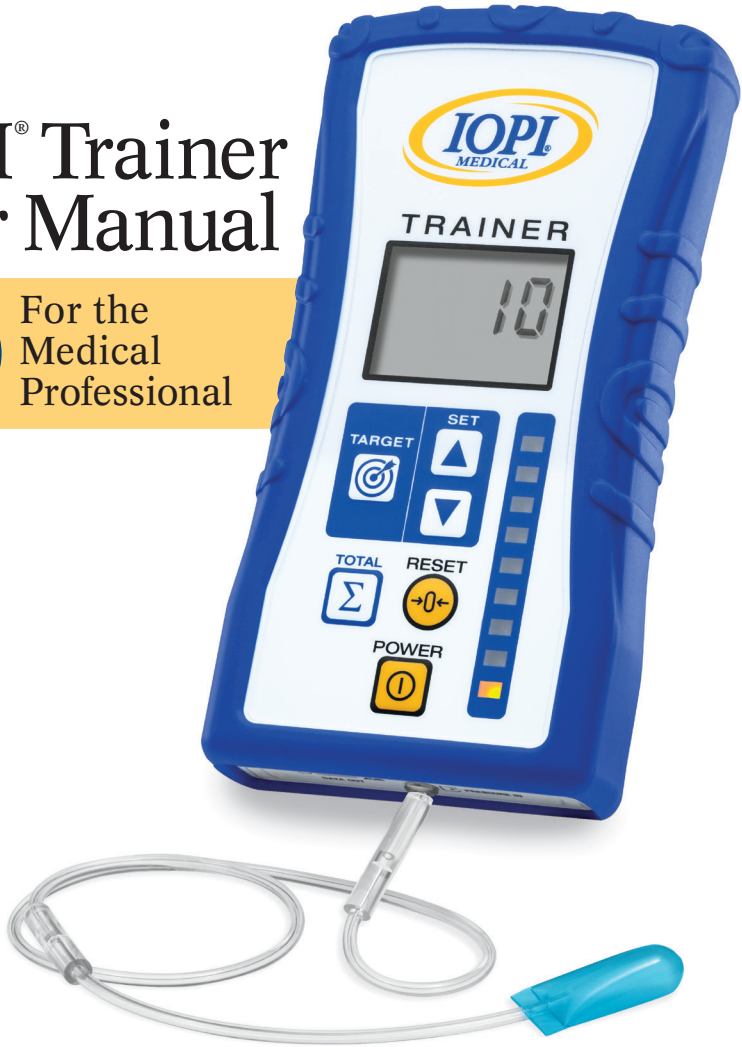
Iowa Oral Performance Instrument

MODEL 3.2

IOPI® Trainer User Manual

For the Medical Professional



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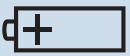
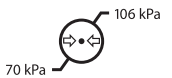
IOPI® Icons

Symbol	Identity
	Catalogue Number
	Serial Number
	Manufacturing Date
	Consult Instructions Before Use
	Caution
	Type BF patient applied part according to IEC 60601-1
IP22	Degree of Ingress Protection
 2 AA alkaline	2 AA Alkaline Batteries
	Nemko N-mark
	Do Not Dispose of in Household Refuse
	Manufactured By

Shipping Icons

Symbol	Identity
	Fragile
	Protect from rain
	This side up
	Storage and Transport Temperature
	Storage and Transport Atmospheric Pressure
	Storage and Transport Humidity

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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 and dysarthria.

The IOPI® Trainer is intended for clinical or home use by patients under the direction of a medical 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** put the Trainer Bulb in a patient's mouth if there is a risk of the patient having a seizure.
- **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," "Myofacial Pain Disorder").

⚠ WARNINGS

- The medical professional should ensure the patient is healthy enough to perform a maximal motor task, recognizing that it may produce a generalized effort response.
- The medical professional or the patient should **hold on to the Trainer Bulb safety grip** (see page 14) any time that it is in a patient's mouth to prevent aspiration or ingestion.
- The Trainer Bulbs, as supplied by IOPI® Medical LLC, are **not sterile and are not intended for sterilization**.
- The Trainer Bulbs, as supplied by IOPI® Medical LLC, are intended for **single patient use only** to prevent cross-contamination between patients.
- Keep the device and device accessories out of the reach of children.
- Only use IOPI® Medical LLC approved accessories, software, and service items with the IOPI® Trainer Kit.

NOTE: The medical 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.

CAUTION: This device is sold directly to patients only on the order of a medical professional who will be directing the use of the device.

Safety & Care Instructions

Safety Precautions

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

- This device is only intended for use with oral motor structures.
- This device is sold to medical professionals who are assisting patients with oral motor problems, including dysphagia and dysarthria, or to the patient on the order of the supervising medical professional. The medical 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.
- To avoid user errors, carefully read this manual before using the IOPI® Trainer.
- Prior to using IOPI® accessories (such as the IOPI® Trainer Bulb) with the IOPI® Trainer, carefully read the Directions for Use for the accessory.

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 Directions for Use.
- For clinic use: Clean the exterior of the IOPI® Trainer and the silicone cover before and after use with a patient by wiping it with a soft, slightly moistened germicidal cloth intended for disinfecting medical equipment. 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 accessories in accordance 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 18) 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 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.

IOPI® Medical LLC

APPROVED ACCESSORIES:

5-6105 Box of 5 Trainer Bulbs

5-0005 Mini-USB to USB Cable

APPROVED SOFTWARE:

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**	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**	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 14.

Introduction

The IOPI® Trainer

The IOPI® Trainer is a device that must be used in parallel with the IOPI® Pro (Model 3.1) or a Series 2 IOPI® (Models 2.1, 2.2, or 2.3). As described in the biofeedback section (page 12), 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 medical 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 [∑] on the IOPI® Trainer allows the medical professional to easily view the total number of successful repetitions without having to connect the device to a computer. The medical 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 medical 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 medical professional to download patient usage data from the IOPI® Trainer and then automatically generates a detailed patient report. This information may assist the medical 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 14.

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 medical 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 13). 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 13) 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 20).[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 medical 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.

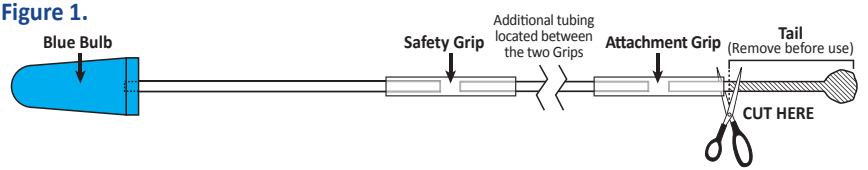
   a. **Adjust the Target Value:** Press the Set Target arrow buttons [▲▼] until the screen shows the desired pressure value.

> **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.

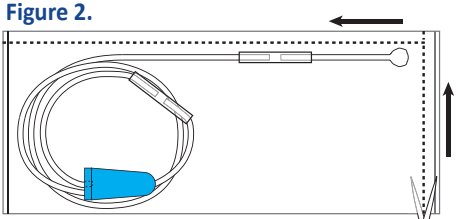
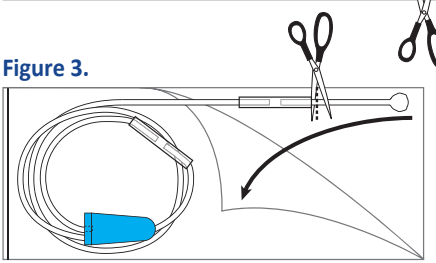


Figure 3.



6. Connect the Trainer Bulb to the Pressure In port [⇦] on the bottom of the IOPI® Trainer (see Page 8) 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 16-17.

Home Use

The IOPI® Trainer Kit comes with a set of IOPI® Patient Instruction forms designed to be completed by the medical professional and provided to the patient to clarify their home therapy protocol. Additional forms are available for purchase from IOPI® Medical or PDF versions are available for download at ***www.IOPImedical.com***.

Before the patient uses the IOPI® Trainer without supervision, the medical 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 Directions 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.

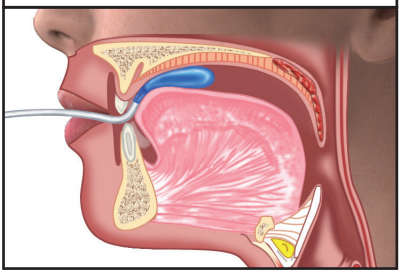
NOTE: IOPI® Medical cannot provide therapeutic instructions to the patient.

Trainer Bulb Positions for Exercise

Tongue - Anterior

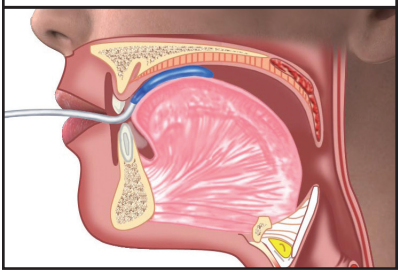
INITIAL POSITION

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

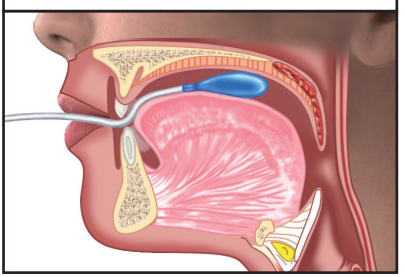
The patient lifts the anterior tongue to compress the Trainer Bulb against the hard palate. The mandible should be intrinsically stabilized during the task (i.e. the jaw should not be opening and closing, but rather remain quietly stable).



Tongue - Posterior

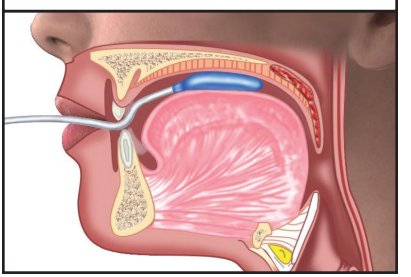
INITIAL POSITION

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

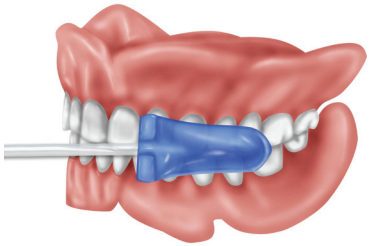


ACTION

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).

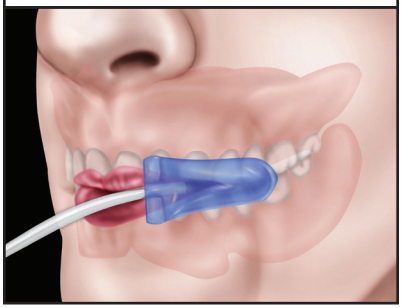


Lip



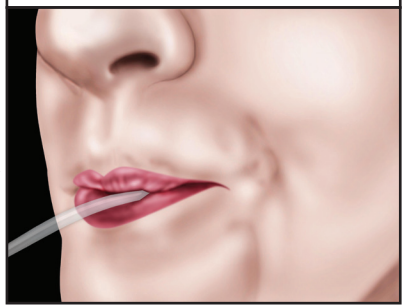
INITIAL POSITION

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.



WARNING: The medical professional or patient should always hold on to the safety grip of the Trainer Bulb when it is in the patient's mouth.

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 medical professional with an opportunity to re-evaluate the patient's strength and endurance measurements using an IOPI® Pro or IOPI® Series 2 device, 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 medical 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 medical professional to generate detailed patient usage reports on a PC. The report includes a 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 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 14.

Data Output

Event data are stored in one file on the IOPI Trainer. The stored event data can be downloaded using the IOPI® Report Generator software. 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 14.

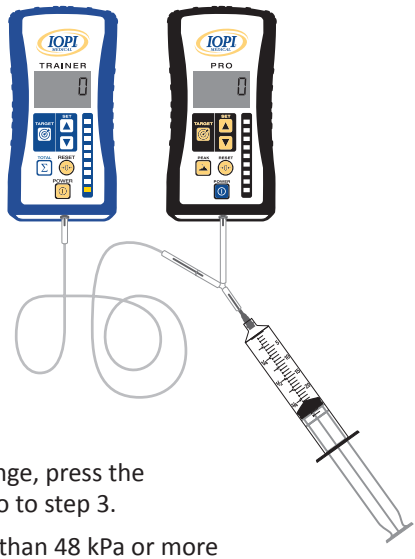
Maintenance

Accuracy Check

Perform the following accuracy check monthly. This procedure can be performed by the medical professional. It is a check only and requires an IOPI® Pro device (or IOPI® 2.1, 2.2 or 2.3). 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 (or IOPI® 2.1, 2.2 or 2.3):
   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. Set the syringe plunger to approximately the 25 cc 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 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.

NOTE: Contact your local waste disposal authority for instructions on how to dispose of used alkaline batteries. Do not dispose of batteries in clinic trash.

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.*
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 19). 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 20. 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 14.* *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 14 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 and dysarthria. The IOPI® Trainer is intended for clinical or home use by patients under the direction of a medical professional.	
APPLIED STANDARDS		
IEC 60601-1:2005 (Third Edition) + CORR. 1:2006 + CORR. 2:2007 + A1:2012		IEC 60601-1-11:2015 IEC/EN 62304:2006
IEC 60601-1-2:2014 + EN 60601-1-2:2015		EN ISO 10993-1:2009
IEC 60601-1-6:2010 (Third Edition) + A1:2013		ISO 14971:2012
IEC 62366:2007 (First Edition) + A1:2014		BS EN ISO 15223-1:2016
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	
Device Classification	**FDA/US**	**TGA/Australia**
	I	I
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 FAX: +1 (425) 558-4596	
AUSTRALIAN SPONSOR		
	EMERGO AUSTRALIA Level 20 Tower II, Darling Park, 201 Sussex Street Sydney, NSW 2000 Australia	

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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