

Instructions for Use

IOPI® Accuracy Check Kit

REF 5-0102

The IOPI® Accuracy Check Kit is an approved SERVICE ITEM for use with the IOPI® System only.

INCLUDES: One Accuracy Check Syringe and one Y-Connector.

INTENDED USE

The IOPI® Accuracy Check Kit is a service item used to check if the displayed values on an IOPI® Pro (Model 3.1) and/or an IOPI® Trainer (Model 3.2) are accurate to within +/-5%.

PRECAUTIONS

- CAUTION: Keep the Accuracy Check Syringe and Y-Connector out of the reach of children. These contain small parts that present a swallowing or gagging hazard for young children.
- CAUTION: Perform this basic field verification monthly using the air-filled syringe test to check if readings fall within the expected range. This simplified check helps identify potential issues but does not calibrate the device. For precise calibration testing using laboratory equipment, please contact IOPI Medical or your local distributor.

SAFETY & CARE INSTRUCTIONS

CARE INSTRUCTIONS:

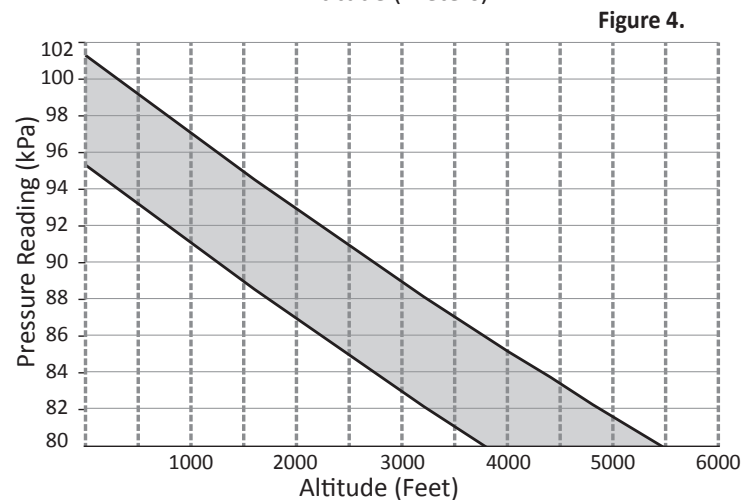
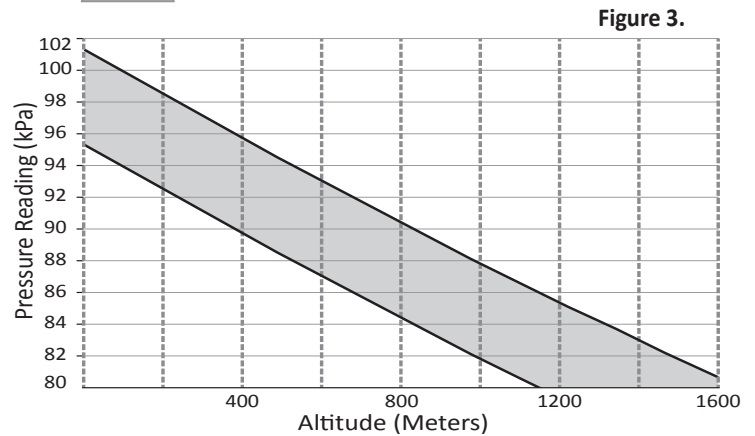
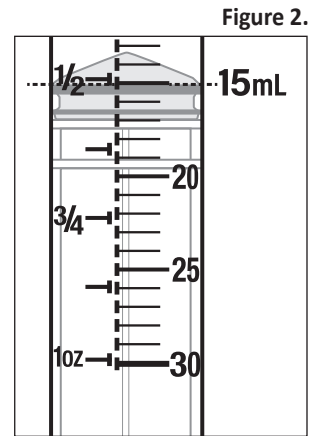
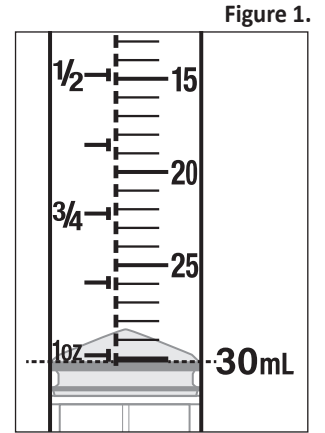
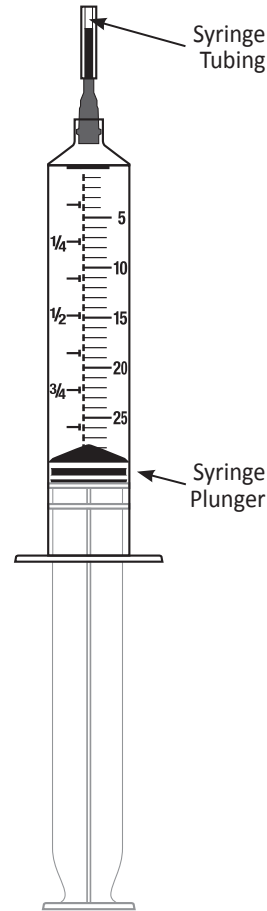
- **Cleaning procedure**
The outside surfaces of the Accuracy Check Syringe and Y-Connector may be cleaned with a moist germicidal cloth.
- **Storage**
Store in a clean, sealed container out of the reach of children.
- **Disposal**
Dispose of out of the reach of children.

IOPI® PRO: ACCURACY CHECK PROCEDURE

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

1. Connect a Connecting Tube to the Pressure In port [] on the IOPI® Pro.
2. Turn on the IOPI® Pro and press the Peak button [].
3. Set the front edge of the plunger of the syringe on the back edge of the 30 mL mark (see **Figure 1**).
4. Leave the plunger in this position and connect the syringe tubing to the metal end of the Connecting Tube.
5. Over a period of about 5 seconds, depress the plunger so that the front edge of it lines up with the back edge of the 15 mL mark (see **Figure 2**).
6. Note the peak pressure reading on the IOPI® Pro display.
7. Disconnect the syringe tubing from the Connecting Tube and push the Reset button [→←].
8. Repeat Steps 3-7 several times. Discard readings where you know you pushed the plunger past the ideal position, or if the depression time was too slow or too fast. If there is variability in the readings, this is due to variability in your method. Repeat until your reading stabilizes (±1 kPa).
9. Using the altitude at your location, compare your pressure reading to **Figure 3** (for altitude in meters) or **Figure 4** (for altitude in feet).

10. If your pressure reading does not fall within the shaded region of **Figure 3** or **4**, contact IOPI® Medical or your local distributor.

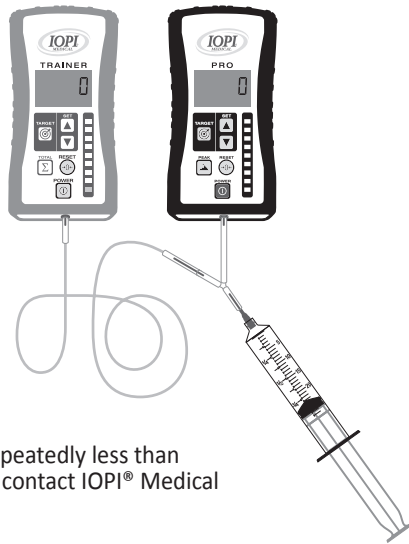


IOPI® TRAINER: ACCURACY CHECK PROCEDURE

Practice this process a few times until the timing is smooth before you record your readings. In order to obtain accurate results, it is necessary to use slow, even pressure when compressing the plunger.

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. Set 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.
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 4.
8. If your pressure reading is repeatedly less than 48 kPa or more than 52 kPa, contact IOPI® Medical or your local distributor.

Figure 5.



REORDER INFORMATION

Reorder PN 5-0102

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
	Lot Number	Indicates the manufacturer's lot number so that the lot can be identified	ISO 15223-1, Clause 5.1.5
	Manufacturer	Indicates the medical device manufacturer	ISO 15223-1, Clause 5.1.1
	Keep Away From Sunlight	Indicates a medical device that needs protection from light sources	ISO 15223-1, Clause 5.1.2
	Refer to Instruction Manual	Indicates that the instruction manual must be read	ISO 7010-M002

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

Technical Specifications

INDICATIONS FOR USE:	The IOPI® Accuracy Check Kit is a service item used to check if the displayed values on an IOPI® Pro (Model 3.1) and/or an IOPI® Trainer (Model 3.2) are accurate.
SYRINGE DIMENSIONS (approximate):	
Height x Width x Length	16.8 cm x 4.3 cm x 2.9 cm
Weight	20.0 g
Y-CONNECTOR DIMENSIONS (approximate):	
Height x Width x Length	5.9 cm x 3.0 cm x 0.5 cm
Weight	1.3 g
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:	
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