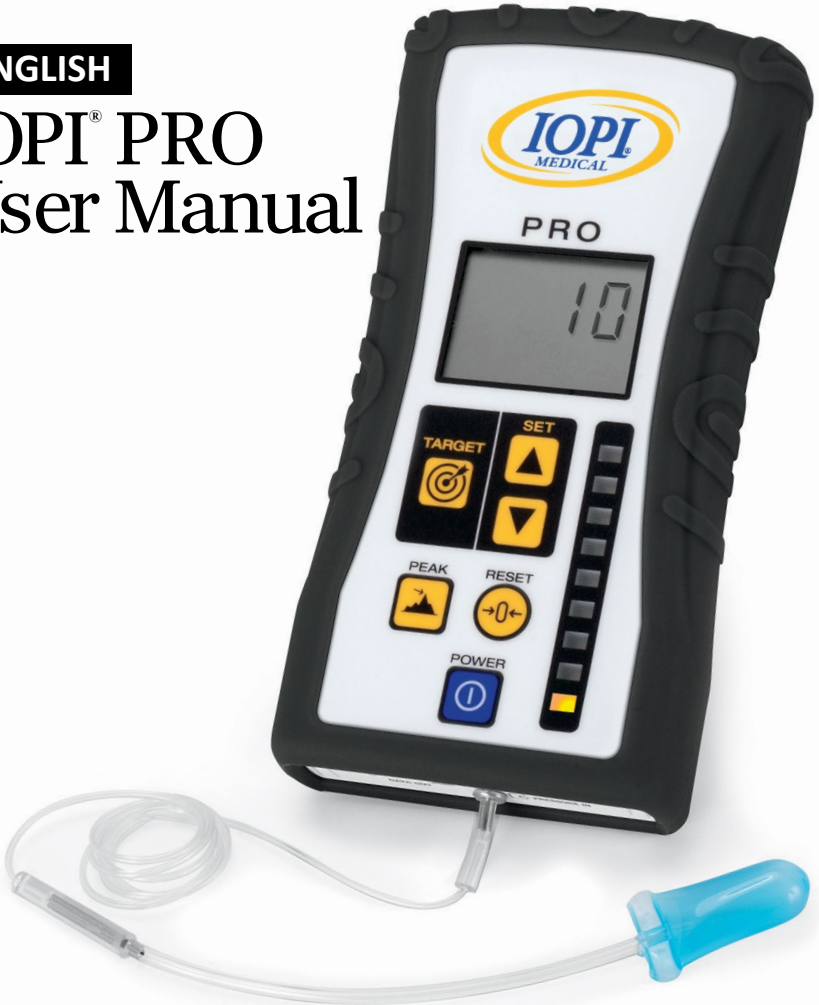
IOPI MEDICAL

Iowa Oral Performance Instrument

MODEL 3.1

ENGLISH

IOPI® PRO User Manual



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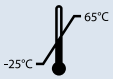
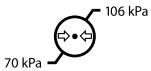
IOPI® Icons

SYMBOL	TITLE	DESCRIPTION	REFERENCE[1]
REF	**Catalogue Number**	Indicates the manufacturer's reference number so that the medical device can be identified	ISO 15223-1, Clause 5.1.6
SN	**Serial Number**	Indicates the manufacturer's serial number so that a specific medical device can be identified	ISO 15223-1, Clause 5.1.7
	**Date of Manufacture**	Indicates the date when the medical device was manufactured	ISO 15223-1, Clause 5.1.3
UDI	**UDI**	Indicates a carrier that contains unique device identifier information	ISO 15223-1, Clause 5.7.10
	**Manufacturer**	Indicates the medical device manufacturer	ISO 15223-1, Clause 5.1.1
	**Refer to Instruction Manual**	Indicates that the instruction manual must be read	ISO 7010-M002
MD	**Medical Device**	Indicates the item is a medical device	ISO 15223-1, Clause 5.7.7
	**Caution**	Indicates that caution is necessary when operating the device close to where the symbol is placed, or that the current situation needs operator awareness or operator action in order to avoid undesirable consequences	ISO 7000-0434B
	**Type BF applied part**	Indicates a Type BF patient applied part complying with IEC 60601-1	IEC 60417-5333
IP22	**Degree of Ingress Protection**	Indicates the device enclosure has an IP22 ingress protection rating	N/A
	**2 AA Alkaline Batteries**	Indicates the device is powered by 2 AA alkaline batteries	N/A
	**Nemko N-mark**	Indicates device has been certified by Nemko as complying with relevant electrical safety and EMC standards	N/A
	**Do Not Dispose of in Household Refuse (WEEE)**	Indicates that separate collection for waste electric and electronic equipment (WEEE) is required	Directive (EU) 2012/19/EU IEC 60417-6414
CE	**CE Marking of Conformity**	Signifies European technical conformity	Regulation (EU) 2017/745 Article 20
UK CA	**UK Conformity Assessed**	Signifies United Kingdom technical conformity	UK MDR 2002 (SI 2002 No 618) Section 10
EC REP	**Authorized Representative in the European Community/ European Union**	Indicates the authorized representative in the European Community/European Union	ISO 15223-1, Clause 5.1.2

1. Standards used: BS EN ISO 15223-1:2021, *Medical devices – Symbols to be used with information to be supplied by the manufacturer.* ISO 7000:2019, *Graphical symbols for use on equipment – Registered symbols.* ISO 7010:2019. *Graphical symbols – Safety colors and safety signs – Registered safety signs.* IEC 60417, *Graphical symbols for use on equipment.*

IOPI® Shipping Icons

SYMBOL	TITLE	DESCRIPTION	REFERENCE[2]
	**Fragile, Handle with Care**	Indicates a medical device that can be broken or damaged if not handled carefully	ISO 15223-1, Clause 5.3.1
	**Keep dry**	Indicates a medical device that needs to be protected from moisture	ISO 15223-1, Clause 5.3.4
	**This way up**	Indicates correct upright position of the transport package	ISO 7000-0623
	**Storage and Transport Temperature Limit**	Indicates the temperature limits to which the medical device can be safely exposed	ISO 15223-1, Clause 5.3.7
	**Storage and Transport Atmospheric Pressure Limit**	Indicates the range of atmospheric pressure to which the medical device can be safely exposed	ISO 15223-1, Clause 5.3.9
	**Storage and Transport Humidity Limit**	Indicates the range of humidity to which the medical device can be safely exposed	ISO 15223-1, Clause 5.3.8

2. Standards used: BS EN ISO 15223-1:2021, *Medical devices – Symbols to be used with information to be supplied by the manufacturer.* ISO 7000:2019, *Graphical symbols for use on equipment – Registered symbols.*

Table of Contents

Indications for Use

The IOPI® Pro (Model 3.1) is used by healthcare professionals to measure, evaluate, and increase the strength and endurance of the tongue and lip in patients with oral motor disorders, including dysphagia, dysarthria, and obstructive sleep apnea.

The IOPI® Pro is intended for clinical use by healthcare professionals.

CONTRAINDICATIONS:

- **Do not** use with children under the age of 3.
- **Do not** use the bulb with a patient who has any current or past problem with pain disorders involving the jaw muscles or temporomandibular joint ("TMJ Disorder," "Myofascial Pain Disorder").

⚠ WARNINGS

- WARNING: **Do not** place a plastic or latex film over the bulb. This presents an unlikely but serious risk of airway blockage due to the patient swallowing or choking on the film, or a risk of toxic or allergic reaction to the film material.
- CAUTION: **Always** hold on to the bulb tubing when it is in the patient's mouth to prevent choking or ingestion.
- CAUTION: **Do not** use a bulb with more than one patient. Single patient use is necessary to prevent cross-contamination.
- CAUTION: **Do not** put the bulb in a patient's mouth if there is an imminent risk of the patient having a seizure. This could pose a choking or ingestion hazard if the bulb detaches during the episode.
- CAUTION: **Do not** use the IOPI® Pro to measure bite force. This could result in a bulb leak, preventing pressure measurement.
- CAUTION: Keep the device and replaceable components, accessories, and service items out of the reach of children. The small parts present a swallowing or gagging hazard for young children.
- CAUTION: Only use IOPI® Medical LLC approved components, accessories, and service items with the IOPI® Pro. Use of non-IOPI® components could result in inaccurate readings, impeding patient treatment.

NOTE: The healthcare professional should inform any patient who is to perform tongue strengthening exercises or the tongue endurance measurement at 50% or more of their maximum pressure that they may experience the sensation of "throat" soreness following the measurement. This condition may persist for as long as 24 hours.

Safety & Care Instructions

Safety Precautions

Please observe the following safety precautions when setting up and using your IOPI® Pro:

- CAUTION: Only use this device for measuring oral motor structures. Using the bulb in another body orifice and then placing it in the patient's mouth could lead to sickness.
- CAUTION: This system is intended for supervised use with adults and children ages 3 or older. Supervision is necessary to prevent choking or ingestion and to ensure accurate measurements.
- CAUTION: To avoid measurement errors, carefully read this manual before using the IOPI® Pro.
- CAUTION: Prior to using IOPI® Pro replaceable components (such as the IOPI® Tongue Bulb), accessories, or service items, carefully read the associated Instructions for Use. This is necessary to prevent misuse leading to choking or ingestion, as well as cross-contamination leading to sickness.

Report any serious incident that has occurred in relation to IOPI medical devices to the manufacturer (IOPI Medical) and the authority having jurisdiction in the locale in which the user and/or patient is established.

Caring for your IOPI® Pro

To ensure that you receive the maximum benefit from using this device, please abide by the following care guidelines:

- When not in use, remove the Connecting Tube from the IOPI® Pro and store the IOPI® Pro in the provided carrying case.
- Do not immerse the IOPI® Pro in water. If the surface of the device comes into contact with water, dry it immediately with a soft cloth.
- The exterior of the IOPI® Pro and the silicone cover can be cleaned with a soft, slightly moistened germicidal cloth intended for disinfecting medical equipment. Do not use abrasive or corrosive cleaning agents.
- The IOPI® Pro is reusable and can be used with multiple patients. Clean the silicone cover and exterior of the IOPI® Pro before and after use with each patient. Remove the silicone cover from the Pro, wipe both items and let dry, then replace the cover on the Pro.
- The bulbs, as supplied by IOPI® Medical LLC, can be reused by the same patient for up to one month after their initial use if cleaning and storage instructions are followed. These instructions are detailed in the IOPI® Tongue Bulb and IOPI® Trainer Bulb Instructions for Use. Do not sterilize the IOPI bulbs. Sterilization could melt or otherwise damage the bulbs.
- The Connecting Tube can be reused as long as it is not exhibiting signs of aging or degradation (e.g., tubing tears, metal pin detaching from the tubing). It can be used with multiple patients if cleaning and storage instructions are followed. These instructions are detailed in the IOPI® Connecting Tube Instructions for Use.
- To disconnect the Connecting Tube from the Pro, grip the thicker part of the tubing and gently pull the Connecting Tube away from the device. To disconnect the Connecting Tube from the Tongue Bulb tubing, hold on to the thicker tubing and gently pull apart while twisting and bending the Tongue Bulb tubing to break the air seal.

- Remove the 2 AA batteries whenever you plan to store the IOPI® Pro for longer than 2 months.
- When replacing the batteries, only use new AA alkaline batteries. Do not use rechargeable batteries.
- Do not expose the IOPI® Pro to strong electromagnetic fields, excessive force, shock, dust, temperature changes, or humidity. These environmental conditions may result in a malfunction, a shorter electronic life span, or damage to the device.
- Do not open the IOPI® Pro and tamper with the internal components; doing so will terminate the product warranty and may cause damage.
- At the end of its useful life, dispose of the IOPI® Pro and its components, accessories, and service items in accordance with the associated Instructions for Use and with local or national disposal or recycling laws.

Instructional Icons

IOPI® Report Generator is an optional software accessory for use with the IOPI® Pro. While the user can record information such as maximum pressure and successful repetition count by hand, the IOPI® Report Generator software generates a report of all Peak and Target event data collected by the device. The following icons are used in the manual to assist the user with specific instructions for each option:

Indicates instructions for users who plan to download stored event data using IOPI® Report Generator.

Indicates instructions for users who plan to record data by hand.

Indicates a tip that may be useful.

Definitions

EVENT: Instance where the bulb pressure reaches at least 5 kPa when the unit is in Peak Mode or Target Mode. Event data is automatically stored in a data file and can be accessed using the associated index number in the IOPI® Report Generator software. See Data Output (page 23) for more details.

HOLD DURATION: Time, in seconds, that the target (green) light is illuminated during an event.

INDEX NUMBER: A number from 100 to 999 that uniquely identifies a data file stored on the IOPI® Pro. See Data Output (page 23) for more details.

REPETITION: An event that forms one complete movement of an exercise.

REPETITION COUNT: The number of repetitions performed in a set in Target Mode.

SUCCESSFUL REPETITION COUNT: Number of repetitions where the pressure reached the target value (green light).

FAILED REPETITION COUNT: Number of repetitions where the pressure did not reach the target value (green light).

SET: A group of consecutive repetitions.

TARGET VALUE: The pressure required to illuminate the green light at the top of the biofeedback light array.

IOPI® Medical LLC

APPROVED COMPONENTS:

5-6010 Box of 10 Tongue Bulbs

5-6105 Box of 5 Trainer Bulbs

5-0001 Connecting Tube

5-0005 Mini-USB to USB Cable

APPROVED ACCESSORIES:

5-8101 IOPI® Report Generator

APPROVED SERVICE ITEMS:

5-0102 Accuracy Check Kit

IOPI® Pro Control Buttons & Symbols

#	Symbol	Identity	Description
1		**Target Mode**	Activates Target Mode. Displays the current target pressure initially and then the successful repetition count. The biofeedback light array adjusts in relation to the input pressure from the Tongue Bulb. Holding this button down while pressing the Power button [⏻] activates Program Mode.
2		**Set Target: Up Arrow**	Increases the target pressure corresponding to the top (green) light of the biofeedback light array in Target Mode.
3		**Set Target: Down Arrow**	Decreases the target pressure corresponding to the top (green) light of the biofeedback light array in Target Mode.
4		**Peak Mode**	Activates a peak-finding function. Displays the maximum pressure achieved when an attached bulb is compressed.
5		**Reset**	In Peak Mode, this button will reset the Peak value to 0. In Target Mode, this button will initiate a new exercise set by resetting the successful repetition count to 0. In Program Mode, when held down for 3 seconds, this button will clear the stored data in memory and reset the index number to 100.
6		**Power (ON/OFF)**	Turns the device on and off. When turned on, the display shows the index number for three seconds. This number is used to identify the stored data that will be collected in Peak and/or Target Mode. The IOPI® Pro will turn itself off after 15 minutes of inactivity.
7		**Data Out**	Mini-USB port for use with IOPI® software.
8		**ESD Sensitive**	Sensitivity to electrostatic discharge.
9		**Type BF**	Patient Isolation: Type BF patient-applied part according to IEC 60601-1.
10		**Pressure In**	Short stainless steel tube that connects to the female end of the Connecting Tube.
11		**Low Battery (Battery Check)**	Indicates that the batteries need to be replaced.
12		**Program Mode**	Indicates that the device is in Program Mode.
13		**Data Storage**	At start-up and in Program Mode, it indicates that the number shown on the display is the index number. When using IOPI® Report Generator software, it indicates that the device is successfully connected to the software.
14		**Memory Warning**	Indicates that the memory capacity is less than 20% (if flashing) or is full (if solid). For memory clearing instructions, see page 22.

IOPI® Pro Components

Included in the IOPI® Pro Kit Deluxe (PN 1-3100-DL) and Standard (PN 1-3100-SD):

Deluxe	Standard	Item	PN	Description
1	1	(A) Iowa Oral Performance Instrument Pro (Model 3.1)	8-3101	Device, which includes a surrounding silicone cover, that measures and displays pressure from an air-filled bulb. The Pressure In port is a short stainless steel tube to which the Connecting Tube (C) is attached.
5	5	(B) Tongue Bulb	5-6001	Sensor squeezed by the tongue or lip to: - measure strength and endurance - provide biofeedback for oral motor exercise
2	1	(C) Connecting Tube	5-0001	Connects the Tongue Bulb to the Pressure In port.
1	1	(D) Pro Carrying Case	5-0003	Padded case for storing and transporting the IOPI® Pro, components, and accessories
1	1	(E) Accuracy Check Kit	5-0102	Service item used in the Accuracy Check procedure.
1	0	(F) Mini-USB to USB Cable	5-0005	Cable to connect the IOPI® Pro to a PC.
1	1	(G) Set of two AA Alkaline Batteries	5-0006	Batteries to power the IOPI® Pro. (Batteries are not included in some markets due to regulatory restrictions)
1	1	Pro User Manual *(not pictured)*	800-3101	IOPI® Pro instructions for use.
1	1	Patient Progress Datasheets *(not pictured)*	800-3102	Sheets for tracking patient progress (15 page pad).
1	1	Tongue Bulb Positioning Sheet *(not pictured)*	800-3103	Information on bulb positioning and designing an IOPI® exercise protocol.
1	0	IOPI® Report Generator *(not pictured)*	5-8101	Generates reports from data stored on the IOPI® Pro.

How Does the IOPI® Work?

How does the IOPI® measure strength?

The IOPI® measures the maximum pressure (P_{max}) a patient can produce in an air-filled bulb when it is compressed as hard as possible by the tongue or lip against a hard surface (e.g. the palate or teeth, respectively). P_{max} is a measure of strength, expressed in kilopascals (kPa, an international unit of pressure).

How does the IOPI® measure endurance?

For patients with dysphagia or dysarthria, oral motor fatigability may be of interest. The IOPI® Pro can be used to assess tongue fatigability by measuring its endurance, which is inversely proportional to fatigability. Low endurance values are an indicator of a high fatigability.

Endurance is measured with the IOPI® Pro by quantifying the length of time that a patient can maintain 50% of his or her P_{max}. This procedure is conducted in Target Mode by setting the target value to 50% of the patient's P_{max} and timing how long the patient can hold the top (green) light on.

How is the IOPI® used for exercise therapy?

The IOPI device is a tool to be used in a comprehensive program as appropriate to the patient. The healthcare professional determines what target value is appropriate for exercise therapy purposes and provides specific instructions to the patient for a particular exercise protocol. In Target Mode, the pressure required to illuminate the green light at the top of the light array can be adjusted using the Set Target arrow buttons [▲▼]. This green light is used as a visual target for the patient.

Modes

Program Mode

Program Mode is used to clear the stored data from memory and reset the index number to 100. For memory clearing instructions, see page 22.

Continuous Mode

Continuous Mode can be used for IOPI® Medical to troubleshoot the device and is not used clinically with patients.

Continuous Mode is automatically entered three seconds after the unit is turned on. In this mode, the display shows the instantaneous pressure in the attached bulb. Events in this mode are not captured and stored.

Peak Mode

Peak Mode is used to measure the maximum pressure (P_{max}), in kilopascals (kPa), generated in an attached bulb when it is compressed. Events in this mode that are greater than or equal to 5 kPa are captured and stored.

Peak Mode is entered by pressing the Peak button [ ]. To reset the display to 0, press the Reset button [→0←].

Target Mode

Target Mode is used to provide biofeedback for oral motor exercises of the tongue and lips.

Target Mode is entered by pressing the Target button [ ]. In this mode, the display shows the current target value and the Set Target arrow buttons [▲▼] can be used to adjust this value. After the new target value has been displayed for three seconds, the bottom light of the light array will illuminate* and the screen will show a successful repetition count of 0. The light array will illuminate in proportion to the bulb pressure relative to the target value. Every time a successful repetition is performed (the bulb pressure reaches the target value), the displayed successful repetition count will increase by +1. Events in this mode that are greater than or equal to 5 kPa are captured and stored.

To reset the displayed successful repetition count, press the Reset button [→0←].

**** When the target value is set to very low pressures (≤ 10 kPa), the two bottom lights will illuminate at zero pressure instead of one light.***

Set Up

1. Remove the IOPI® Pro from the carrying case and place it on a flat surface.
2. Remove the Connecting Tube from the package and notice that it has two ends: a female end (plastic tubing) and a male end (metal).
3. Connect the female end (plastic tubing) to the Pressure In port [ ] on the IOPI® device by sliding the tubing over the metal port as far as it will go.
4. Look at the Tongue Bulb in the package and notice that one end is a blue bulb and the other end is clear tubing.
5. Use scissors to cut the seal off the end of the tubing by cutting across the package while the Tongue Bulb is still in its package (See **Figure 1**). Cut along the long edge of the packaging to easily access the Tongue Bulb in Step 7 (See **Figure 2**).

Figure 1.

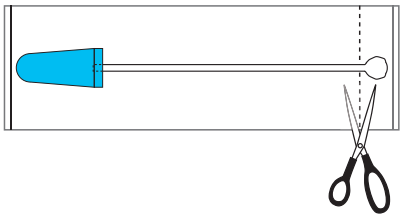
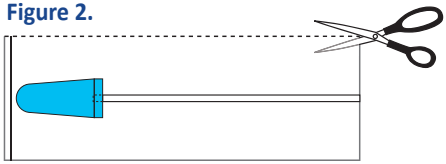


Figure 2.



6. Insert the metal (male) end of the Connecting Tube into the opened end of the Tongue Bulb tube.
7. Remove the Tongue Bulb from its package to use it with a patient, taking care not to touch the parts of the Tongue Bulb that will go into the patient's mouth.

A Trainer Bulb may be used with the IOPI® Pro in place of the Tongue Bulb and Connecting Tube. Information on connecting a Trainer Bulb to the Pro can be found in the IOPI®Trainer Bulb Instructions for Use.

8. Turn the IOPI® Pro device on by pressing and holding the Power button [ ] until the display turns on. The display will show the index number for three seconds and then enter Continuous Mode.

Make note of the patient ID, index number, and bulb location in order to correctly identify stored data when downloading.

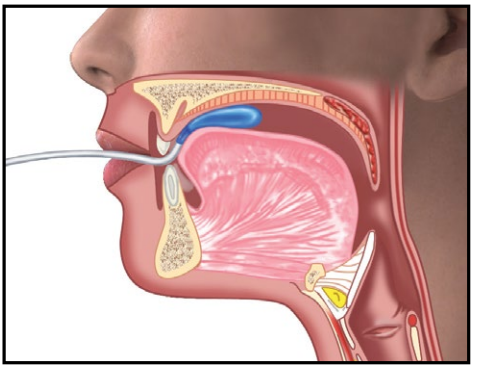
9. Press [ ] to enter Peak Mode or [ ] to enter Target Mode.

Tongue

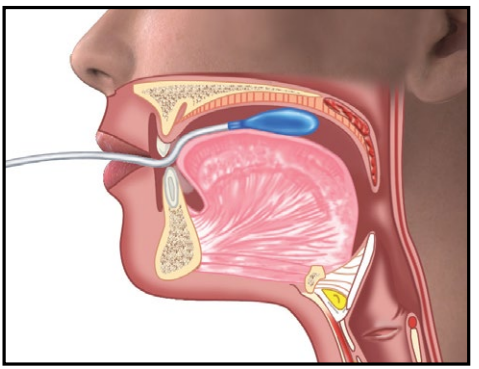
Measuring Tongue Strength

1. With the IOPI® Pro device turned on, push the Peak Mode button [ ] followed by the Reset button [→0←]. The display will show “0”.
2. Place the Tongue Bulb in the position of interest:

ANTERIOR: Position the Tongue Bulb against the patient’s hard palate, just behind the alveolar ridge *(See image to the right)*. The blue bulb seal should be behind the incisors and the bulb should be flat on the blade of the tongue.



POSTERIOR: Position the tip of the Tongue Bulb at the transition between the hard and soft palate *(See image to the right)*. The blue bulb seal should be approximately in alignment with the first molar. The Tongue Bulb should be compressed when the patient lifts the posterior tongue as in making the “k” sound.



3. The tubing should rest gently between the incisors. The mandible should be intrinsically stabilized during the task (i.e. the jaw should not be opening and closing, but rather remain quietly stable).

CAUTION: Always hold on to the bulb tubing when it is in the patient’s mouth to prevent choking or ingestion.

4. Tell the patient: **“Press the Tongue Bulb with your tongue as hard as you can for about 2 seconds.”**
   - Visual and verbal encouragement during the test is acceptable, and helps some people.
   - The 2 second hold time is not important; it just avoids the question “How long should I hold it?” when you tell them to squeeze the bulb.
5. Let the patient rest for 30–60 seconds.

Record the displayed pressure value.

6. Press the Reset button [→0←] and then repeat steps 2–5 three more times.
7. The tongue strength is the highest of the three recorded values (P_{max}). If the values consistently decrease over the three trials, the rest period may not be long enough.

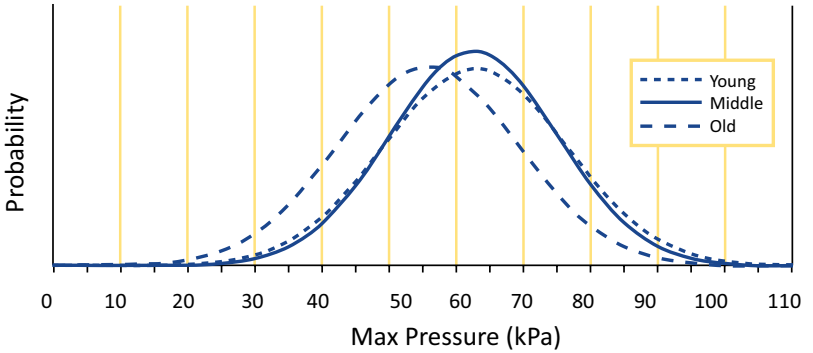
Use the index number to download the patient’s stored event data to the IOPI® Report Generator software. The maximum pressure (P_{max}) recorded in Peak Mode will be reported in the Summary tab.

There is a tendency to want to average the Peak values. Remember that a maximum is just that—a maximum, not an average. The goal of repeating the task is to try to capture the true maximum. For example, the patient may be new to the task and the first attempt may not reflect their true maximal strength.

Anterior Tongue Strength Normal Values

These normal values are derived from 10 studies conducted on the US population. New research indicates there may be international variation in these normal values, perhaps dependent on the language spoken by the subjects/patients. For the latest studies that IOPI Medical is aware of, please visit ***www.IOPImedical.com***.

Estimated normal probability distributions of maximum anterior tongue pressure of three age groups of normal U.S. subjects are shown in the table below:



Group	Mean	SD	Age (years)	Number of Subjects
Young	63	13.6	20–39	276
Middle	63	12.5	40–60	219
Old	56	13.5	>60	198

Most groups contained approximately equal numbers of males and females. In some studies, males were somewhat stronger than females by about 5-10 kPa, but only for young subjects. For middle-aged and old subjects, there was no consistent gender difference.

Maximum tongue strength (P_{max}) values corresponding to various percentiles from the estimated normal distributions are shown below. It is common to consider values below the 5th percentile to be "abnormal" *(shaded table cells)*.

Group	TONGUE STRENGTH (kPa)					
	1%	5%	10%	20%	25%	50%
Young	**31**	**41**	**46**	**52**	**54**	**63**
Middle	**34**	**43**	**47**	**53**	**55**	**63**
Old	**25**	**34**	**39**	**44**	**48**	**56**

Posterior Tongue Strength Normal Values

Posterior tongue strength is usually 5-10% lower than anterior tongue strength.[1,2,3]

Measuring Tongue Endurance

1. Measure and record the patient's maximum tongue pressure (P_{max}) as described on pages 14-15.
2. Press the Target Mode button [◎]. Use the Set Target arrow buttons [▲▼] to adjust the target value to 50% of the patient's P_{max}.
3. Position the Tongue Bulb in the patient's mouth as described for tongue strength measurement.
4. Instruct the patient to **"Squeeze the Tongue Bulb until the top (green) light comes on, and keep it on for as long as possible."**
5. When the top (green) light illuminates, the internal timer will start to time the hold duration. If the pressure drops 1 light, encourage the patient to press harder to get back to the green light; if the patient cannot return to the target value within 2 seconds then end the trial.

Use a stopwatch to measure the length of time the patient can illuminate the top (green) light.

Use the index number to download the patient's stored event data to the IOPI® Report Generator software. On the Target Data tab, identify the endurance trial event and note the Target Duration; this duration is the endurance measurement. The time of the event may be used as a reference if multiple target events were recorded in the same data file.

Usually this test is done only once per session with each patient.

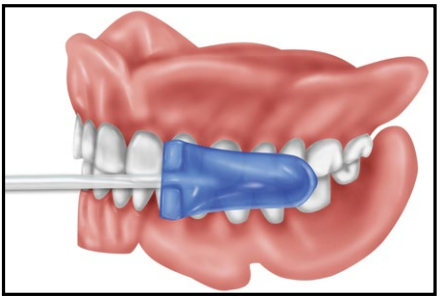
Tongue Endurance Normal Values

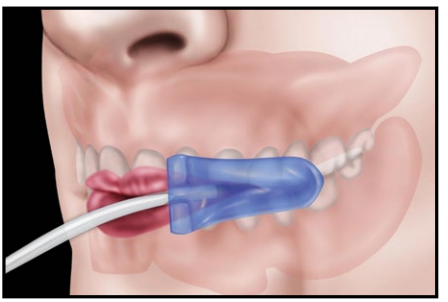
The current data are thus far insufficient to assume the statistical normality of the endurance distributions in the normal population, so an estimate of a normal probability function is not yet warranted. However, the studies published so far suggest that healthy individuals have endurance times of 15-30 seconds. Endurance times of 10 seconds or less would be an indication that a patient probably has low endurance; it may be useful to consider fatigability as a contributing factor to this patient's oral motor problems.[1,2,6,7]

Lip
Measuring Lip Strength

NOTE: In the following method of measuring lip strength, the bulb is not placed directly between the lips. The described method is valid, however, because the pressure developed in the bulb depends upon the strength of the orbicularis oris (the circumferential muscle complex that surrounds the mouth). It is tension in this muscle that allows the lips to be compressed against one another.

1. With the IOPI® Pro on, push the Peak Mode button [ ]. In this mode, the display will show the highest pressure applied to the attached bulb.
2. Press the Reset button [→0←]. The display will show "0".
3. Position an IOPI® Tongue Bulb under the orbicularis oris (just inside the corner of the patient's lips), lateral to the central incisor.
4. Instruct the patient to **"Press the Tongue Bulb against your teeth by squeezing your lips as hard as you can for about 2 seconds."**





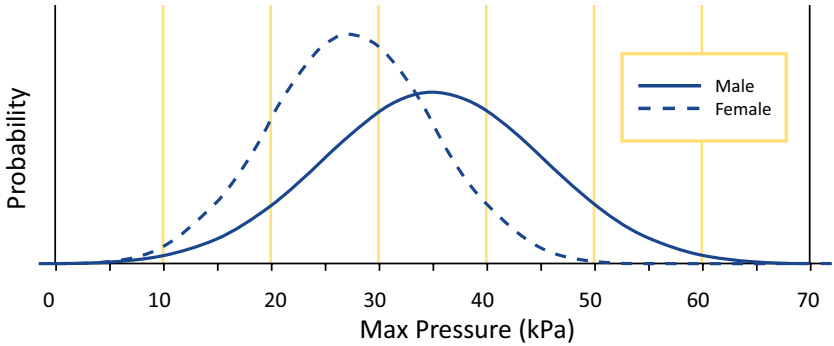
- Visual and verbal encouragement during the test is acceptable, and helps some people.
- The 2 second hold time is not important; it just avoids the question "**How long should I hold it?"** when you tell them to squeeze the bulb.

5. After the patient has made his or her maximum response and relaxed, record the value you see on the display, and then push the Reset button [→0←].
6. Let the patient rest for 30–60 seconds, and then repeat Steps 3–5 two more times.
7. The lip strength is the highest of the three recorded values (P_{max}). If the values consistently decrease over the three trials, the rest period may not be long enough.

Peak Mode events can be downloaded using the associated index number and maximum pressure will be reported on the Summary tab.

Lip Strength Normal Values

An estimated normal probability distribution of a group of 171 normal US people, aged 18–89, is shown below. Although there were no consistent age differences, there was a pronounced gender difference.



Gender	Mean	SD	Number of Subjects
Male	35	10.3	88
Female	28	7.7	83

No significant differences were found when comparing the right and left lip strengths, so these data have been pooled.[3]

Biofeedback

How is the IOPI® used for exercise therapy?

In Target Mode, the pressure required to illuminate the green light at the top of the biofeedback light array can be adjusted to a specific value. This target value provides feedback to the patient regarding his or her level of effort. The healthcare professional determines what target value is appropriate for exercise therapy purposes and provides specific instructions to the patient for a particular exercise protocol.

A typical exercise protocol would include the following parameters:

(1) Intensity (the target value)

$$T = P_{max} \times \left(\frac{E}{100}\right)$$

T= Target value, P_{max} = Maximum pressure, ***E*** = Effort Level (%)

a. Based on 2 factors: the maximum pressure (P_{max}) and the effort level
b. Adjusted as therapy progresses.

(2) Frequency

a. # Repetitions per set
b. # Sets per session
c. # Sessions per day
d. # Days per week
e. # Weeks

Progressive isometric resistance programs are commonly used to increase strength, and have been successfully applied to the tongue. The protocol's intensity should be reassessed and adjusted as appropriate over time as (a) the patient's P_{max} increases, and (b) the effort level is increased as therapy progresses. For example:

(a) A patient's P_{max} week 1 is 22 kPa and the effort goal is 60%. The target value would therefore be 60% of 22 kPa, or 13 kPa (see the Target Value Table, page 20). The patient's P_{max} is reassessed week 2 and it has changed to 24 kPa. If the effort goal stays at 60%, the target value should increase to 14 kPa.

(b) 60% effort may be difficult for beginning patients, but as they get stronger they may need to be challenged by increasing the effort level to 80% (e.g. overload principle).[8] The intensity for a patient with a P_{max} of 24 kPa would be 14 kPa if the effort goal was 60% versus 19 kPa if it was 80%. The Target Value Table, (page 21) provides target values for effort levels ranging from 60-80%.

The protocol frequency for a progressive resistance exercise program typically involves 2–3 sets/day, 3–5 days/week, over 6–12 weeks. Several protocols reported in the literature are cited in the references section.[9–12] For more information on applying the principles of exercise science to the tongue, see Burkhead et al.[8]

TARGET VALUES (kPA) Based on Maximum Pressure (P_{max}) x Effort Level (%)					
Pmax (kPa)	Effort Level (%)				
	60%	65%	70%	75%	80%
40	24	26	28	30	32
38	23	25	27	29	30
36	22	23	25	27	29
34	20	22	24	26	27
32	19	21	22	24	26
30	18	20	21	23	24
28	17	18	20	21	22
26	16	17	18	20	21
24	14	16	17	18	19
22	13	14	15	17	18
20	12	13	14	15	16
18	11	12	13	14	14
16	10	10	11	12	13
14	8	9	10	11	11
12	7	8	8	9	10
10	6	7	7	8	8

The healthcare professional may wish to use IOPI® Patient Progress Datasheets to record protocol details and track patient progress over the course of exercise therapy. These datasheets are available for purchase from IOPI® Medical.

Neuromuscular Coordination Tasks

In addition to strength development, the IOPI® Pro can provide biofeedback for tasks related to neuromuscular coordination. Two examples are:

(1) **Controlled-Timing Tasks:** The light array can provide a patient with biofeedback so that they can practice controlling the speed of a tongue movement. A quick rise, for example, could correspond to a power phase while a slow release could correspond to a control phase.[3]

(2) **Awareness Training:** The light array can provide a patient with biofeedback to increase awareness of pressure exerted by muscle(s) against a hard surface such as the palate or teeth.

Additional References

Please refer to ***www.IOPImedical.com*** for a list of up-to-date references that may be useful for understanding normal values and applications of the IOPI® Pro. This reference list also includes normal values of other populations and protocols that have been published by researchers.

“Err” Message

When there is 20% or less available device memory, the **“Err”** message flashes three times when the device is turned on. When the memory is full, the **“Err”** message remains solid and your device cannot perform any functions until the memory is cleared.

Clearing the Memory

If using IOPI® Report Generator, be sure to download and save stored data prior to clearing the memory or the data will be lost.

Enter Program Mode before clearing the memory:

1. Start with the device off.
2. Press and hold the Target button [ ].
3. While still holding the Target button [ ], press and hold the Power button [ ] until PROG [PROG] is displayed in the bottom left corner of the screen.
4. Let go of the Target [ ] and Power [ ] buttons.

Next, clear the device memory of all data and reset the index number to 100:

1. Hold down the Reset button [→0←] while a countdown from 3 is displayed on the screen followed by 000 and then the index number 100.
2. Once 100 is displayed, the memory clearing process is complete.
3. To exit Program Mode and resume normal use, press the Power button [ ] to turn the unit off and then again to turn it back on.

Data Output

The IOPI® Pro records all Peak and Target Mode event data. Every time the device is turned on, an index number is displayed for three seconds in order to uniquely identify the data to be collected. If the user wishes to associate indexed data with a particular patient, bulb location, and data collection session, it is recommended that they make note of the index number(s).

The index number ranges from 100 to 999 and increments automatically each time the unit is turned on if the previous index number is associated with a data file. In situations where the unit is turned on and off without any Peak or Target events occurring, the index number will not increment.

To distinguish events with different bulb positions or tasks, turn the device off and then on again to increment the index number and thus create a unique identifier.

Stored event data can be downloaded from the Pro using the IOPI® Report Generator software, which is included in the IOPI® Pro Deluxe Kit or can be purchased separately. Use the cable provided with the Report Generator software to connect the Pro to the computer on which the software is installed. Plug the mini-USB end of the cable into the Pro Data Out [⟲] port, and plug the USB end of the cable into the computer. Further instructions for downloading data can be found in the Report Generator user manual.

IOPI® Maintenance

Accuracy Check

Perform the following accuracy check monthly. Note that this procedure can be performed by the healthcare professional and is a check only; it is not a calibration procedure. If you would like IOPI® Medical to check the calibration rigorously, contact IOPI® Medical or your local distributor for instructions.

Practice this process a few times until the timing is smooth before you record your readings. The exact starting and ending positions are important.

1. Connect the female end of the Connecting Tube to the Pressure In port [⇇] on the IOPI® Pro.
2. Turn on the device and press the Peak button.
3. Draw air into the syringe by setting the front edge of the plunger of the syringe so it is just touching the back edge of the 30 mL mark (see **Figure 3**).
4. Leave the plunger in this position and connect the syringe tubing to the metal end of the Connecting Tube.
5. Over a period of about 5 seconds, compress the plunger of the syringe so that the front edge ends up just touching the back edge of the 15 mL mark (see **Figure 4**).
6. Note the peak pressure reading on the display.
7. Disconnect the syringe tubing from the Connecting Tube and push the Reset button [→0←].
8. Repeat Steps 3–7 several times. Discard readings where you know you pushed the plunger past the ideal position, or if the depression time was too slow or too fast. If there is variability in the readings, this is due to variability in your method. Repeat until your reading stabilizes (±1 kPa).
9. Using the altitude at your location, compare your pressure reading to **Figure 5** (for altitude in meters) or **Figure 6** (for altitude in feet).
10. If your pressure reading does not fall within the shaded region of **Figure 5** or **6**, contact IOPI® Medical or your local distributor.

Figure 3.

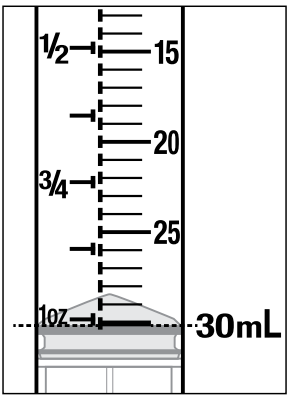


Figure 4.

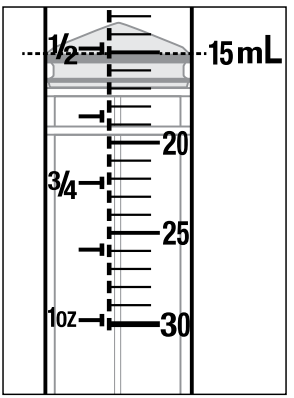


Figure 5.

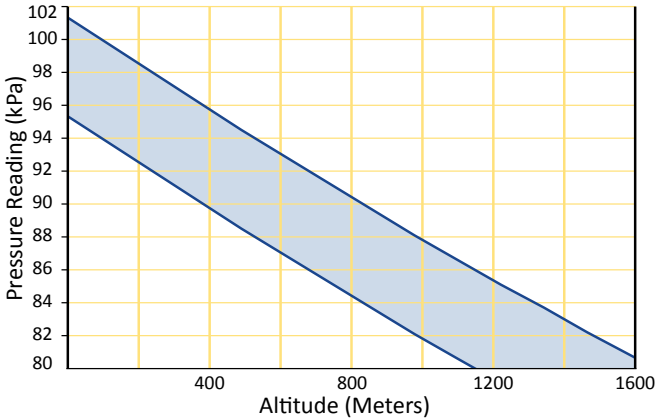
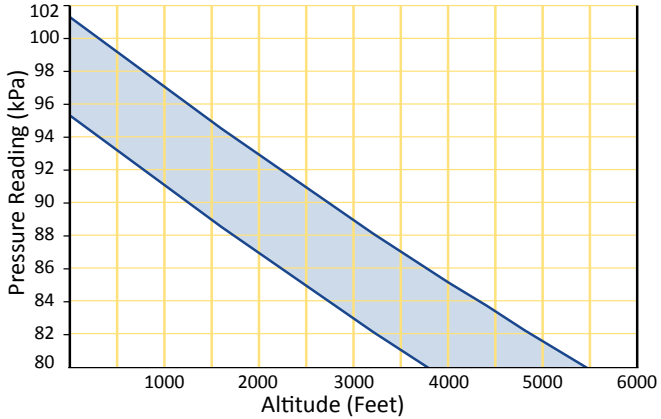
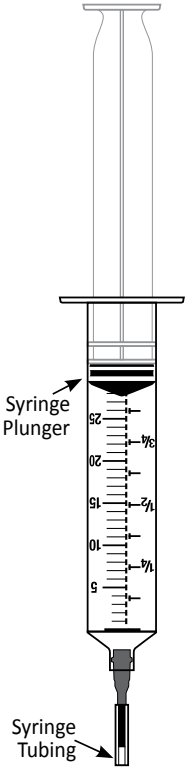


Figure 6.





Replacing the Batteries

1. Replace the two AA alkaline batteries if the display shows a low battery symbol [ ], if the display is dim, or if the display does not illuminate when the Power button [⏻] has been pressed.
2. To replace the batteries, remove the black silicone cover and then press and slide the battery cover on the back of the IOPI® Pro off.
3. Install two new AA alkaline non-rechargeable batteries, being sure to correctly match the polarity.
4. Replace the battery and silicone covers.

CAUTION: Remove and immediately recycle or dispose of used batteries according to local regulations and keep away from children. Do not dispose of batteries in household or clinic trash or incinerate. Even used batteries may cause severe injury or death.

The IOPI® Pro also contains one non-replaceable lithium coin cell battery (CR2032 lithium 3V) within its enclosure. This coin cell battery should NOT be accessed or removed by the user or patient. If a coin cell battery is ingested, call a local poison control center immediately for treatment information.

⚠ WARNING

- **INGESTION HAZARD:** This product contains a button cell or coin battery.
- **DEATH** or serious injury can occur if ingested.
- A swallowed button cell or coil battery can cause **Internal Chemical Burns in as little as 2 hours.**
- **KEEP** new and used batteries OUT OF REACH of CHILDREN.
- **SEEK immediate medical attention** if a battery is suspected to be swallowed or inserted inside any part of the body.

References

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Troubleshooting

Symptom	Possible Cause	Actions
Tongue Bulb stays flattened or dimpled after compression.	An air leak can occur anywhere in the system (Tongue Bulb, Connecting Tube, or inside the IOPI® Pro device itself).	*1. Determine if the Tongue Bulb is leaking by trying another Tongue Bulb.* *2. Determine if there is a leak where the Connecting Tube connects to the Pressure In port. Put some soap bubbles around the seam between the Pressure In port and the end of the attached Connecting Tube. Apply a squeeze to the Tongue Bulb and look for soap bubbles that get larger or move around.* *3. While leaks inside the IOPI® Pro device are unlikely, if steps 1 and 2 have been tried and the cause of the leak has not been detected, then please contact IOPI® Medical LLC or your local distributor as soon as possible.*
Abnormally short endurance values.	A small air leak.	*See steps above to determine the source of the air leak.*
The LCD display reads ≥ 2 kPa when there is no bulb attached to the IOPI® Pro device.	A change in accuracy.	*Contact IOPI® Medical LLC or your local distributor as soon as possible.*
Repetitions are not being counted.	Pressure is not released to below 5 kPa.	*Instruct the patient to fully release pressure on the bulb in between repetitions.*
Peak pressure measurements that seem too high or too low based on experience with the IOPI® Pro device and the patient.	A change in accuracy.	*Perform an Accuracy Check (see page 24). If the pressure reading is not within specifications, contact IOPI® Medical LLC or your local distributor as soon as possible.*
The IOPI® Pro device will not turn on. *(Make sure you have tried holding down the Power button for a full second)*	Batteries are dead.	*Follow the Replacing the Batteries procedure in the Maintenance section as described on page 26. If the device still does not turn on, contact IOPI® Medical LLC or your local distributor as soon as possible.*
The display flashes Err.	There is less than 20% of memory remaining.	*Clear device memory following the procedure described on page 22.* *DOWNLOAD ANY STORED DATA PRIOR TO CLEARING.*
The display shows a solid Err message.	The device memory is full.	*The device memory must be cleared following the procedure described on page 22 before continuing use.* *DOWNLOAD ANY STORED DATA PRIOR TO CLEARING.*

Technical Specifications

APPLICATION	
Measuring method	Pressure in an air-filled bulb (in kPa).
Indications for use	The IOPI® Pro is used by healthcare professionals to measure, evaluate, and increase the strength and endurance of the tongue and lip in patients with oral motor disorders, including dysphagia, dysarthria, and obstructive sleep apnea. The IOPI® Pro is intended for clinical use by healthcare professionals.
DIMENSIONS OF IOPI® DEVICE	
Height x Width x Depth	17.7 cm x 8.8 cm x 3.0 cm
Weight	309 g
MEASURING RANGE	
Pressure	0 to 100 kPa
ACCURACY	
Pressure	±2 kPa
EXPECTED SERVICE LIFE	
Years	5 yr
POWER	
Power supply	2 AA alkaline batteries
CLASSIFICATIONS	
Protection against electric shock	According to IEC 60601-1; Type BF
Ingress protection	IP22: Protected against objects > 12.5mm and dripping water when tilted up to 15°
Mode of operation	Continuous duty
OPERATING ENVIRONMENT	
Temperature	5°C to 40°C (41°F to 104°F)
Humidity	15% to 93% relative humidity
Atmospheric Pressure	70 kPa to 106 kPa
STORAGE/TRANSPORT ENVIRONMENT	
Temperature	-25°C to 65°C (-13°F to 149°F)
Humidity	10% to 93% relative humidity
Atmospheric Pressure	70 kPa to 106 kPa
MANUFACTURER	
	**IOPI® Medical LLC** 18500 156th Ave NE, STE 104, Woodinville, WA 98072 U.S.A. Tel: +1 (425) 549-0139
AUSTRALIAN SPONSOR	
	EMERGO AUSTRALIA Level 20 Tower II, Darling Park, 201 Sussex Street Sydney, NSW 2000 Australia
EU AUTHORIZED REPRESENTATIVE	
	**EMERGO EUROPE** Westervoortsedijk 60 6827 AT Arnhem The Netherlands
UK RESPONSIBLE PERSON	
	SEVERN HEALTHCARE TECHNOLOGIES LTD. 42 Kingfisher Court, Hambridge Rd. Newbury, Berkshire RG14 5SJ United Kingdom

Limited Warranty

WARRANTY

IOPI® Medical LLC warrants your product to be free from defects in material and workmanship for a period of two years from the original date of purchase. If you discover a defect in a product covered by this warranty, we will repair it using new or refurbished components, or if repair is not possible, replace the item.

EXCLUSIONS

This warranty covers defects in manufacturing discovered while using the product as recommended by the manufacturer. The warranty does not cover loss or theft, nor does coverage extend to damage caused by misuse, abuse, unauthorized modification, improper storage conditions, and other failures to use or maintain in accord with the manufacturer's instructions. The warranty does not cover parts that are subject to normal wear and tear.

LIMITS OF LIABILITY

Should the product(s) fail, your sole recourse shall be repair or replacement, as described in the preceding paragraphs. IOPI® Medical LLC will not be held liable to you or any other party for any damages that result from the failure of this product. Damages excluded include, but are not limited to, the following: lost profits, lost savings, loss of or injury to data, damage to person or property, and incidental or consequential damages arising from the use, or inability to use, this product. In no event will IOPI® Medical LLC be liable for more than the amount of your purchase price, not to exceed the current list price of the product, and excluding tax, shipping, and handling charges.

IOPI® Medical LLC disclaims any and all other warranties, express or implied.

By using the product, the user accepts all terms described herein.

HOW TO OBTAIN SERVICE UNDER THIS WARRANTY

Before sending the unit for repair, contact IOPI® Medical LLC:

+1 (425) 549-0139
info@IOPImedical.com

REQUIREMENTS

The cost of shipping to the manufacturer and payment of any customs clearance fees or duties are the responsibility of the user. These costs may be credited to the user's account if the product is determined to be under warranty. Return shipping costs for products repaired or replaced under this warranty will be paid for by IOPI® Medical LLC.

Notes

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www.IOPImedical.com