

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.



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.



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 oxygen meter 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.

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

#### 1-3. Add a device

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

(\* Tabs are located on the bottom side of display for iPhones.)

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.

:30 😤 🗉	*		Ջ 46 "Ո⊧ 🗎 84%
	MEASUREMENT	MONITORING	
Start	Event TOHb -		🌣 🗁
StO2[%]		TOHb[mM]	StO2[%]
75		0.2	
			TOHb[mM]
50		0.1	
25		0.0	
			00:00:00



接続	イベント	ТОНЬ		🌣 🗁
StO2[%]			TOHb[mM]	StO2[%]
75			0.2	TOHb[mM]
50			0.1	
25			0.0	
				00:00:00
	計測		モニター	

Figure 2. iPhone display

1:32 🗳 🔋	*					岌 4G	ⅆԲ 🗎 84%
	MEAS	SUREMENT				MONITORING	
DevID	Status	Batt[V]	Count	StO2[%]	TOHb[mM]		
200801-02	I						
			Entry/Delete	Hide	Unhide		<

Figure 3. Android display

機器番号	状態	電池電圧[V]	蓄積データ	StO2[%]	TOHb[mM]	
200501-002						
		登	録/削除	非表示	非表示解除	
	計測				モニター	



# 2. Setting screen

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

Tap "Start" in the upper left corner (The tab is displayed at the bottom of the screen on the iPhone).

30 ኛ 🗉	*		\& 4G <b>.₁1 🗎 84%</b>	
	MEASUREMENT	MONITORING		
Start	Event TOHb -	-	🌣 🗁	
3tO2[%]		TOHb[mM]	StO2[%]	
75		0.2		
			TOHb[mM]	
50		0.1		
25		0.0		
			00:00:00	



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

1:33 🗳 🔋 🗄	8 🗢		ኳ 46 <b>.</b> ₄በ <sup>‡</sup> <b>🗎 83%</b>
	200801-021		Storage Mode
Connect to:		0 selected.(max. 2)	Set
Samp. Rate:	0.05s - Aut	o Off: Disable 👻	Upload
Fat Thick[mn	n]: (1) < 3.0 >		Real Time Mode
Range: Acc.	2G 👻 Gyr	o. 125 deg/s →	Check
Destination F	Folder:/storage/emulated/0//	ndroid/data/com.astem_jp.OxyPro/files/data	Connect
			<
Ver 2.0.11			Cancel



#### 2-1. Connection destination

The serial number (registered device number) of the Oxy-Pro that is currently available for communication will be displayed. Tap the serial number displayed to select it. When using two Oxy-Pro units at the same time, turn on the power of the two Oxy-Pro units and the serial numbers of the two Oxy-Pro units will be displayed, and tap the serial numbers of the two Oxy-Pro units to select them.

# 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 at the same time, some smartphones and tablets cannot support sampling as fast as 0.05 sec due to their capabilities. Please check it before taking measurements. 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 the 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 measurement area of the Oxy-Pro and set the value to 1/2 of the thickness (For example, if the thickness is 8 mm, set 4 mm).

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

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

#### 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).

The "Set" button sends the settings made in the dialog 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 document.

1:40 🖪 📽 🗑	\\$ 46.aft <b>182%</b>	
MEASUREMENT		
Start Event TOHb - Rate:50[ms] Thickness: 3.0[mm] Start:2021/9/15 13:39:21	* 🗅	
	StO2[%]	
Storage data upload completed.	TOHb[mM]	
515/515 100% Received. 20210915-004.csvへ出力		
ОК		<
	0:00:54	

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.

1:38 🗳 📽	8					՝Ջ 46,₁⊫ 🗎 82%	
	ME	EASUREMENT			MONITORING		
Start	Event	TOHb 👻	Rate:50[ms] Thickness: 3.0[mm Start:2021/9/15 13:37:10	I		* 🗁	
StO2[%]	13:	37:55	13	:38:00	TOHb[mM]	StO2[%]	
75				<b>_</b>	 0.2		
50					 0.1	TOHb[mM]	
25					 0.0	•==	
	0.0	20:45	0	00:50			<
	0.0	JU.40	U	00.00		0:00:54	



## 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 a good measurement.

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

When the sensor confirmation is checked and measurement is started, the measured value of the optical element is displayed on a trend graph where red = 20 mm and blue = 30 mm.

The measured values with no external light from gaps, 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.

1:34 🗷 🗑 😨	Ջ 4ն∡⊪ 🗎 83%	
MEASUREMENT	<b>D C</b>	<b>`</b>
End Event TOHb - Rate:50[ms] Thickness: 3.0[mm] Start:2021/9/15 13:34:18	*	,
St02[%] T0Hb[mM]	StO2[%]	
75	<b>76</b>	
50 0.1	06	
	.00	
25 0.0		<
	2.6[V] 0:00:19	

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 mark data. When tapped, the data will be marked.

#### 3-4. Moving average

This function processes the moving average of the displayed data during measurement. However, it is not reflected in the csv file.

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" as the trend to be displayed in the sensor display area.

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

The data will not be displayed in the graph area 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 used.

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



#### 3-8. Oxygen Saturation Digital Display

(When two units are used, "CH1" and "CH2" are displayed on the left side of ① in Figure 9. The unit is [%].

#### 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 run out.
2.5 V or less	Red	Replace the battery.

## 3-11. Confirming measurement data

About the display after measurement is completed or data is downloaded in Real-time mode and Storage mode.

The measured data can be checked on the spot. Please select from (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 in the graph area to switch between full view and normal view. (If the graph is displayed in normal view on one screen, it will not be switched.)

1:34 🖪 🕸 🗉 👻	ֆ 46.₄⊫ 🗎 83%	
MEASUREMENT		
End Event TOHb - Rate:50[ms] Thickness: 3.0[mm] Start:2021/9/15 13:34:18	* 🖻	
St02[%] 14:57:56 14:58:16 TOHb[mM]	StO2[%]	
75 0.2		I
50 0.1	TOHD[mM]	
25 0.0		
		<
0:00:20 0:00:40		
	0:02:30	

Figure 10. Real-time mode display during measurement

Information about the loaded data is displayed in the center on the graph. These include sampling rate, fat thickness, and date of measurement start.

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

## 3-12. Scale display

The left side of the trend graph shows the oxygen saturation (StO<sub>2</sub>: %), 25 % on the first scale. Normal StO<sub>2</sub> is around 65 %.

The right side of the trend graph shows the amount of each hemoglobin, and the symbol is 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 in exercises where the host device may interfere with the exercise.

#### 4-1. Setting

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

1:33 🗷 👻 🗊 😤	∖Ջ 46⊿⊪≑ 🗎 83%
200801-021 Connect to: 0 selected.(max. 2)	Storage Mode Set
Samp. Rate: 0.05s - Auto Off: Disable -	Upload
Fat Thick[mm]: (1) $\langle 3.0 \rangle$ Range: Acc. 2G = Gyro 125 deg/s =	Real Time Mode
Destination Folder:/storage/emulated/0/Android/data/com.astem_jp.0xyPro/files/data	Connect
Ver 2.0.11	Cancel

Figure 11. Setting display (Storage mode)

#### 4-2. Measurement

Check that the green LED on the Oxy-Pro is blinking 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 in storage mode to your smartphone or tablet. The data will be saved in the internal storage document.

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

1:40 🖪 📽 🖲 💝		ঽ ४৫.₁ি 🕯 82%	
	MEASUREMENT		
Start Event TOHb	Rate:50[ms] Thickness: 3.0[mm] Start:2021/9/15 13:39:21	🌣 🗁	
		StO2[%]	
	Storage data upload completed.	TOHb[mM]	
	515/515 100% Received.		
	20210915-004.csvへ出力		
	ОК		<
		0:00:54	

Figure 12. Readout display

Tap "OK" after the message "Output to 00000-0000.csv" is displayed. 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, but it is not possible to compare multiple data, so we recommend using the "Oxy-Pro data Viewer" program.

#### 5. Monitor display

The status of the Oxy-Pro is monitored in the accumulation mode, since it is unclear whether the measurement is being performed normally. The monitor updates the measurement data and status display approximately every 5 seconds. The Oxy-Pro that is able to be monitored must be turned on.

When the monitor is selected in the measurement and monitor switching tabs, the screen switches to the one shown below (The status of the registered devices will be displayed). In the monitor function, all Oxy-Pro devices in the surrounding area that are turned on will be received, but registered devices will be displayed with priority, and the serial number of the device will be displayed in bold. If the device is not registered, only the serial number of the device will be displayed in fine print. The list is saved in a file, so it will be valid the next time the application is started. (There is no limit to the number of devices that can be registered. Four monitors can be

displayed. (There is no limit to the number of monitors that can be registered.) Four monitors can be displayed. Select the one that is not needed and tap "Hide" to hide it.

37 🗳 🕈 🖻 🕈						ኳ 46 <b>⊿i<sup>⊫</sup> </b>
	MEAS	UREMENT				MONITORING
	-					
DevID	Status	Batt[V]	Count	St02[%]	TOHb[mM]	
200801-021	RUN	2.5	313	78	.06	
		F	ntrv/Delete	Hide	Unhide	
				Thu o	onnido	

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 to indicate the timing for battery replacement.	
Count:	Indicates the number of stored data in the built-in flash memory of the Oxy-Pro. The number data increases during the measurement in the storage mode.	
StO <sub>2</sub> [%], TOHb[mM]:	Measured values are displayed during the stored mode measurement.	
Hide button:	Hides the monitor display of the selected device.	
Unhide button:	Restores all hidden devices to the display status.	

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

\*The list of registered devices will be stored in the file, but the hidden information will not be stored in the file, so it will be unhidden the next time the program is started.

# 6. Notes (Description of units)

The unit of StO<sub>2</sub> (oxygen saturation) displayed by Oxy-Pro 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<sub>2</sub>, 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)

The data measured by Oxy-Pro can be viewed in the Oxy-Pro Data Viewer.

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 (<u>https://www.astem-jp.com</u>).

ASTEM website:



Software download



# 8. Specifications

Measurement method	SR-NIRS (spatially resolved method, near-infrared spectroscopy)
Measurement	Oxygen saturation (StO <sub>2</sub> :%)
item	Oxygenated hemoglobin (Oxy-Hb:mM)
	Deoxygenated hemoglobin (Deoxy-Hb:mM)
	Total Hemoglobin (T-Hb:mM)
	Accelerometer, gyroscope
Measurement	Real-time mode: Measurement data is displayed in real-time time on a smartphone, etc.
mode	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 for fat thickness increases accuracy when calculating oxygen saturation
correction	(StO <sub>2</sub> : %).
	Fat thickness setting range: 1-11 mm (including skin thickness)
Measurement	For iOS, install from the App Store.
display program	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 cell 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

# Manufactured and distributed by: Astem Corporation

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