User Manual MY01 Mobile Application







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Symbols Glossary

Symbol	Title and Description	Reference
R ONLY	Caution: Federal law (USA) restricts this device to sale by or on the order of a physician	21 CFR 801.109
	Manufacturer	ISO 15223-1 (5.1.1)
MD	Medical Device	ISO 15223-1 (5.7.7)
UDI	Unique Device Identifier (UDI)	ISO 15233-1 (5.7.10)
LOT	Batch code	ISO 15233-1 (5.1.5)
REF	Catalogue number	ISO 15233-1 (5.1.6)

Introduction



Intended use

The MY01 Mobile Application is intended for use with the MY01 Continuous Compartmental Pressure Monitor to display the measured muscle compartment pressure and the calculated muscle perfusion pressure that is derived using a manually entered diastolic blood pressure.



Intended Users

Trained trauma surgeons/Physicians.



Warning

Displayed patient data is not for diagnosis or active patient monitoring.



Application download





Recommended smart device settings

Ensure your smart device settings correspond with the following parameters before downloading and installing the MY01 Mobile Application:

- Ensure you are using a Bluetooth 4.2 compatible mobile device that meets or exceeds the minimum performance specifications. Additional information on the most up to date device requirements and compatible systems can be found at <u>help.my01.io</u>.
- Ensure your device is Bluetooth enabled. Instructions on enabling BLE connection are provided in the following section.
- Ensure that the date & time settings on your mobile device are set to automatic. Instructions on enabling those settings are provided on page 6.
- Recommended: Access to your mobile device should be password protected.



Enabling Bluetooth on your iOS or Android device



Date & Time

Update Date & Time on your iOS or Android device



Signing Up

To connect the MY01 Mobile Application via BLE to the MY01 device for the first time, users must follow these steps:

Users are invited by their institution to join the MY01 Mobile Application. Choose a secure password and confirm your account.

Install the MY01 Mobile Application from the Google Play Store or Apple AppStore.

Signing In

Open the MY01 Mobile Application.

Login using your credentials.

If you've forgotten your password, click on reset password and follow the on-screen instructions.



Application Interface (Continued...)



Active Device Information



Getting Started



Instructions

Connecting to the MY01 device

Open the MY01 Mobile Application and pull down to scan for nearby MY01 devices. Each entry in the list contains the unique MY01 Device identifier.

Notes:

The application will try to automatically reconnect to nearby MY01 devices in-use. At times, the application won't be able to connect automatically. For more information on what to do, refer to the technical issues section.



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Verify that the MY01 device identifier displayed on the application matches the one displayed on the MY01 device's LCD top-left corner.





Data Display

Once the MY01 device has been successfully connected to the MY01 Mobile Application, users can view the pressure graph by clicking on the MY01 device identifier. A Bluetooth symbol will be displayed if the device is connected and streaming data.



WARNING:

Displayed patient data is not for diagnosis or active patient monitoring.

IMPORTANT:

In order for the recorded data to be successfully transferred to the Cloud for later retrieval, the user MUST ensure that the MY01 device is connected to the MY01 Mobile Application.

To change the display from portrait to landscape mode, simply rotate your mobile device by 90 degrees and the screen will automatically rotate.





Instructions

1

5:13

69

Tap on the **Diastolic Entry** to enter the diastolic pressure value.

65.2

0403

4.2



Entry

Physicians can manually input a patient's diastolic pressure in the mobile application within the range 10-200 mmHg.

Notes:

A prompt will appear if the value entered is out of range (10-200 mmHg).



3 A message confirming the entry will pop up.

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5:15

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0403

5.6

You've made a diastolic entry

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67.3

L Diastolic Pressure Entry Editing

User can edit a diastolic pressure entry by doing the following:



Click on All Records



A **Diastolic Entries** list will pop up. Click on a diastolic entry to edit it (i.e. 25 mmHg).



Select the checkmark on the top right of the screen.

Copying Diastolic Pressure Across Multiple Devices

The entered diastolic pressure can be copied to all MY01 devices used on the same patient.



Instructions





Diastolic Pressure Reminders -

User can also set reminders to enter the diastolic pressure by tapping on the notification icon.

The app will send reminder notifications on the mobile device.



In-app reminders can also be viewed on the notifications tab.



Perfusion Pressure Calculation and Display

Perfusion pressure is computed using the latest diastolic and muscle pressure available at a given time.



Perfusion Pressure = (diastolic pressure - muscle pressure)



User-to-User Invite

Users that are registered within an organization are able to invite other users into that organization.



Notes:

- If you screenshot or send the QR code as a URL, it will only be valid until the date marked at the bottom right corner.
- When inviting a new user to an organization, make sure the correct organization has been selected.

The organization's name is displayed at the bottom left corner of the QR code.

Switching Organizations

Users that are registered with multiple organizations are able to toggle between different organizations by clicking on the drop down list at the top of the home screen.



Notes:

A device can only be registered within one organization. Should you try to connect to a device that has been previously registered to another organization the warning below will appear. Ensure that you have selected the correct organization and connect to the device again.



Disconnecting from a MY01 device

To disconnect from a MY01 device, slide the device entry to the left and click on the "Disconnect" button. The Bluetooth logo will disappear from the MY01 Device.

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Displayed p	atient data is not for diagn patient monitoring.	osis or active
SEPTEMBER 5	5, 2024	
	mmHg 2.1	X Disconnect

List of inactive devices

A list of the inactive devices that have been used in the past is shown and pressure measurements can be viewed.



Logging out of the MY01 Mobile Application

Once users have finished using the MY01 device, they can log out of the mobile application by tapping opening the "Menu" and clicking on "Log Out".



Help Center & Chat

Help Center/FAQs

We have compiled a list of tutorials and documentation to help users and respond to any questions that should arise. The "Help Center" can be accessed from the Menu screen, located on the upper left of the Home screen.



Help Center & Chat

Chat

Should you not find the required information on our help center we invite you to go to our chat system. A MY01 Representative can be contacted directly in the MY01 Mobile Application by pressing the "Chat" button on the upper right of the home screen.

9:41		
=	MY01 Inc.	
Displayed patient data is not for diagnosis or active monitoring.		
READY TO C	ONNECT	
• A1A1	mmHg	



Technical Issues

Issues	Resolution
Application will not start	 Delete and reinstall the app. Check for application updates in the applicable digital distribution platform (iOS App Store & Google Play Store).
Application crashes	 Close the application and restart the app. Check for application updates in the applicable digital distribution platform (iOS App Store & Google Play Store).
Application cannot connect to a device Device does not appear in the active device list, or does not appear in the "Ready to Connect" section	 Ensure the MY01 device is turned on and in the same room, within 4 meters of the mobile application device. Ensure the device's LCD is not displaying any error. Ensure your mobile device has Bluetooth turned on. Ensure your mobile device has network connectivity (Wi-Fi or cellular connection is turned on). Ensure that the device is not already connected via BLE to another user's mobile device. The MY01 Device should not display \$. Refresh the active device list by "pulling down". If the steps above are not successful, close and restart the app. Check for application updates in the digital distribution platforms (iOS App Store & Google Play Store).
Application cannot connect to a device. When a device entry is pressed, the application displays the device's pressure chart instead of connecting via Bluetooth.	 Ensure the device entry appears in the "Ready to Connect" section before pressing it. If the device entry is not in the "Ready to Connect" section, refer to the section above.

Technical Issues

	 Ensure the device is turned on and in the same room, within 4 meters of the mobile device.
	 Ensure the device's LCD is not displaying any error.
	 Ensure your mobile device has network connectivity (Wi-Fi or cellular connection is turned on).
Application cannot connect to a device	 Open Bluetooth setting on your mobile device, click on the appropriate MY01 device ID, click "forget".
An error is displayed upon connection	 Open MY01 Mobile Application, under the "ready to connect" section click on the appropriate MY01 device to reconnect.
	 If the steps above are not successful, close and restart the app.
	 Check for application updates in the applicable digital distribution platform (iOS App Store & Google Play Store).
A device with incompatible firmware has been scanned	 Ensure you are using the latest version of MY01 Mobile Application.
	• Try to reconnect to the device
Cannot find a device turned on	 Ensure your mobile device has network connectivity (WiFI or cellular connection).
	 Ensure the inactive devices list is currently displayed. Press the right tab on the main application screen.
more than 24 hours ago.	 Refresh the device list by "pulling down".
	 If not successful, it may indicate that MY01 service is undergoing maintenance or is unavailable. Please try again later.
Application displays "Bluetooth is off."	Turn on bluetooth on your mobile device. If not successful, close the application and restart it.
Application displays "Bluetooth is not supported on this mobile device."	Ensure you are using a Bluetooth 4.2 compatible mobile device. For the latest list of compatible mobile device open the in-application help center or visit <u>https://help.my01.io</u>

Application opens but cannot login	 Ensure your mobile device has network connectivity (Wi-Fi or cellular connection). Try to re-enter your credentials. You can use the "eye" icon to reveal your password before submitting. Press the "Forgot Password" button on the login screen or open <u>https://gateway.my01.io/account/reset/request</u> using a web browser.
Application displays "Mobile device not secure" when started.	Indicates that your mobile device is not protected by a passcode. You can configure a passcode in your mobile device's security settings.
Application displays "Server unreachable"	 Ensure your mobile device has network connectivity (Wi-Fi or cellular connection). If not successful, it may indicate that MY01 service is undergoing maintenance or is unavailable. Please try again later.

Paper IFU manuals are available upon request free of charge, within 7 business days of the request. If you want to request a paper copy of the IFU, please email <u>info@MY01.io</u> or call +1 (855) 799-6901.

For bug reporting, technical difficulties, any related quality issues, or any serious incident that has occurred in relation to the device, please contact <u>info@MY01.io</u> or call +1 (855) 799-6901.

For additional resources, visit <u>help.my01.io</u> or call +1 (855) 799-6901.

A MY01 representative will assist you with any quality issues related to the MY01 device and MY01 Mobile Application in a timely manner.