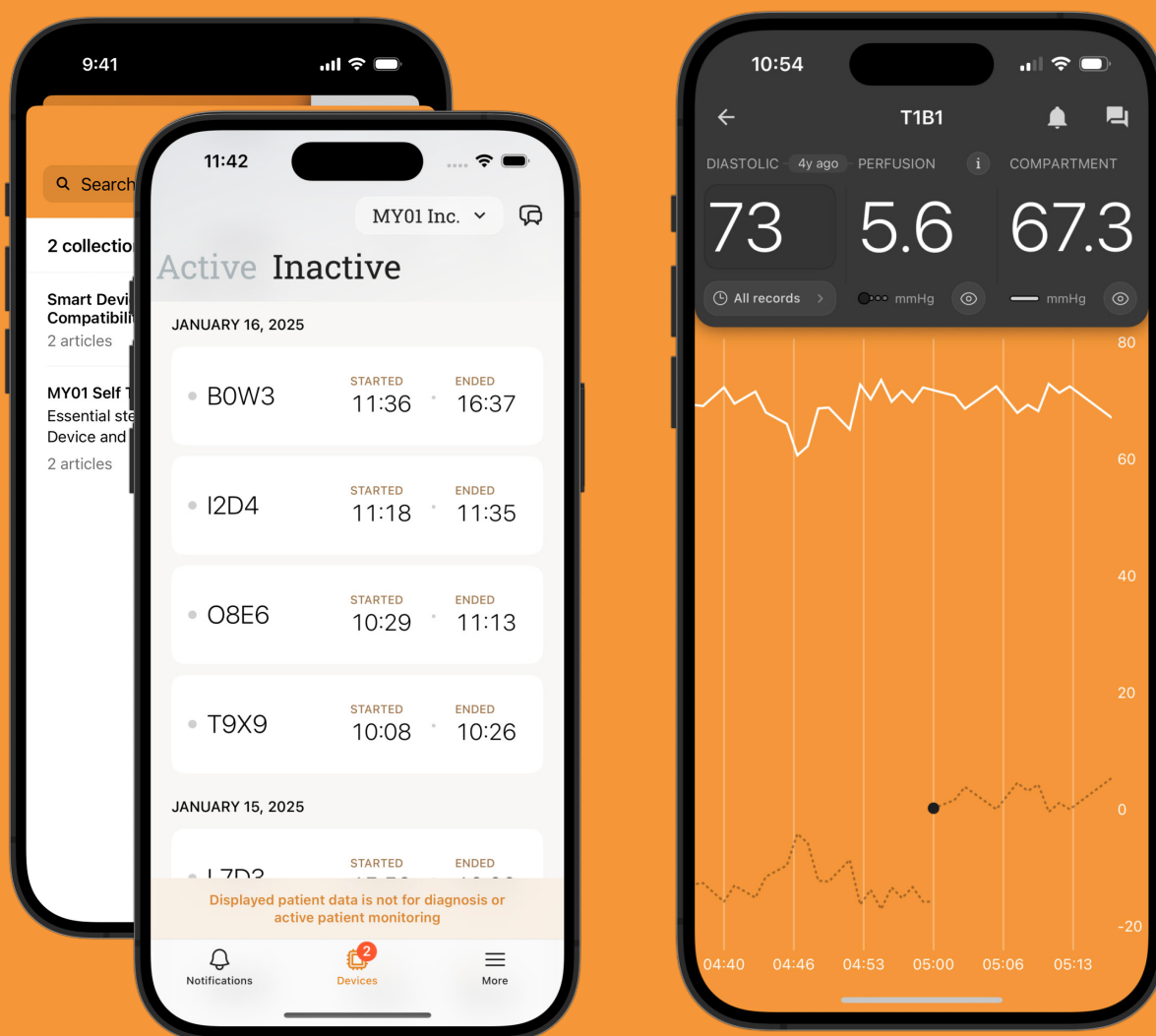


User Manual

MY01 Mobile Application



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AU	REP
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Symbols Glossary

Symbol	Title and Description	Reference
	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)
	Medical Device	ISO 15223-1 (5.7.7)
	Unique Device Identifier (UDI)	ISO 15223-1 (5.7.10)
	Batch code	ISO 15223-1 (5.1.5)
	Catalogue number	ISO 15223-1 (5.1.6)
	Authorized representative in the Therapeutic Goods Administration	ISO 15223-1 (5.1.2)

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. This device is prescription only.



Warning

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



Application download

Always update to the latest version of the app to ensure you benefit from the newest security protections.



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 help.my01.io.
- ✓ 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.

Bluetooth

Enabling **Bluetooth** on your **iOS** or **Android** device



- 1 Tap on **Settings** on your **iOS** device
- 2 Select **General**
- 3 Tap on **Bluetooth**
- 4 Toggle Bluetooth to **On**



- 1 Tap on **Settings** on your **Android** device.
- 2 Look for **Bluetooth** or the **Bluetooth Symbol** in your settings and tap it.
- 3 There should be an option to enable. Please tap or swipe **On** it so that is in the on position.

Date & Time

Update **Date & Time** on your **iOS** or **Android** device



- 1 Tap on **Settings** on your **iOS** device
- 2 Select **General**
- 3 Tap on **Date & Time**
- 4 Make sure that the option **Set Automatically** is turned on
- 5 If this option is turned off, check that the correct **Date, Time and Time Zone** are selected.



- 1 Tap on **Settings** on your **Android** device.
- 2 Tap on **Date & Time**
- 3 Tap on **Automatic**
- 4 If this option is turned off, check that the correct **Date, Time and Time Zone** are selected.

Signing Up

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

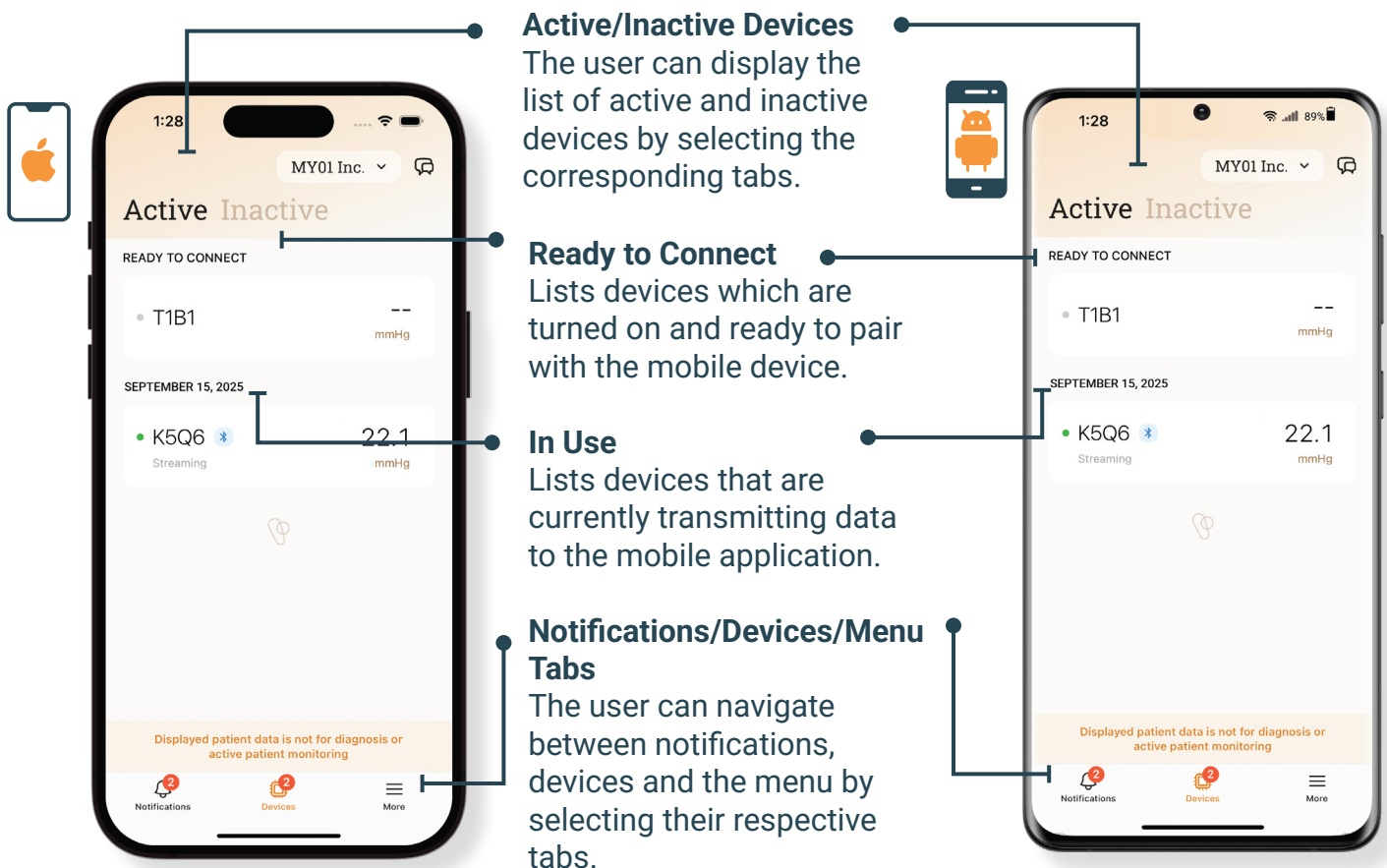
- 1 Users are invited by their institution to join the MY01 Mobile Application. Choose a secure password and confirm your account.
- 2 Install the MY01 Mobile Application from the Google Play Store or Apple AppStore.

Signing In

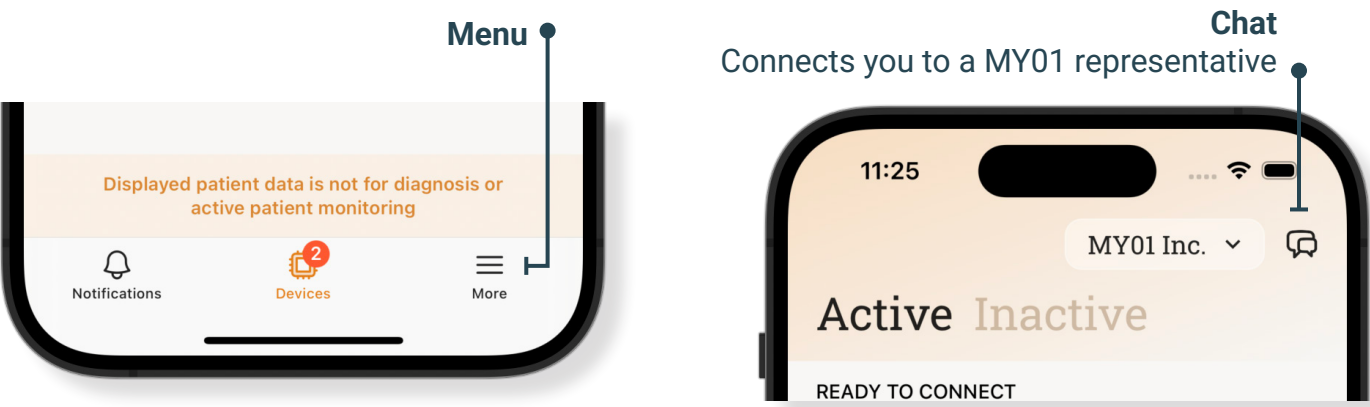
- 1 Open the MY01 Mobile Application.
- 2 Login using your credentials.
- 3 If you've forgotten your password, click on reset password and follow the on-screen instructions.

Application Interface

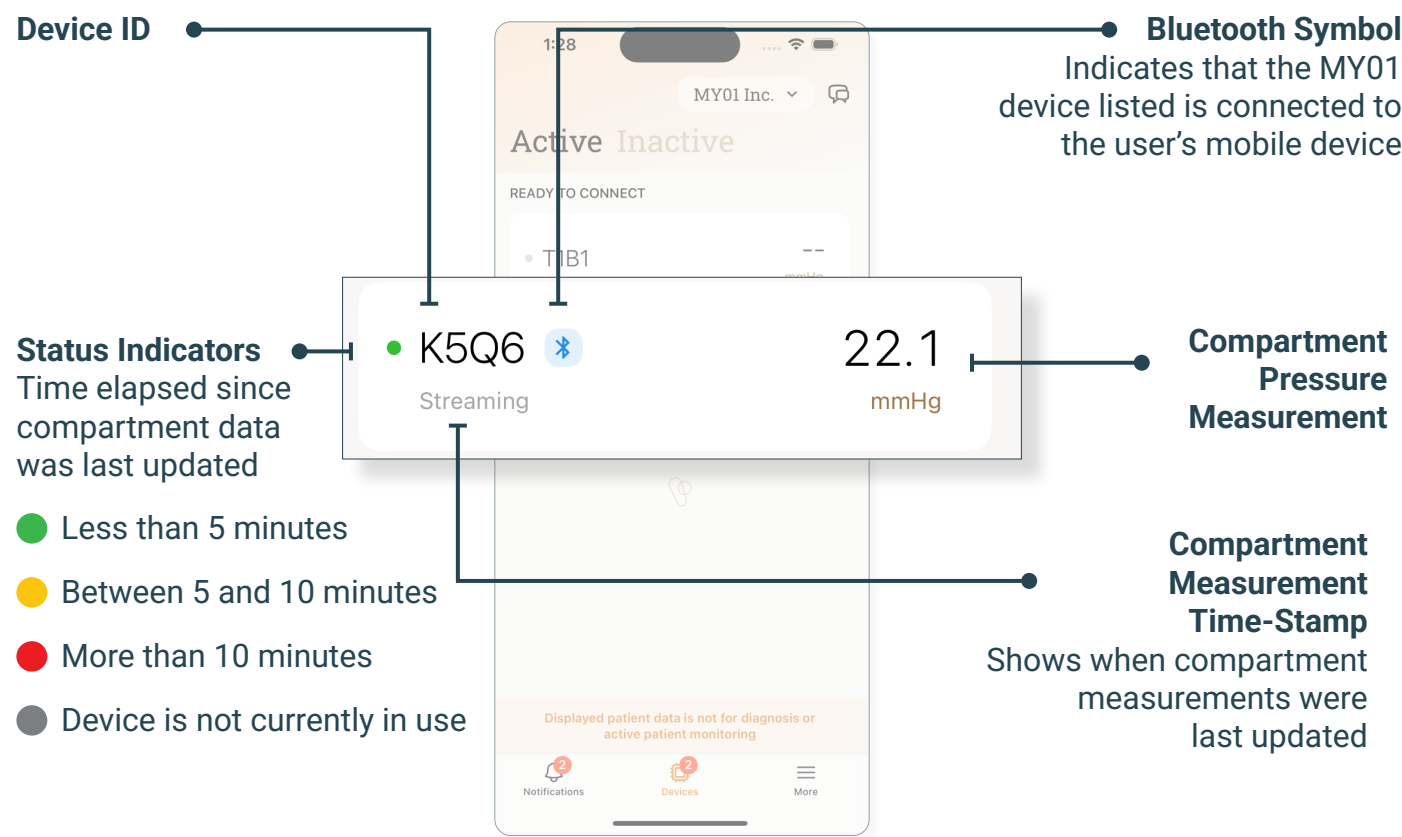
The first page the user sees when logged in to the mobile application is a list of active devices. To refresh the list of active devices, swipe down.



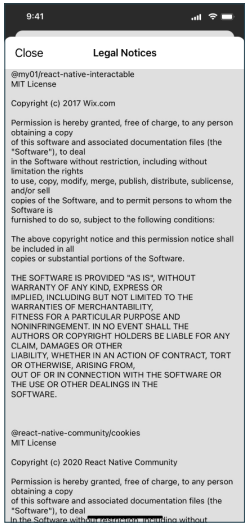
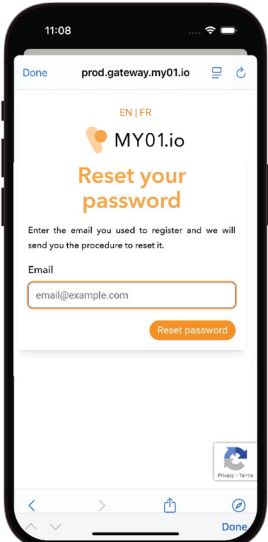
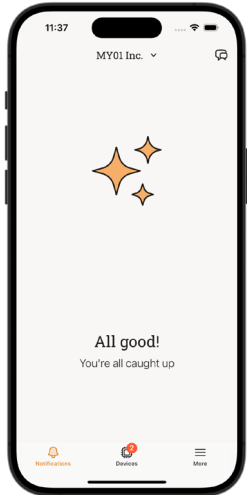
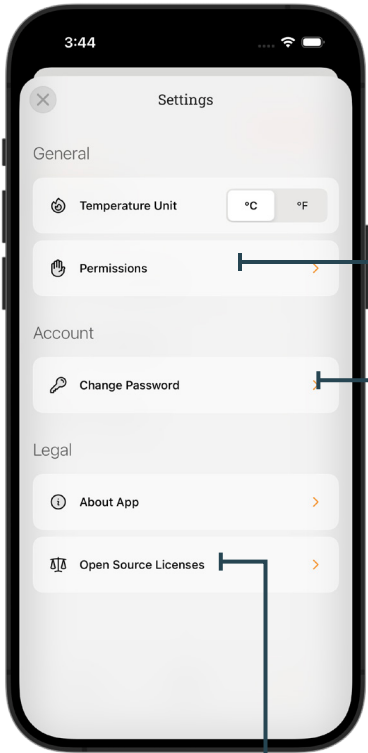
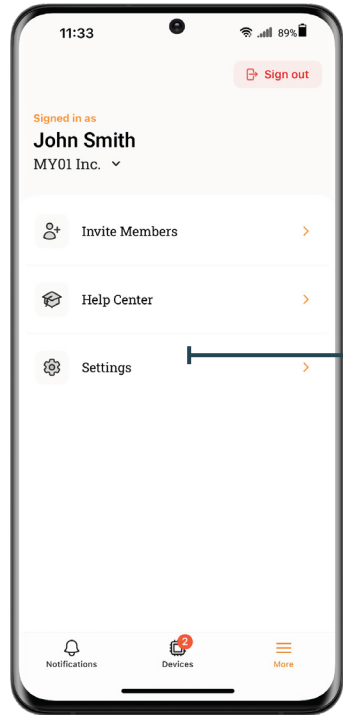
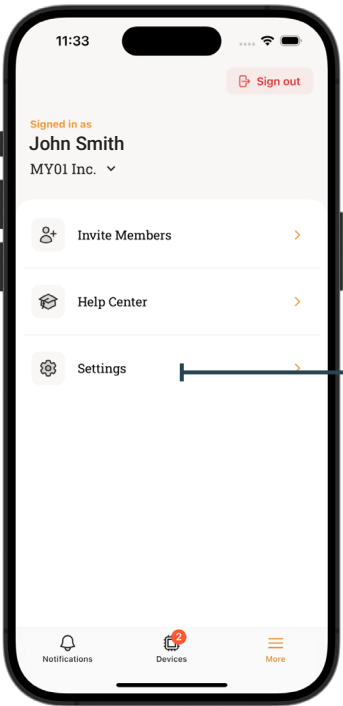
Application Interface (Continued...)



Active Device Information



Settings



Instructions

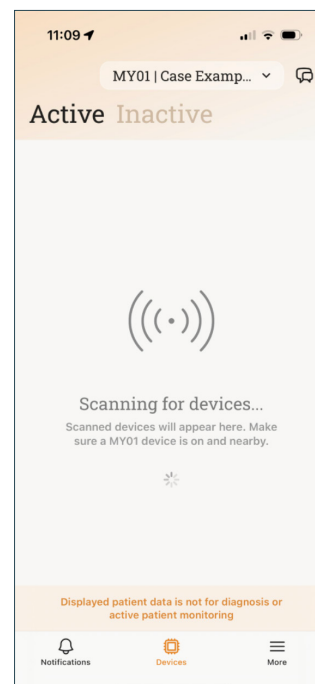
Connecting to the MY01 device

1

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.

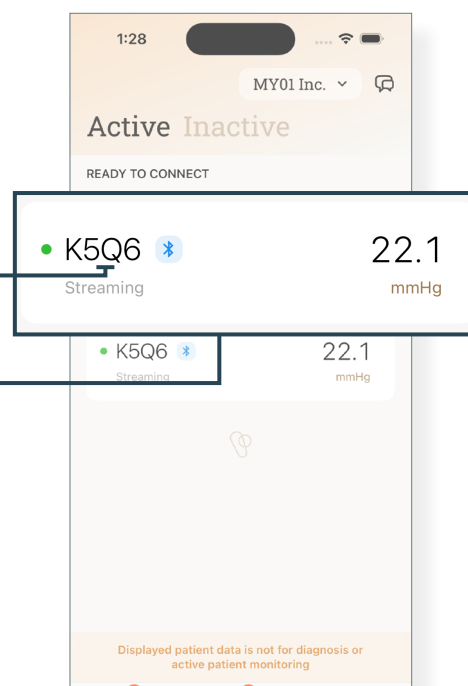


2

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

Unique MY01 Device Identifier

Nearby MY01 Device



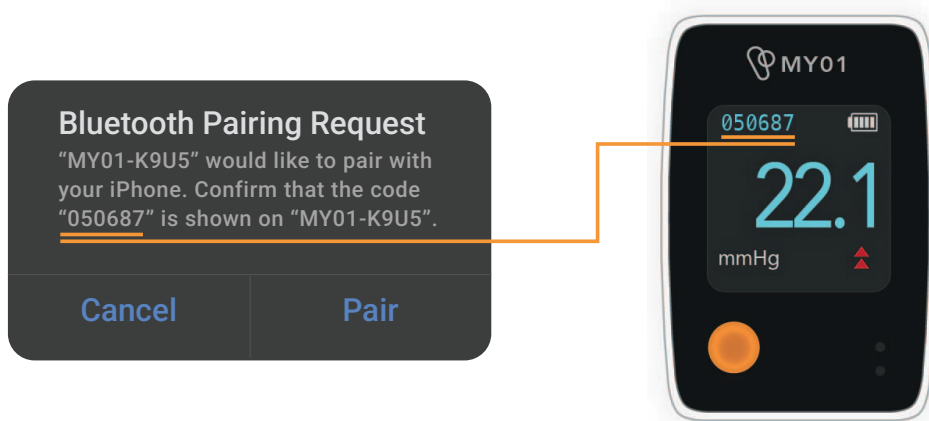
Notes:

Only one mobile device can be connected to a device at a time, via Bluetooth.

Connecting to the MY01 device (continued...)

3

Tap on a device identifier 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.



4

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



Notes:

If the application doesn't connect to the device, refer to the technical issues section for help.

Data Display

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



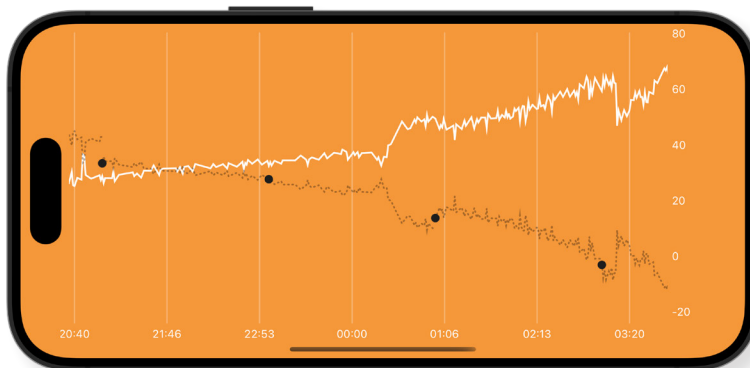
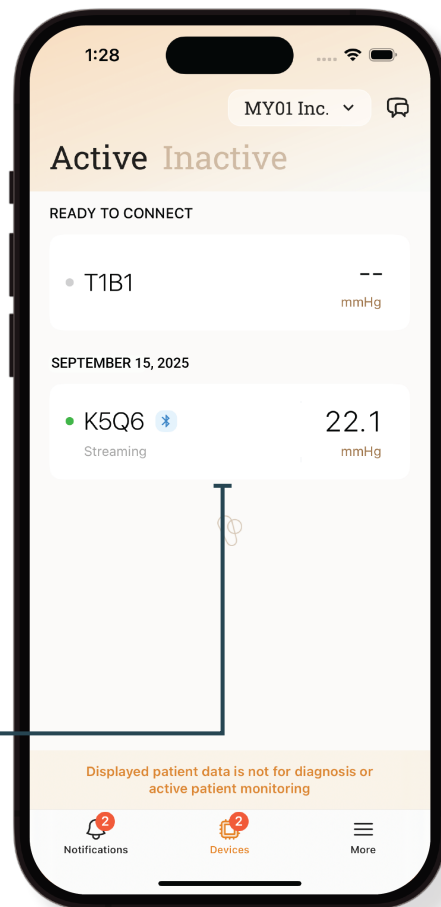
WARNING:

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.

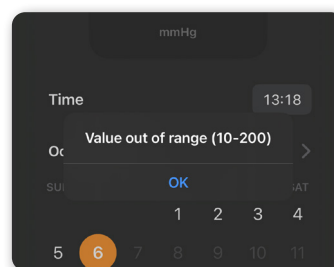


Diastolic Pressure Entry

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



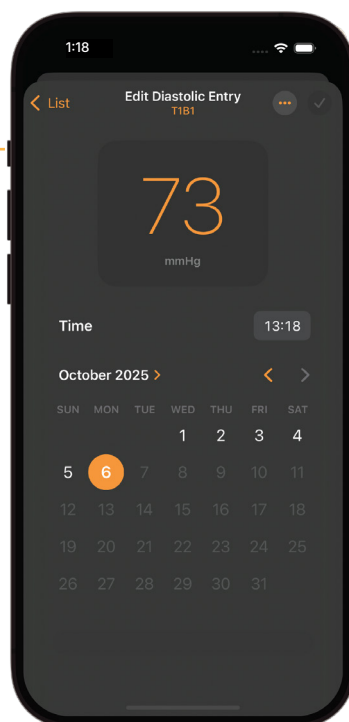
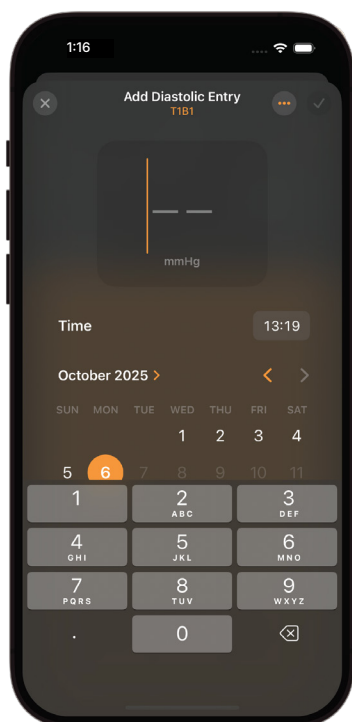
Physicians can manually input a patient's diastolic pressure in the mobile application within the range 10-200 mmHg.



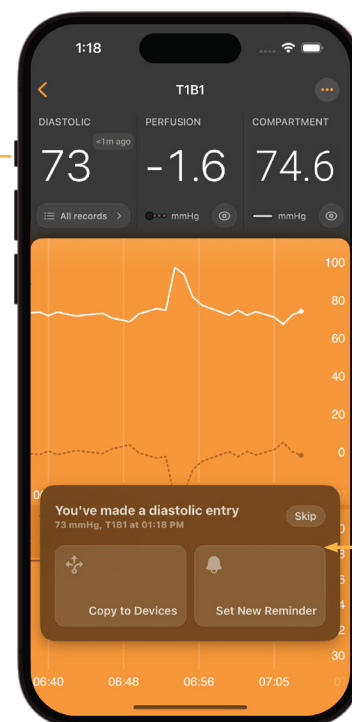
Notes:

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

- 2 Type in the **Diastolic Pressure**, select the **Date** and **Time**, then select the **checkmark**.

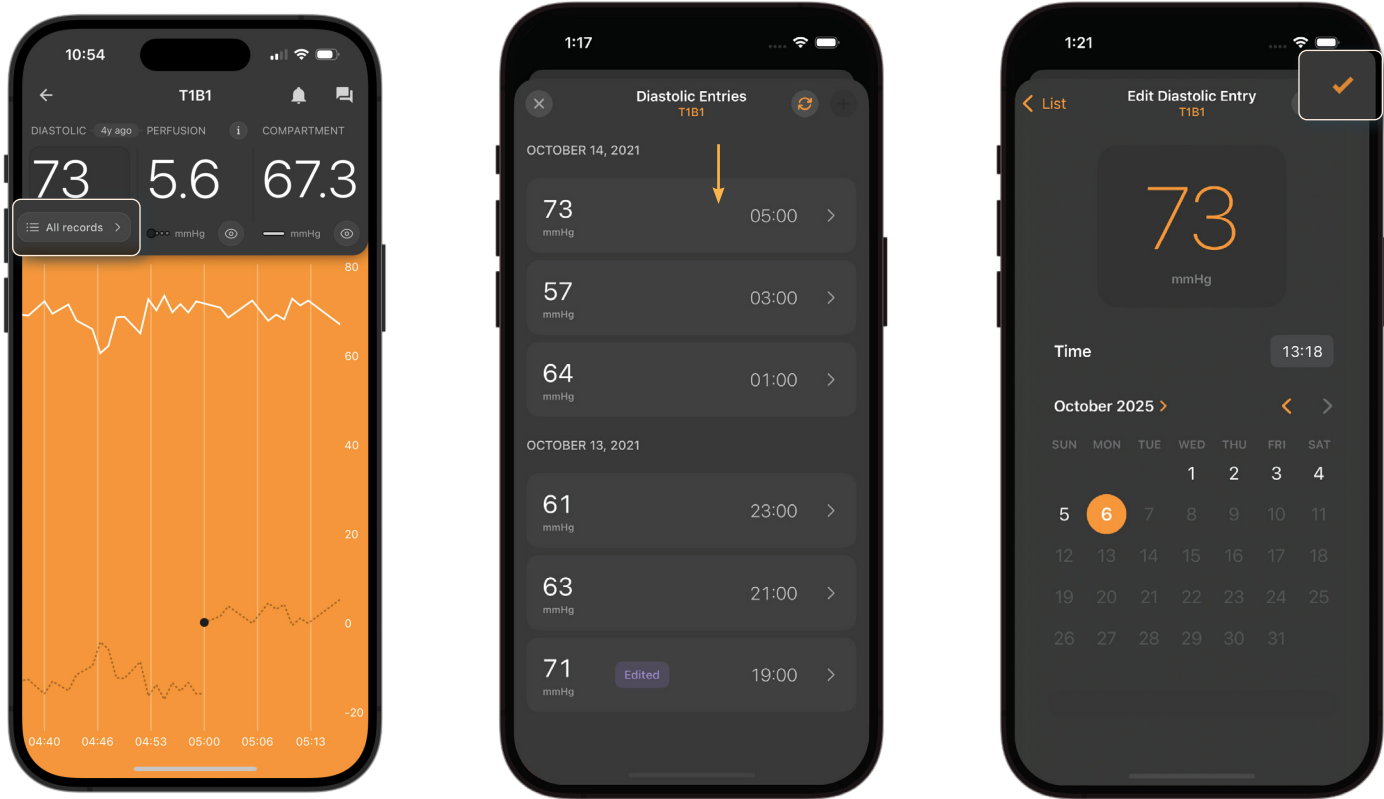


- 3 A message confirming the entry will pop up.



Diastolic Pressure Entry Editing

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



Click on **All Records**

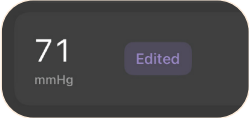
A **Diastolic Entries** list will pop up.
Click on a diastolic entry to edit it (i.e. 73 mmHg).

Select the checkmark on the top right of the screen.



Notes:

If a diastolic entry has already been edited, a pop up indicating “Edited” will appear next to the entry.



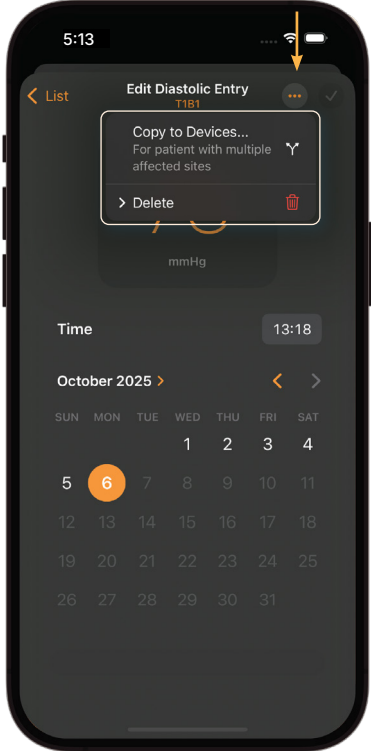
Copying Diastolic Pressure Across Multiple Devices

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

1.a

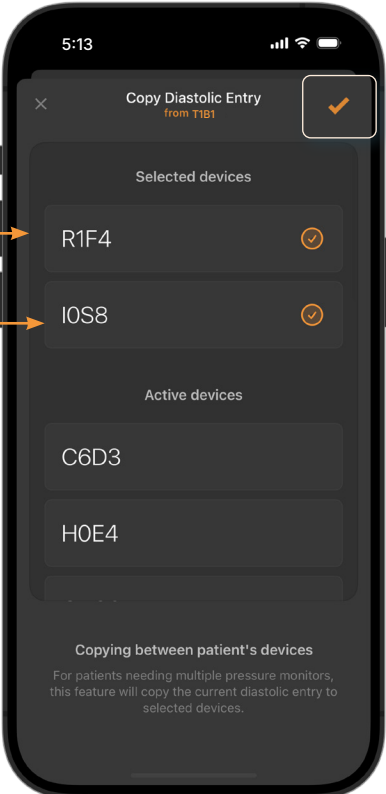


1.b



Press on the  icon from (1.a) or on the device menu of (1.b).

2



Select the devices to set a common diastolic pressure value

Select the checkmark

Diastolic Pressure Reminders

User can also set reminders to enter the diastolic pressure by tapping on the notification icon (1.a) or the menu (1.b). The app will send reminder notifications on the mobile device.



Notes:

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.

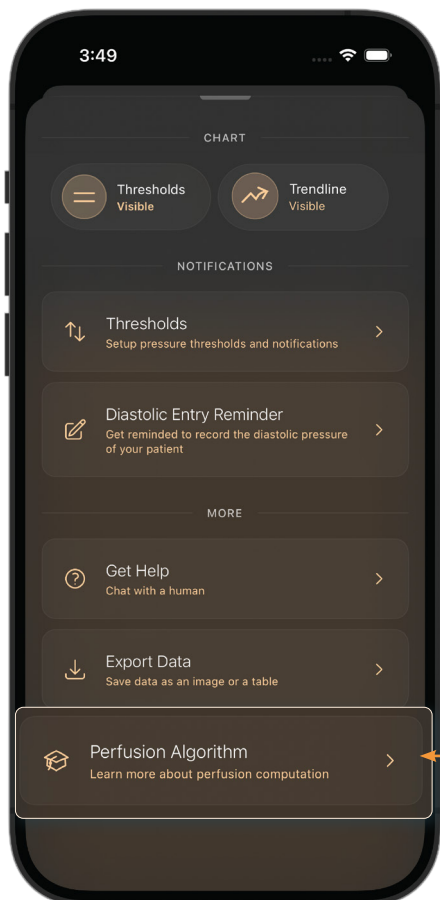


Formula:

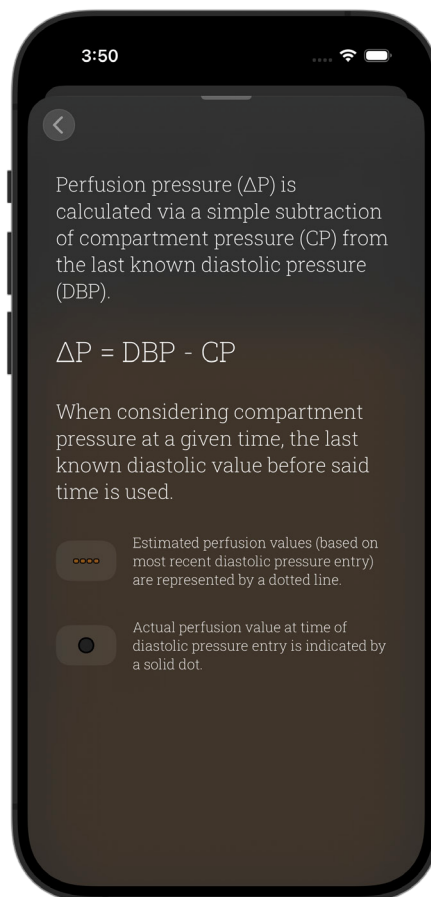
Perfusion Pressure = (diastolic pressure - muscle pressure)

1

Click on the three dots then on **Perfusion Algorithm**.



2



Threshold Notifications

Floor & Ceiling

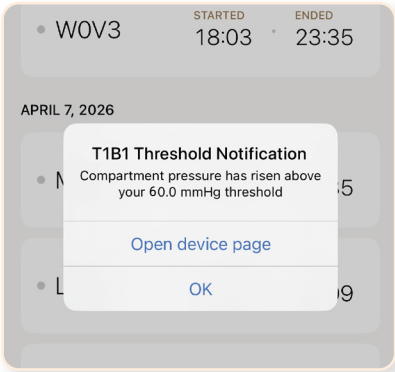
App users can set ceiling and floor threshold notifications via the device menu. Notifications will be sent and threshold lines will turn red when compartment pressure exceeds or falls below the defined limits.



Notes:

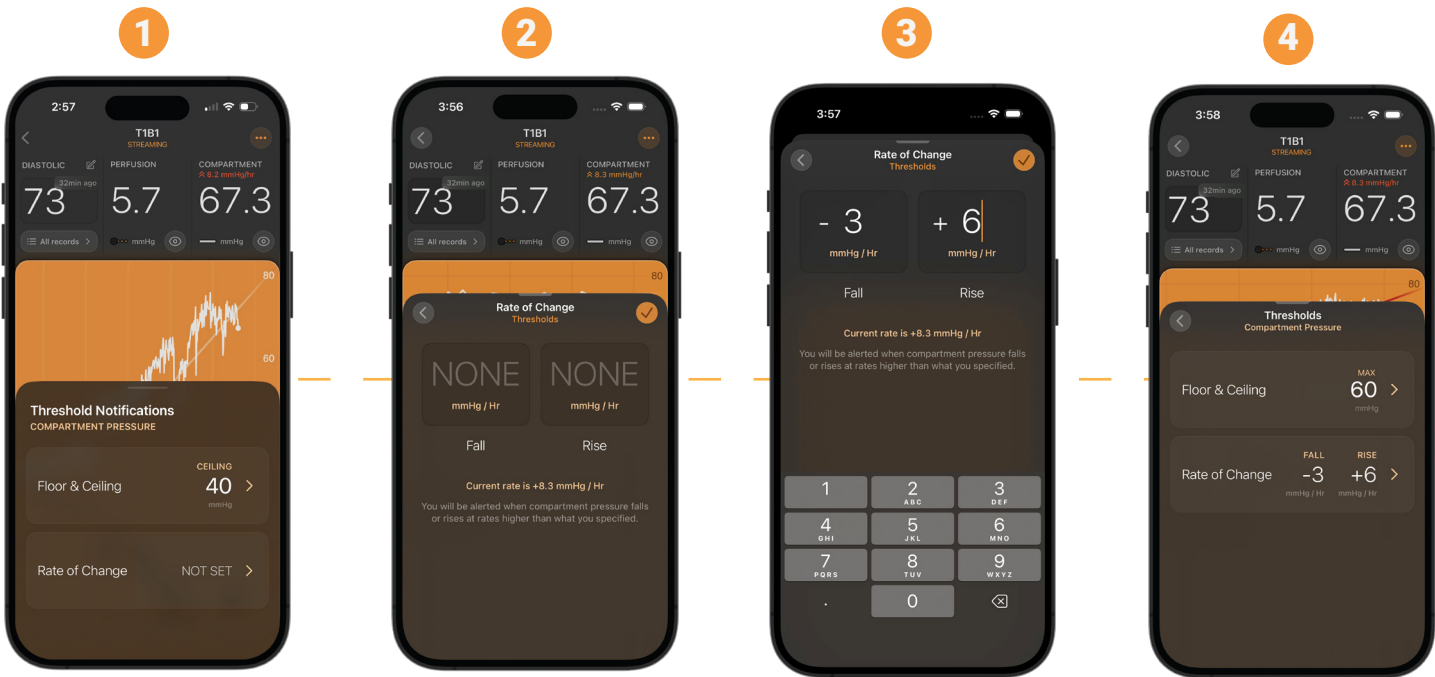
Threshold settings can be modified by any organization users.

In-app pop-up

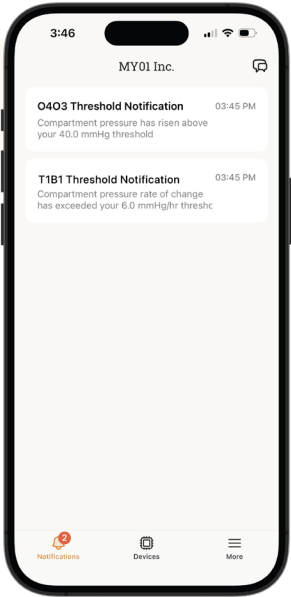


Rate of Change

Users can also configure rate of change thresholds to trigger notifications when pressure changes exceed specified rise or fall rates. The rate of change is derived from the slope of the trendline calculated over the last 30 minutes of compartment pressure data.



In-app notification tab



Mobile notification dropdown



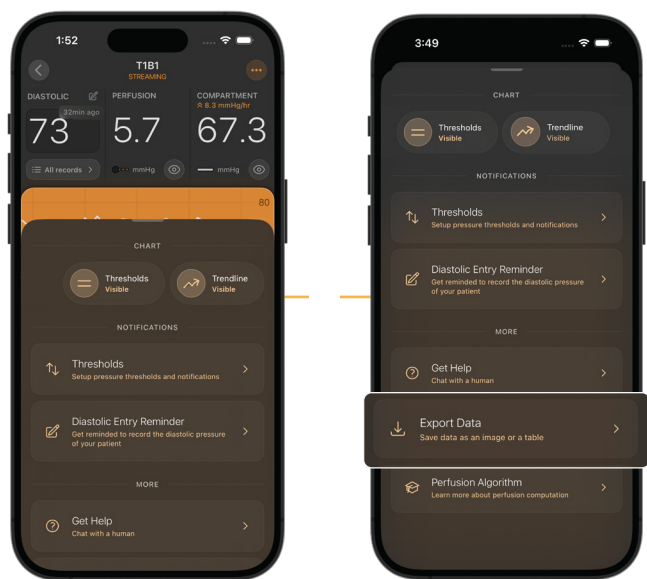
Notes:

Users who have been logged out of the application for more than 24 hours will not receive app notifications.

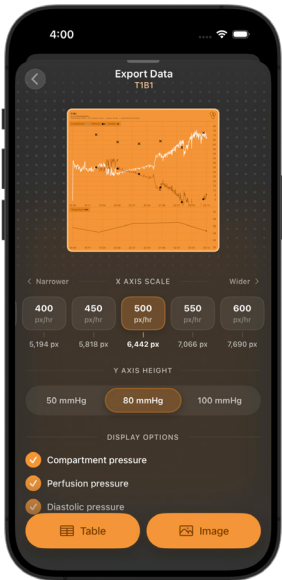
Data Export

The MY01 Mobile App allows you to save a case’s pressure and perfusion data as a chart image or a data table, right from your mobile device.

- 1
- Tap the “...” button next to the case name at the top of the screen then tap on **Export Data**.

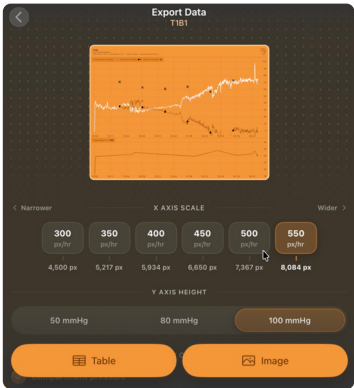


- 2
- Adjust the chart as you like and choose the device measurements you’d like included (*Compartment Pressure, Perfusion Pressure*)



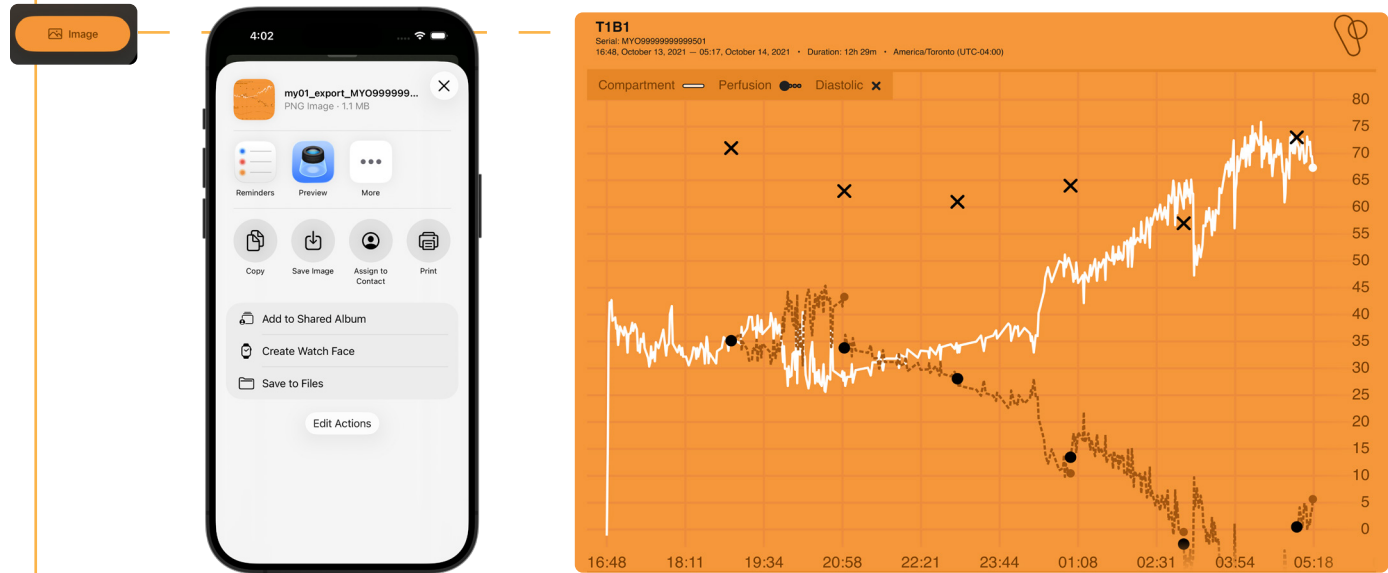
Notes:

- The X Axis scale makes the timeline wider or narrower.
- The Y Axis Height sets the pressure scale.



3.a

Image export saves a downloadable, .PNG version of the chart with the case details and legend in the header.



3.b

Table export saves the data as a spreadsheet (CSV) file, with both UTC and local timestamps plus a column for every selected measurement.

Diastolic pressure

Table

MY01_T1B1_2026-09-02_16...

Text Document - 38 KB

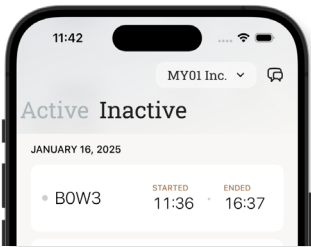
Reminders More

Copy Save to Files

timestamp_utc	timestamp_America/Toronto	compartment_mmhg	perfusion_mmhg	diastolic_mmhg
2021-10-13 23:00:00	2021-10-13 19:00:00	36	35	71
2021-10-13 23:01:00	2021-10-13 19:01:00	36	35	71
2021-10-13 23:02:00	2021-10-13 19:02:00	34.8	36.2	71
2021-10-13 23:03:00	2021-10-13 19:03:00	35.4	35.6	71
2021-10-13 23:04:00	2021-10-13 19:04:00	36	35	71
2021-10-13 23:05:00	2021-10-13 19:05:00	34.7	36.3	71
2021-10-13 23:06:00	2021-10-13 19:06:00	35.3	35.7	71
2021-10-13 23:07:00	2021-10-13 19:07:00	35.8	35.2	71
2021-10-13 23:08:00	2021-10-13 19:08:00	33.9	37.1	71
2021-10-13 23:09:00	2021-10-13 19:09:00	34.2	36.8	71
2021-10-13 23:10:00	2021-10-13 19:10:00	34.6	36.4	71
2021-10-13 23:11:00	2021-10-13 19:11:00	37.7	33.3	71
2021-10-13 23:12:00	2021-10-13 19:12:00	36	35	71
2021-10-13 23:13:00	2021-10-13 19:13:00	36.4	34.6	71

Notes:

- Data can be exported at any time during the monitoring period, even after the device has moved to the inactive tab.

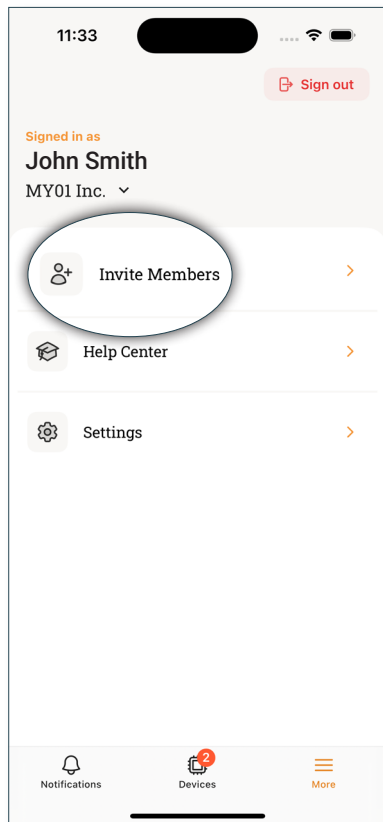


User-to-User Invite

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

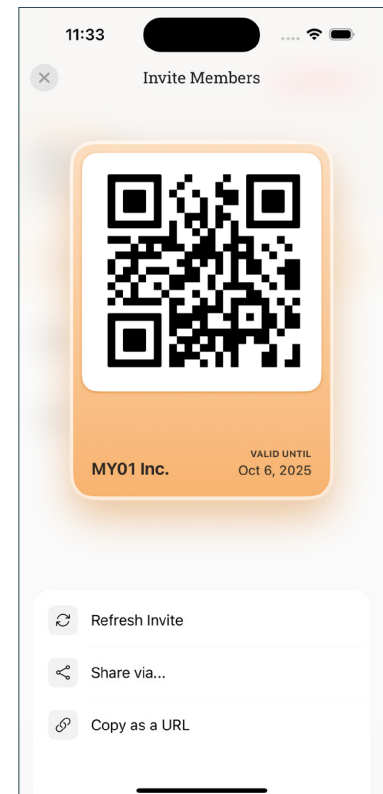
1

Go to the Menu and tap on “Invite Members”.



2

The new user can scan the generated QR code to join the 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.

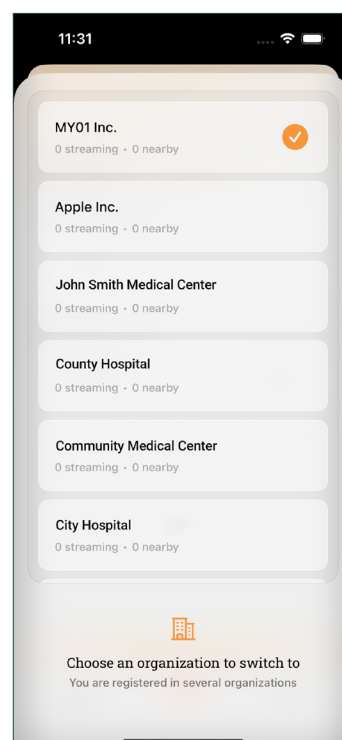
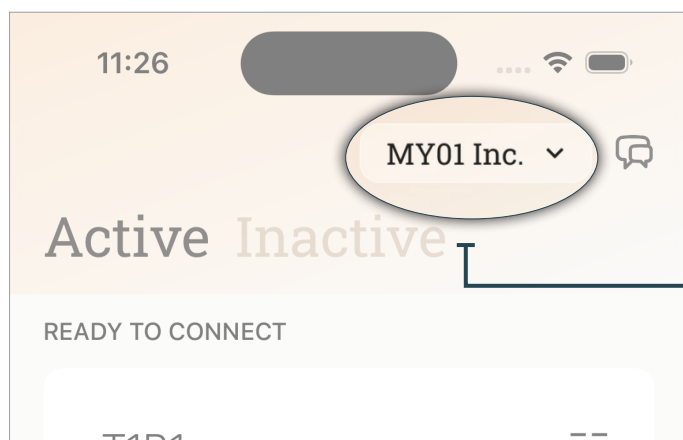
The organization's name is displayed at the bottom left corner of the QR code.

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.

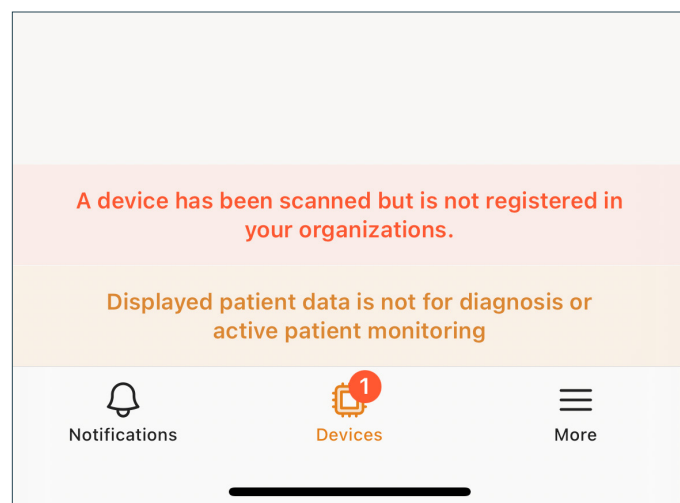
Notes:

The drop down arrow will only appear for users who are registered in more than one organization.



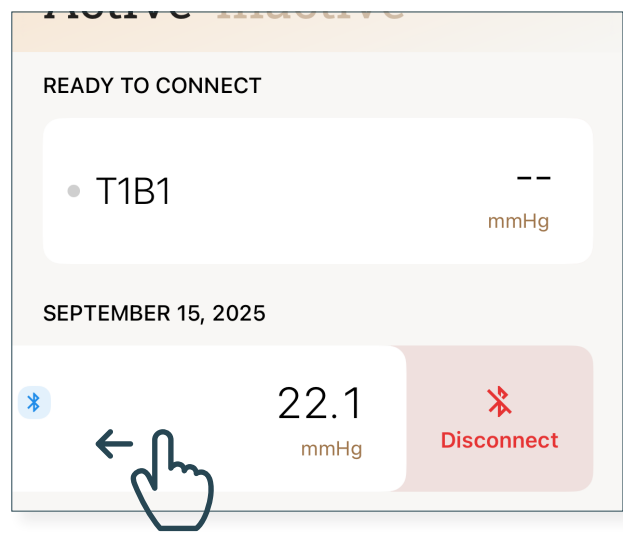
Notes:

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.



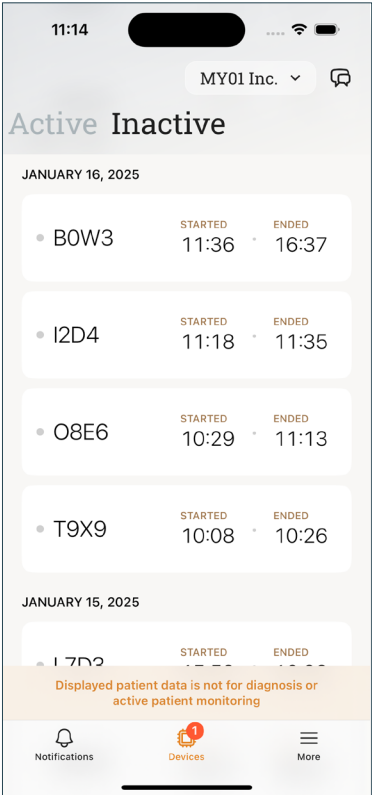
Disconnecting from a MY01 device

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.



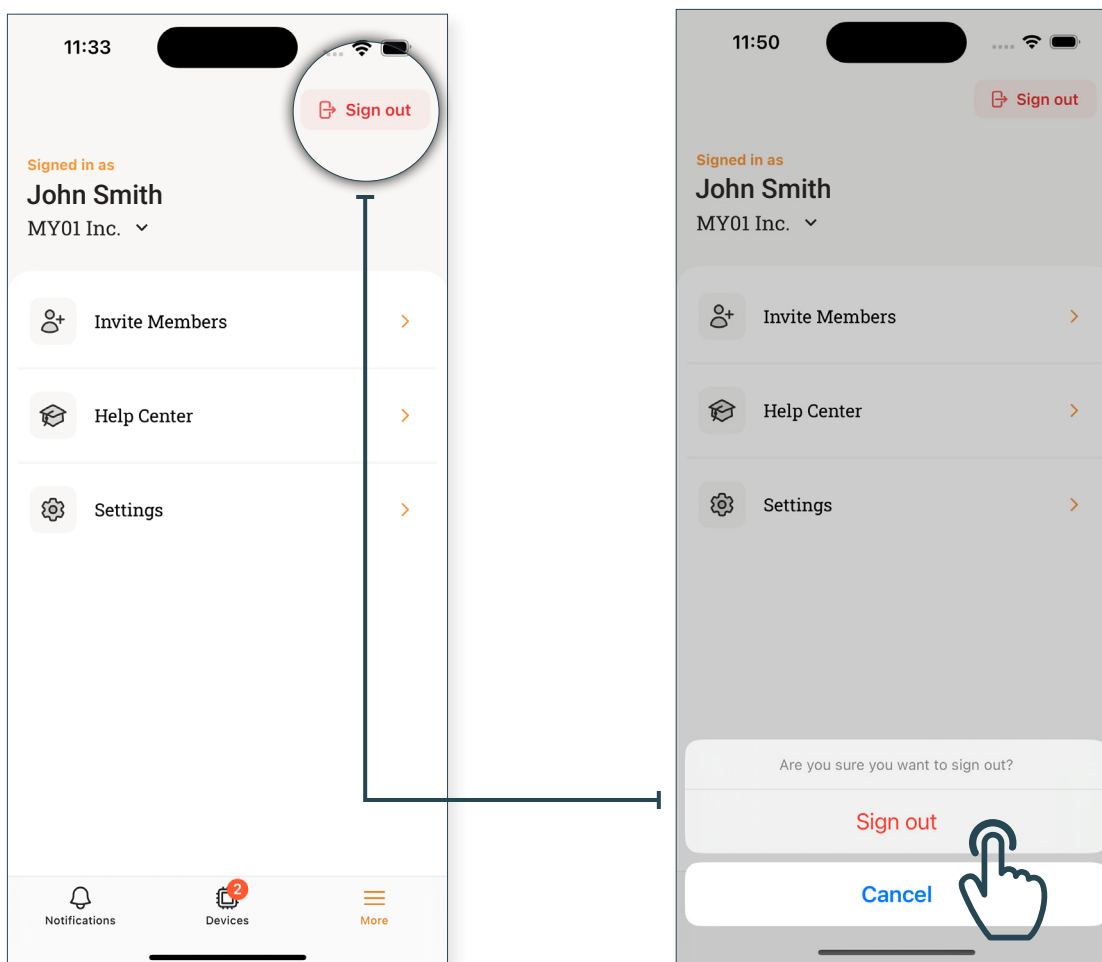
List of inactive devices

A list of the inactive devices that have been used in the past is shown, along with their start and end times, and their data can be viewed.



Logging out of the MY01 Mobile Application

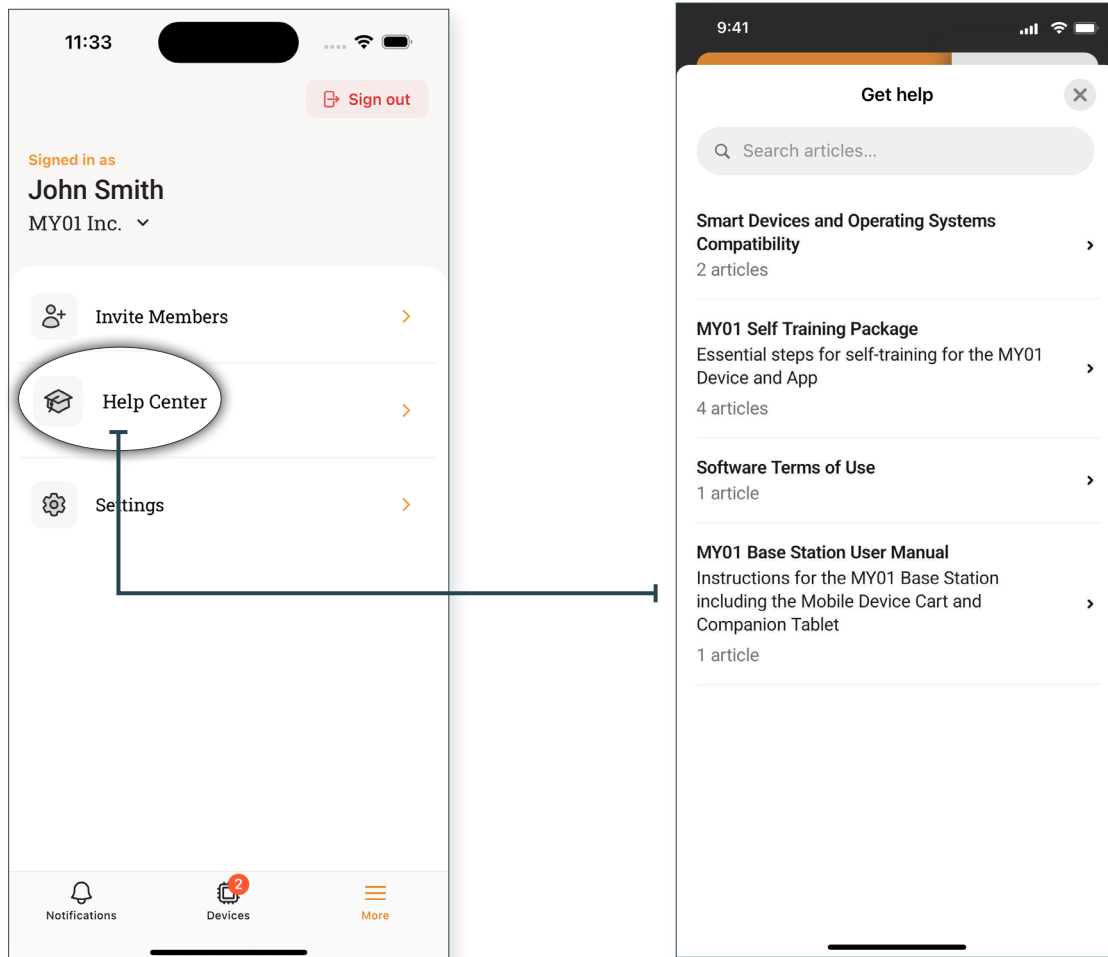
Once users have finished using the MY01 device, they can log out of the mobile application by tapping opening the “Menu” and clicking on “Sign Out”.



Help Center & Chat

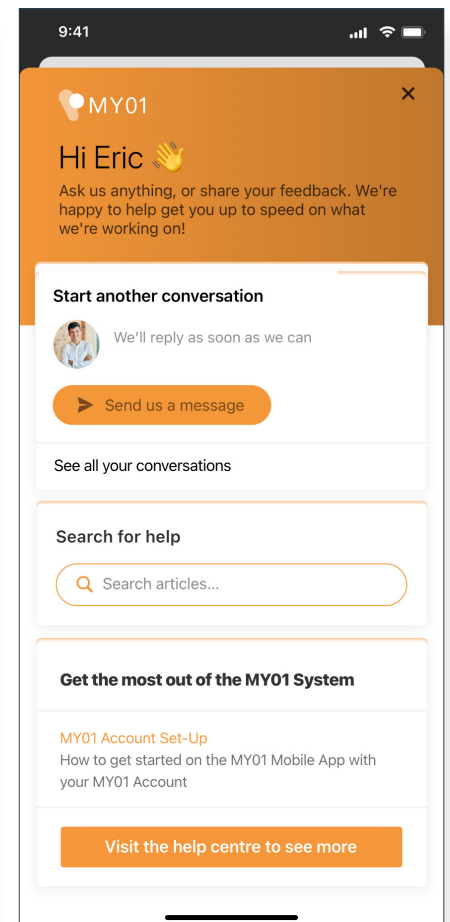
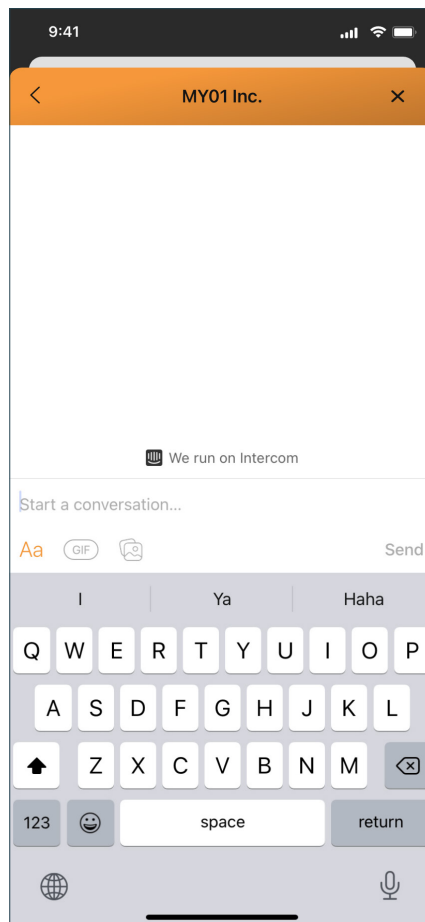
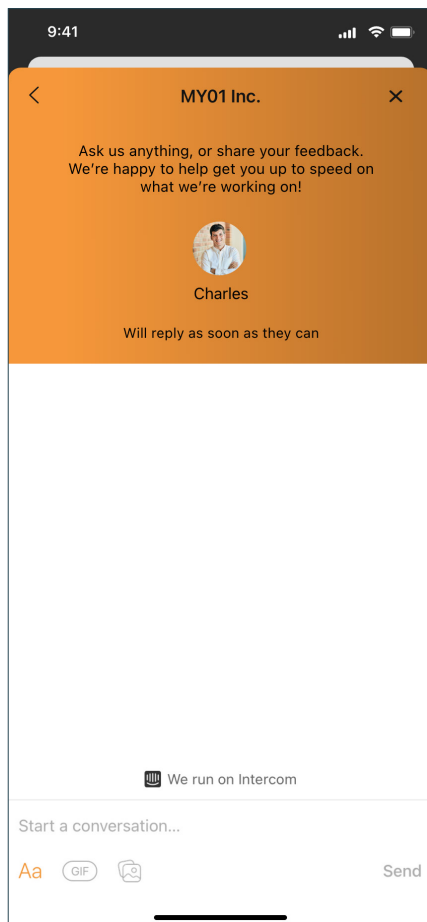
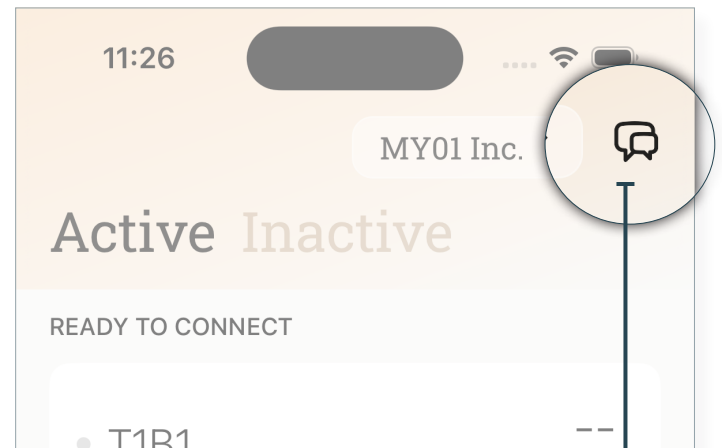
Help Center/ FAQs

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.



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.



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 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.

Application cannot connect to a device An error is displayed upon connection	• 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). • Open Bluetooth setting on your mobile device, click on the appropriate MY01 device ID, click "forget". • 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 more than 24 hours ago.	• 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. • 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 https://help.my01.io

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 https://gateway.my01.io/account/reset/request 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 calendar days of the request. If you want to request a paper copy of the IFU, please email info@MY01.io 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 info@MY01.io or call +1 (855) 799-6901.

For additional resources, visit help.my01.io 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.

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