MY01®

REF: MYO-00119-M Ver. 20
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USER MANUAL

Continuous Compartmental Pressure Monitor

This device is protected by patents and has additional patents pending.

Device Name: MY01 Continuous Compartmental Pressure Monitor

Model number: MY01-0001

℞ ONLY

CE
2862

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Glossary of Labeling Symbols

DEVICE LABELING SYMBOLS

Symbol	Title and Description	Reference
	Caution	ISO 15223-1 (5.4.4)
	Follow instructions for use	ISO 7010-M002
℞ ONLY	Caution: Federal law (USA) restricts this device to sale by or on the order of a physician	21 CFR 801.109
	Sterilized using ethylene oxide	ISO 15223-1 (5.2.3)
	Type BF applied part	IEC 60417 (5333)
	Do not resterilize	ISO 15223-1 (5.2.6)
	Do not use if package is damaged	ISO 15223-1 (5.2.8)
	Do not re-use. Single use only	ISO 15223-1 (5.4.2)
	Manufacturer	ISO 15223-1 (5.1.1)
	Maximum and minimum temperature limits	ISO 15223-1 (5.3.7)
	Maximum and minimum relative humidity limits	ISO 15223-1 (5.3.8)
	Maximum and minimum pressure limits	ISO 15223-1 (5.3.9)
	Keep away from sunlight	ISO 15223-1 (5.3.2)
	Use-by date	ISO 15223-1 (5.1.4)
LOT	Batch code	ISO 15223-1 (5.1.5)
REF	Catalogue number	ISO 15223-1 (5.1.6)
IPn1n2	Ingress Protection (IP Rating): The first digit indicates the level of protection that the enclosure provides against the ingress of solid foreign objects (Scale: 0-6). The second digit indicates the level of protection of the equipment inside the enclosure against the ingress of liquids (Scale: 0-8).	IEC 60529

	Consult instructions for use	ISO 15223-1 (5.4.3)
	Serial number	ISO 15223-1 (5.1.7)
	Unique device identifier	ISO 15223-1 (5.7.10)
	Medical device	ISO 15223-1 (5.7.7)
	Model Number	ISO 15223-1 (5.1.10)
	Signifies conformity with European legislation	Regulation (EU) 2017/745 (Article 20)
	Keep away from magnetic resonance imaging (MRI) equipment	ASTM F2503-23
	Importer	ISO 15223-1 (5.1.8)
	Indicates the authorized representative in Switzerland	ISO 15223-1 (5.1.2)
	Authorized representative in the European Community	ISO 15223-1 (5.1.2)
	UK Responsible Person	ISO 15223-1 (5.1.2)

DEVICE INTERFACE SYMBOLS

Symbol	Title and Description	Reference
	Bluetooth	Trademark of Bluetooth Special Interest Group (Bluetooth SIG, Inc.), Bluetooth ® wireless or enabled technology
	Full battery	Proprietary
	Warning: Low battery level	Proprietary
	Trend arrows: indicates rising or falling pressure values	Proprietary

Introduction

WARNINGS AND NOTES

This User Manual is intended for medical professionals who have completed appropriate MY01 training within their respective healthcare facilties. It provides information to ensure safe and effective use of the product. The following terminology is used:

⚠ **WARNING: The personal safety of the patient may be involved. Disregarding this information could result in injury to the patients, users, and/or others.**

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

INTENDED USE

CANADA AND UNITED-STATES

The MY01 Continuous Compartmental Pressure Monitor is used for real-time and continuous measurement of the muscle compartment pressure. The measured muscle compartment pressure can be used as an aid in diagnosis of Compartment Syndrome (Acute and Chronic). The MY01 Mobile Application is an application intended for storing and displaying identical pressure values from the MY01 Continuous Compartmental Pressure Monitor device and calculating critical muscle perfusion pressure utilizing diastolic pressure manual entry by the physician. Diagnosis should always be made in conjunction with clinical assessments.

NOTE:

- Refer to MY01 Mobile Application User Manual (REF: MYO-00566-M)
- The MY01 App and MY01 device must be used in tandem.

IN CONFORMITY WITH EUROPEAN LEGISLATION

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. The trend arrows displayed are meant for qualitative purposes only and are not intended to have any clinical significance. The MY01 Mobile Application is an optional application intended for storing and displaying identical pressure values from the MY01 Continuous Compartmental Pressure Monitor device. The data is for informational purposes only and is not intended to be used for diagnosis of any nature or active patient monitoring.

NOTE: The MY01 Mobile Application that is currently available in conformity with European Legislation does not include functionality for the display of muscle perfusion pressure; see MY01 Mobile Application User Manual (REF: MYO-00319-M)

℞ ONLY **Caution**: Federal law (USA) restricts this device to sale by or on the order of a physician.

User & Patient Safety Precautions

⚠ WARNING

- The device should only be used in a healthcare facility environment.
- Users (Medical Professionals) must complete the required training **BEFORE** attempting to use the device to ensure safe and effective use. Training package can be accessed here https://qrco.de/my01-training or by scanning the QR code.
- 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 4).
- 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.

CONTRAINDICATIONS

No known contraindications

Components

Packaging and Device

Figure 1: Packaged MY01 Device

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

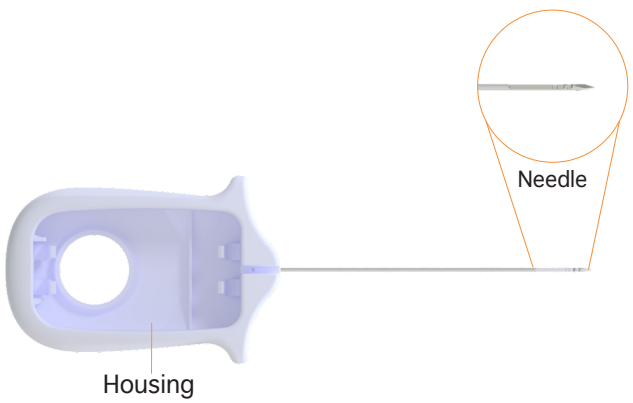


Figure 2: Introducer

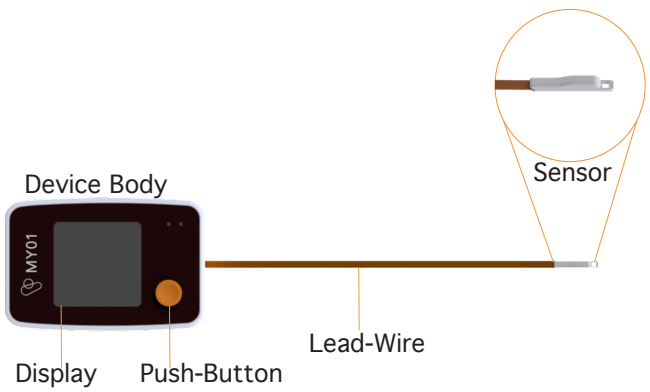


Figure 3: Pressure Monitor (Applied Part)

Device Interface

Figure 4: 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

- Trend arrows are meant for qualitative purposes only and are not clinically significant. Do not use trend arrows for diagnostic purposes. Always use pressure measurements and clinical judgment along with the current standard of care.

Figure 5: Rotating Display Orientation

Wireless Connection

BLUETOOTH SPECIFICATIONS

The MY01 device transmits identical pressure readings collected over time to the MY01 Mobile Application using an authenticated BLE link. The MY01 device uses Bluetooth Low Energy (BLE) technology specification 4.2. Ensure that the mobile phone uses BLE-compatible wireless technology.

Table 1: BLE Specifications

Wireless technology version	BLE specification 4.2
Frequency	2.4GHz
RF frequencies bandwidth	2.402GHz – 2.4835GHz
RF radiated output power	0dBm, 1mWatts
Modulation type	Gaussian Frequency Shift Keying (GFSK)
Bluetooth Interface Security	Authenticated LE Secure Connections pairing uses Numeric Comparison with P-256 ECDH.
	Application layer Device-Application authentication using AES encryption

MY01 MOBILE APPLICATION

The MY01 Mobile Application (MY01 App) provides a graphical user interface for storing and displaying identical pressure values from the MY01 device. The version of the MY01 App that is authorized for use in the US and Canada, in addition to the muscle compartment pressure, calculates and displays the muscle perfusion pressure over time based on manual entries of the patient's diastolic blood pressure. Diagnosis should always be made in conjunction with clinical assessments.

For directions on how to use the MY01 App, please refer to the MY01 Mobile Application User Manual that is available in your region:

- MY01 App with compartmental and perfusion pressure display (P/N: MYO-00566-M);
- MY01 App with compartmental pressure display only (P/N: MYO-00319-M).

NOTE:

- The MY01 App does not control the MY01 device in any way.

MY01 MOBILE APPLICATION DOWNLOAD

Operational Instructions

Step 1 : Peel the Tyvek lid where indicated. Lift the top cover and remove the device from the packaging. While holding the Introducer (see Figure 6), remove the Needle Cap before turning on the device.

⚠ 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.

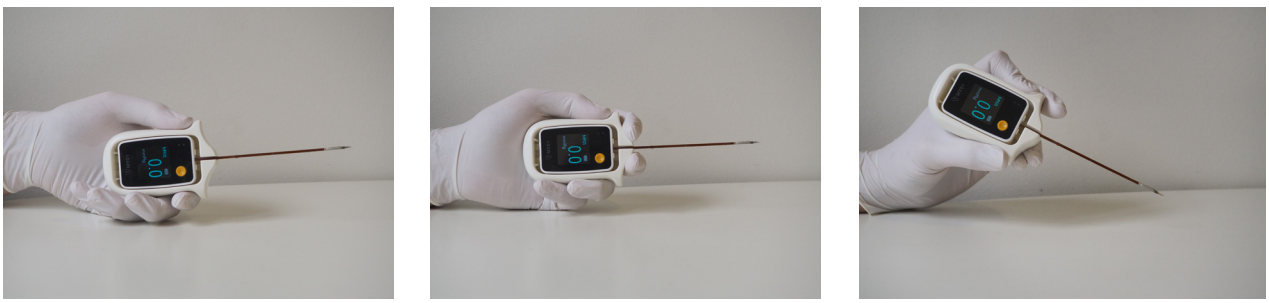
NOTE

- Make sure to not touch the sensor tip while turning ON the Device.

Figure 6: Removing Needle Cap and Turning ON the Pressure Monitor

⚠ WARNING

- Always turn ON the device BEFORE introducing into patient.
- Do not use the device if pressure measurements are not within -2.5 to 2.5 mmHg prior to insertion.



A B C

Figure 7: Recommended Device Grips

Step 3 : 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.

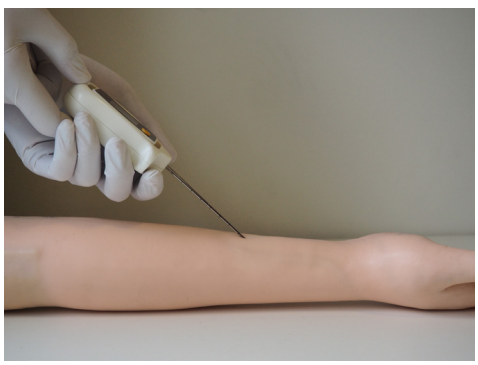


Figure 8: Introducing the Device

CAUTION

- Prior to insertion, identify the target anatomical compartment based on clinical assessment. The selected compartment must provide sufficient depth and volume to accommodate the MY01 needle's length and diameter. The sensor must be positioned within the intended compartment to ensure reliable intracompartmental pressure measurements. Improper placement may result in inaccurate readings.

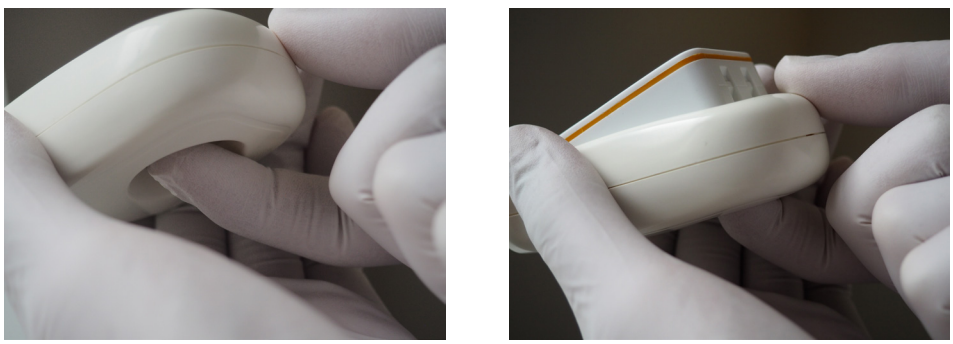
NOTE

- The Display can be rotated to the desired orientation to ensure visibility during the insertion (see Figure 5).
- 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.
- If necessary, a small incision can be made to facilitate the insertion process.
- The Introducer can be retracted and re-inserted (up to 5 total insertions) to perform additional single-point measurements without ejecting the Pressure Monitor.

⚠ WARNING

- Always keep the Atmospheric Pressure Vents on the bottom-right of the screen unobstructed (see Figure 4).
- Do not use the device if the Sensor unhooks unexpectedly after removing the Needle Cap or at any point 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.

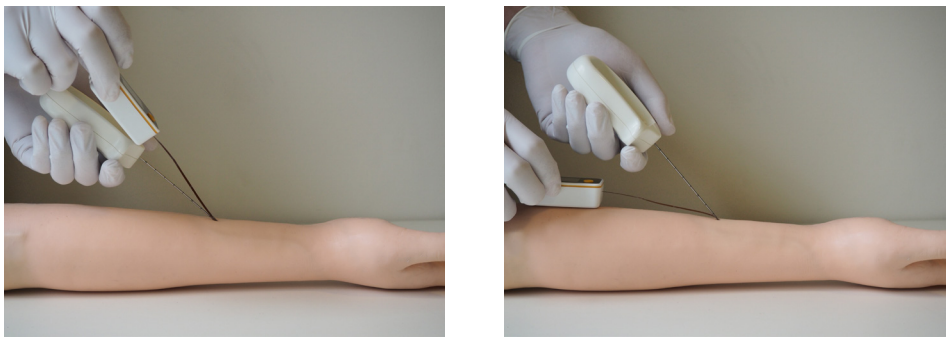
Step 4 : When the Sensor is in the desired position and readings have stabilized, eject the Pressure Monitor from the Introducer by pressing gently through the back opening of the Introducer. An adhesive strip will be exposed on the back of the Device Body when ejected.



A B

Figure 9: 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 10: 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

- If the adhesive strip is not exposed after ejecting the Pressure Monitor from the Introducer (see Figure 9), manually remove the protective liner. 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 Atmospheric Pressure Vents (see Figure 4) are not covered by the medical tape.

Step 6 : To disengage the Sensor, use a finger to firmly press the lead-wire against the skin on the insertion site, then rotate the Introducer 180 degrees. While keeping the finger pressed on the lead-wire, gently remove the Introducer from the patient. After removing the Introducer, dispose of it in a biohazard-sharps receptacle, following 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.

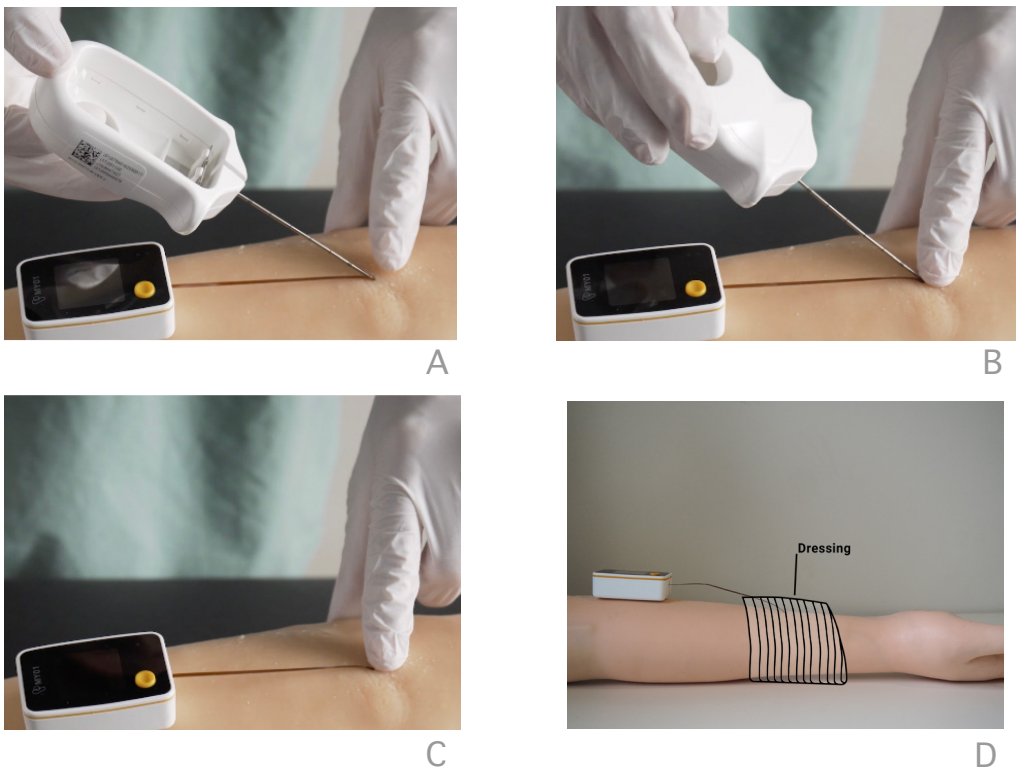


Figure 11: Removing the Introducer

Step 7 : Monitor pressure readings for a period of up to 18 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

- The Pressure Monitor may stop functioning correctly after 18 hours when the battery is depleted. Do not leave the Sensor inside the patient for a period longer than 18 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-use only (a single monitoring session). Do not attempt to reassemble the device, to reuse or replace the batteries after use.
- Take necessary precautions while using the device intraoperatively (e.g. fasciotomy, amputation, debridement, skin graft).

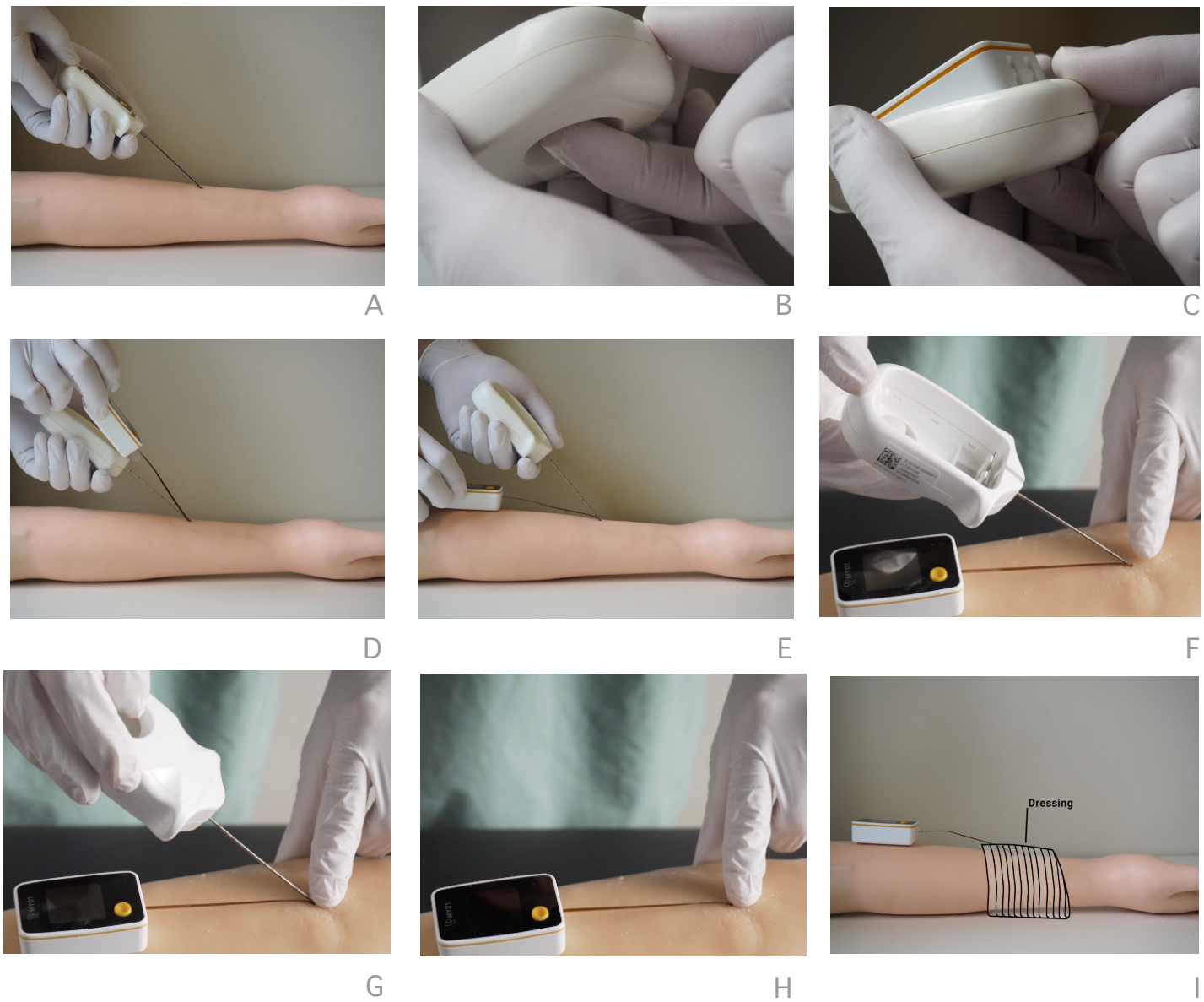


Figure 12: Insertion Procedure Summary

Troubleshooting

DEVICE INTERFACE ERROR CODES

Table 2: Error Code List

ERROR CODE	ERROR NAME	DESCRIPTION	ACTION
		NON-CRITICAL ERRORS	
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
4	Outside Operating Pressure Range	The absolute pressure reading from sensors is outside operating pressure range	Disregard the pressure values while error sign is visible
		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 instructions on how to return the device.
ERR 11	Software Error	Software malfunction	DO NOT use the device. Call customer support for instructions on how to return the device.

Figure 13: Error Code Display

INSTRUMENT DEFECTS OR PRODUCT DEFICIENCIES

- For defective device concerns, or any related quality issues, please contact info@MY01.io or call +1 (855) 799-6901.
- A MY01 representative will deal with any quality issues related to hardware, software, or wireless functionality in a timely manner.
- Additional paper User Manuals can be made available upon request, free of charge. To request one, please email info@MY01.io or call +1 (855) 799-6901.

Specifications

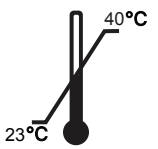
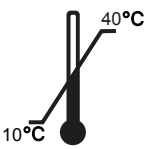
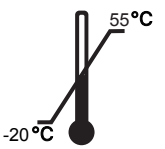
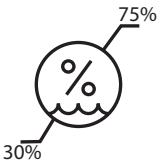
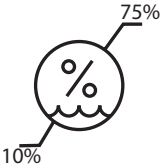
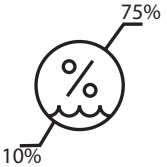
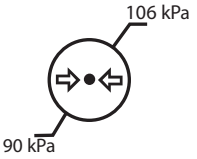
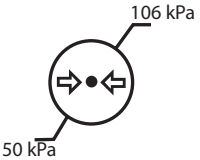
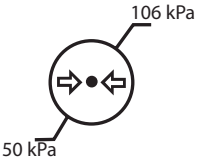
DEVICE

Table 3: Device Specifications

Device Specifications	
Model	MY01-0001
Pressure range	-99.9 to 99.9 mmHg
Power	Two (2) 3 V batteries (non replaceable)
Battery type	Lithium coin cell
Display resolution	0.1 mmHg
Battery life	18 hours
IP Rating	IP52
Weight	85 g (+/- 5g)
Dimensions	20 cm x 6.5 cm x 3 cm (+/- 1cm)
Needle gauge	17-gauge
Electrical Safety	
Standard	EN/IEC 60601-1
Type of protection against electric shock	Internally Powered Equipment
Degree of protection against electric shock	Type BF Applied Parts
Mode of operation	Continuous

ENVIRONMENTAL CONDITIONS

Table 4: Environmental Conditions

	Operation	Storage	Transportation
Temperature			
Humidity			
Pressure			

ELECTROMAGNETIC COMPATIBILITY

The MY01 device has been tested and found to comply with the requirements of EN/IEC 60601-1-2.

⚠ WARNING

- Use of the 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

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

Table 5: Electromagnetic Emissions

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 6: 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

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.

CAUTION: Any changes or modifications to this product not authorized by MY01 Inc. could void your authority to operate the product.

Industry Canada Compliance Statement / Avis de conformité à la réglementation d'Industrie 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.

Reorder information

REF	Product Description
MY01-0001	MY01 Continuous Compartmental Pressure Monitor
MY01-APP	MY01 Mobile Application