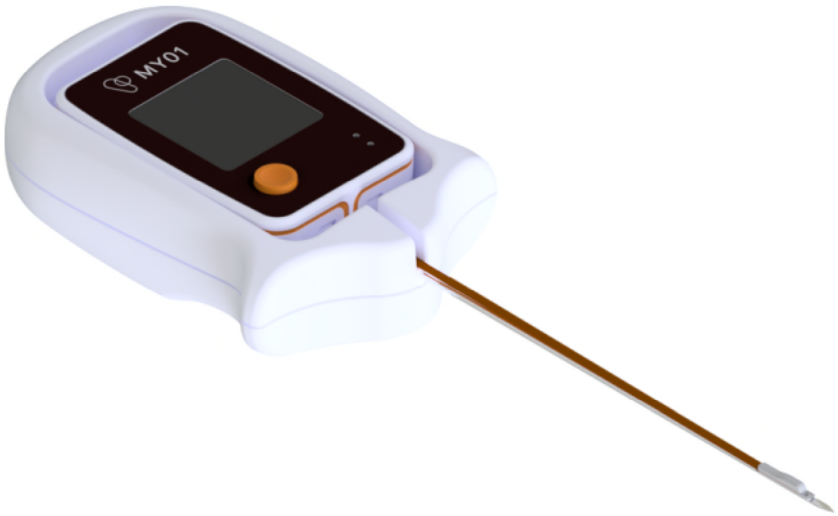
MY01

REF: MY01-000M

Version 6

USER MANUAL



Continuous Compartmental Pressure Monitor

MY01 Inc.
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EC REP
CEpartner4U BV
Esdoormlaan 13
3951 DB Maarn
The Netherlands

℞ ONLY

TABLE OF CONTENTS

Symbol Explanation

Caution	
Read instructions for use before operating the device	
Caution : Federal law (USA) restricts this device to sale by or on the order of a physician	℞ ONLY
Sterilized using ethylene oxide	STERILE EO
Type BF applied part	
Do not resterilize	
Do not use if package is damaged	
Single patient-use device	
Manufacturer	
Maximum and minimum temperature limits	
Maximum and minimum relative humidity limits	
Maximum and minimum pressure limits	
Keep away from sunlight	
Use-by date	
Batch code	LOT
Catalogue number	REF
Authorized representative in the European Community	EC REP
Ingress Protection (IP Rating)	IP53
Signifies European technical conformity	CE 0459

DEVICE INTERFACE SYMBOLS

Full battery	
Warning: low battery level	
Trend arrows	

Introduction

WARNINGS AND NOTES

Please read this manual and follow its instructions. The words WARNING and NOTE carry special meanings and should be reviewed carefully.

⚠ WARNING: The personal safety of the patient may be involved. Disregarding this information could result in injury to the patient.

NOTE: This provides additional important information the user should be aware of.

INTENDED USE

The MY01 Continuous Compartmental Pressure Monitor is intended for real-time and continuous measurement of compartmental pressures. The measured compartmental pressures can be used as an aid in the diagnosis of compartment syndrome.

COMPONENTS

Packaging and Device

Figure 1 : MY01 Device Dispenser

Figure 2 : Packaged MY01 Device

The MY01 Continuous Compartmental Pressure Monitor comprises the following 2 major components: the Introducer and the Pressure Monitor.

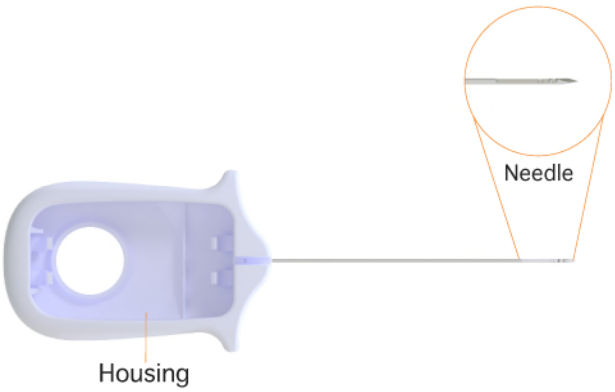


Figure 3 : Introducer

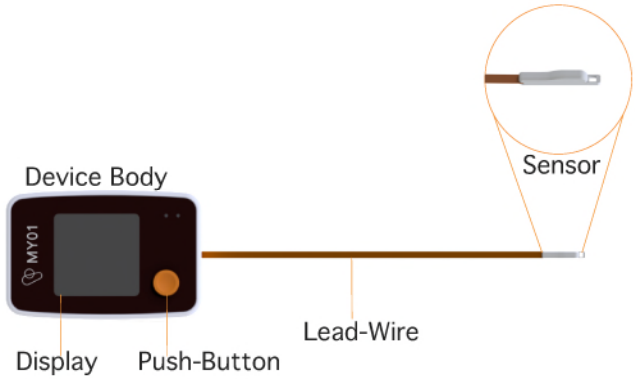


Figure 4 : Pressure Monitor (Applied Part)

User & Patient Safety Precautions

⚠ WARNING

- The device should only be used in a healthcare facility environment by medical professionals who have received the appropriate training.
- Do not perform a diagnosis solely based on pressure measurements of the device. Always use the device with the current standard of care.
- Use aseptic practices during usage - follow healthcare facility guidelines.
- Do not ship, store or use the device outside the specified environmental conditions (See Table 3).
- Single-use device, do not reuse. Patient safety may be compromised.
- Do not use the device past the expiration date.
- Do not resterilize the device. It is initially ETO sterilized and cannot be reprocessed.
- Do not clean the device.
- Do not perform any maintenance on the device.
- Do not use the same device in multiple patients.
- Do not use the device in proximity to MRI equipment and high frequency surgical equipment.
- Do not use the device if it is believed to be faulty. The user should exercise clinical judgment when performing measurements.
- Do not dispose of dispenser packaging until all devices are used.

No known contraindications

Device Interface

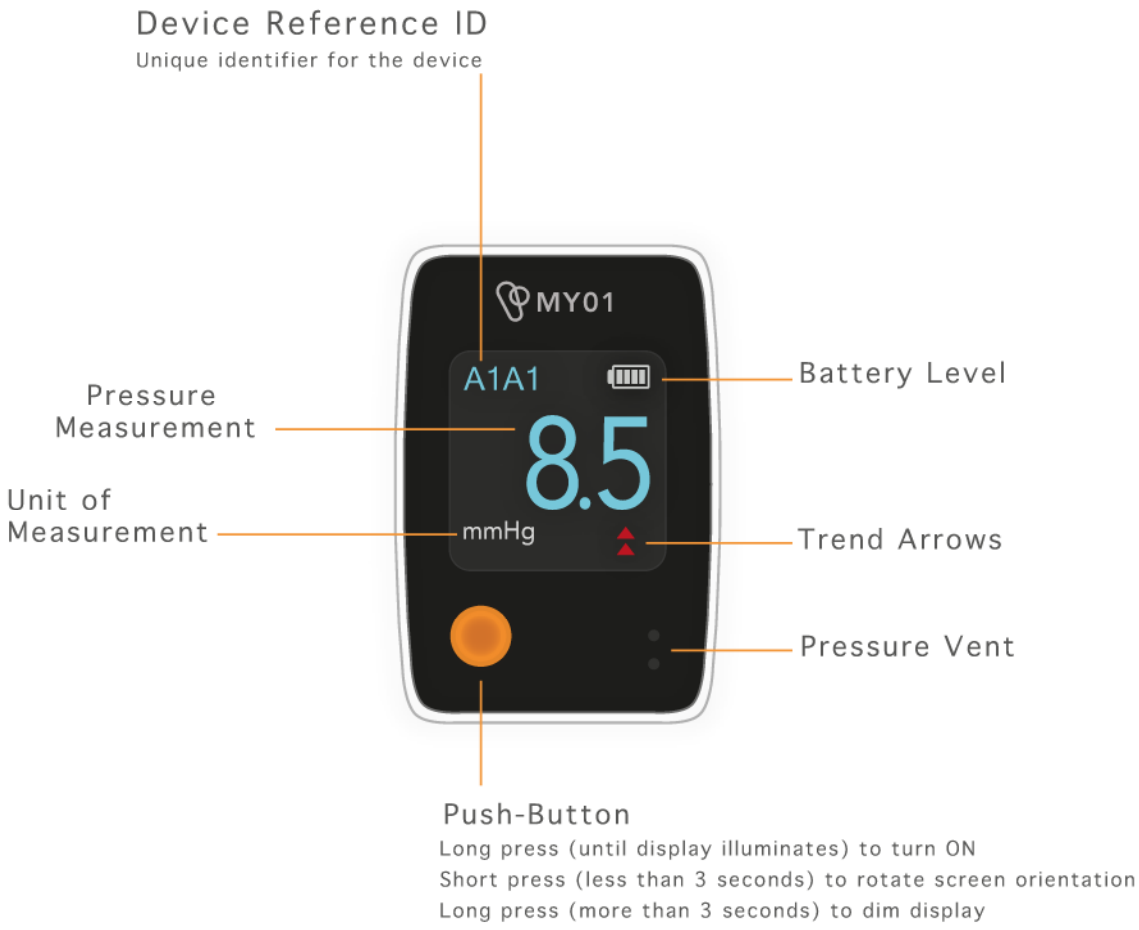


Figure 5 : Device Controls and Display Icons

Significance of Trend Arrows

- The decrease in pressure is greater than or equal to 0.5 mmHg/hour.
- The decrease in pressure is greater than or equal to 2 mmHg/hour.
- The increase in pressure is greater than or equal to 0.5 mmHg/hour.
- The increase in pressure is greater than or equal to 2 mmHg/hour.

⚠ WARNING

- Do not use trend arrows for diagnostic purposes. Always use pressure measurements and clinical judgment along with the current standard of care.

Figure 6 : Rotating Display Orientation

Operational Instructions

Step 1 : Peel the Tyvek lid where indicated. Lift the top cover and remove the device from the packaging.

⚠ WARNING

- Do not use the device if the Sensor is found unhooked from the Needle after opening the package. Never attempt to re-assemble the device.
- Do not use the device if the integrity of the packaging is compromised.

Step 2 : Activate the Pressure Monitor by pressing and holding the Push-Button until the MY01 logo appears. The Display will subsequently show the MY01 logo and a pressure value of 0.

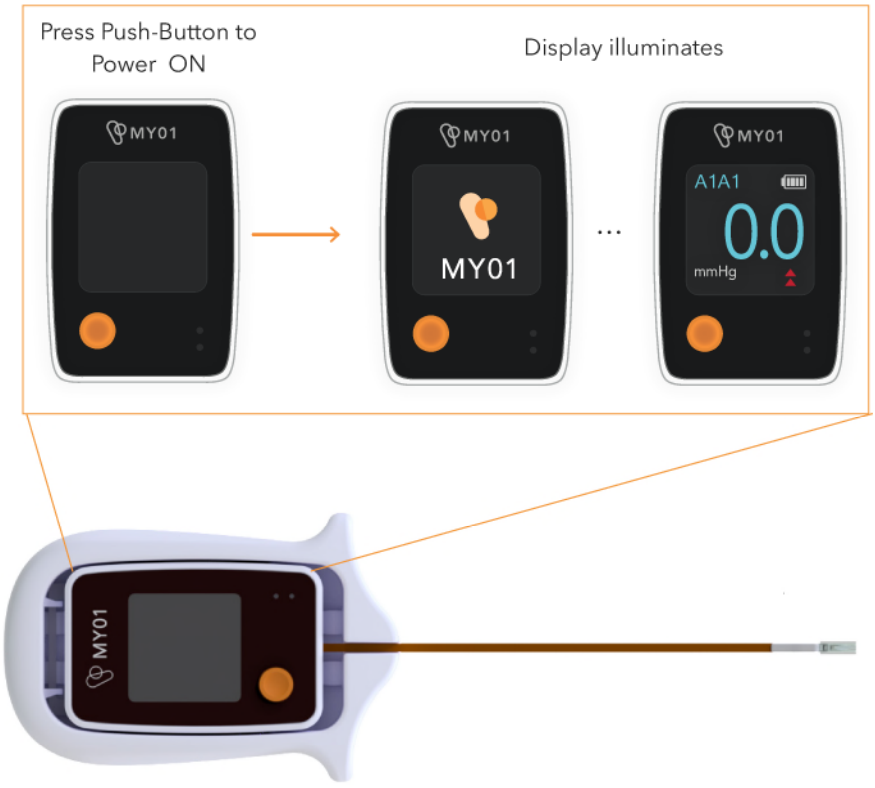
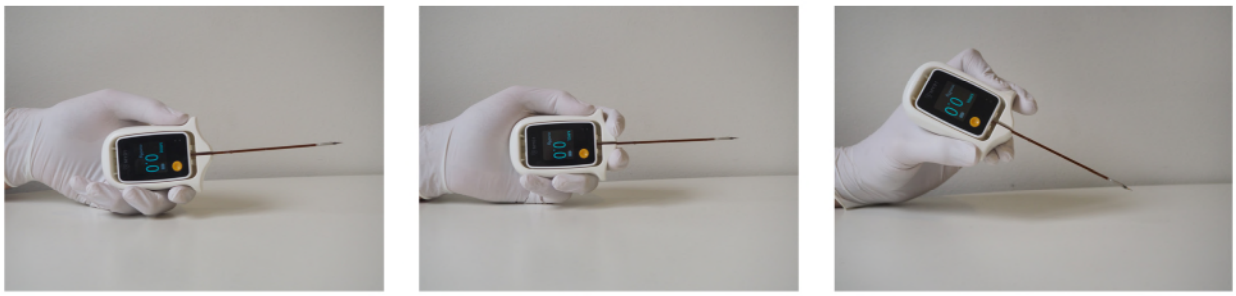


Figure 7 : Turning ON the Pressure Monitor

⚠ WARNING

- Always turn ON device BEFORE introducing into patient.
- Do not use the device if pressure measurements are not within 0- 9 mmHg prior to insertion.



A B C

Figure 8 : Recommended Device Grips

Step 3 : While holding the Introducer (see Figure 8), ensure that the information on the Display is visible. Remove Needle Cap. Without applying excessive force on the Display, insert the Needle gently into the muscle compartment in a controlled linear motion. Markings on the Needle should be used to estimate the depth of the insertion.

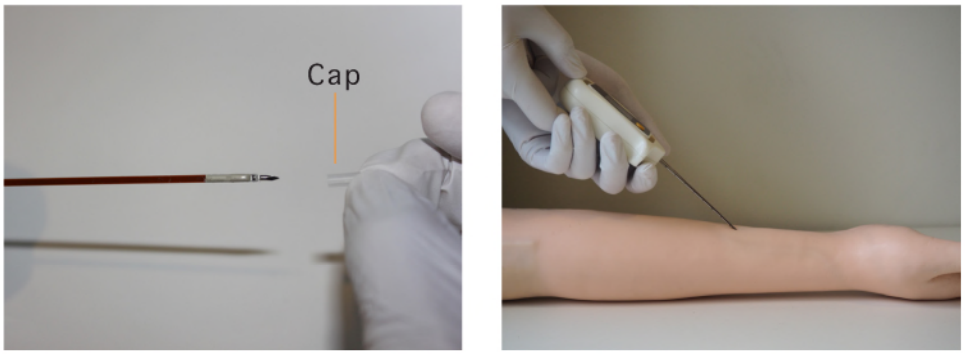


Figure 9: Introducing the Device

NOTE

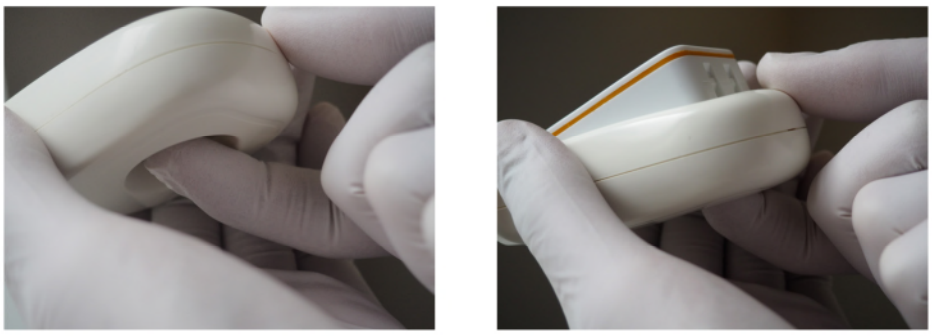
- The Display can be rotated to the desired orientation to ensure visibility during the insertion (see Figure 6).
- Single marks are spaced along the needle at 1 cm intervals with the first located 2 cm from the Needle tip. Double marks are placed at 5 cm intervals as measured from the Needle tip.
- Consider applying local anesthetic before insertion. Ensure there are no allergies to anesthetic use.

- The Introducer can be retracted and re-inserted to perform additional single-point measurements without ejecting the Pressure Monitor.

⚠ WARNING

- Always keep the Pressure Vent on the bottom-right of the screen unobstructed (see Figure 5).
- Do not use the device if the Sensor unhooks unexpectedly during the insertion (up to 5 single-point insertions). Never attempt to re-assemble the device.
- Do not rotate the Introducer during insertion to prevent premature Sensor unhooking.

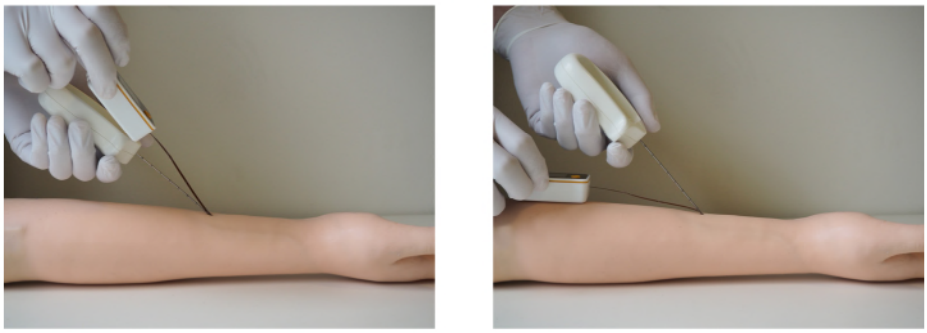
Step 4 : When the Sensor is in the desired position and readings have stabilized, eject the Pressure Monitor from the Introducer by pressing gently through the back opening of the Introducer. An adhesive strip will be exposed on the back of the Device Body when ejected.



A B

Figure 10 : Ejecting the Pressure Monitor

Step 5 : While holding the Introducer in one hand, use the other hand to adhere the Device Body to the patient's skin using the exposed adhesive strip on the back of the Device Body. Position the Device Body face-up on the patient's skin near the insertion point, ensuring sufficient slack in the Lead-Wire. The Lead-Wire should extend straight out from the insertion site indicating the insertion angle of the Sensor.



A B

Figure 11 : Placing the Device Body on Patient Skin

NOTE

- Care should be taken when moving the Device Body to not pull the Lead-Wire which can displace the Sensor within the muscle compartment.
- The Device Body should be installed in a location which won't interfere with adhesion during the monitoring period.
- It is recommended to prepare the skin appropriately to improve adhesion, especially on hairy or oily skin.

⚠ WARNING

- Do not re-apply the adhesive. Additional medical tape should be used if the location of the Device Body is changed after the first application. Ensure that the Pressure Vent (see Figure 5) is not covered by the medical tape.

Step 6 : Disengage the Sensor by rotating the Introducer by 180 degrees. Slowly remove the Introducer from the patient and dispose of it in a biohazard-sharps receptacle, as per facility guidelines.

NOTE

- It is recommended to apply a dressing to the insertion site to fix the Lead-Wire in place.

⚠ WARNING

- Sharps biohazard - dispose as per facility guidelines and/or local regulations.

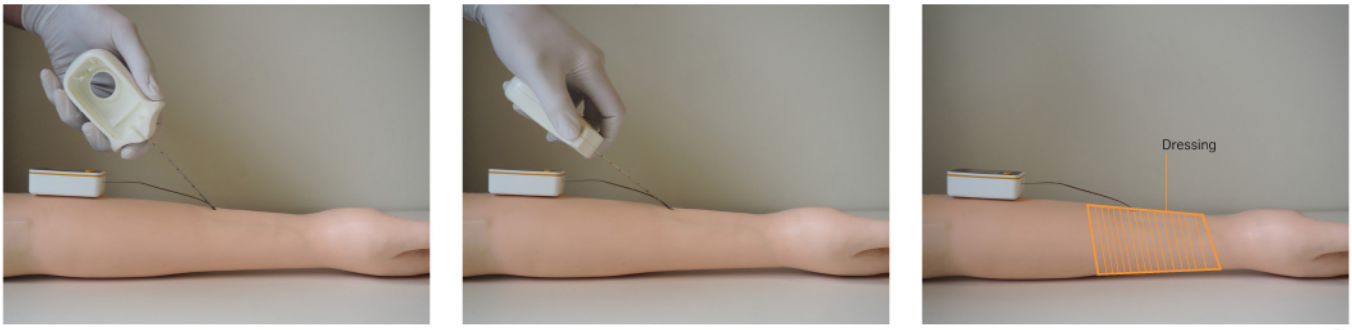


Figure 12 : Removing the Introducer

Step 7 : Monitor pressure readings for a period of up to 24 hours. The Pressure Monitor should be routinely checked to ensure that it is secured to the patient throughout the monitoring period and that the Lead-Wire does not pull on the Sensor and displace it.

⚠ WARNING

- Do not leave the Sensor inside the patient for a period longer than 24 hours.

Step 8 : When monitoring is complete, remove the dressing and gently pull on the Lead-Wire by hand to remove the Sensor from the patient. Dispose the Pressure Monitor in a biohazard container, as per facility guidelines.

NOTE

- The Lead-Wire should be pulled out at the same angle used for insertion of the Sensor to minimize removal forces.

⚠ WARNING

- The device is for single patient-use only. Do not attempt to reassemble the device or replace the batteries after use.
- Always remove the Pressure Monitor from the patient before performing a corrective procedure (e.g. fasciotomy, amputation, debridement, skin graft).

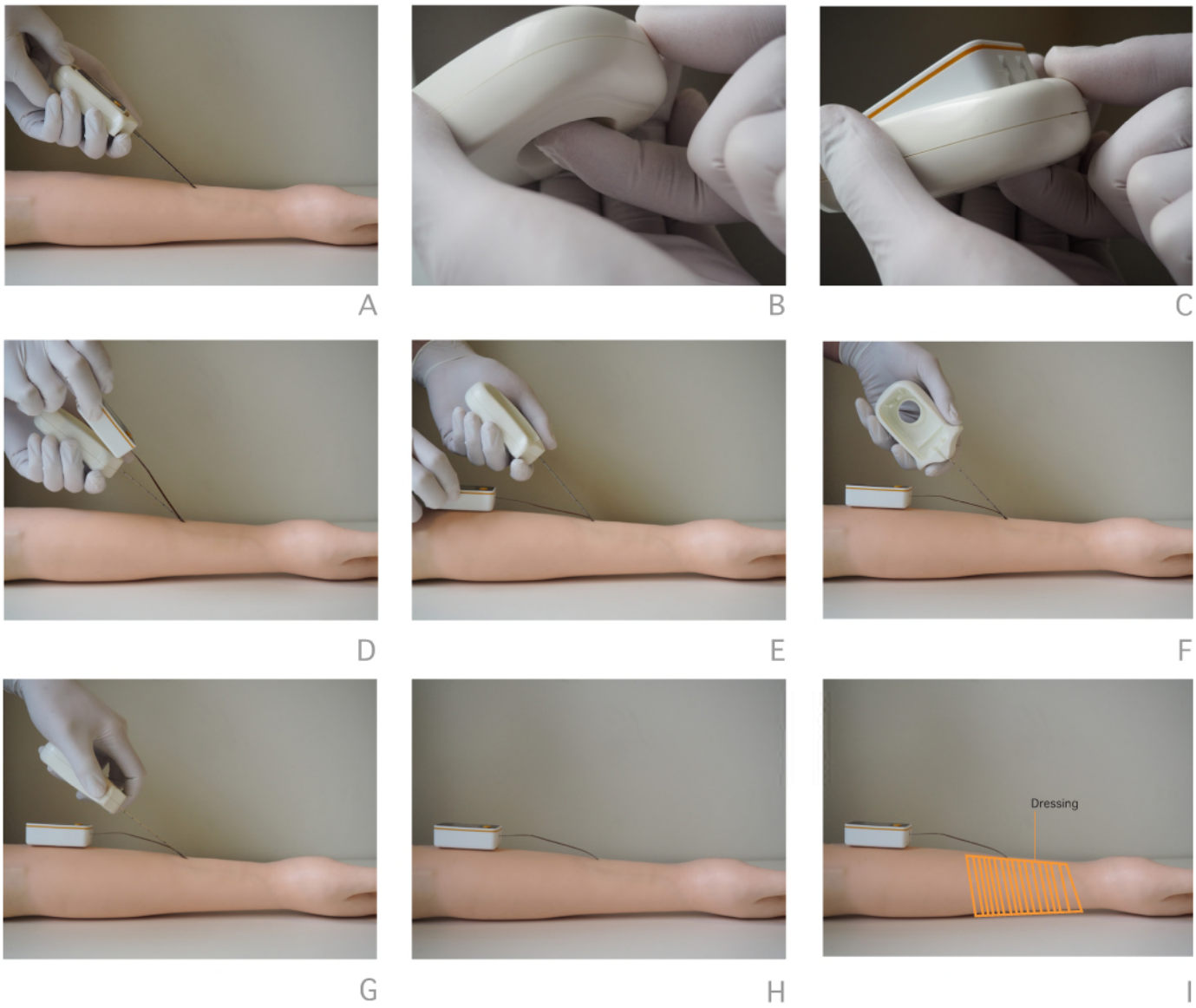


Figure 13 : Insertion Procedure Summary

Troubleshooting

DEVICE INTERFACE ERROR CODES

Table 1 : Error Code List

ERROR CODE	ERROR NAME	DESCRIPTION	CORRECTIVE ACTION
		NON-CRITICAL ERRORS	
1	BLE Security Error	A non-authorized or non-compatible mobile phone is trying to pair with the device	N/A *
2	Other BLE Error	Bluetooth communication problem	N/A *
3	Lifetime Exceeded	Device has been running for longer than intended operating time	Device operation is not recommended beyond this time, if device is currently being used cease operations immediately
		CRITICAL ERRORS	
ERR 10	Sensor Integrity Compromised	System has detected a critical malfunction in the sensing element	DO NOT use the device. Call customer support for instruction on how to discard the device
ERR 11	Software Error	Software malfunction	DO NOT use the device. Call customer support for instruction on how to discard the device

* Future feature to be implemented at a later date

Figure 14 : Error Code Display

INSTRUMENT DEFECTS OR PRODUCT DEFICIENCIES

- For defective device concerns, or any related quality issues, please contact help@MY01.io or call +1 (855) 292-6901.
- A MY01 representative will deal with any quality issues related to hardware or software functionality in a timely manner.

Specifications

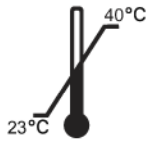
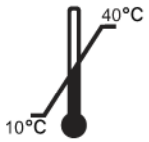
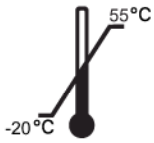
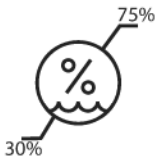
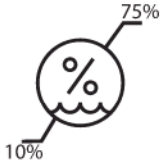
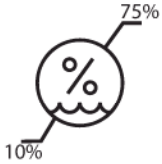
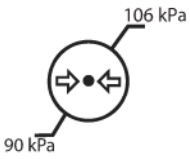
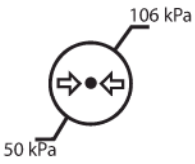
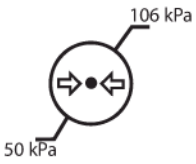
DEVICE

Table 2: Device Specifications

Model	MY01-0001
Pressure range	0 - 99.9 mmHg
Power	Two (2) 3 V batteries (non replaceable)
Display resolution	0.1 mmHg
Battery life	24 hours
IP Rating	IP53
Weight	85 g (+/- 5g)
Dimensions	20 cm x 6.5 cm x 3 cm (+/- 1cm)
Needle gauge	17-gauge

ENVIRONMENTAL CONDITIONS

Table 3: Environmental Conditions

	Operation	Storage	Transportation
Temperature			
Humidity			
Pressure			

ELECTROMAGNETIC COMPATIBILITY

⚠ WARNING:

- Use of MY01 device adjacent to or stacked with other electrical equipment should be avoided as it could result in improper operation. If such use is necessary, the MY01 device and other electrical equipment should be observed to verify that they are operating normally.
- Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the MY01 device, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

Note

- MY01 has no cables or accessories. Do not attempt to add any cables or accessories to the device.
- MY01 can communicate over a frequency band of 2.402MHz-2.4835MHz with GFSK modulation and effective radiated power of 1mWatts]

Table 4: Electromagnetic Emissions Group and Classification

Attribute	Compliance/ Class Group
RF Emissions Group per CISPR 11	Group 1
RF Emissions Class per CISPR 11	Class B (although the device is not for residential environment use)

Table 5: Electromagnetic Immunity Levels

Attribute	Compliance/ Class Group
Electrostatic Discharge (ESD)	± 8 kV contact ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV air Per IEC 61000-4-2
Radiated RF EM fields	3 V/m 80 MHz - 2.7 GHz 80 % AM at 1 kHz Per IEC 61000-4-3
Proximity fields from RF wireless communications equipment	As indicated in IEC 60601-1-2
Immunity to Rated Power frequency magnetic field	30A/m at 60Hz, 50Hz Per IEC/EN 61000-4-8

Date of release : 15 Dec 2019
REF # : MYO-00119-M

Electrical Safety Compliance Statement

The MY01 compartmental pressure monitor complies to IEC 60601-1 and IEC 60601-1-2

FCC Compliance Statement

This device complies with FCC Subpart 15C rules 15.247. Operation is subject to the following two conditions: (1) this device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation. Changes or modifications to this product not authorized by MY01 Inc. could void the electromagnetic compatibility and negate your authority to operate the product.

Canadian Regulatory Statement / Déclaration réglementaire Canadienne

This device complies with Industry Canada licence-exempt RSS standard(s). Operation is subject to the following two conditions: (1) this device may not cause interference, and (2) this device must accept any interference, including interference that may cause undesired operation of the device.

Le présent appareil est conforme aux CNR d'Industrie Canada applicables aux appareils radio exempts de licence. L'exploitation est autorisée aux deux conditions suivantes: (1) l'appareil ne doit pas produire de brouillage, et (2) l'utilisateur de l'appareil doit accepter tout brouillage radioélectrique subi, même si le brouillage est susceptible d'en compromettre le fonctionnement.