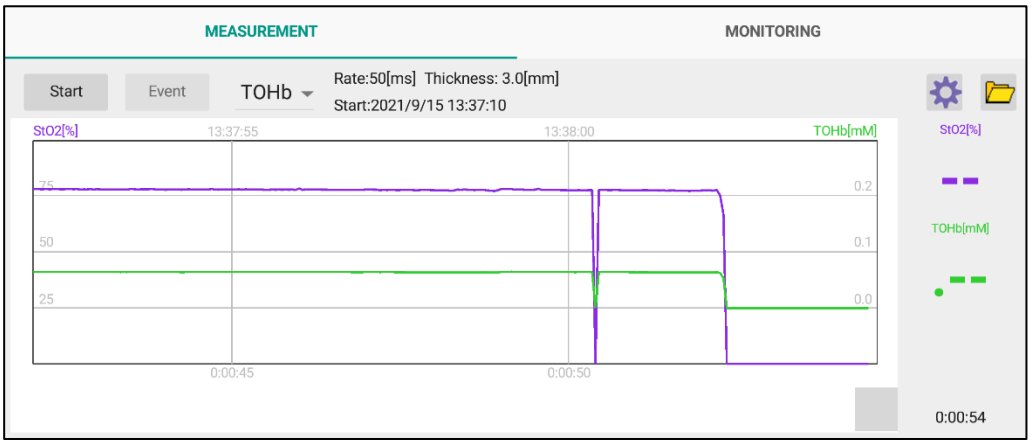


Figure 8. Data display screen for data downloaded in storage mode

2-8. Sensor check

By measuring the optical sensor readings, it is possible to check if the Oxy-Pro is properly attached to the skin.

If the Oxy-Pro is lifted off the skin, external light will enter through the gap, so it must be completely attached to the skin for conducting good measurement.

Two optical sensors are used to measure the tissue oxygen saturation. They are placed at 20 mm and 30 mm from the light source (LED), respectively.

When starting measurement with the "sensor check" is checked, the measured value of the optical element will be displayed on a trend graph where red = 20 mm and blue = 30 mm.

The measured values with no external light coming in from openings etc., are the values of sunlight etc., that has penetrated the living body. Ideally, the two values should be close to zero.

2-9. Functional purpose of the fixing belt

1. To fix the Oxy-Pro to the skin.
2. To shield the Oxy-Pro from sunlight (even on cloudy days).

When taking measurements outdoors, make sure to wear the fixing belt. If it slips off, fix it with a tape and use the fixing belt on top of it to shield the sunlight.

3. Measurement (Real-time mode)

The following is the screen during measurement, and the explanation of each command is given below.

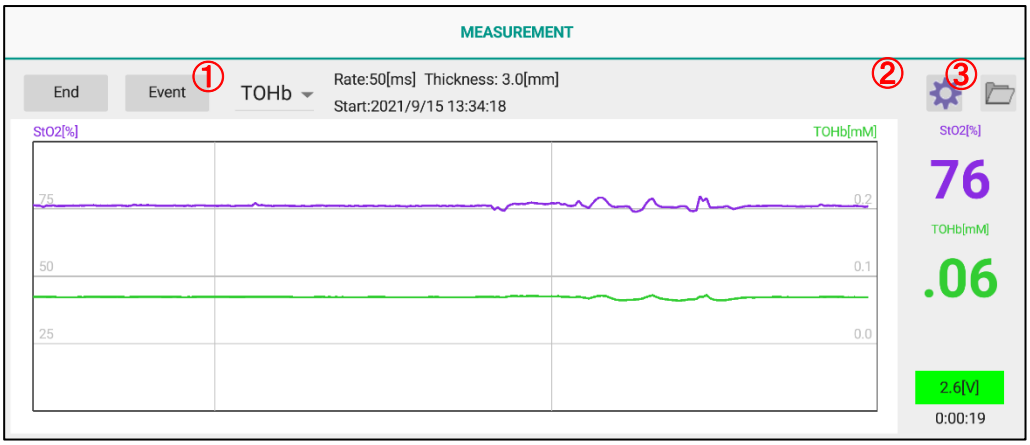


Figure 9. Screen during measurement in Real-time mode

3-2 Disconnect

Tap this button when the measurement is finished. The measurement data (csv) will be saved in the internal storage.

3-3. Event

A function that allows users to insert a marker during measurement. When tapped, a marker will be inserted. .

3-4. Moving average

This function processes the moving average of the displayed data during measurement. However, these data will not be saved in the csv file (raw data will be saved). This function is only for displaying the trend graph.

Select from the upper right of the measurement screen (① in Figure 9) and set: None", "3 points", "5 points", "7 points", "9 points", or "11 points".

3-5. Display selection

Select "Accelerometer" or "Gyroscope" to be displayed on the trend graph.

Select "Accelerometer" or "Gyroscope" from the upper right corner of the measurement screen (① in Figure 9).

This will not be displayed on the trend graph on the smartphone.

3-6. Data display

Select and display the value of each hemoglobin. (Figure 9, ②)

OXHb" Oxygenated Hemoglobin, "DXHb" Deoxygenated Hemoglobin, "TOHb" Total Hemoglobin

Unit: millimoles mM

3-7. CH display selection

Select the trend display when two units are simultaneously used.

(When two units are used, "CH1" and "CH2" will be displayed on the left side of ① in Figure 9.)

3-8. Digital Display of Oxygen Saturation

The measured values will be displayed in figures with the unit of %on the right side of the screen.

3-9. Selected hemoglobin concentration digital display

Displays the current measurement value of the hemoglobin selected in 3-6 "Data Display".

Red = oxygenated hemoglobin

Blue = Deoxygenated hemoglobin

Green = Total hemoglobin Unit : mM

3-10. Battery voltage

Displays the battery voltage of the Oxy-Pro.

Battery voltage	Display color	Status
2.6 V - 3.1 V	Green	Safe to use.
2.5 V - 2.6 V	Yellow	It is expected that the measurement will be interrupted.
2.5 V or less	Red	Replace the battery.

3-11. Check the measured data

The measured data can be checked on the spot. Tap the gear icon (③ in Figure 9).

Slide the slide bar at the bottom to the left or right to check the data in the area of interest. Double-tap on the graph area to switch between full and normal view. (If the graph is displayed in normal view on one screen, it will not be switched.)

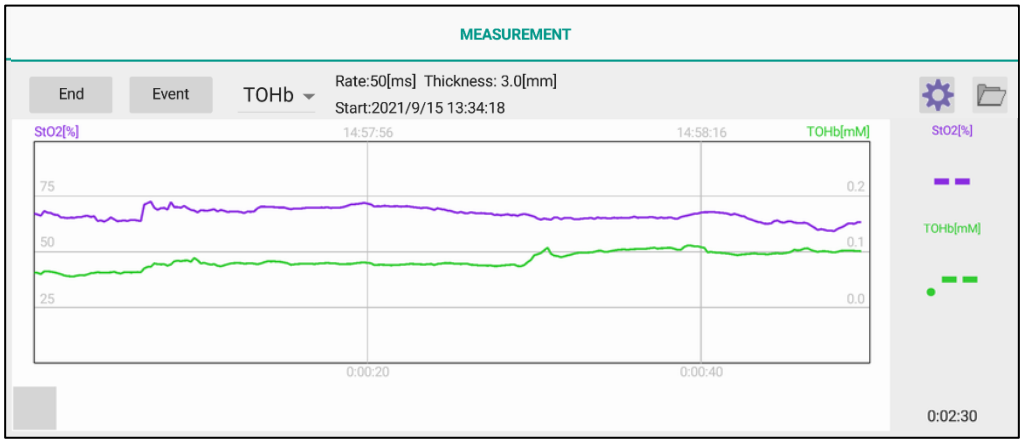


Figure 10. Real-time mode display during measurement

Information on the loaded data will be displayed in the upper center to the graph. These include sampling rate, fat thickness, and the date of measurement start.

The upper part of the trend graph shows the time at the measurement (JST), the lower part shows the elapsed time since the start of measurement, the axis on the left of the trend graph is the oxygen saturation (%), and the axis on the right is the unit of hemoglobin (mM).

3-12. Axis of the trend graph

The axis on left is the oxygen saturation (StO_2: %), starting from 25 % at the bottom. Normal StO_2 value is around 65 %.

The axis on right is the amount of each hemoglobin with the unit of mM (simplified notation of m mol/L).

4. Measurement (Storage mode)

In the storage mode, the device is not wirelessly connected to the host device (smartphone, tablet, PC, etc.), so the storage mode is useful in water where radio waves do not propagate, or during exercises where the host device may interfere with the exercise.

4-1. Setting

Tap "Set" in the upper right corner of the "Storage Mode" dialog box to set the various setting values to Oxy-Pro.

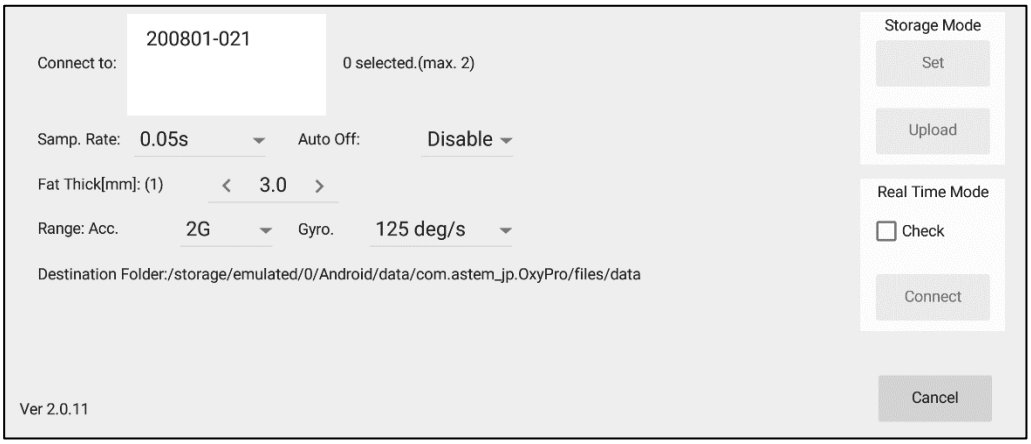


Figure 11. Setting display (Storage mode)

4-2. Measurement

Confirm that the indicator lamp is blinking green and press the power button again. The green color will change to red.

The measurement data is stored in the built-in flash memory while taking measurements.

4-3. Readout

Download the data measured on the storage mode to your smartphone or tablet. The data will be saved in the internal storage.

After completing the measurement, turn off the Oxy-Pro and turn it on again to confirm the indicator lamp blinking green, then tap "Start" button, then tap "Upload" in the "Storage mode" box. The measurement data will be downloaded to the internal storage. While downloading, "Storage data upload completed" and "XX% Received" will be displayed.

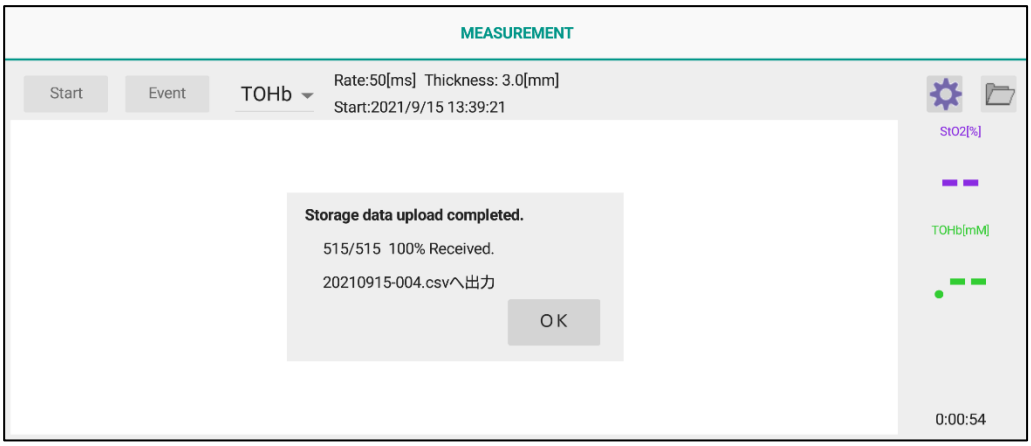


Figure 12. Readout display

Tap "OK" after the message " 00000-0000.csv Created" is shown. After the download is completed successfully, the data will be saved in the file.

The Oxy-Pro measurement application allows you to check the acquired data. The saved data can also be reopened on the application, but it is not possible to compare multiple data, so we recommend using the "Oxy-Pro data Viewer" program for it.

※ Only one record can be saved on storage mode. The previously saved record will be overwritten every time when a new measurement starts on the storage mode. Please refer to 4. Measurement (Storage mode) for details.

5. Monitor display

The status of the Oxy-Pro is monitored on the storage mode, since it is unclear whether the measurement is successfully being performed. The status will be updated and displayed approximately every 5 seconds. Only devices that are turned on can be monitored.

When tapping “MONITORING” tab, the screen will switch to the one shown below (The status of the registered devices will be displayed). All Oxy-Pro devices that are turned on in the surrounding area will be listed. Registered devices will be listed as priority in bold. Non-registered devices will be displayed in fine print. The application stores the list of devices (There is no limit to the number of devices that can be registered). Four

devices can be monitored simultaneously. Unhide unnecessary devices by selecting the serial number of the device and tapping "Hide".

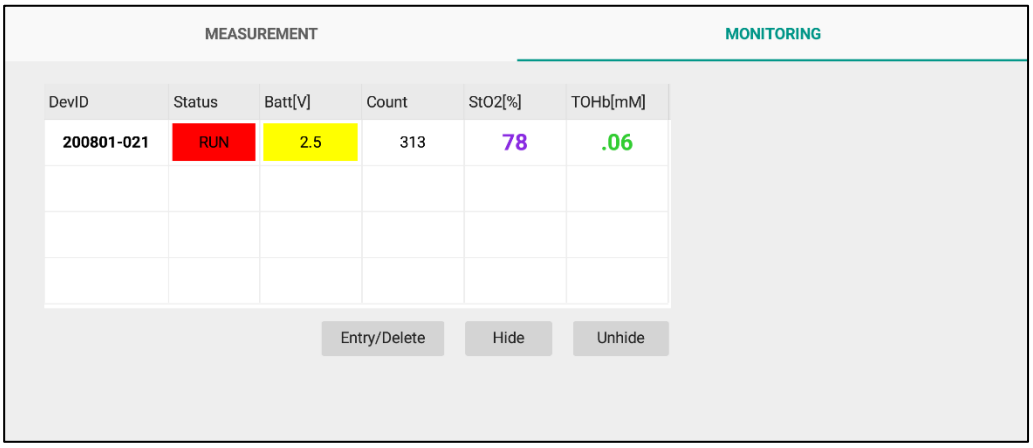


Figure 13. Monitor display

Status: Indicates operating status, standby status, or storage mode measurement.

Batt[V]: Indicates the battery voltage. When the voltage drops below 2.5 V, the display turns red informing the timing for battery replacement.

Count: Indicates the number of stored data in the built-in flash memory of the Oxy-Pro. The count increases during the measurement on the storage mode.

StO_2[%], TOHb[mM]: Measured values are displayed during the storage mode measurement.

Hide button: Hides the selected device from the list.

Unhide button: Restores all hidden devices to the list.

The "Hide" button hides the selected device, but the hidden device cannot be selected. The list of registered devices will be stored in a file.

*The list of registered devices will be saved in the file, but the status (unhidden) will not be saved in the file, so all registered devices will be listed next time when the program is started.

6. Notes (Description of units)

The unit of StO_2 (oxygen saturation) is %, which indicates the average oxygenation state of blood in capillaries. The blood volume index, which is displayed in arbitrary units, is equivalent to the hemoglobin (OX, DX, TOHb) concentration [mmol/L], assuming optical constants based on the literature.

For example, a blood volume index of 0.2 is equivalent to an Hb concentration of 0.2 mmol/L, which is 1.3 g/dL if the Hb molecular weight is 65,000. This value means that there is 1.3 g of Hb in 1 dL of biological tissue, not

the amount per dL of blood. Since the blood volume index is proportional to the reciprocal of the scattering coefficient of biological tissue, it is necessary to take into account the possibility that a scattering coefficient variation of about 20~30 % is superimposed when comparing values among individuals.

For StO_2, the error due to the difference in the scattering coefficient is small because the "ratio" of the concentration is calculated.

Hemoglobin 1 mol = 65,000 g

Hemoglobin concentration 0.2 m mol/L

= 0.2 * 65,000g * 10-3 /L

= 13 g/L = 1.3 g /dL

Note: In the measurement program, the unit m mol/L is written as mM.

・Bluetooth-BLE = Bluetooth Low Energy

(2.4 GHz band communication method, specification added in Ver 4.0 or later.)

7. Data display program (Oxy-Pro Data Viewer)

Oxy-Pro data viewer application can open saved csv files that contains measured data by Oxy-Pro .

The data viewing program is for Windows only. Please refer to the help of the program for detailed instructions.

Download the data viewing program (Oxy-Pro_data_viewer)

Please download the Oxy-Pro data viewer program from the catalog software download page of the product introduction on our website (https://www.astem-jp.com).

ASTEM website:

Software download

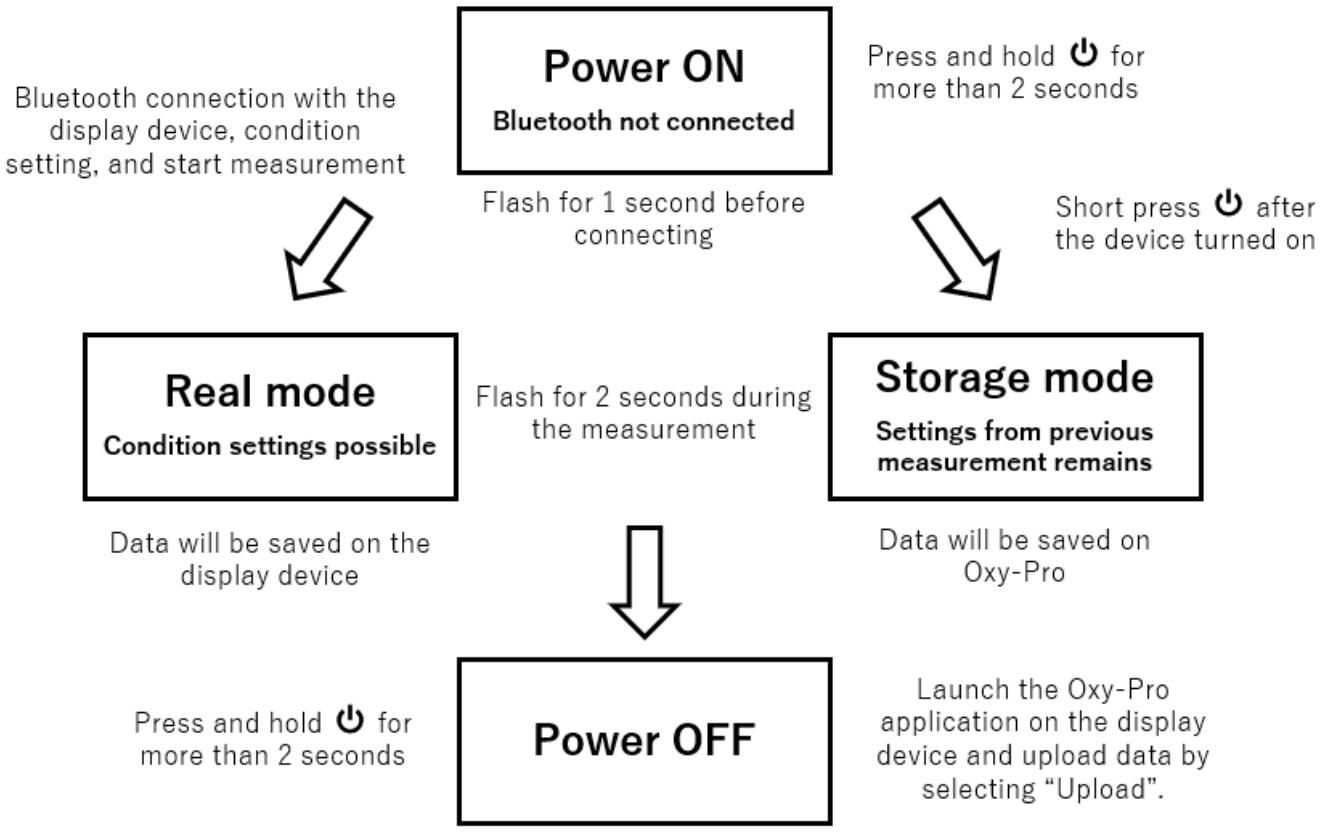
8. Specifications

Measurement technology	SR-NIRS (spatially resolved method, near-infrared spectroscopy)
Measurement item	Oxygen saturation (StO_2 : %)
	Oxygenated hemoglobin (Oxy-Hb : mM)
	Deoxygenated hemoglobin (Deoxy-Hb : mM)
	Total Hemoglobin (T-Hb : mM)
	Accelerometer, gyroscope
Measurement mode	Real-time mode: Measurement data is displayed in real-time time on a smartphone, etc.
	Storage mode: Store measurement data and downloads the data to a smartphone or other device for display after completion.
Sampling rate	Single-Mode: 0.05 sec/20 Hz ,0.1 sec/10 Hz ,0.2 sec/5 Hz ,0.5 sec/2 Hz ,1.0 sec/1 Hz ,5.0 sec/0.2 Hz
	Dual-Mode: 0.05 sec/20 Hz ,0.1 sec/10 Hz ,0.2 sec/5 Hz ,0.5 sec/2 Hz ,1.0 sec/1 Hz ,5.0 sec/0.2 Hz (In Dual-Mode, 0.05 sec and 0.1 sec may not be available depending on the capability of the host device and the surrounding radio wave environment.)
Fat thickness correction	Correction for fat thickness increases accuracy when calculating oxygen saturation (StO_2: %).
	Fat thickness setting range: 1-11 mm (including skin thickness)
Measurement display program	For iOS, install from the App Store.
	For Android, install from the Play Store or download from our website. (In the case of Android, there are some models that do not work, so we recommend that you check beforehand.)
	Windows version and data display program can be downloaded from our website.
Wireless	Bluetooth-BLE, registered ID=D047733
Battery	Coin battery: CR2032R (Murata recommended) / *High current type

	Continuous measurement time: approx. 5 hours with 1 second sampling, approx. 30 minutes with 0.05 second sampling
Display device	Tablet, smartphone（iOS、Android ）, and PC（Windows）
Dimension	Size: Length: 46 mm, Width: 30 mm, Thickness: 8 mm, Drip-proof (sweat-proof) IPX2
	Weight: 11 g (Battery included, shade excluded)

9. Other

State change



Meaning of LED lamps

Battery lamp	Status	Action
Green/Flashing	Power on (Bluetooth not connected)	Condition setting, Connect and start measurement
Green/Flashing (2 sec)	In the real-time mode	Display measured data on display device
Red/Flashing (2 sec)	In the storage mode	Upload data after the measurement

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