MY01

REF: MY01-000M
Version 18

USER MANUAL

Continuous Compartmental Pressure Monitor

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Symbol Explanation

DEVICE LABELING SYMBOLS

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
Model Number	#
Authorized representative in the European Community	EC REP
Ingress Protection (IP Rating)	IP52

Signifies European technical conformity	CE 2862
Keep away from magnetic resonance imaging (MRI) equipment	MR
Importer	
Indicates the authorized representative in Switzerland	CH REP

DEVICE INTERFACE SYMBOLS

Bluetooth	
Full battery	
Warning: low battery level	
Trend arrows	

Introduction

WARNINGS AND NOTES

The instructions for use manual 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 patient and/or user.**

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. 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.

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.
- Do not dispose of dispenser packaging until all devices are used.

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.

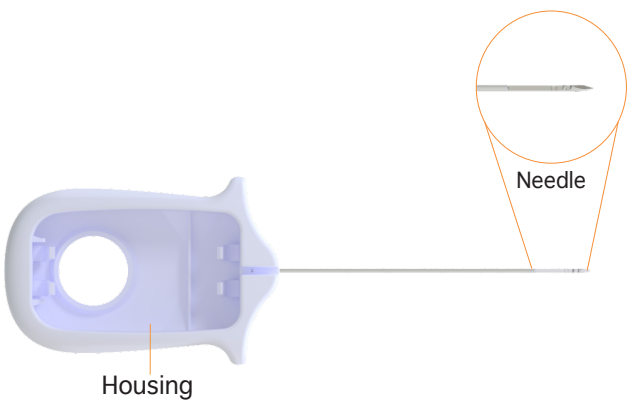


Figure 2: Introducer

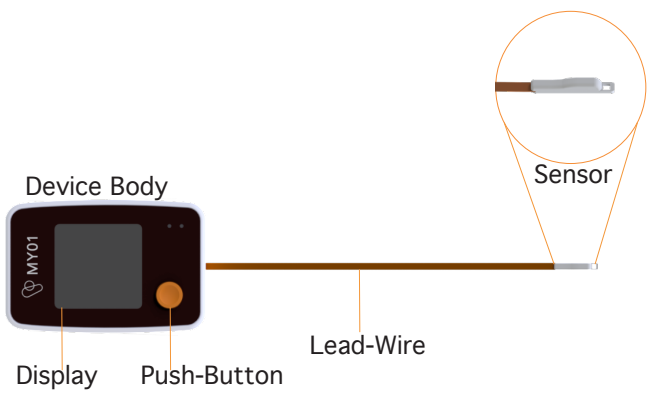


Figure 3: Pressure Monitor (Applied Part)

Device Interface

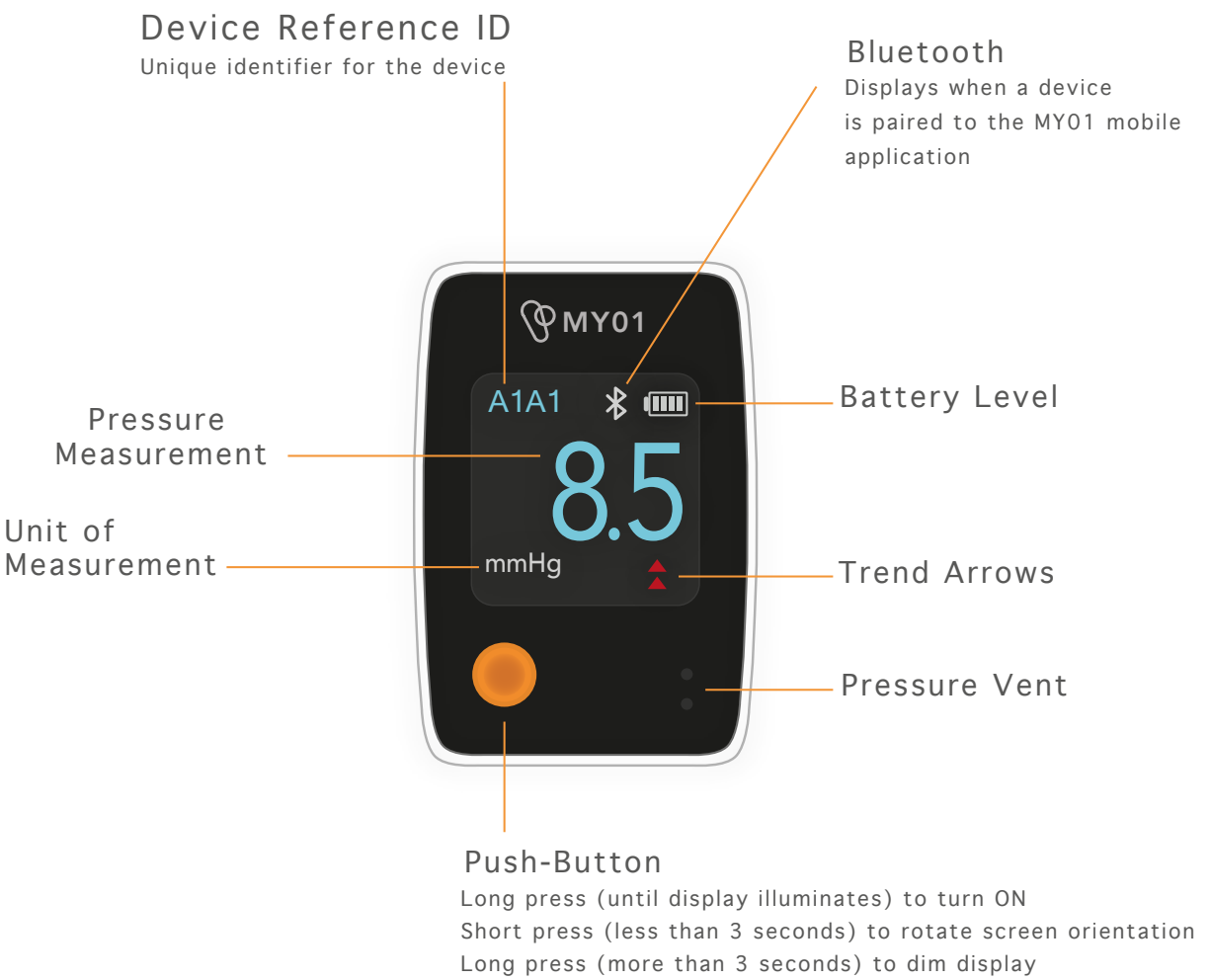


Figure 4: Device Controls and Display Icons

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

APPLICATION DESCRIPTION

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. The MY01 Mobile Application does not control the MY01 Continuous Compartmental Pressure Monitor in any way.

APPLICATION FEATURES

The MY01 Mobile Application only allows users with valid login credentials to access the software application. The MY01 Mobile Application home screen displays a list of MY01 devices by device unique identifier. The user can securely connect to a device via BLE by tapping on the device unique identifier. Once securely connected, the pressure data points are sent over an encrypted BLE link from the MY01 device. The MY01 Mobile Application displays the latest pressure data point as a duplicate display (Figure 9). The full pressure log can also be seen as a graph (Figure 10). Pressure data points are forwarded via an encrypted network link to a Cloud-based service (MY01 Application Server) for archival purposes. The data stored by the MY01 Mobile Application can be later retrieved.

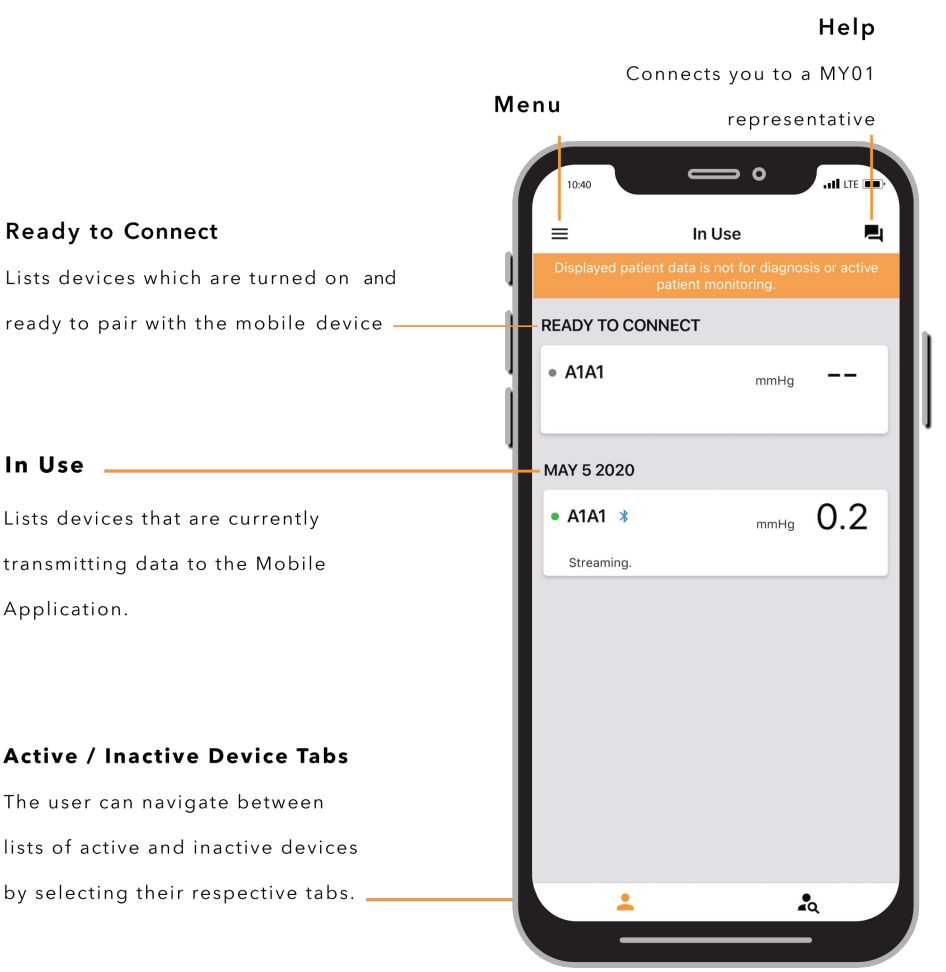


Figure 6: Device Interface

APPLICATION DOWNLOAD

GET IT ON Google Play

Download on the App Store

CONNECTING TO THE MY01 DEVICE

Open the MY01 Mobile Application and pull down to scan for nearby advertising MY01 devices. Each entry in the list contains the unique MY01 Device identifier. Verify that the unique identifier displayed on the application matches the one displayed on the MY01 device's LCD top-left corner.

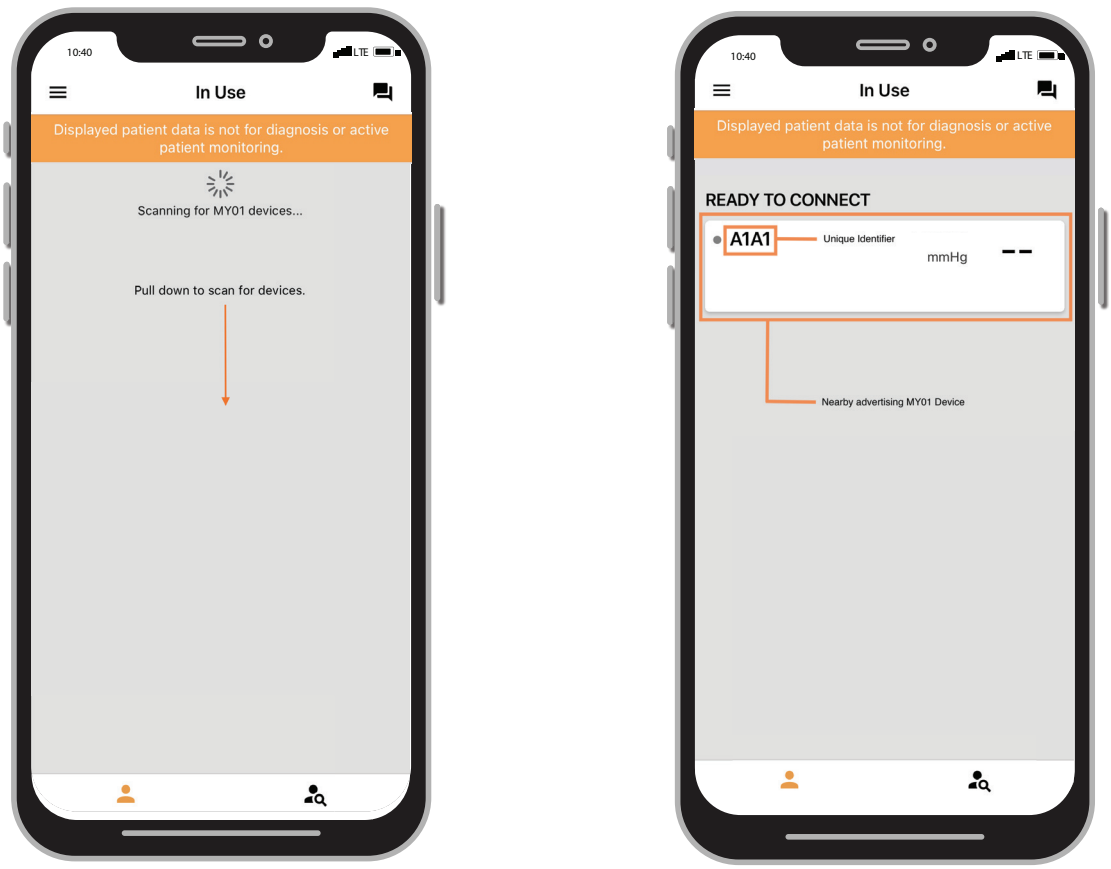


Figure 7: Refreshing the Device list

Tap on a device entry to connect to the MY01 device. If connecting for the first time, a Bluetooth pairing request will appear. Confirm that the pairing PIN displayed on the application matches the pairing PIN displayed on the MY01 device's LCD. Click on the "Pair" button to confirm and connect.

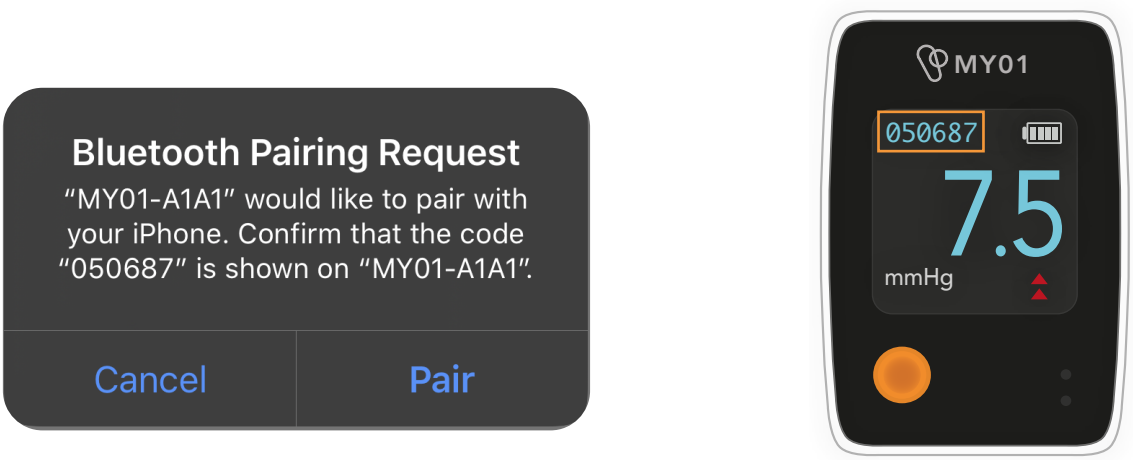


Figure 8: Pairing the Device

Once connected to a MY01 device, a Bluetooth mark will appear next to the MY01 device unique identifier. Pressure data transmission will begin shortly after connection.

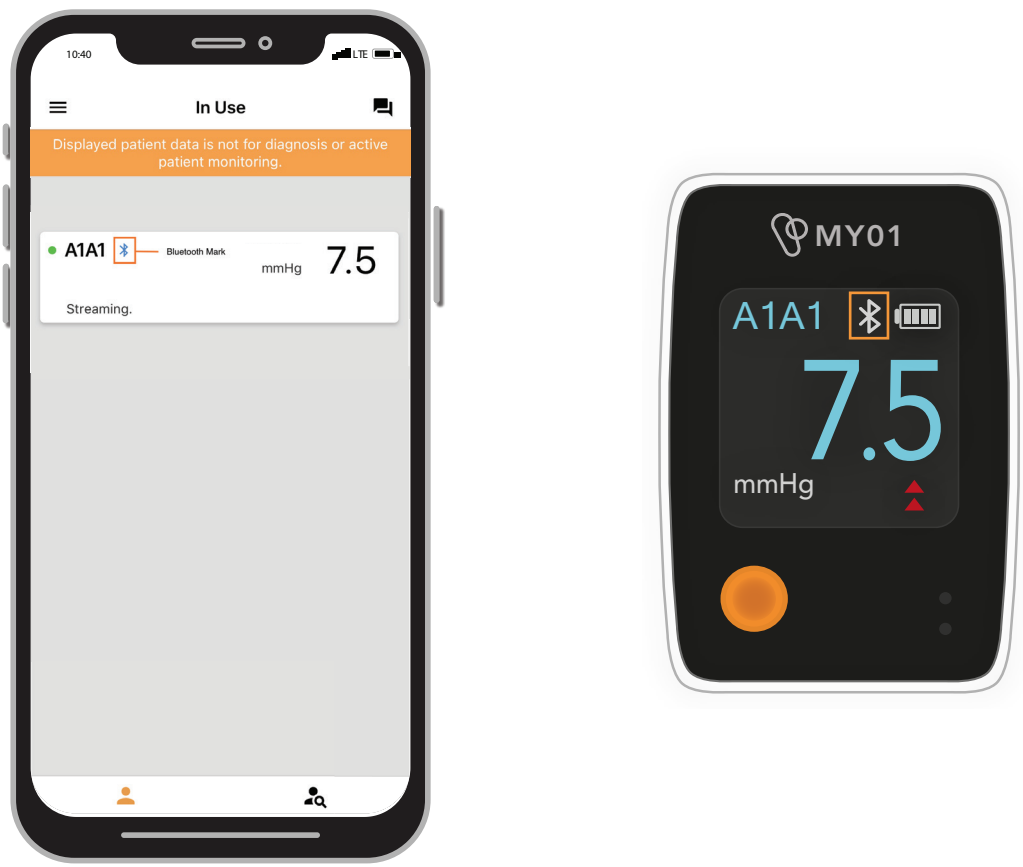
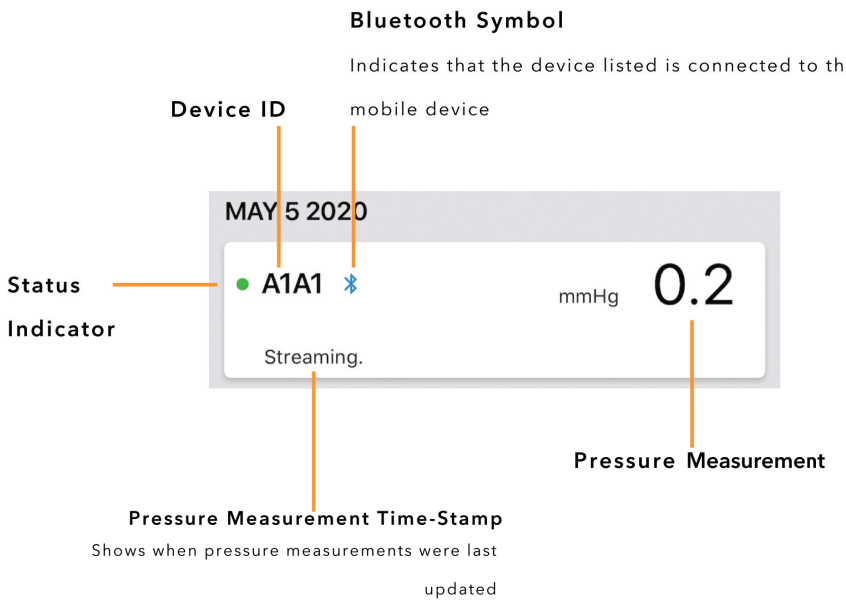


Figure 9 : Device Connected

ACTIVE DEVICE INFORMATION & DATA DISPLAY



Once the MY01 device has been successfully connected to the MY01 Mobile Application the graphing function can be accessed by pressing on the Device of choice section of the interface.

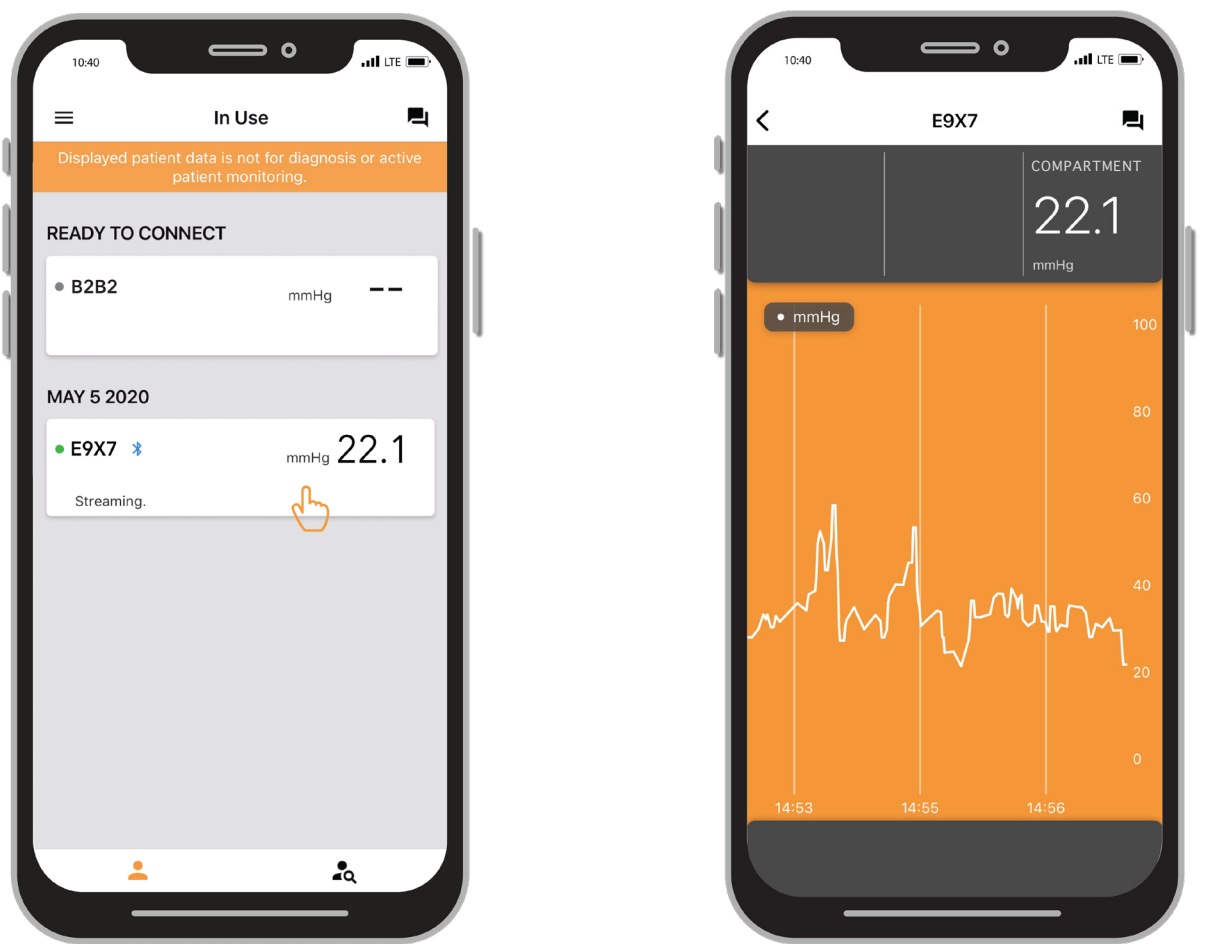


Figure 10: Data Display

Time elapsed since
Pressure data was last updated

- Less than 5 minutes
- Between 5 and 10 minutes
- More than 10 minutes
- Device is not currently in use

DISCONNECTING FROM THE MY01 DEVICE

To disconnect from a MY01 device, slide the Device entry to the left and click on the “Disconnect” button.

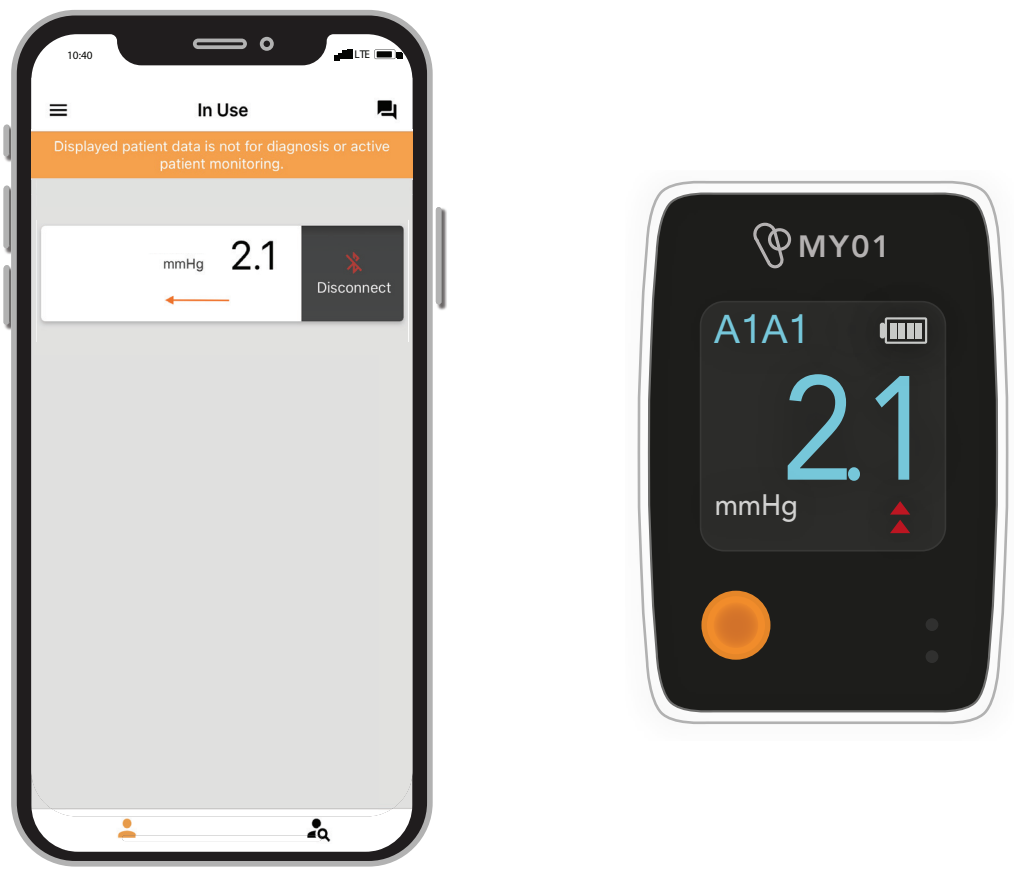


Figure 11: Disconnecting

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 12), remove 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. (See Page 24)

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

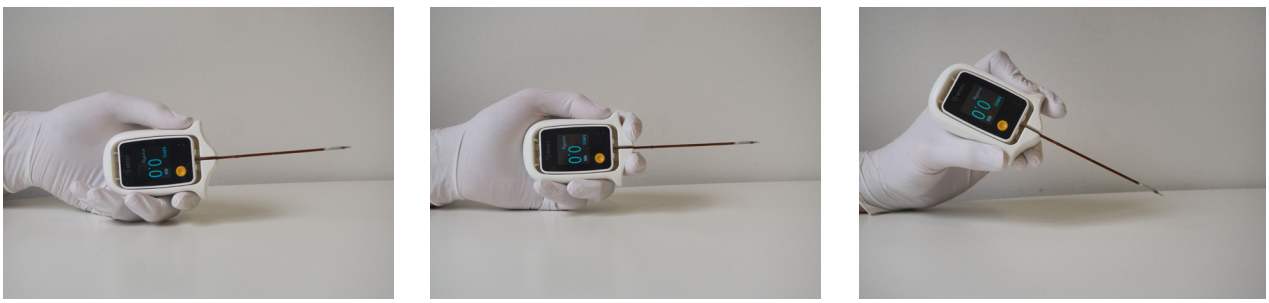
NOTE

- Avoid short presses on the push-button prior to turning on the Device.
- Make sure to not touch the sensor tip while turning on the Device.

Figure 12: Removing Needle Cap and 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 -2.5 to 2.5 mmHg prior to insertion.



A B C

Figure 13: 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.

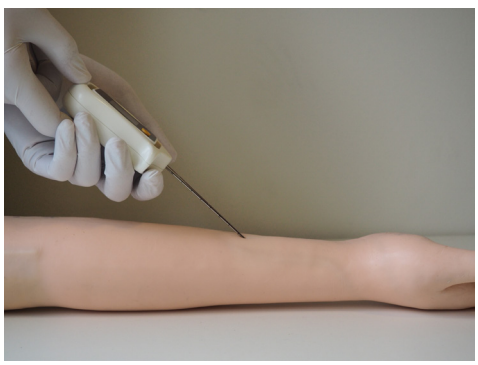


Figure 14: Introducing the Device

NOTE

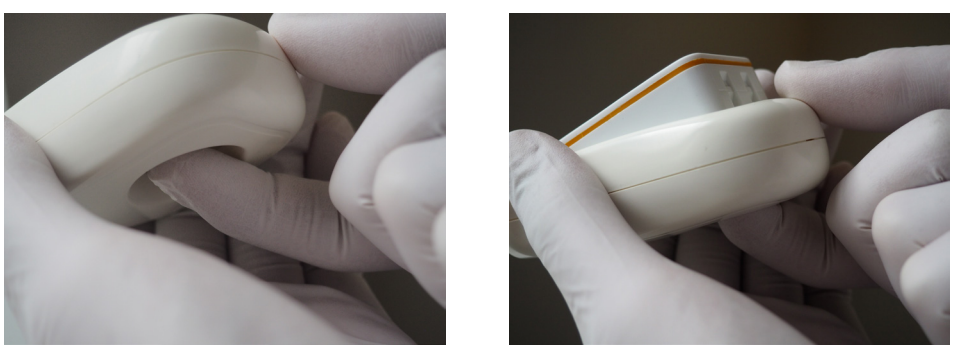
- The Display can be rotated to the desired orientation to ensure visibility during the insertion (see Figure 5).
- Single marks are spaced along the needle at 1 cm intervals with the first located 2 cm from the Needle tip. Double marks are placed at 5 cm intervals as measured from the Needle tip.
- 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 Pressure Vent 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.

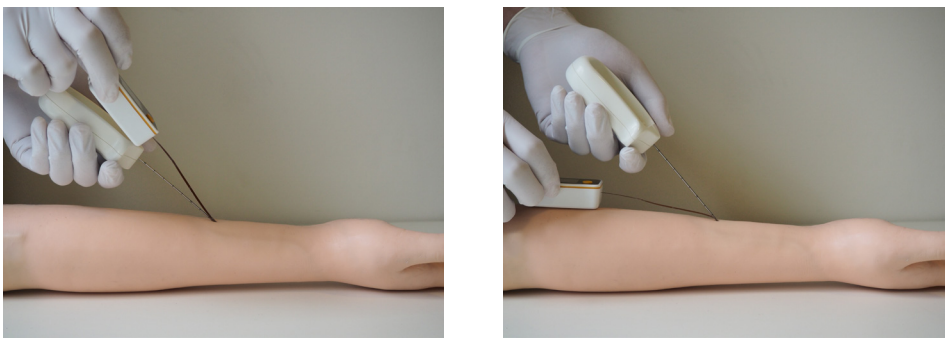
Step 4 : When the Sensor is in the desired position and readings have stabilized, eject the Pressure Monitor from the Introducer by pressing gently through the back opening of the Introducer. An adhesive strip will be exposed on the back of the Device Body when ejected.



A B

Figure 15: 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 16: 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 15), 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 Pressure Vent (see Figure 4) is 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.

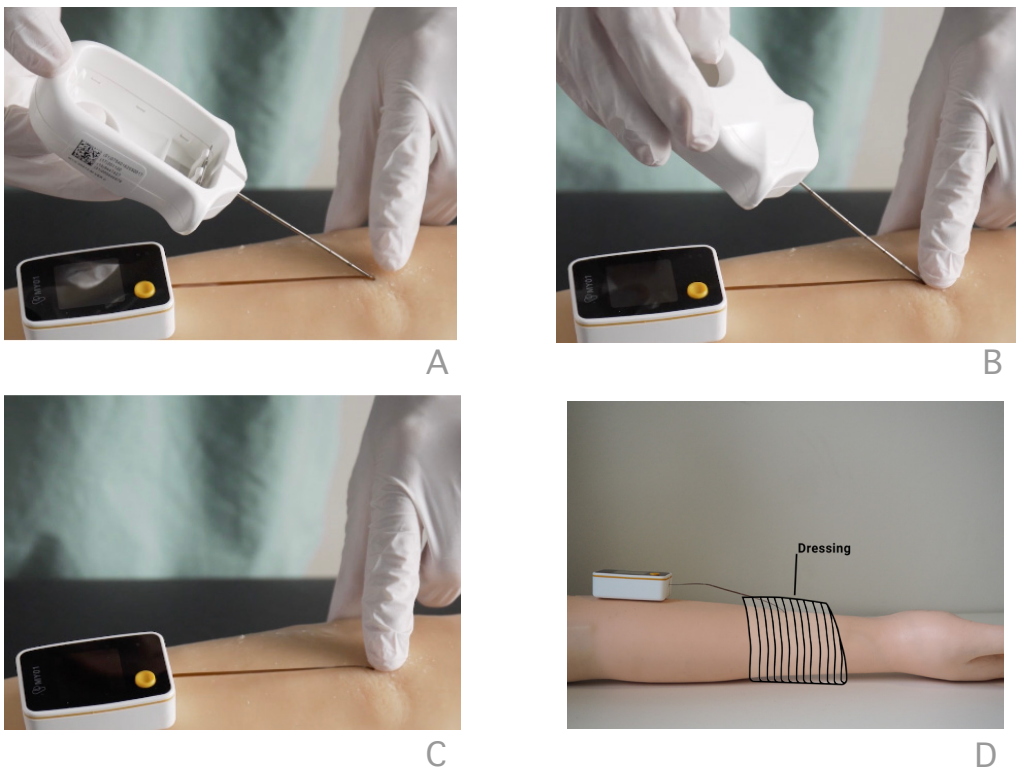


Figure 17: Removing the Introducer

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

- 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 patient-use only. Do not attempt to reassemble the device or replace the batteries after use.
- The device is single-use, do not reuse on the same patient. Patient safety may be compromised.
- Take necessary precautions while using the device intraoperatively (e.g. fasciotomy, amputation, debridement, skin graft).

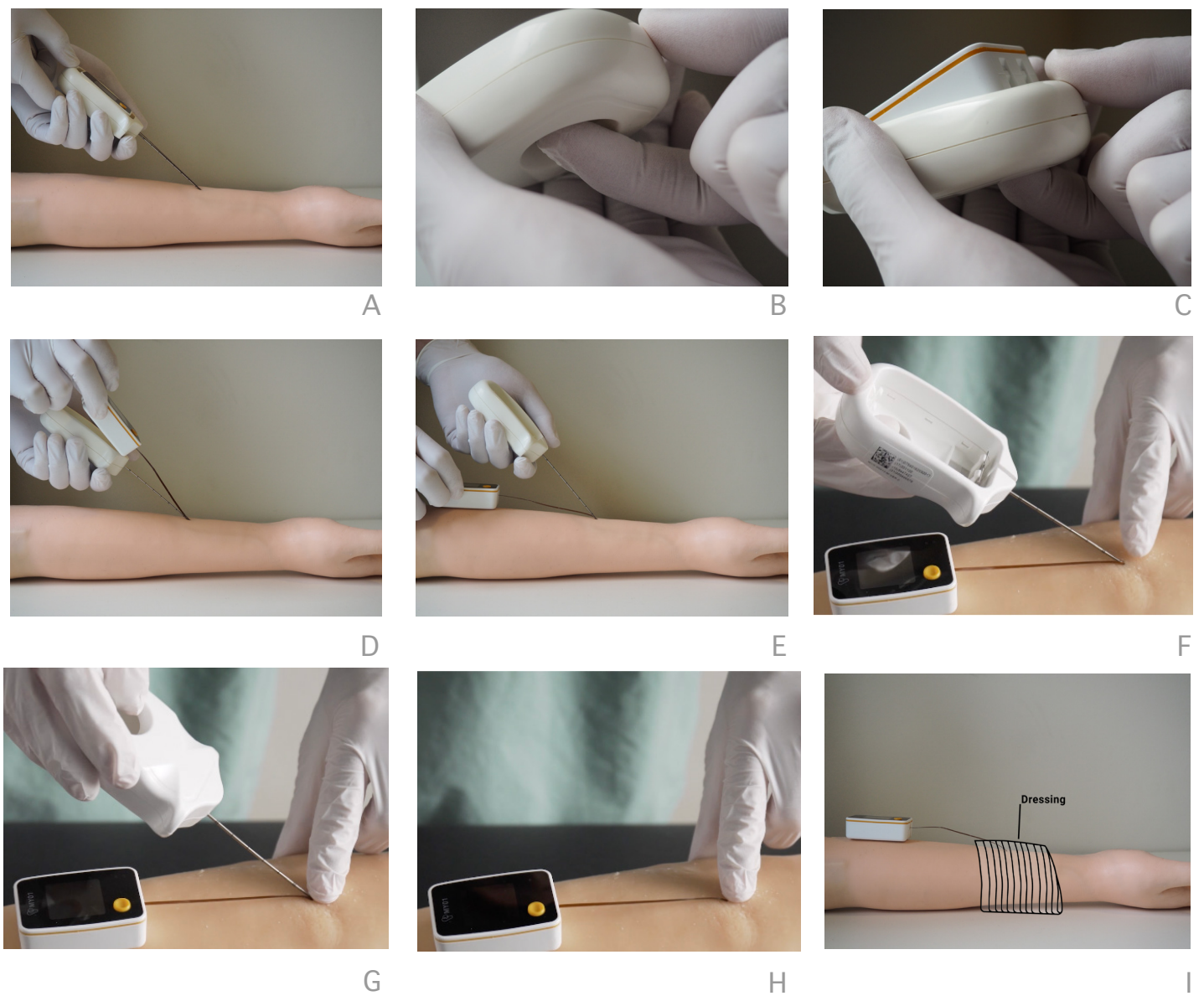


Figure 18: Insertion Procedure Summary

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 19: 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

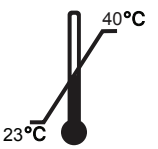
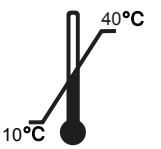
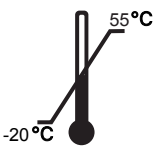
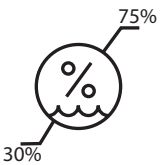
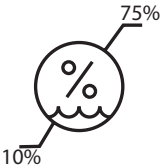
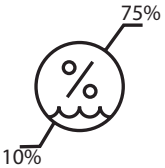
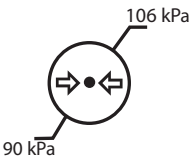
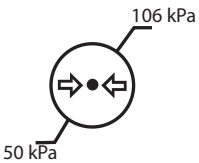
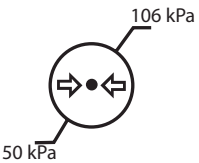
DEVICE

Table 3: Device Specifications

Model	MY01-0001
Pressure range	-99.9 to 99.9 mmHg
Power	Two (2) 3 V batteries (non replaceable)
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

ENVIRONMENTAL CONDITIONS

Table 4: 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 physical accessories. Do not attempt to add any cables or accessories to the device.
- MY01 can communicate over a frequency band of 2.402GHz-2.4835GHz with GFSK modulation and effective radiated power of 1mWatts.

Table 5: 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 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

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.

Reorder information

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

Date of release : 28 October 2024

P/N : MYO-00119-M

CE
2862

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