



Iowa Oral Performance Instrument

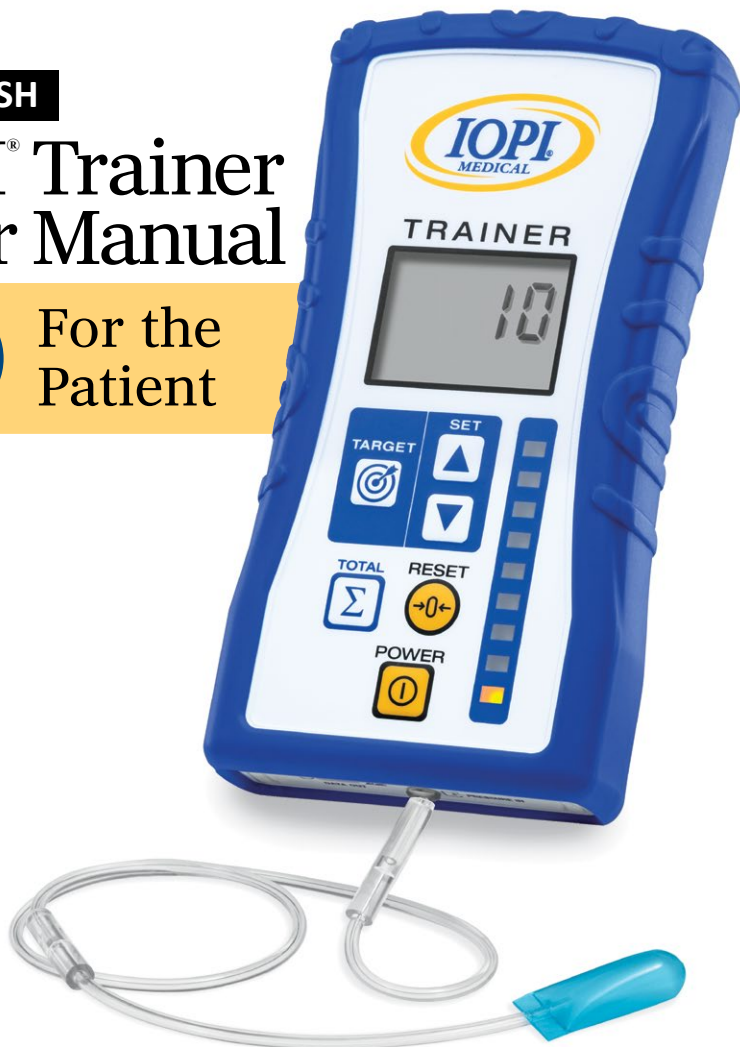
MODEL 3.2

ENGLISH

IOPI® Trainer User Manual



For the
Patient



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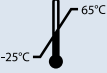
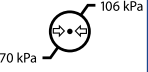
www.IOPImedical.com

IOPI® Icons

SYMBOL	TITLE	DESCRIPTION	REFERENCE ¹
	Catalogue Number	Indicates the manufacturer's reference number so that the medical device can be identified	ISO 15223-1, Clause 5.1.6
	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	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
	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 Marking of Conformity	Signifies European technical conformity	Regulation (EU) 2017/745 Article 20
	UK Conformity Assessed	Signifies United Kingdom technical conformity	UK MDR 2002 (SI 2002 No 618) Section 10
	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*.

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CAUTION: This device is only sold to patients by the order of a healthcare professional who will be directing the use of the device. Direction is necessary to prevent unsafe use and make sure your treatment is effective.

Indications for Use

The IOPI® Trainer (Model 3.2) is used to increase the strength and endurance of the tongue and lip in patients with oral motor disorders, including swallowing and speech problems and sleep apnea.

The IOPI® Trainer is intended for clinical use and use by patients outside their therapy sessions under the direction of a healthcare professional.

CONTRAINDICATIONS:

- **Do not** use with children under the age of 3.
- **Do not** use if you have current or past problem with pain disorders involving the jaw muscles or joint of the jaw (“TMJ Disorder,” “Myofascial Pain Disorder”).

NOTE: This user manual is intended for patient reference. Its content relates to 800-3201-08_EN, IOPI® Trainer User Manual for the Healthcare Professional.



WARNINGS

- **WARNING: Never** cover the Trainer Bulb with plastic wrap, latex, or other material, as it presents a choking hazard and may cause an allergic reaction.
- **CAUTION: Do not** share your Trainer Bulb. It is only intended for use by one person. Sharing it could spread germs or make you sick.
- **CAUTION: Do not** put the Trainer Bulb in your mouth if there is an imminent risk of you having a seizure. You could swallow or gag on the bulb during the seizure.
- **CAUTION: Always** hold on to the safety grip of the Trainer Bulb (see page 14) any time it is in your mouth; otherwise you could swallow or gag on the bulb.
- **CAUTION:** Clean the Trainer Bulb after each use to prevent reintroducing germs into your mouth. Directions for cleaning and storing the Trainer Bulb are included in the Instructions for Use that come with this component.
- **CAUTION:** Keep the IOPI® Trainer and the Trainer Bulbs out of the reach of children. The small parts present a swallowing or gagging hazard.
- **CAUTION:** Only use IOPI® Trainer Bulbs with the IOPI® Trainer. Using bulbs from other manufacturers could make your treatment less effective.

NOTE: You may experience the sensation of “throat” soreness following your therapy. 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® Trainer:

- **CAUTION:** Only use the bulb for exercising your tongue and lips. Use in other areas of your body could transfer germs.
- **CAUTION:** This device is sold to healthcare professionals assisting patients with oral motor problems, including swallowing and speech problems and sleep apnea, or sold to the patient on the order of the supervising healthcare professional. The healthcare professional is in charge of directing a patient's use of the IOPI® Trainer in order to ensure that it is only used as intended.
- **CAUTION:** To avoid user errors, carefully read this manual before using the IOPI® Trainer.
- **CAUTION:** Prior to using the IOPI® Trainer Bulb with the IOPI® Trainer, carefully read the associated Instructions for Use. This will help you use it correctly, avoiding the risk of swallowing or gagging on the bulb.

Report any serious incident that has occurred in relation to IOPI® medical devices to the manufacturer (IOPI® Medical) and your local regulatory authority.

Caring for your IOPI® Trainer

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

- When not in use, store the IOPI® Trainer in the carrying case provided with the device.
- Do not immerse the IOPI® Trainer in water. If the surface of the device comes into contact with water, dry it immediately with a soft cloth.
- The IOPI® Trainer is reusable. To clean the exterior of the IOPI® Trainer, the patient may wipe down the device with a soft, slightly moistened disinfecting cloth intended for cleaning household surfaces.
- The Trainer Bulbs can be reused for up to one month after their first use if cleaning and storage instructions are followed. These instructions are detailed in the IOPI® Trainer Bulb Instructions for Use. CAUTION: **Do not** place the IOPI Trainer Bulbs in a dishwasher or boiling water. This could melt or otherwise damage them.
- Remove the 2 AA batteries whenever the IOPI® Trainer device is stored 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® Trainer to strong electromagnetic fields, excessive force, shock, dust, pet hair, temperature changes, or humidity. These environmental conditions may result in malfunction, a shorter electronic life span, or damage to the device.
- Do not open the IOPI® Trainer 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® Trainer and its components, accessories, and service items in accordance with the associated Instructions for Use and with local or national disposal or recycling laws.

Definitions

REPETITION: One complete movement of an exercise.

REST PERIOD: Time to rest between sets of exercises.

SET: A group of consecutive repetitions.

TARGET VALUE: The pressure required to illuminate the top green light.

IOPI® Trainer Components

Included in the IOPI® Trainer Kit (PN 1-3200):



Item	PN	Description
(A) Iowa Oral Performance Instrument Trainer (Model 3.2)	8-3201	Device, which includes a surrounding silicone cover, that displays pressure indicated by LEDs from an air-filled bulb relative to a target value. The Pressure In port is a short stainless steel tube to which the Trainer Bulb is attached (B).
(B) Box of Trainer Bulbs	5-6105	Sensors squeezed by the tongue or lip to provide biofeedback for oral motor exercise.
(C) Trainer Carrying Case	5-0004	Padded case for storing and transporting the IOPI® Trainer.
(D) Set of 2-AA Alkaline Batteries	5-0006	Batteries to power the IOPI® Trainer. <i>(Batteries are not included in some markets due to regulatory restrictions)</i>
Trainer User Manual for Healthcare Professional <i>(not pictured)</i>	800-3201	IOPI® Trainer instructions for use for the healthcare professional.
Trainer User Manual for Patient <i>(not pictured)</i>	800-3202	IOPI® Trainer instructions for use for the patient.
Trainer Patient Instructions <i>(not pictured)</i>	800-3203	Information for the patient on their assigned IOPI® exercise protocol and bulb positioning.



IOPI® Medical LLC Approved Components:
5-6105 Box of 5 Trainer Bulbs

IOPI® Trainer Control Buttons & Symbols

#	Symbol	Identity	Description
①		Target Mode	This button displays the target pressure.
②		Set Target: Up Arrow	This button is inactive and is only used by your healthcare professional.
③		Set Target: Down Arrow	This button is inactive and is only used by your healthcare professional.
④		Total	Displays the total number of successful repetitions since the device memory was last cleared.
⑤		Reset	This button will initiate a new exercise set by resetting the displayed successful repetition count to 0.
⑥		Power (ON/OFF)	This button turns the device on and off. The IOPI® Trainer will turn itself off after 15 minutes of inactivity.
⑦		Data Out	Mini-USB port for optional use by your healthcare professional.
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 metal tube that connects to the attachment grip of the Trainer Bulb.
⑪		Low Battery (Battery Check)	Indicates that the batteries need to be replaced.
⑫		Memory Warning	Indicates that the memory capacity is less than 20% (if flashing) or is full (if solid). Notify your healthcare professional for instructions.

Introduction

Welcome to the IOPI® Family!

IOPI® Medical LLC is a family-owned medical device company that specializes in measuring and strengthening the tongue and the lips, and we are dedicated to helping YOU! You hold in your hands the guide to your new IOPI® Trainer, which will become an important part of your therapy. Before you begin, however, there are several things you should be familiar with. Carefully read and discuss the information that is in this manual with the healthcare professional who will be assisting you with the use of your Trainer. If you ever have any questions, ask your healthcare professional before using this device.

The Trainer was invented with your best interests in mind. Before, patients like you had to go to appointments in order to do therapy exercises with an IOPI® product. Now, with the Trainer, you can do your therapy exercises at home! You will still need to go to appointments to check in with your healthcare professional, but in general you will be more independent.

The Trainer is very easy to use. At your appointments, your healthcare professional will program your target value into the device, which is the amount of pressure you need to apply to the Trainer Bulb to turn on the top green light when you do your therapy exercises. The screen will count how many times you get to the green light. Each count stands for one repetition of therapy exercise.

Finally, you only need two buttons: the POWER button [ⓘ] and the RESET button [→0←]. The POWER button turns the device on and off, and the RESET button changes the count on the screen back to zero so you can start a new set of exercises. These are the only buttons on the device that are colored yellow, so they are easy to find.

Overall, the IOPI® Trainer is an exciting addition to home healthcare for strengthening the tongue and the lips. With patient-friendly features designed especially for you, the goal of IOPI® Medical is to provide you with an experience that encourages you to take charge of your health. We wish you much success in this next step of your therapy!

We would love to hear your thoughts on the IOPI® Trainer! Contact us at info@IOPImedical.com if you would like to tell us about your experience.

Frequently Asked Questions

How is the IOPI® Trainer used for exercise therapy?

Your healthcare professional will provide the instructions that you need to do exercises with your IOPI® Trainer. Basically, doing your exercises is like going to the gym. The tongue and lip must have regular work-outs to increase or maintain strength. The IOPI® Trainer has lights for biofeedback that can be used to assess your effort during exercise. As you get tired from the exercise, the lights may help motivate you to reach your target value—the top green light!

What does biofeedback mean?

Biofeedback means that a body function causes some type of response that provides information about the function. In the case of the IOPI® Trainer, the function is applying tongue or lip pressure on the Trainer Bulb and the response is the number of lights that turn on. The yellow lights show how your effort relates to your target value (that top green light!). In other words, the more pressure you apply to the Trainer Bulb, the more yellow lights will turn on until you reach the green light.

I only need to use two of the buttons.

Why are there others?

The other buttons are mainly for use by your healthcare professional. If you are curious, however, you can use two of the other buttons as well. The TARGET button [⊙], when pressed, shows the target value pressure in kilopascals (kPa) that the Trainer is set to. The TOTAL button [Σ], when pressed, shows the number of repetitions you have completed since your healthcare professional has last cleared the device.

The SET arrow buttons [▲▼] are only for use by your healthcare professional to program your target value into the device. When you press them, there will not be a response.

How do I take care of my Trainer Bulb?

Clean your Trainer Bulb after every use using warm soapy water like you would wash silverware. Rinse it off and let it dry before you store it in a clean container. A toothbrush holder works well and helps to keep it away from children.

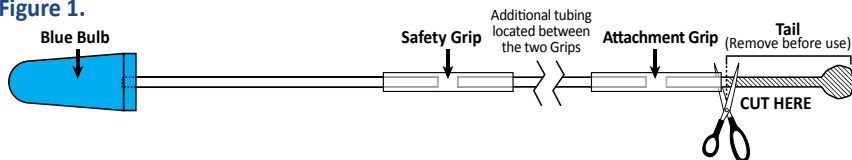
You can prevent liquid from getting down the tubing during cleaning by plugging it with a black rod that comes in your box of Trainer Bulbs. If you do get liquid in the tubing, you will need to replace the Trainer Bulb.

Home Use

Set up

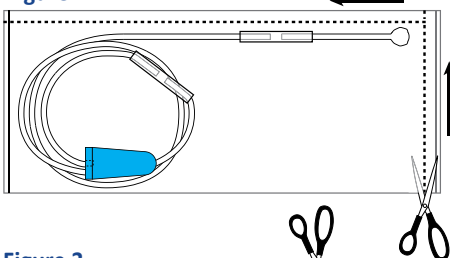
1. Remove your IOPI® Trainer from the carrying case and place the device on a flat surface.
2. Look at your Trainer Bulb in the package and notice that one end is a blue bulb and the tail end is clear tubing with a seal. All of the parts of the Trainer Bulb are labeled in **Figure 1**.

Figure 1.



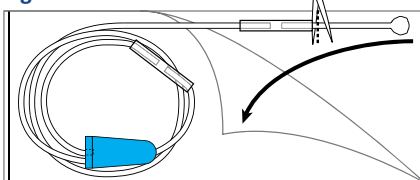
3. Use scissors to cut along the short and long edge of the package as shown in **Figure 2**.
4. Slide the tail end of your Trainer Bulb out of the package. Use scissors to cut the tail tubing off next to the attachment grip as shown in **Figures 1 and 3**.

Figure 2.



5. Connect your Trainer Bulb to the Pressure In port [↶], the short metal tube on the bottom of the IOPI Trainer (see page 10), by sliding the attachment grip over the metal tube.

Figure 3.



6. Remove your Trainer Bulb from its package, taking care to not touch the parts of the Trainer Bulb that go into your mouth.
7. Turn the IOPI® Trainer on by pressing and holding the Power button [ⓘ] until the screen turns on. The bottom light on the light column will be a yellow color and the screen will show the repetition count as 0.
8. Place the blue bulb of your Trainer Bulb in the position designated by your healthcare professional and you will be ready to perform your exercises.



CAUTION: Always hold on to the safety grip of the Trainer Bulb when it is in your mouth; otherwise you could swallow or gag on the bulb.

Using the Trainer Bulb for Exercise

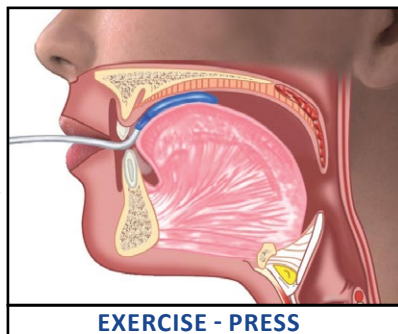
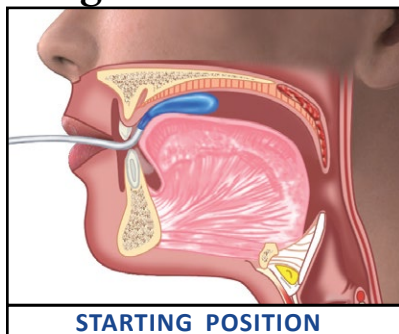
Position the Trainer Bulb based on the instructions from your healthcare professional. He or she will also explain what exercises you will be doing for your home program. The following pictures show some common examples of exercises you may be asked to do. Your healthcare professional will also tell you how many sets and repetitions of each exercise to perform and how long to rest between sets of exercises (called the **rest period**).



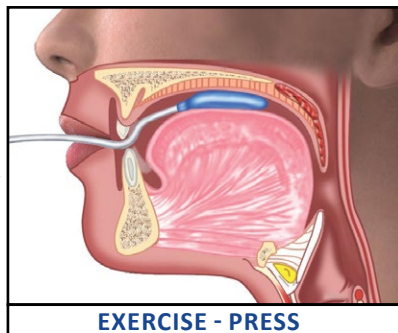
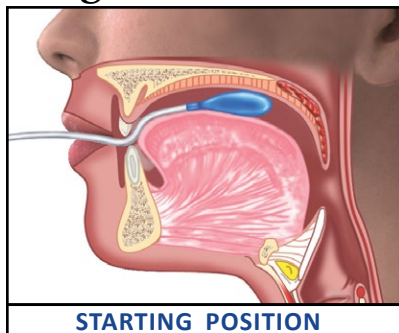
CAUTION: Only perform exercises that have been assigned to you by your healthcare professional. Doing unapproved exercises could negatively impact your treatment.

Trainer Bulb Positions for Exercise

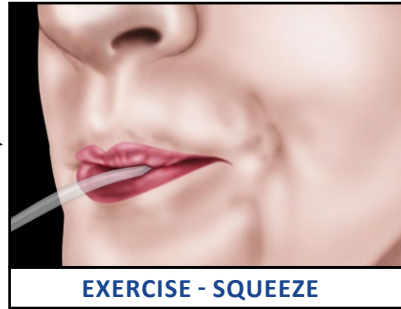
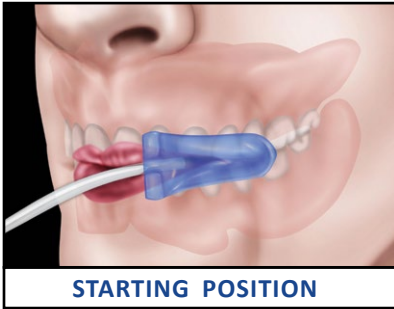
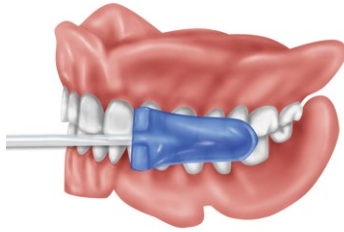
Tongue - Front



Tongue - Back



Lip



Maintenance

Replacing Batteries

1. Replace the two AA alkaline batteries if the display shows a low battery icon [🔋], if the display is dim, or if the display does not turn on when the Power button has been pressed.
2. To replace the batteries, remove the blue protective cover from the device and slide the battery door on the back of the IOPI® Trainer off.
3. Install two new AA alkaline non-rechargeable batteries, being sure to correctly match the +/- symbols.
4. Replace the battery door and then put the blue protective cover back on the device.

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 trash or incinerate. Even used batteries may cause severe injury or death.

The IOPI®Trainer 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 you or your healthcare professional. 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.



Maintenance *(continued)*

Accuracy Check

Your healthcare professional should check the accuracy of the IOPI® Trainer every so often following instructions provided in the IOPI® Trainer User Manual for the Healthcare Professional. If you would like IOPI® Medical or an authorized electronics shop to check the calibration, contact IOPI® Medical or your local distributor for instructions.

Troubleshooting

Symptom	Possible Cause	Actions
Trainer Bulb stays flattened or dimpled after compression.	An air leak can occur anywhere in the system (Trainer Bulb or inside the IOPI® Trainer itself).	1. Determine if the Trainer Bulb is leaking by trying another Trainer Bulb. 2. While leaks inside the IOPI® Trainer are unlikely, if step 1 has 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.
More than 1 light is illuminated when there is no bulb attached to the 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.	Fully release pressure on the bulb in between repetitions.
The IOPI® device will not turn on.	Battery is dead.	Follow the Replacing Batteries procedure in the Maintenance section as described on page 16. If the device still does not turn on, contact IOPI® Medical LLC or your local distributor as soon as possible.
The display flashes E r r.	There is less than 20% of memory remaining.	Tell your healthcare professional that you are seeing an error message and the device memory needs to be cleared.
The display shows solid E r r.	The device memory is full.	Tell your healthcare professional that you are seeing an error message and the device memory needs to be cleared.

Technical Specifications

APPLICATION	
Measuring method	Pressure in an air-filled bulb (in kPa).
Indications for use	The IOPI® Trainer (Model 3.2) is used to 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® Trainer is intended for clinical use and use by patients outside their therapy sessions under the direction of a healthcare professional.
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.



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