IOPI MEDICAL

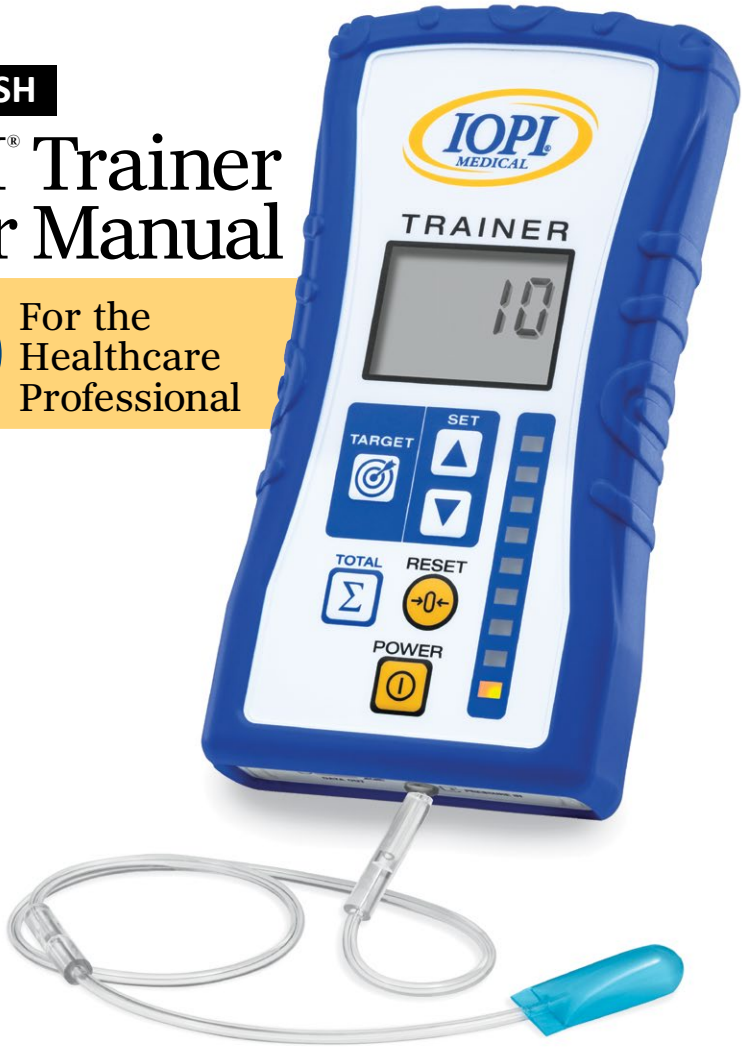
Iowa Oral Performance Instrument

MODEL 3.2

ENGLISH

IOPI® Trainer User Manual

For the Healthcare Professional



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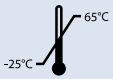
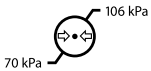
IOPI® Icons

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.*

Table of Contents

CAUTION: This device is sold directly to patients only on the order of a healthcare professional who will be directing the use of the device. Direction is necessary to prevent choking or ingestion.

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.

CONTRAINDICATIONS:

- **Do not** use with children under the age of 3.
- **Do not** approve unsupervised use by patients who are mentally incapable of safely operating the IOPI® Trainer.
- **Do not** use the Trainer 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: **Do not** use a bulb with more than one patient. Single patient use is necessary to prevent cross-contamination.
- CAUTION: **Always** hold on to the Trainer Bulb safety grip (see page 16) any time it is in a patient's mouth (or have the patient hold on to it) to prevent choking or ingestion.
- CAUTION: **Do not** sterilize the IOPI Trainer Bulbs or Trainer base unit; this could damage them.
- 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: 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® Trainer. 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 a 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 the IOPI® Trainer:

- CAUTION: Only use this device with 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 device is sold to healthcare professionals who are assisting patients with oral motor problems, including dysphagia, dysarthria, and obstructive sleep apnea, or 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 IOPI® replaceable components (such as the IOPI® Trainer Bulb), accessories, or service items with the IOPI® Trainer, carefully read the associated Instructions for Use. This is necessary to prevent misuse leading to choking or ingestion.

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® Trainer

Please abide by the following care guidelines:

- When not in use, store the IOPI® Trainer in the provided carrying case.
- 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 Trainer 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® Trainer Bulb Instructions for Use.
- FOR CLINIC USE: The IOPI® Trainer is reusable and can be used with multiple patients. Clean the exterior of the IOPI® Trainer and the silicone cover before and after use with a patient with a soft, slightly moistened germicidal cloth intended for disinfecting medical equipment. Remove the silicone cover from the Trainer, wipe both items and let dry, then replace the cover on the Trainer. Do not use abrasive or corrosive cleaning agents.

  FOR HOME USE: 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. Do not use abrasive or corrosive cleaning agents.
- 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 a 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.

Instructional Icons

IOPI® Report Generator is an optional software accessory for use with the IOPI® Trainer. While the user can record the target value and successful repetition count by hand, the IOPI® Report Generator software generates a report of all 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. Event data is automatically stored in a data file and can be accessed using IOPI® Report Generator software. See Data Output (page 20) for more details on stored event data.

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: The number of repetitions where the pressure reached the target value (green light).

FAILED REPETITION COUNT: The 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® 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 biofeed-back 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. *(Batteries are not included in some markets due to regulatory restrictions)*
Trainer User Manual for Healthcare Professional *(not pictured)*	**800-3201**	IOPI® Trainer instructions for use for the healthcare professional.
Trainer User Manual for Patient *(not pictured)*	**800-3202**	IOPI® Trainer instructions for use for the patient.
Trainer Patient Instructions *(not pictured)*	**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

5-0005 Mini-USB to USB Cable

APPROVED ACCESSORIES:

5-8101 IOPI® Report Generator

APPROVED SERVICE ITEMS:

5-0102 Accuracy Check Kit

IOPI® Trainer Control Buttons & Symbols

#	Symbol	Identity	Description
1		**Target Mode**	In Run Mode, this button displays the target pressure. Holding this button down while pressing the Power button [⏻] activates Program Mode.
2		**Set Target: Up Arrow**	In Run Mode, this button is inactive. In Program Mode, this button increases the target pressure corresponding to the top (green) light of the biofeedback light array. The highest target value setting is 60 kPa.
3		**Set Target: Down Arrow**	In Run Mode, this button is inactive. In Program Mode, this button decreases the target pressure corresponding to the top (green) light of the biofeedback light array. The lowest target value setting is 5 kPa.
4		**Total**	Displays the total number of successful repetitions since the device memory was last cleared.
5		**Reset**	In Run Mode, this button will initiate a new exercise set by resetting the displayed successful repetition count to 0. In Program Mode, when held down for 3 seconds, this button will clear the stored data in memory.
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 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 attachment grip of the Trainer Bulb.
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**	In Program Mode, it indicates that the memory is being cleared. When using IOPI® Report Generator software, it indicates the device is successfully connected to the computer.
14		**Memory Warning**	Indicates that the memory capacity is less than 20% (if flashing) or is full (if solid). For memory clearing instructions, see Set Up section 2b on page 16.

Introduction

The IOPI® Trainer

The IOPI® Trainer is a device that must be used in parallel with the IOPI® Pro (Model 3.1). As described in the biofeedback section (page 14), the maximum pressure value (P_{max}) is needed to create an effective therapy plan. P_{max} can only be measured using the IOPI® Pro or a Series 2 IOPI® device.

The main purpose of the IOPI® Trainer is to allow for the continuation of therapy at home. This allows the patient to be more independent after initial instruction from the healthcare professional.

The IOPI® Trainer was designed to be easy to use for the patient. There are only two buttons intended for patient use: the Power button [⏻] to turn the device on and off and the Reset button [→0←] to zero the successful repetition count shown on the display. These buttons are colored yellow to easily distinguish them for the patient.

The Total button [$\sum$] on the IOPI® Trainer allows the healthcare professional to easily view the total number of successful repetitions without having to connect the device to a computer. The healthcare professional can hold the patient immediately accountable for their compliance with the assigned exercise regimen. For example, if the patient was assigned 3 sets of 10 repetitions to be conducted on Monday, Wednesday and Friday, their total successful repetitions per week should be 90 (10 repetitions/set x 3 sets/day x 3 days). If the IOPI® Trainer shows a weekly total of 46 successful repetitions instead of 90, then the healthcare professional can explain to the patient that if they want to improve and reach their goals, they must comply with the therapy protocol.

Optional PC-based software, called IOPI® Report Generator, is available for purchase from IOPI® Medical. This software allows the healthcare professional to download patient usage data from the IOPI® Trainer and then automatically generates a detailed patient report. This information may assist the healthcare professional in making informed decisions about how the protocol parameters should be adjusted.

Overall, the IOPI® Trainer is a safe and innovative solution to home healthcare for strengthening the tongue and the lips. The device has been engineered to provide a patient-friendly experience with clinic level results.

Modes

Program Mode

Program Mode is used to set the target pressure for the patient and clear the device memory. For instructions see Set Up section on page 16.

Run Mode

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

Run Mode is automatically entered when the device is turned on by pressing and holding the Power button [⏻] until the display turns on. In this mode, the display shows the successful repetition count. To start a new set of exercises, reset the displayed count to 0 by pressing the Reset button [→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 displayed successful repetition count will increase by +1.

Biofeedback

How is the IOPI® used for exercise therapy?

In Program 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)

a. Based on 2 factors: the maximum pressure (P_{max}) and the effort level

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

T= Target value, P_{max} = Maximum pressure, ***E*** = 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 Target Value Table, page 15). 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).[5] 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 15) provides target values for effort levels ranging from 60-80%.

The protocol frequency for a progressive resistance exercise program typically involves 2-3 sets/session, 1 session/day, 3-5 days/week, over 6-12 weeks. Several protocols reported in the literature are cited in the references section (page 22).[1-4] For more information on applying the principles of exercise science to the tongue, see Burkhead et al.[5]

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.

Clinic Use

Set Up

1. Remove the IOPI® Trainer device from the carrying case and place it on a flat surface.

2. Enter Program Mode by starting with the device off. Press and hold the Target button [◎]. 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. Let go of the buttons.

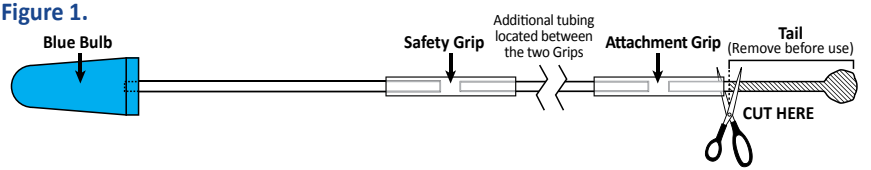
   a. **Adjust the Target Value:** Press the Set Target arrow buttons [▲▼] until the screen shows the desired pressure value.

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

   b. **Clearing the Memory:** Hold down the Reset button [→0←] while a countdown from 3 is displayed on the screen, followed by 000. Once the 000 is displayed, the memory clearing process is complete.

3. Exit Program Mode by pressing the Power button [⏻] to turn the unit off.

Figure 1.



3. Look at the 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**.

4. Use scissors to cut along the short and long edge of the package as shown in **Figure 2**.

5. Expose the tail end of the Trainer Bulb. Use scissors to cut the tail tubing off next to the attachment grip as shown in **Figures 1 and 3**.

Figure 2.

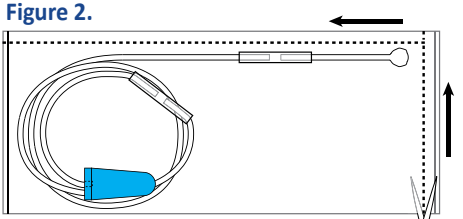
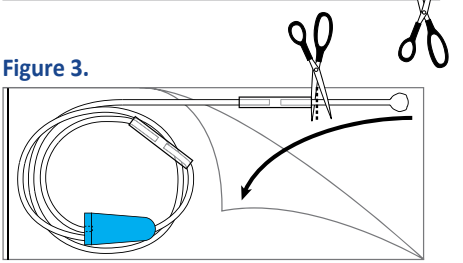


Figure 3.



6. Connect the Trainer Bulb to the Pressure In port [⇦] on the bottom of the IOPI® Trainer (see Page 10) by sliding the attachment grip over the metal port as far as it will go.
7. Remove the Trainer Bulb from its package, taking care to not touch the parts of the Trainer Bulb that go into the patient's mouth.
8. Turn the IOPI® Trainer on by pressing and holding the Power button [⏻] until the display turns on. The device will enter Run Mode and the display will show a repetition count of 0.
9. Position the Trainer Bulb in the mouth based on the exercise protocol design. Typical positions for the Trainer Bulb are shown on pages 18-19.

Home Use

The IOPI® Trainer Kit comes with a set of IOPI® Patient Instruction forms designed to be completed by the healthcare professional and provided to the patient to clarify their home therapy protocol.

Before the patient uses the IOPI® Trainer without supervision, the healthcare professional is responsible for ensuring the following:

1. The patient is mentally capable of safely operating the IOPI® Trainer in an unsupervised setting.
2. The patient has read the IOPI® Trainer Patient User Manual and Trainer Bulb Instructions for Use and understands all the Warnings as well as the Safety & Care Instructions.
3. The patient demonstrates that they can set up the IOPI® Trainer with a Trainer Bulb.
4. The patient understands the Trainer Bulb position for the home therapy protocol and that they must hold on to the safety grip whenever the Trainer Bulb is in their mouth.

NOTE: It is recommended that this position is circled on page 2 of the IOPI® Patient Instruction form.

5. The patient understands the details of their exercise therapy protocol, including days to perform the exercises, the number of sessions per day, the number of sets per session, the number of repetitions per set, and how long to rest between sets.
6. The patient understands who to contact should they have any questions.

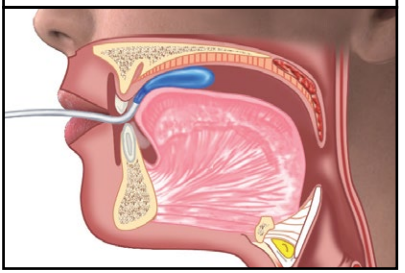
NOTE: IOPI® Medical cannot provide therapeutic instructions to the patient.

Trainer Bulb Positions for Exercise

Tongue - Anterior

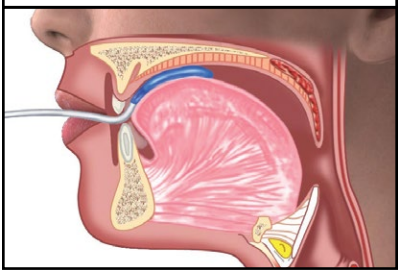
INITIAL POSITION

Position the Trainer Bulb against the patient's hard palate, just behind the alveolar ridge. The blue bulb seal should be behind the incisors, the bulb should be flat on the blade of the tongue, and the tubing should rest gently between the incisors.



ACTION

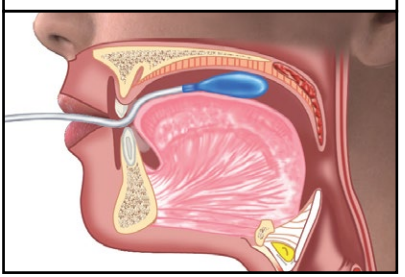
The patient lifts the anterior tongue to compress the Trainer Bulb against the hard palate. The mandible should be intrinsically stabilized during the task (i.e. the jaw should not be opening and closing, but rather remain quietly stable).



Tongue - Posterior

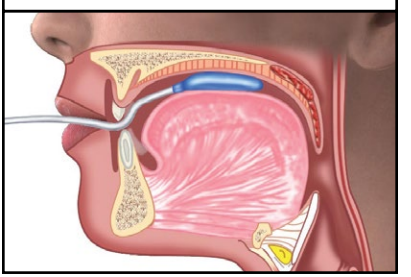
INITIAL POSITION

Position the tip of Trainer Bulb at the transition between the hard and soft palate. The tubing should rest gently between the incisors.

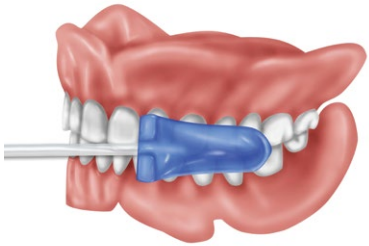


ACTION

The patient lifts the posterior tongue to compress the Trainer Bulb against the hard palate. The mandible should be intrinsically stabilized during the task (i.e. the jaw should not be opening and closing, but rather remain quietly stable).

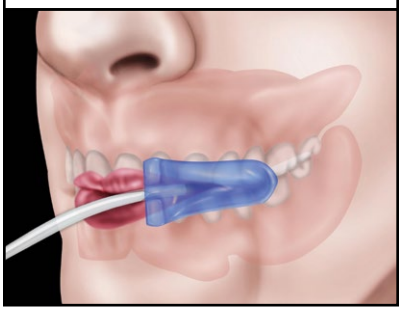


Lip



INITIAL POSITION

Position the Trainer Bulb under the orbicularis oris (just inside the corner of the patient's lips, lateral to the central incisor).



ACTION

The patient squeezes the Trainer Bulb against the teeth.

CAUTION: Always hold on to the safety grip of the Trainer Bulb (or have the patient hold on to it) when it is in the patient's mouth to prevent choking or ingestion.

Follow-Up Appointments

In order to supervise patient use of the IOPI® Trainer, it is critical to schedule regular follow-up appointments. These appointments provide the healthcare professional with an opportunity to re-evaluate the patient's strength and endurance measurements using an IOPI® Pro, review home compliance in terms of both usage and technique, and adjust the exercise protocol parameters if needed.

There are two options for reviewing patient usage data during follow-up appointments:

The healthcare professional can press and hold the Total button [∑] to observe and record the number of successful repetitions displayed on the screen. This value reflects the total number of successful repetitions since the device memory was last cleared.

IOPI® Report Generator software allows the healthcare professional to generate detailed patient usage reports on a PC. The report includes summary of patient usage, a bar graph for easily assessing patterns of successful versus failed repetitions, and detailed rep and set data including date, time, target value, repetition, maximum pressure, target duration, and success/failure status.

The follow-up appointments are also an opportunity to re-motivate patients by allowing them to see the change in or maintenance of their strength and endurance over time. The IOPI® Patient Progress Datasheets, which are available for purchase from IOPI® Medical, provide an easy way to track the P_{max} and endurance measurements as well as to document the protocol adjustments at each appointment.

"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. For memory clearing instructions, see Set Up section 2b on page 16.

Data Output

Event data are stored in one file on the IOPI® Trainer. Stored event data can be downloaded from the Trainer using the IOPI® Report Generator software, which is included in IOPI® Pro Deluxe Kits or can be purchased separately. Use the cable provided with the Report Generator software to connect the Trainer to the computer on which the software is installed. Plug the mini-USB end of the cable into the Trainer 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. For a meaningful report, the bulb position must remain the same until the memory is cleared.

To clear the device memory of all data for a new patient or to start a new file for the current patient, follow the instructions as described in the Set Up section 2b on page 16.

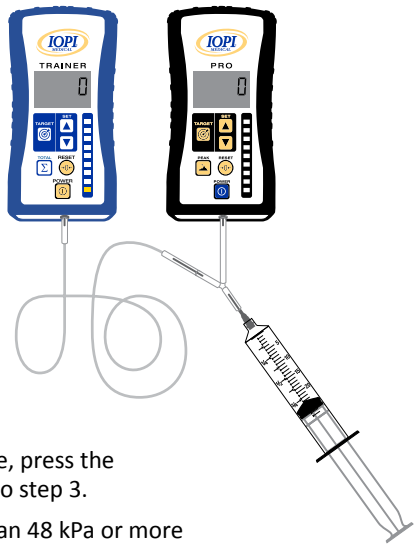
Maintenance

Accuracy Check

Perform the following accuracy check monthly. This procedure can be performed by the healthcare professional. It is a check only (not a calibration procedure) and requires an IOPI® Pro device. If you would like IOPI® Medical to check the calibration rigorously¸ contact IOPI® Medical or your local distributor for instructions.

NOTE: Practice this process a few times until the timing is smooth before you record your readings.

1. Set up the IOPI® Pro:
   a. Turn on the IOPI® Pro and press the Peak button [⛰].
   b. Connect the longer Y-Connector tubing to the Pressure In port [⇐].
2. Set up the IOPI® Trainer:
   a. Enter Program Mode on the IOPI® Trainer by holding down the Target button [◎] and then pressing the Power button [⏻]. The Program symbol [PROG] should be shown on the display.
   b. Use the Set Target arrows buttons [▲▼] to adjust the target value to 50 kPa.
   c. Exit Program Mode by turning the device off.
   d. Attach the Connecting Tube to the Pressure In port [⇐].
   e. Connect the shorter Y-Connector tubing to the metal end of the Connecting Tube.
   f. Turn the IOPI® Trainer back on by pressing the Power button [⏻].
3. Draw air into the syringe by setting the syringe plunger to approximately the 25 mL mark.
4. Leave the plunger in this position and connect the syringe tubing to the unoccupied barb on the Y-Connector.
5. Observe the biofeedback light array on the Trainer as you slowly compress the plunger of the accuracy check syringe. Immediately release the plunger when the top green light illuminates.



NOTE: In order to gather accurate results it is necessary to use slow, even pressure when compressing the plunger.

6. Observe the pressure value on the IOPI® Pro. It should read between 48-52 kPa.
7. To repeat this process, disconnect the syringe, press the Reset button [→0←] on both devices, and go to step 3.
8. If your pressure reading is repeatedly less than 48 kPa or more than 52 kPa, contact IOPI® Medical or your local distributor.

Replacing the 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 illuminate when the Power button [⏻] has been pressed.
2. To replace the batteries, remove the blue silicone cover and press and slide the battery cover on the back of the IOPI® Trainer 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® 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 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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3 Yeates, E.M., Molfenter, S.M., & Steele, C.M. (2008). Improvements in tongue strength and pressure-generation precision following a tongue-pressure training protocol in older individuals with dysphagia: Three case reports. *Clinical Interventions in Aging,* 3(4), 735-747.

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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 LED 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.	*Instruct the patient to fully release pressure on the bulb in between repetitions..*
Biofeedback response that seems unexpectedly high or low based on experience with an IOPI® Trainer and the patient.	A change in accuracy.	*Perform an Accuracy Check (see page 21). If the pressure reading is not within specifications, contact IOPI® Medical LLC or your local distributor as soon as possible.*
The IOPI® device will not turn on. *(Make sure you have tried holding down the Power button for a full second.)*	Battery is dead.	*Follow the Replacing the Batteries procedure in the Maintenance section as described on page 22. 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 in Set Up section 2b on page 16.* *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 in Set Up section 2b on page 16 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® 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 or 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	
EC REP	**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

Notes

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