

## JMS Tongue Pressure Measurement Device

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# INTRODUCTION

Thank you for purchasing Digital Tongue Pressure Meter. Read this instructions for use (IFU) carefully before use.

The device is used with Tongue Pressure Probe (REF No. JF-TPP) and Connecting Tube (REF No. JF-TPT5). For Tongue Pressure probe and Connecting Tube, read each IFU.





In addition, any serious incident that has occurred in relation to the device should be reported to the manufacturer and to the competent authority of the Member State in which the user and/or patient is established.

## SAFETY PRECAUTIONS


















### SYMBOLS

This manual and product use symbols to highlight important precautions and things that we want you to know. Symbols and their content are shown below.

#### ■ Symbols used in this manual

 <b>CONTRA-INDICATIONS</b>	Indicates the target and usage methods that exceed the scope of responsibility, such as design limits or improper use of the device.
 <b>CAUTIONS</b>	Indicates items that may cause damage or property damage if handled incorrectly.
	Indicates a prohibited action. Please do not attempt to do this.
	Indicates an action that must be followed. Please be sure to follow the instructions.

#### ■ Symbols displayed on the device

	Consult instructions for use		Date of manufacture
	The degree of protection against electrical shock is BF-type applied parts (Tongue Pressure Probe and Connecting Tube)		Manufacturer
	Catalogue number		Serial number
	Batch		Expiry date
	Single use only		Storage temperature limit is -20 ~ +50°C (-4 ~ +122 °F)
	Keep dry		Keep away from sunlight and heat
	Medical device		Do not use if package is damaged
	Caution: Federal (U.S.A.) law restricts the device to sale by or on the order of a physician and a dentist.		WEEE mark Not for general waste.
	Authorized representative in the European Community		

## CONTRA-INDICATIONS AND CAUTIONS



### CONTRA-INDICATIONS



**Reuse of the Tongue Pressure Probe is prohibited.**

Replace for each measurement to avoid measurement errors or infection.

### ■ Precautions for use



### CAUTIONS



1. **As the device is a measuring device, it should not be used for definite diagnosis such as the assessment for swallowing function.**
2. **Do not sterilize Tongue Pressure Probe and Connecting Tube.** [Deformation or deterioration of components may cause measurement error or measurement failure.]
3. **Do not touch the balloon at internal pressure adjusting. Also, do not adjust internal pressure while the balloon is placed in the oral cavities.** [Incorrect internal pressure adjustment may cause measurement error or measurement failure.]
4. **Do not pinch the balloon and Connecting Tube with forceps or tweezers.** [Damage to the balloon and Connecting Tube may result in measurement failure.]
5. **Do not drop or give physical impact to the device.** [It may cause the device to break.]
6. **Do not use the device by connecting to another device.** [It may cause malfunction or measurement failure.]
7. **Do not use unintentionally radiating devices (electrosurgical devices that are outputting, radios, TVs, etc.) nearby.** [It may cause malfunction.]
8. **Do not use devices that use radio waves (mobile RF communication equipment such as mobile phones and transceivers, peripheral devices such as antenna cables and external antennas) within 30 cm of the device.** [It may cause malfunction. If it is unavoidable, check the operation.]
9. **Do not use anything other than the enclosed items or specified items.** [Increased electromagnetic emissions or decreased electromagnetic immunity may cause malfunctions.]



1. **Should be used by a physician, a dentist, or a nurse, a speech language pathologist, or a dental hygienist under the direction of the physician or the dentist.**
2. **Regardless the frequency of use, replace the Connecting Tube with a new one monthly after unpacking.** [It may cause measurement error or measurement failure.]
3. **Instruct patients not to bite or pull the balloon.** [It may cause the balloon damage and measurement failure. It also may result in accidentally swallowing of broken pieces of the balloon.]
4. **When hold the hard ring with the front teeth, instruct patients not to bite strongly.** [It may damage teeth and prostheses.]
5. **Use a USB cable with a length of less than 3 m (enclosed item recommended).** [It may cause communication error.]
6. **Use a CISPR 32 compliant personal computer.** [It may cause communication error.]

## ■ Storage method and validity period



### CAUTIONS

#### 1. Store and use the device within the following conditions.

<Storage condition>

- Ambient Temperature: -20 ~ 50 °C (-4 ~ 122°F)
- Ambient Humidity: 10 ~ 95%RH (no condensation)

<Operating environment>

- Ambient Temperature: 10 ~ 40 °C (50 ~ 104°F)
- Ambient Humidity: 30 ~ 75 %RH (no condensation)

#### 2. Do not store or use in the following locations.

- Where the device is exposed to direct sunlight or strong light
- Where the atmospheric pressure is depressurized or pressurized
- Where there is dust or corrosive gases (salt, sulfur), etc. in the atmosphere
- Where vibration occurs or the area is not level
- Where heating devices or devices that generate heat are nearby
- Where the device is exposed to excessive humidity or moisture

#### 3. Please observe the following validity period.

<Validity period> (Refer to the validity date on the package)

- Tongue Pressure Probe and Connecting Tube: 3 years [based on self-certification (Manufacturer's own data)]

<Period of endurance>

- Digital Tongue Pressure Meter: 5 years [based on self-certification (Manufacturer's own data)](When specified maintenance, inspection, and replacement of consumables are performed)
- Connecting Tube: 1 month after opening package [based on self-certification (Manufacturer's own data)]



## ■ Maintenance and Inspection



### CAUTIONS

#### 1. Do not use benzene, thinner or other volatile chemicals to clean the device.

[There is a risk of deterioration or deformation of the device body.]

#### 2. Be careful not to apply liquid to the device and the Connecting Tube. [Liquid may penetrate the device, and it may cause malfunction or failure.]

#### 3. Do not mix old batteries and different types of batteries. [Battery fluid leakage may cause the failure of the device.]

#### 4. Do not disassemble or modify the device. [It may cause the failure or damage of the device.]

#### 5. Turn off the power before replacing the batteries. [It may cause the device failure.]



#### 1. Insert the batteries in correct direction. [Battery fluid leakage may result in damage.]

#### 2. When the device is not used for a long time, remove the batteries for the storage. [Battery fluid leakage may result in damage.]



# DEVICE DESCRIPTION

## INTENDED PURPOSE

The intended purpose of the device is to investigate tongue motor function with Tongue Pressure Probe and Connecting Tube and measuring maximum tongue pressure.

The device is intended for clinical use by a physician and a dentist, or a nurse, a speech language pathologist or a dental hygienist under the direction of the physician or the dentist.

However, the device is not adapted for the following patients; patients may have difficulties on measuring maximum tongue pressure or moving their tongues.

If judgment of adaptivity is difficult due to the patient's condition, check the condition by the physician or the dentist, and then use the device safely under the instruction of their.

- Patients who cannot recognize instructions by the operator (e.g. patients who cannot recognize instructions by the operator with dementia, anepia, agnosia, higher brain dysfunction, infants the intellectual disabled, etc.)
- Patients who cannot hold the device with the front teeth (e.g. patients with edentulous jaw and without dentures)
- Patients who cannot compress the device (e.g. patients who cannot move the tongue at all)

## OPERATING PRINCIPLE

The air in the device is compressed by pressing the tongue pressure probe balloon. The pressure sensor of the device detects the pressure at this time and displays “Tongue Pressure Value” on the LCD screen.

In addition, The device is no basic performance as the lack or deterioration of performance cannot lead to unacceptable risks. (Any abnormality will not cause harm to the patient or user.)

## CONSTITUTION

The device should be used in combination with the following accessories.

Model name	REF No.	Reference page
Tongue Pressure Probe	JF-TPP	Page EN-8
Connecting Tube	JF-TPT5	Page EN-8

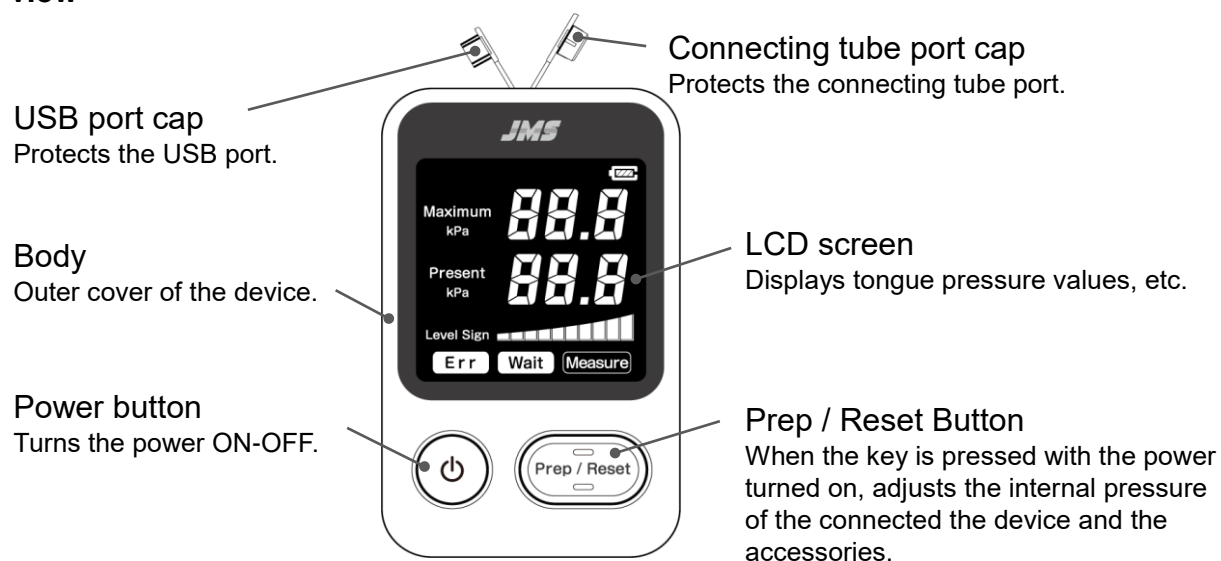
## DEVICE SPECIFICATIONS

Item		Specification
Device name		JMS Tongue Pressure Measurement Device
Model name		Digital Tongue Pressure Meter
Model type		TPM-02
Power supplies		AA alkaline battery × 2 or AA nickel-metal-hydride rechargeable battery × 2
Electrical rating	Voltage	DC 3V (Two AA alkaline batteries) DC 2.4V (Two AA nickel-metal-hydride rechargeable batteries)
	Measureable number	Approx. 2,500 times (Assuming use of a new batteries or rechargeable batteries within one month at room temperature)
Durability		5 years (About 45,000 pressurization pump operations)
Dimensions		74 (W) × 120 (L) × 27.5 (H) mm
Internal pressure adjustment	Set value	19.6 kPa (Automatically displays zero after internal pressure adjustment)
	Adjustment time	Within 20 seconds
	Accuracy	±1.0 kPa (at the set value of internal pressure 19.6 kPa)
Measurement	Display unit	kPa
	Display range	-9.9 to 99.9 kPa (when the zero is set at 19.6 kPa)
	Accuracy	±1 kPa (at 0.0 to 80.0 kPa when internal pressure setting value of 19.6 kPa is set to zero.)
	Display format	Digital numbers and bar graphs (Level sign indication)
Electric shock protection type		Internal power supply BF type applied parts
Drip-proof properties		IPX0
EMC		IEC 60601-1-2 : 2014 / EN IEC 60601-1-2: 2015
External output function		USB (data transmission only)
Option		Software for Tongue Pressure Measurement Data
MFDS Import Certificate No.		20-164

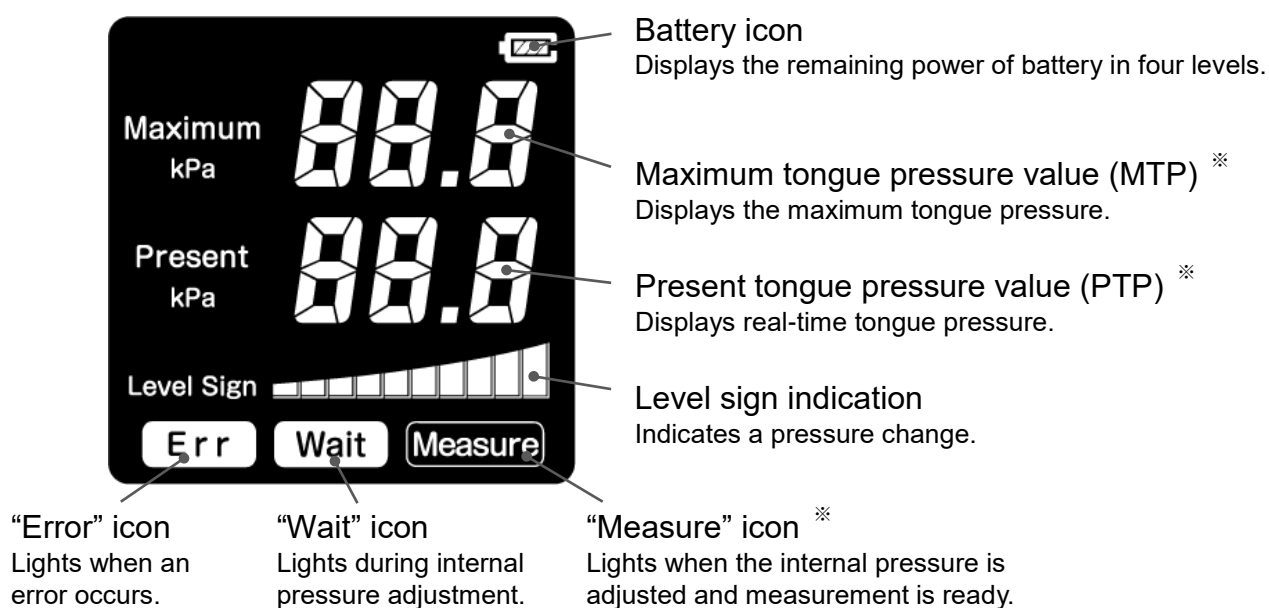
## DESCRIPTION OF EACH PART

### ■ Digital Tongue Pressure Meter

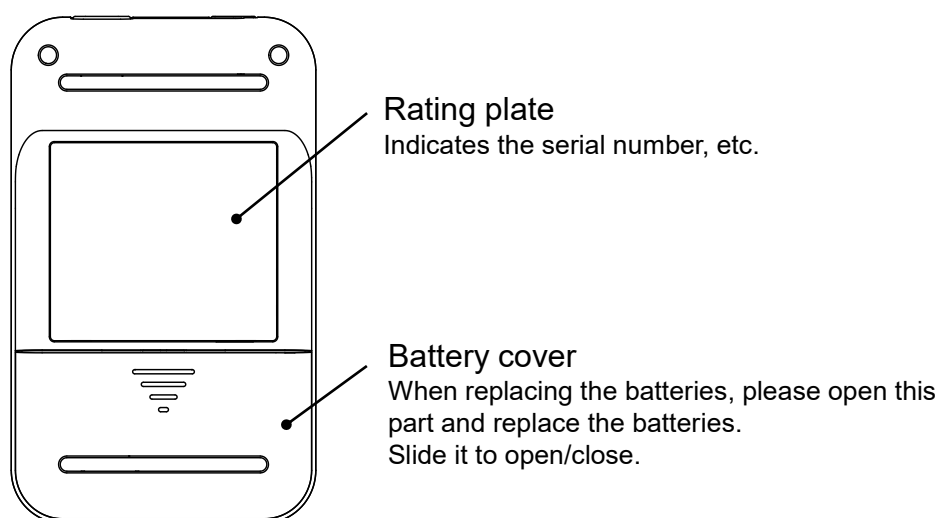
#### 1. Front view



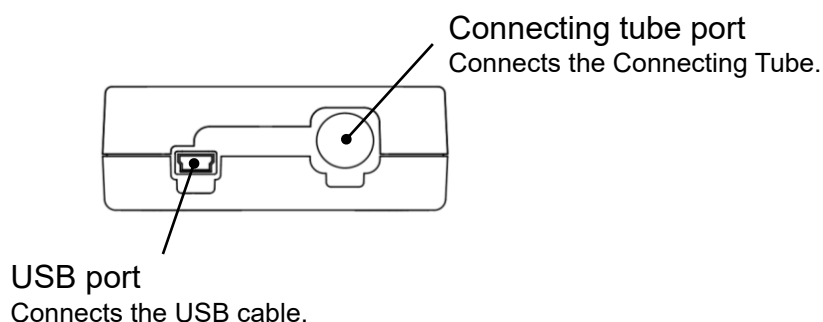
## 2. LCD screen



## 3. Rear view

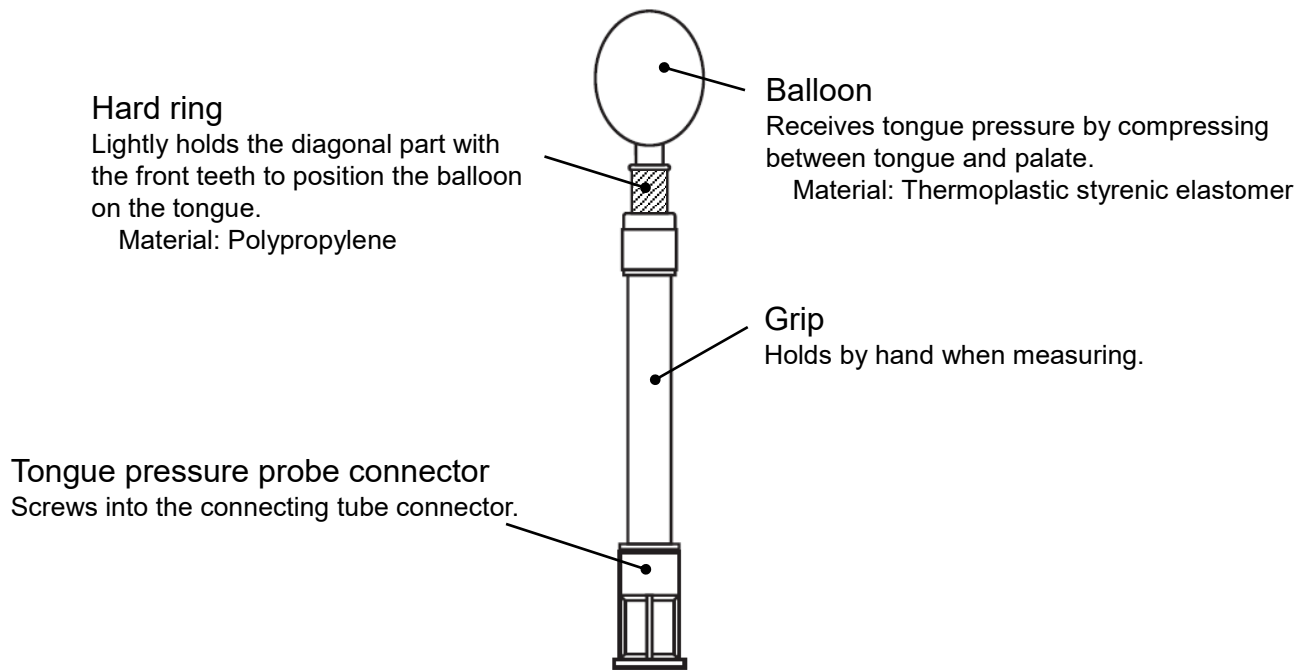


## 4. Top view



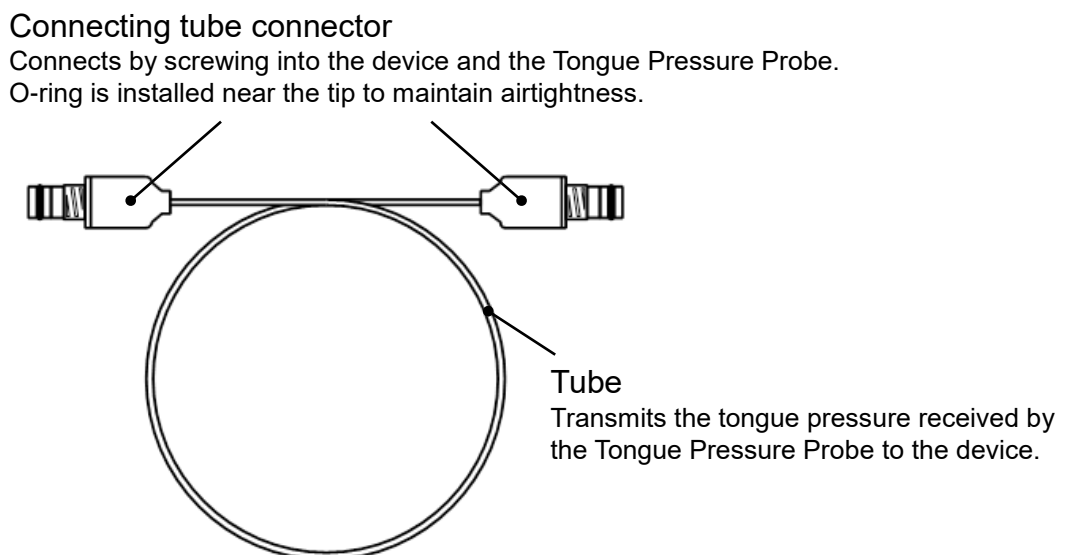
## ■ Tongue Pressure Probe (Accessory)

Tongue Pressure Probe receives tongue pressure during measurement. (single use only).



## ■ Connecting Tube (Accessory)

Connecting Tube connects the device to the Tongue Pressure Probe. The accessory is a replacement part which can be used for one month after opening the individual package.



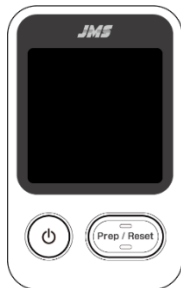


# PREPARATION

## PACKAGING CONTENT

The device package contains the following items. If anything is missing, contact your local dealer.

- Digital Tongue Pressure Meter  
(1 unit)



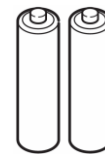
- USB cable  
(1 unit)



- Storage case  
(1 bag)



- AA alkaline batteries  
(2 units)

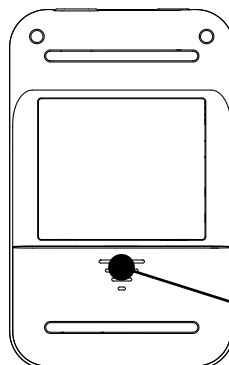


\* The supplied batteries are for trial use only. It may expire within 2,500 measurements, and please replace it as soon as possible.

- IFU (this manual, 1 copy)

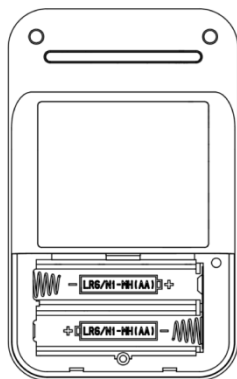
## BATTERIES

1. Remove the battery cover from the device.



Slide with holding down here

2. Mount AA batteries in the proper direction.



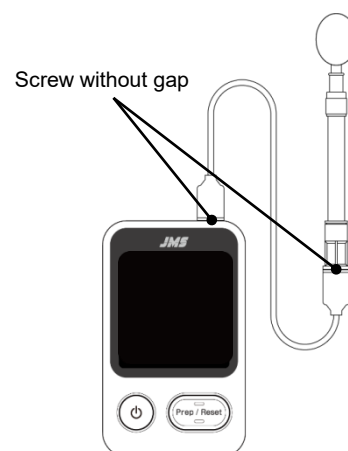
3. After mount batteries, slide the battery cover tightly.

# DIRECTIONS FOR USE

## NORMAL MEASUREMENT

### Measurement preparation

1. Connect each accessory to the device
  - 1) Remove the connecting tube port cap from the device.
  - 2) Connect one side of the connecting tube connector securely to the connecting tube port and the other side of the connecting tube connector securely to the Tongue Pressure Probe.

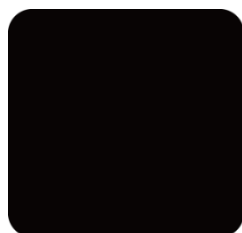


### 2. Turn on

Press the power button on the device to turn it on.

The LCD screen lights with a buzzer sound and after all indications are displayed, the unit automatically enters the standby mode.

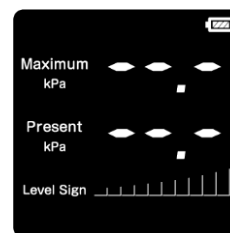
<Power OFF>



<FULL Display>



<Standby mode>



### 3. Adjust the internal pressure automatically

Make sure the device is in standby mode and press the Prep/Reset button.

The internal pressure is automatically adjusted and zero-point correction is performed.



### CAUTIONS

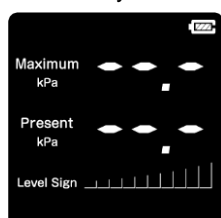


Hold only the grips of the Tongue Pressure Probe while adjusting the internal pressure. Touching the balloon or tube at this time may cause incorrect internal pressure adjustment resulting in measurement errors or impossibility.

### <Operation of the device>

1. When the Prep/Reset button is pressed, the pressurization pump operates with a beeping sound, and the internal pressure adjustment starts. At this time, the "Wait" icon on the LCD screen flashes and the "PTP" value increases. The Level sign indication will also increase to the right. When the total number of the Level sign indication reaches 10, it indicates that the set value of internal pressure has reached 19.6 kPa.
2. When the inside of the connected the device and accessories is adjusted to 19.6 kPa, "MTP", "PTP" and Level sign indication are automatically reset and "Measure" icon lights. In this status, it is ready for the measurement.

<Standby mode>



<Adjusting internal pressure>



<Ready for the measurement>



## Measuring

### 4. Measure the maximum tongue pressure

- 1) Confirm that the “Measure” icon of the device lights and it is ready for measurement.
- 2) Insert the Tongue Pressure Probe into the patient's oral cavity and instruct the patient to gently hold the hard ring of the Tongue Pressure Probe with the front teeth.

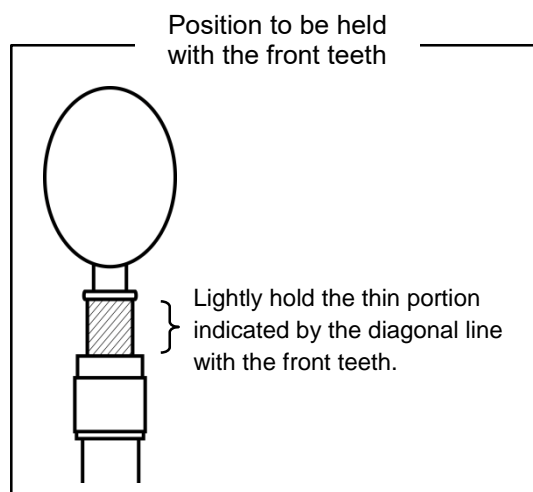
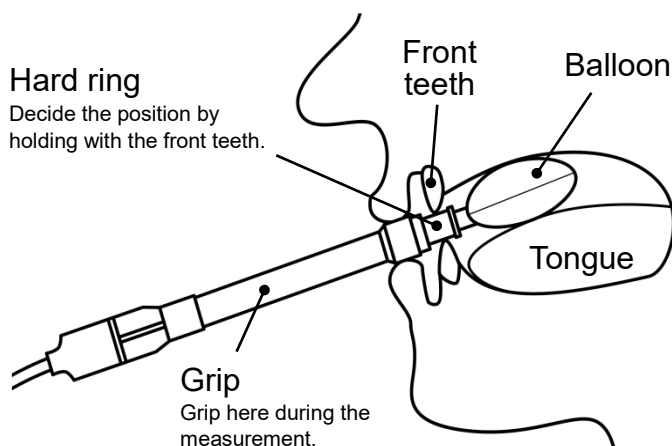
This will position the balloon on the tongue and allow you to take correct measurements. At the same time, the lower jaw is fixed.



### CAUTIONS



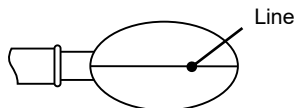
- A denture user should wear a denture for the measurement.
- Instruct not to bite the balloon absolutely. It may damage the balloon and result in unmeasurable. Also there is a risk of swallowing the fragments.
- When gripping the hard ring with the front teeth, instruct not to grip it strongly. It may damage the teeth and prostheses.



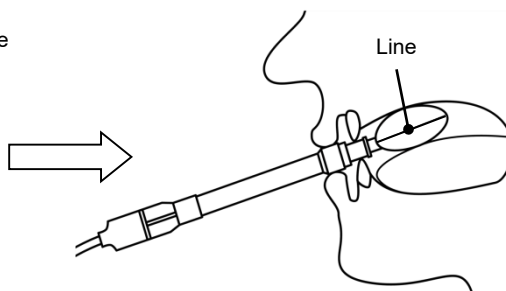
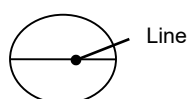
### <POINT>

Please pay attention to the orientation of the balloon and insert the balloon into the oral cavity so that the flat surface of the balloon (the surface without the “line”) can be put on the tongue. Check the orientation before adjusting the internal pressure for easy identification.

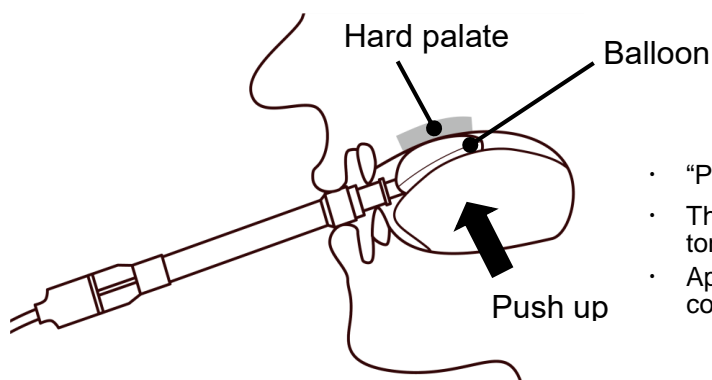
#### <Balloon Side View>



#### <Balloon Front View>



- 3) While keeping the patient gently holding the hard ring with the front teeth, instruct the patient to push up the tongue with the maximum force against the hard palate and compress the balloon for several seconds.



- “PTP” display shows real-time tongue pressure.
- The Level sign indication display shows a real-time tongue pressure of 0-50 kPa with 10-part icons.
- Approximately 7 seconds should be used for the compressing time.

- 4) Stop compressing with the signal from the operator, and record the value displayed on the “MTP” display of the device as the maximum tongue pressure.



In this case, “37.6 kPa” is the maximum tongue pressure.

- 5) After measuring, remove the Tongue Pressure Probe from the patient's mouth.
- 6) To repeat measuring the same patient, press the Prep/Reset button again to reset the “MTP” and “PTP” displays. After that, perform the operations 4.1) to 5) in the same way.

※ If the “PTP” exceeds 1 kPa, the Prep/Reset button becomes invalid, and turn the power off and on again.

## End of the measurement

### 5. Complete the measurement

- 1) Press the power button on the device to turn it off.
- 2) Disconnect the Tongue Pressure Probe from the Connecting Tube and dispose of properly.
- 3) If you want to continue measuring the next patient, connect the new Tongue Pressure Probe to the Connecting Tube and repeat the procedure from step 2.
- 4) After all patients' measurements are completed, disconnect the Connecting Tube from the device.
- 5) Attach the connecting tube port cap to the connecting tube port.

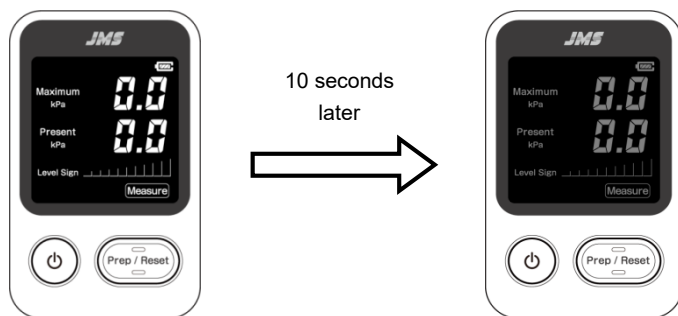
## MEASUREMENT CONNECTED WITH A PERSONAL COMPUTER

1. Remove the device's USB port cap.
2. Connect the device's USB port to the personal computer's USB port with a USB cable.
3. Turn on the personal computer and the device.
4. The tongue pressure is measured and the tongue pressure value is displayed and stored on a personal computer.

## AUTO SAVE FUNCTION

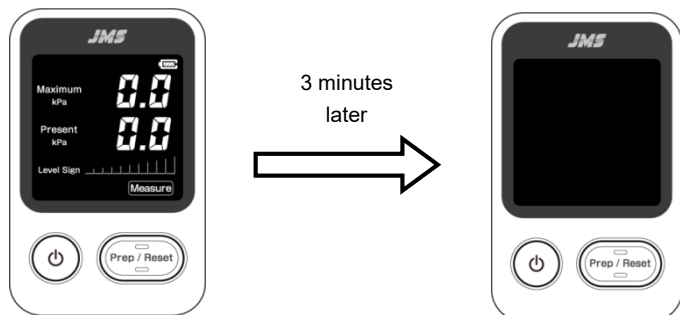
The device changes to the following status if no operation is performed after the power is turned ON or if the pressure fluctuation of 1.0 kPa or more is not detected.

### 1) 10 seconds later ⇒ Backlight dimming



- ※ Measurement is possible even when the backlight is dimmed. When a pressure fluctuation of 1.0 kPa or more is detected, the brightness returns to the original level.
- ※ When the Prep/Reset button is pressed to enter the internal pressure adjustment mode, the brightness also returns to the original value.

### 2) 3 minutes later ⇒ Power OFF



- ※ If this happens, turn the power on again.

# MAINTENANCE AND INSPECTION

## DAILY MAINTENANCE

### ■ Digital Tongue Pressure Meter

1. Turn the power off and remove the batteries.
2. Wipe the dirty area with a soft and dry cloth.
3. For stubborn dirt, soak the cloth in water and a neutral detergent, wring well, and then wipe the dirt off. Remove wetness with a dry cloth.

### ■ Connecting Tube

1. Disconnect Connecting Tube from the device.
2. Wipe the dirty area with a soft and dry cloth.
3. For stubborn dirt, replace it with a new Connecting Tube even if it is less than one month after unpacking.

## DAILY INSPECTION

Correct operation and daily inspection are essential to maintain the device performance over a long period of time and to ensure safe use. Check the following items before use.

(Copy it to use.)

Daily check item		Check
Inspection before use		
<input type="checkbox"/>	Check the device for damage, cracks, etc.	
<input type="checkbox"/>	Is the tongue manometer free of liquid or dirt?	
<input type="checkbox"/>	Is there any foreign matter and damage on the connecting tube port of the device or the connecting tube connector?	
<input type="checkbox"/>	Check if the Connecting Tube is not bent or damaged.	
Inspection during use		
<input type="checkbox"/>	Is the power turned on correctly?	
<input type="checkbox"/>	Is the battery icon low?	
<input type="checkbox"/>	Is the standby display normal?	
<input type="checkbox"/>	Is the internal pressure adjustment operating normally?	
<input type="checkbox"/>	Are the "PTP" display, the "Wait" icon's flashing, and the Level sign indication display normal during internal pressure adjustment?	
<input type="checkbox"/>	Is the pressurization error occurring during internal pressure adjustment?	
<input type="checkbox"/>	Check that the device is ready for measurement after adjusting the internal pressure. Is the "Measure" icon lighted normally?	
<input type="checkbox"/>	Is a measurement error occurring during measurement?	
<input type="checkbox"/>	Is there any smoke/unusual smell generating from the device?	
<input type="checkbox"/>	Is there any abnormal noise?	
Inspection after use		
<input type="checkbox"/>	Is the device free of liquid or dirt?	
<input type="checkbox"/>	Is there a specific part of the device that is hot?	
<input type="checkbox"/>	Is there any foreign matter on the connecting tube port or the connecting tube connector of the device, or is it damaged?	
<input type="checkbox"/>	Check that the Connecting Tube is not bent or damaged.	

## MAINTENANCE BY DISTRIBUTOR

We perform maintenance and inspections described below. Contact your supplier for more information.

Item	Frequency	Inspection details
Periodic inspection	Once a year	Check the internal pressure adjustment accuracy and measurement accuracy with special jigs and measuring instruments, and perform periodic adjustments and repairs.

## REPLACEMENT FREQUENCY AND TIMING

Exchange frequency	Replacement part
Approximately 2,500 measurements	AA alkaline batteries or AA nickel-metal hydride rechargeable batteries (two batteries at the same time) ※ Refer to page EN-9 for the replacement procedure.
Every measurement	Tongue Pressure Probe
One month after opening	Connecting Tube



### CONTRA-INDICATIONS



The Tongue pressure Probe is prohibited from being reused because it causes measurement errors and infections.



### CAUTIONS



- When replacing batteries, replace two AA alkaline batteries or AA nickel-metal hydride rechargeable batteries at the same time.
- If the connecting tube becomes severely dirty or folded, it may cause measurement error. Replace the connecting tube as needed.

## DISPOSAL INFORMATION

WEEE (Waste Electrical and Electric Equipment) should not be disposed as general waste.

After using the device, dispose of it properly according to local or national regulations.

Tongue Pressure Probe is medical waste.

For other items, please refer to the following table and dispose it as general waste under the instructions of local or national authorities.


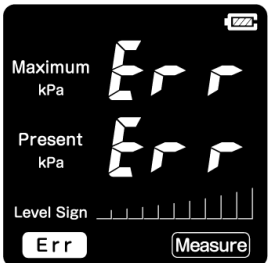
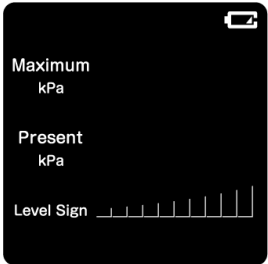


Product Name	Component	Raw material
Packaging (common materials)	Box	Paper
	Cushioning material or individual packaging bag	Polyethylene
Digital Tongue Pressure Meter	Body (including operation buttons and battery cover)	Acrylonitrile-butadiene-styrene copolymer
	Internal part	General electrical parts, Stainless steel
Connecting Tube	Connecting tube connector	Polycarbonate
	Tube	Polyvinyl chloride
	O-ring	Nitrile rubber
USB cable		General electrical parts
Storage case		Polyamide

# TROUBLESHOOTING

## ERROR INDICATION

If an error occurs during use, the error message shown below appears.

Error indicator	Cause	Corrective action
<p>&lt;Pressurization error&gt;</p>  <p>The beeper beeps three times to notify you.</p>	Each component is not connected properly.	If any of the connections are loose, reconnect them correctly. (See page EN-10.)
	A broken Tongue Pressure Probe or the Connecting Tube was used.	Replace with new Tongue Pressure Probe or new Connecting Tube. (See page EN-10.)
	The power button or Prep/Reset button was accidentally pressed during internal pressure adjustment.	Press the Prep/Reset button again to adjust the internal pressure. (See page EN-10.)
	The balloon of the Tongue Pressure Probe was mistakenly crushed during internal pressure adjustment.	Press the Prep/Reset button again to adjust the internal pressure. (See page EN-10.)
	The internal pressure adjustment was not completed within the specified time because the battery level was low.	Replace with new batteries. (See page EN-9.)
	The device is defective.	Please contact your supplier for repair.
<p>&lt;Measurement Error&gt;</p>  <p>The beeper beeps three times to notify you.</p>	Loose connections in each component during the measurement.	If any of the connections are loose, reconnect them correctly. (See page EN-10.)
	The Tongue Pressure Probe or Connecting Tube was broken during the measurement.	Replace with a new Tongue Pressure Probe or Connecting Tube. (See page EN-10.)
	The device is defective.	Please contact our personnel for repair.
<p>&lt;Low Battery&gt;</p> 	The batteries are exhausted.	Replace with new batteries. (See page EN-9.)



## TROUBLESHOOTING

Phenomenon	Cause	Corrective action
Internal pressure adjustment takes time.	Each component is not connected properly.	Check the connection of each part. If not, connect properly. (See page EN-10.)
	A broken Tongue Pressure Probe or a Connecting Tube was used.	Replace with new Tongue Pressure Probe or Connecting Tube. (See page EN-10.)
	The batteries are exhausted.	Replace with new batteries. (See page EN-9.)
	The device is defective.	Please ask for repair service.
Maximum tongue pressure cannot be measured correctly and is measured at an abnormally low (high) value.	The device is defective.	Please ask for repair service.
	Measurements were made when the Connecting Tube was bent.	Perform measurement again without bending.
	The balloon was bitten during the measurement.	Position the balloon correctly and compress the balloon with tongue only. (See page EN-11-12.)
	Loose connections in each component part during the measurement.	Check for loose connections and reconnect correctly. (See page EN-10.)
	Tongue Pressure Probe or Connecting Tube was broken during the measurement.	Replace with new Tongue Pressure Probe or Connecting Tube. (See page EN-10.)
The device does not start when the power button is pressed.	The batteries are exhausted.	Replace with new batteries. (See page EN-9.)
	The "+" and "-" side of the battery are reversed.	Mount the batteries in the correct direction. (See page EN-9.)
A "click" sound is heard when the power is turned ON, when the Prep/Reset button is operated, or when the power is turned OFF.	The solenoid valve opens and closes automatically to return the measuring system circuit to the atmospheric pressure.	This is normal and does not indicate a problem. The device can be used safely.
Even if a new battery is installed, the remaining Battery icon is displayed low or the Low battery is displayed.	Battery performance may not meet the device criteria, or may be degraded or depleted. ※ Batteries may deteriorate depending on the storage environment.	If Low Battery is displayed, replace batteries with new ones. Even if Battery icon is displayed low, you can still use it if Low Battery is not displayed. (See page EN-9.)

# EMC INFORMATION

The device complies with the EMC (Electromagnetic Compatibility) standard (IEC 60601-1-2: 2014/ EN IEC 60601-1-2: 2015).

The device may cause malfunctions such as LCD error (MTP, PTP, other indications), freeze, reset, power off etc. if it is not used under specified environmental conditions and exposed to strong Electromagnetic disturbances.

Check the following compatibility carefully before installation and use.

Intended environment: Home medical environment (residential area\_residential/home/nursing facility)

## ■ Emission test

Emission test	Standard / Test level	Compliance
Conducted emissions	CISPR 11 Group 1, Class B	Not applicable
Radiated emissions		Group 1, Class B
Harmonic emissions	IEC 61000-3-2	Not applicable
Voltage fluctuations/flicker emissions	IEC 61000-3-3	Not applicable

## ■ Immunity test

Immunity test	Standard / test level	Compliance level
Electrostatic discharge (ESD)	IEC 61000-4-2 ±8 kV contact ±2, 4, 8, 15 kV air	±8 kV contact ±2, 4, 8, 15 kV air
Electrical fast transient/burst	IEC 61000-4-4 ±2 kV for power supply lines ±1kV for input/output lines	USB cable ±1kV for input/output lines
Surge	IEC 61000-4-5 ±1 kV for line(s) to line(s) ±2 kV for line(s) to earth	Not applicable
Voltage dips, short interruptions and voltage variations on power supply input lines	IEC 61000-4-11 Voltage dips 0 % $U_T$ 0.5 cycle Phase angle 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0 % $U_T$ 1 cycle and 70 % $U_T$ 25/30 cycle Single layer phase angle 0° Short interruption 0 % $U_T$ 250/300 cycle	Not applicable
Power frequency (50/60 Hz) magnetic field	IEC 61000-4-8 3 A/m	3 A/m (50/60 Hz)
Conducted RF	IEC 61000-4-6 3 Vrms in between 0.15 MHz and 80 MHz 6 Vrms in ISM and amateur radio bands between 0.15 MHz and 80 MHz 80% Amplitude modulation (1 kHz)	USB cable 3 Vrms in between 0.15 MHz and 80 MHz 6 Vrms in ISM and amateur radio bands between 0.15 MHz and 80 MHz 80% Amplitude modulation (1 kHz)
Radiated RF	IEC 61000-4-3 10 V/m 80MHz ~ 2.7GHz 80% Amplitude modulation (1 kHz)	10 V/m
Immunity to near electromagnetic fields from RF wireless communication equipment	IEC 61000-4-3 According to Table-1	According to Table-1

Recommended separation distances between portable and mobile RF communications equipment and the device.			
The device is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customers or user can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the device as recommended below, according to the maximum output power of the communications equipment.			
Rated maximum output power of the transmitter (W)	Separation distance according to frequency of transmitter (m)		
	150 kHz to 80MHz $d=1.2\sqrt{P}$	80 MHz to 800 MHz $d=1.2\sqrt{P}$	800 MHz to 2.5 GHz $d=2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23
For transmitters rated at a maximum output power not listed above, the recommended separation distance $d$ in meters (m) can be estimated using the equation applicable to the frequency of the transmitter. Where $P$ is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.			
Remarks 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.			
Remarks 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			
Field strengths from fixed RF transmitters as determined by an electromagnetic site survey <sup>a)</sup> , should be less than the compliance level in each frequency range <sup>b)</sup> . Interference may occur in the vicinity of equipment marked with the following symbol:			
Note a) Field strength from fixed transmitters such as base stations for radio (cellular/cordless) telephone and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters an electromagnetic site survey should be considered. If the measured field strength in the location in which the device is used exceeds the applicable RF compliance level above the device should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the device.			
b) Over the frequency range 150 kHz and 80 MHz, field strengths should be less than 3V/m.			



Table 1 – Test specifications for Enclosure port immunity to RF wireless communications equipment

Test frequency (MHz)	Band (MHz)	Communication service	Modulation	Maximum power (W)	Separation distance (m)	Immunity test level (V/m)	Compliance (Compliance level)
385	380 - 390	TETRA400	Pulse modulation 18 Hz	1.8	0.3	27	27
450	430 - 470	GMRS 460 FRS 460	Frequency modulation ※ ±5 kHz deviation 1 kHz sine	2	0.3	28	28
710	704 - 787	LTE Band 13, 17	Pulse modulation 217 Hz	0.2	0.3	9	9
745							
780							
810	800 - 960	GSM 800/900 , TETRA 800, iDEN 820 , CDMA 850, LTE Band 5	Pulse modulation 18 Hz	2	0.3	28	28
870							
930							
1720	1700 - 1990	GSM 1800, CDMA 1900, GSM 1900 DECT, LTE Band 1, 3, 4, 25, UMTS	Pulse modulation 217 Hz	2	0.3	28	28
1845							
1970							
2450	2400 - 2570	Bluetooth, WLAN 802.11 b/g/n, RFID 2450 LTE Band 7	Pulse modulation 217 Hz	2	0.3	28	28
5240	5100 - 5800	WLAN 802.11 a/n	Pulse modulation 217 Hz	0.2	0.3	9	9
5500							
5785							

※ As an alternative to frequency modulation, 50 % pulse modulation at 18 Hz may be used because while it does not represent actual modulation, it would be worst case.

# WARRANTY AND DISCLAIMERS

## WARRANTY

JMS CO., LTD. hereby warrants to the original purchaser that reasonable care has been used in the manufacture of DIGITAL TONGUE PRESSURE METER and that, when properly used, it will be free from defects in material and/or workmanship for a period of 18 months after the date of shipment from JMS's factory. The exclusive remedy with respect to any instrument or component found within this warranty period not to meet these standards is that, after return to and examination by JMS's designated representative, JMS will without charge at its option either repair or replace an instrument found to be defective.

This warranty shall not apply if the instrument has been repaired by anyone other than a qualified service personnel member approved by JMS, or altered in any way which, in JMS's judgment, affects its stability or reliability; nor if the serial number has been altered, effaced, or removed; nor if the fault has been caused by misuse or abnormal conditions of operation.

In such cases, JMS or its designated representative will notify the purchaser of JMS's determination, and repairs, if requested, be billed at JMS's designated representative's normal rates. Estimates will be submitted before any repair work is started, if requested.

THIS WARRANTY IS MADE IN LIEU OF OTHER WARRANTIES, EXPRESS OR IMPLIED, INCLUDING ANY IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE.

## DISCLAIMERS

1. The device is a device that provides valuable information for evaluating the function of swallowing, but does not provide diagnostic information. We are not responsible for any adverse effect on health conditions as a result of diagnoses based on the device measurements.
2. The result measured by the device is the data obtained at the time of measurement. As the symptom may change suddenly, do not judge the measurement data by yourself, and contact a doctor. We are not responsible for any adverse effects on health conditions.
3. We are not responsible for damages caused by earthquakes, thunders, winds, floods, fires other than our responsibility, actions of third parties, other accidents, your intent or negligence, misuse, or other abnormal conditions.
4. We are not responsible for any involuntary damages (loss of business profits, business interruption, etc.) arising from the device use or device failure.
5. We are not responsible for any damages arising from failing to follow this manual's contents.
6. We are not responsible for any damages arising from malfunction due to a combination of connected devices and software in which we are not involved.