



Instructions for use

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This manual applies to 901156 MOBILE MEDICAL SOFTWARE

HR CONNEX APP

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Introduction

Intended use

Modifications to Hillrom Connex App Intended use

(modifications are underlined)

The Hillrom[™] Connex[®] software is designed to collect, track, trend, and retrospectively transmit health information (e.g., blood pressure, SpO2, temperature, and pulse rate) from commercially available wireless FDA cleared medical in-home devices, and health and wellness devices, to an online (cloud) database. With user's consent, this information will be shared with a health care provider.

The Hillrom Connex software is not intended for use in the diagnosis, cure, treatment, or prevention of disease. It is not intended as a substitute for medical care by a health care provider. It is not intended for emergency use or real-time monitoring.

FDA guidance

The FDA issued Enforcement Policy for Non-Invasive Remote Monitoring Devices Used to Support Patient Monitoring During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency. During this emergency and while the policy is in effect, the FDA does not intend to object to limited modifications to indications, claims, functionality, hardware, or software of cleared noninvasive remote monitoring devices that are used to support patient monitoring without prior submission of a 510(K) where the modifications do not create an undue risk. Based on this guidance, Hillrom has released the Welch Allyn[®] Spot Vital Signs 4400 Extended Care for use in the home with Hillrom Connex software.

When the device is used in the home, it is not intended for use in the diagnosis, cure, treatment or prevention of disease on its own. It is not intended as a substitute for medical care by a healthcare provider. It is not intended for emergency use or realtime monitoring.

Purpose of this document

This manual helps you use the Hillrom Connex App to track and send readings to your health care provider.



NOTE If you haven't done so already, download the Hillrom Connex App from the App Store or Google Play Store.



NOTE Your health care provider must set up an account for you.

The manual covers the following topics:

- how to set up the Hillrom Connex App on your smartphone
- how to use the app
- how to fix or troubleshoot some common problems (see Troubleshooting)

This manual does not explain medical terms and concepts or mobile app terms and concepts.

Patient device requirements

The Hillrom Connex App runs on smartphone devices. Requirements follow.

iOS smartphone

- iOS 12+
- Bluetooth Low Energy (BLE) (standard for iOS 12+)
- Internet connection
- Email account

Android smartphone

- Android 7.0+
- Bluetooth Low Energy (BLE)
- Internet connection
- Email account

Patient data and security on your iPhone

Hillrom recommends enabling device-level security. Users are responsible for the security of the smartphone.

The Hillrom Connex App allows the home user to share patient data using cloud-based storage. When sharing patient data through cloud-based storage, users should only share the data with other authorized users in accordance with HIPAA regulations. It is the user's sole responsibility to protect patient data. Users must verify patient identity before storing or sending patient records.

When home users finish using the Hillrom Connex App to capture and send vitals, they should delete the Hillrom Connex App with all patient data from their smartphones.

Medical disclaimer

The Hillrom Connex App software simply transmits data. The content of the Hillrom Connex App, including text, images, user manuals, and other materials, is for informational purposes only. The app content is intended only for use by patients using the Hillrom Connex App and linked Hillrom devices. Hillrom does not make, advise, or influence treatment decisions.

Patients using the app and remote patient measurement devices agree to do the following:

always seek the advice of a physician or other qualified health provider with any questions regarding a medical condition

 never disregard or delay professional medical advice because of the Hillrom Connex App content and readings

What you should know before you start

This manual assumes that you already know how to perform these basic tasks:

- access the Internet through a wireless or cellular data connection
- locate and download apps from the smartphone App Store or Google Play Store
- open applications
- use the keypad to enter, edit, and save data
- use buttons/keys to select or activate controls
- send and receive emails
- navigate between multiple active applications
- pair phones via Bluetooth with other devices

Instructions in this manual build upon the skills demonstrated by your health care provider in the use of the Hillrom Connex App. However, if you need assistance with the setup or the Connex App, contact support at <u>https://www.welchallyn.com/en/other/contact-us.html</u>.

Disclaimer and limitation of liability

Disclaimer of actions caused by and/or under the control of third parties

Hillrom has no responsibility for the availability of the Internet and other telecommunication services necessary to access the Hillrom Extended Care Solution or for the functioning of the software.

Customer service

This document is a reference for understanding the Hillrom Connex App. When you encounter a difficulty, please use this manual first to answer your questions. If you continue to have difficulties, visit the Hillrom Technical Support website (<u>www.hillrom.com/en-us/about-us/locations/</u>) or contact your health care provider.

Symbols

Documentation symbols



WARNING The warning statements in this manual identify conditions or practices that could lead to illness, injury, or death.



CAUTION The caution statements in this manual identify conditions or practices that could result in damage to the equipment or other property, or loss of data.

Consult instructions for use.

Miscellaneous symbols

#	Product identifier		Manufacturer
GTIN	Global Trade Item Number	REF	Reorder number
*	Bluetooth	+	Add
\heartsuit	Pulse	Ø	Settings menu, Advanced menu
	Reminder	8	Account
() *	Followers		Devices
i	About	?	Help
<	Back	>	Move forward, Next
\checkmark	Data sync successful	!	Data sync unsuccessful
÷	Cancel (Android)		

About warnings and cautions

Warning and caution statements can appear on the product, the packaging, the shipping container, or in this document.

This product is safe for patients and clinicians when used in accordance with the instructions and with the warning and caution statements presented in this manual.

Before using the product, familiarize all operating personnel with the general safety information in this summary. Specific warnings and cautions are also found throughout this manual.



WARNING Failure to understand and observe any warning statement in this manual could lead to patient illness, injury, or death.



CAUTION Failure to understand and observe any caution statement in this manual could lead to damage to the equipment or other property, or loss of patient data.

Warnings and cautions



WARNING Patient harm risk. The Hillrom Connex App is not an emergency medical response application. The app does not provide alarms or real-time, critical-care monitoring of vital signs. All data that is transmitted with the app may be evaluated by your clinician at a later time.



WARNING Patient harm risk. The Hillrom Connex App should be used only by the patient for whom it is intended. Save only your own readings on your app. Saving readings that belong to someone else can cause inaccurate information to be sent to your clinician, which could lead to improper treatment.



WARNING Make sure that you read and understand all user documentation provided with your remote patient monitoring devices to ensure patient safety, accurate readings, and proper operation of all those devices.



CAUTION Use only Hillrom-authorized medical equipment with the Hillrom Connex App.



CAUTION To ensure the privacy of your medical information and to protect yourself against cyber threats, review and adjust the security settings on your phone.



CAUTION To ensure the privacy of your medical information, only send reports with your medical information to people you trust.

6 About warnings and cautions

Using the Hillrom Connex App

This section shows you how to use the app and covers the following topics:

Getting started

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- Download the application
- Accept the Terms and Conditions
- Change password

Working with readings

- Take vitals reading
 - Blood pressure
 - SpO2 (also detects pulse rate)
 - o Pulse rate
 - Temperature
 - Weight
- Save vitals reading
- Review readings
- Delete readings

Reminders and notifications

- Set a reminder
- Edit a reminder
- Delete a reminder

View Clinician followers

Account details

- View your profile
- Change your password
- Log out of the application
- Delete your account

Getting started

Launch the Hillrom Connex App for the first time



NOTE This instruction assumes that your health care provider's office has created an account for you. You will log in to your app for the first time with a temporary password. Check your email for a message from Hillrom Extended Care Solution for the temporary password. The App may only be used with an account set up by your health care provider.



NOTE Be sure to check your spam folder if the email doesn't arrive in your inbox.

- 1. If you have not installed the Hillrom Connex App, download and install it now from the App Store or Google Play Store.
- 2. Tap 2 on your smartphone to open the Hillrom Connex App.

The Hillrom Connex splash screen appears while the app loads. Then the Log in screen appears.



NOTE Images shown are for illustrative purposes. Your screen may look slightly different.

ŀ	Hillrom.
Email address	
name@dom	lin.com
Password	Forgot Password?

	LOGIN

3. Enter your email address and your temporary password.

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NOTE If you misplaced or don't have a temporary password, touch **Forgot password?** and follow the instructions to reset your password.

4. Touch Log in.

The Terms and conditions screen appears.

5. Read the Terms and conditions, and then touch **Agree** to proceed.

The Change password screen appears.

6. Enter a password that satisfies the rules listed on the screen, and write it down for future reference. Then re-enter the password and touch **Continue**.

Launch the Hillrom Connex App after account setup



NOTE This instruction assumes that your health care provider has already set up your account.

Tap 2 on your smartphone to open the Hillrom Connex App.

The *Hillrom Connex* screen appears while the app loads. The app remembers your username and password, so no additional login information is required. The *Home* screen then appears, allowing you to take **New Vitals** or review **Previous Vitals**.

Hillrom Connex	Ø
Welcome Catherine!	
NEW VITALS	
PREVIOUS VITALS	
PREVIOUS VITALS	>
PREVIOUS VITALS NIBP (Blood pressure) Pulse rate	>
PREVIOUS VITALS NIBP (Blood pressure) Pulse rate SpO2 (O2 saturation)	> > >
PREVIOUS VITALS NiBP (Blood pressure) Puise rate Sp02 (02 saturation) Temperature	> > > >

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NOTE If you misplaced your password, touch **Forgot password?** and follow the instructions to reset your password.

Working with readings

Take your vitals

- 1. Tap the **Hillrom Connex** App on your phone
- 2. Tap **New Vitals** to begin capturing your health information.

Hillrom Connex	¢
Welcome Catherine!	
NEW VITALS	
NEW VITALS	
NEW VITALS PREVIOUS VITALS NIBP (Blood pressure)	>
PREVIOUS VITALS NIBP (Blood pressure) Pulse rate	>
PREVIOUS VITALS PREVIOUS VITALS NIBP (Blood pressure) Pulse rate Sp02 (02 saturation)	>
NEW VITALS PREVIOUS VITALS NIBP (Blood pressure) Pulse rate Sp02 (02 saturation) Temperature	> > > >



NOTE The Hillrom Connex App must be open to successfully capture from the Welch Allyn Spot Vital Signs 4400 Extended Care.



NOTE Your phone must have an internet connection to transmit your vitals to your health care provider.

3. If Bluetooth is not enabled on the smartphone, a message appears to turn on Bluetooth. Follow the prompts to turn on Bluetooth.



NOTE If this is the first time the App and the Welch Allyn Spot Vital Signs 4400 Extended Care are connecting, pairing is initiated when vitals are captured.

a. For first-time pairing with an iOS smartphone, tap **Pair** on the smartrphone *Pairing request* message.



Tap **OK** on the device to pair it with the smartphone.



b. For first-time pairing with an Android smartphone, tap **OK** on the device.

	PULSE RATE	
9	Do you want to pair with your mobile device?	
	OK Cancel	
	Adult Clear	

Tap **OK** on the smartphone to clear the *Pairing successful* message.



4. Tap **OK** to clear the *Pairing successful* message on the device.



- 5. Capture NIBP/Blood pressure.
 - a. Put the blood pressure cuff on your bare upper arm. (If you have a cuff already wrapped and sized for your arm, just slide it onto your arm and skip to step f.)
 - b. Place the artery marker (1) over your brachial artery.



- c. Apply the cuff snugly, allowing room for no more than two fingers underneath.
- d. Fasten the cuff, leaving the hose port (2) poking through the window (3).
- e. Attach the blood pressure hose by pinching the connector sides and snapping it into the port.



- f. Sit quietly for a few minutes.
- g. Make sure your back and feet are supported and keep your legs uncrossed.
- h. Keep your upper arm at heart level with the lower arm supported, i.e., resting on a table.
- i. Keep your arm still during the measurement cycle.
- j. On the Welch Allyn Spot Vital Signs 4400 Extended Care, tap either **Start** or **Start**

Average , as directed by your health care provider.

Once the blood pressure cuff has deflated, the capture is complete.

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NOTE If your health care provider has directed you to take an average blood pressure reading, wait until the averaging process is complete before continuing to the next step.

- 6. Capture SpO2/Saturation and pulse rate.
 - a. Clean the application site (ring finger, middle finger, or index finger of the opposite arm from where you placed the blood pressure cuff) for the SpO2 sensor. Remove anything, such as nail polish, that could interfere with sensor operation.
 - b. Put the SpO2 sensor on your finger, aligning your fingernail with the graphic on the top of the sensor.



- c. Keep your arm at heart level.
- d. Once the SpO2 reading is achieved on the Welch Allyn Spot Vital Signs 4400 Extended Care, remove the SpO2 clip from your finger.
- 7. Capture temperature.



CAUTION Temperatures should not be taken within 20 minutes of strenuous exercise, ingesting hot or cold liquids, eating, chewing gum or mints, brushing teeth, or smoking.

- a. Remove the temperature probe from the probe well.
- b. The device sounds a tone as it enters the ready state.
- c. Insert the probe into a new probe cover and press the probe handle down firmly.
- d. For an oral temperature, hold the probe tip in place under your tongue as shown below.



e. For an axillary temperature, hold your arm up and place the probe tip as high as possible in your armpit. Hold your arm snugly at your side while taking your temperature.



- f. Hold the probe tip in place at the measurement site.
- g. The device sounds a tone when the final temperature is obtained (in approximately 6 to 15 seconds).
- h. Remove the probe and firmly press the eject button on the top of the probe to release the probe cover.
- i. Dispose of the probe cover properly.
- j. Return the probe to the probe well.
- 8. Enter weight
 - a. Measure your weight with your scale.
 - b. On the Hillrom Connex App, tap **New Vitals**.
 - c. Tap the Weight field.
 - d. Use the pop-up number pad to enter your weight.
 - e. To continue on iOS, tap **Done** on the number pad. To continue on Android, tap **Next** or the arrow button on the number pad.
- 9. On your phone, tap **Save** to transmit your vitals to your health care provider.



10. Review the data sync message.

Hillrom Connex	{)
Welcome Catherine!		
Data sync in process		
NEW VITALS		
PREVIOUS VITALS		
PREVIOUS VITALS NIBP (Blood pressure)	>	
PREVIOUS VITALS NIBP (Blood pressure) Pulse rate	> >	
PREVIOUS VITALS NIBP (Blood pressure) Pulse rate Sp02 (02 saturation)	> > >	
PREVIOUS VITALS NIBP (Blood pressure) Pulse rate Sp02 (02 saturation) Temperature	> > > >	

A "Data sync successful" message appears.

Hillrom Connex	
Welcome Catherine!	
Data sync successful	
NEW VITALS	
PREVIOUS VITALS	
PREVIOUS VITALS NIBP (Blood pressure)	;
PREVIOUS VITALS NIBP (Blood pressure) Pulse rate	3
PREVIOUS VITALS NIBP (Blood pressure) Pulse rate SpO2 (O2 saturation)	3
PREVIOUS VITALS NIBP (Blood pressure) Pulse rate Sp02 (02 saturation) Temperature	

If the data sync is unsuccessful, a "Data not sent" message appears. Pull down the screen to refresh. If the issue persists, visit the help screens or the *Troubleshooting* section.

Hillrom Connex	٥
Welcome Catherine!	
Data not sent. Pull down the screen to refresh if issues persist, visit the help screen	Is.
NEW VITALS	
PREVIOUS VITALS	
PREVIOUS VITALS NIBP (Blood pressure)	>
PREVIOUS VITALS NIBP (Blood pressure) Pulse rate	>
PREVIOUS VITALS NIBP (Blood pressure) Pulse rate SpO2 (O2 saturation)	> > >
PREVIOUS VITALS NIBP (Blood pressure) Pulse rate Sp02 (02 saturation) Temperature	> > > >

Review vitals

You can review your previous vitals (Blood pressure, Pulse rate, SpO2, Temperature, or Weight) and the last time your vitals data was sent to your healthcare provider.

- 1. Tap the **Hillrom Connex** App on your phone 🕋
- 2. Tap any of the previous vital measurements to display them by date and timestamp.



3. On the *Home* screen, tap

The Settings screen appears.

- 4. Tap your name in the header.
- 5. View the date and time of the **Last sync** to see the last time your vitals data was sent to your healthcare provider.

Delete vitals

You do not need to delete any vitals, but you can if you wish. Deleting a vitals record will be reflected in your patient record in the Hillrom Connex Portal and it will be hidden from your health care provider.

- 1. Tap the **Hillrom Connex** App on your smartphone
- 2. Tap a previous vitals measurement.
- 3. On iOS, swipe the vitals record you want to delete. On Android, long press the vitals record you want to delete.
- 4. Tap the **Delete** button.

Reminders

Set a reminder

You can set reminders to take your vital measurements on your app. The reminders appear as notifications on your phone.



NOTE If notifications from the Hillrom Connex App are disabled, the app displays an "Allow notifications" message. You must give permission for the app to send you notifications before you can set reminders. Follow the prompts on your phone to go to *Settings* and then unblock or allow notifications.

1. Open the **Hillrom Connex** App 🕋

If you are already logged in, the Home screen appears.

2. On the Home screen of the app, tap

The Settings screen appears.

3. Tap Reminders.

The Reminders screen appears. ("No reminders set" appears if you haven't set any reminders.)

<	Reminders	+
lse remino linician's i	ders to take your readings nstructions.	according to your
Take you	r vitals readings	4:00 PM

4. Tap the + on the top right of the screen.

The Reminder screen appears.

- 5. Tap the *Time* field and follow the prompts to set the reminder time.
- 6. Tap **Save** to save the reminder or **Cancel** to reject it.

Edit a reminder

1. Open the **Hillrom Connex** App

If you are already logged in, the Home screen appears.

2. On the Home screen of the app, tap

The Settings screen appears.

3. Tap **Reminders**.

The Reminder screen appears.

- 4. Tap the reminder that you want to edit. The *Reminder* screen appears.
- 5. Tap the **Time** field and follow the prompts to set the reminder time. See *Set a reminder*.
- 6. Tap **Save** to save the reminder or **Cancel** to reject it.

The *Reminders* screen appears with updated reminders.

Delete a reminder

1. Open the **Hillrom Connex** App 🕋.

If you are already logged in, the Home screen appears.

2. On the Home screen of the app, tap 🙆

The Settings screen appears.

3. Tap Reminders

4. On iOS, tap and swipe left on the reminder you want to delete. On Android, long press on the reminder you want to delete.

A Delete or Remove button appears onscreen.

5. In iOS, tap **Delete**. In Android, tap **Remove**.

The reminder disappears from the *Reminders* screen.

Clinician followers

Followers

Health care providers can view your data in the Hillrom Extended Care Solution's Clinician Portal.

1. Open the **Hillrom Connex** App 🕋.

If you are already logged in, the Home screen appears.

2. On the Home screen of the app, touch

The Settings screen appears.

3. Tap Followers.

Health care providers who are following your account to keep track of your vital readings are displayed in a read-only list.

Account details

View your profile

You can view your profile in the app after initial setup.

1. Open the **Hillrom Connex** App

If you are already logged in, the Home screen appears.

- 2. On the Home screen of the app, touch Omega. The Settings screen appears.
- 3. To view your profile, touch your name in the header.

The Profile screen appears with your profile information in a read-only format.

Change your password

1. Open the **Hillrom Connex** App

If you are already logged in, the Home screen appears.

2. Touch 🙆

The Settings screen appears with current app information.

3. Touch your name in the header.

The Profile screen appears.

4. Touch Change password.

The Change password screen appears.

5. Enter a password that satisfies the rules listed on the screen, and write it down for future reference. Then re-enter the password and touch **Save**.

The Profile screen appears. You have successfully changed your password.

Log out of the application

You can log out of the app. To resume using the app, you will have to log in with your password.

1. Open the **Hillrom Connex** App 🕋.

If you are already logged in, the Home screen appears.

2. Touch 🙆

The Settings screen appears with current app information and options.

3. Touch your name in the header.

The Profile screen appears.

4. Touch Log out.

The *Log out* confirmation dialog appears with a description of what happens when you log out.

5. Touch **OK** to log out or **Cancel** to stay logged in.

The Log in screen appears if you touch OK. You have successfully logged out.



NOTE Enter your password on the *Log in* screen to log into the app once again.

Delete your account

If you decide to exit Hillrom Extended Care Solution, you can delete your account. Once you delete your account, your vitals data will remain stored in the cloud database for 90 days. You will no longer be able to login or access your account but, during that retention period, your health care provider can view your vitals data. After 90 days the data is deleted.

1. Open the Hillrom Connex App 🕋

If you are already logged in, the *Home* screen appears.

2. On the Home screen of the app, touch

The Settings screen appears.

3. Touch your name in the header.

The Profile screen appears.

4. Touch **Delete account**.

The *Delete account* confirmation dialog appears with a description of what happens when you delete your account.



NOTE Deleting your account removes all saved readings.

5. Touch **OK** to delete your account or **Cancel** to keep it active.

The *Log in* screen appears, but you can no longer log in if your account was successfully deleted. If you cancelled, your account remains active.

Troubleshooting

lssue	Possible cause	Suggested action
Bluetooth device successfully connected. 074030	Bluetooth connected	No action required.
Bluetooth device disconnected. 74040	Bluetooth not connected	Attempt to re-establish Bluetooth connection.
l cannot pair the Welch Allyn Spot Vital Signs 4400 Extended	Bluetooth is not active on the smartphone	Open Bluetooth settings on the smartphone and turn on Bluetooth.
Care ("device") with my smartphone OR A "Connection failed" message appears	You tried to pair the device with your smartphone using the smartphone's Bluetooth settings	Once the smartphone's Bluetooth is turned on, pair the device and the smartphone using the Hillrom Connex App. When you open the app and press New Vitals , you are prompted to pair the device. Follow the prompts to complete the pairing.
when I try to pair	The device is too far away from your smartphone	Move the smartphone closer to the device. The smartphone should be no more than 5 feet away from the device.
	The initial Bluetooth pairing is no longer functioning	Delete the device from the Hillrom Connex App. Re- pair the device with your smartphone.
		Delete the pairing to the device from the smartphone settings. Re-pair the device using the Hillrom Connex App.
	The Bluetooth dongle is loose	Unplug the Bluetooth dongle in the back of the device and plug it back in. Delete the pairing to the device from the smartphone settings. Re-pair the device with your smartphone.
l forgot my password	Varies	Tap Forgot password? on the <i>Log in</i> screen. Follow the instructions to reset your password.
OR Login failed		
l did not receive a password reset email	Your email address is not established in the Hillrom Connex system	Make sure that the email address used to request the password reset is the same as the address used to sign up for the Hillrom Connex App. You might need to confirm your email address with your health care provider.

capture readings from the device.

lssue	Possible cause	Suggested action
	A different or incorrect email address was used to sign you up	NOTE If the wrong email address was used to sign you up, your health care provider will have to sign you up again. No patient email addresses can be edited in the Hillrom Connex system.
	The email went to spam instead of your inbox	Check your spam folder for the email.
The Hillrom Connex App collected the readings but did not send them to my health care provider	The smartphone's WiFi connection is out of range or failed transmission	Refer to the smartphone manual. Set your smartphone to the correct transmission mode.
	The smartphone is out of cellular range or failed transmission	Refer to the smartphone manual. Relocate the smartphone. If it is out of WiFi range, switch to cellular.
	The cellular connection has been turned off on the smartphone	Refer to the smartphone manual. Relocate the smartphone. If it is out of cellular range, switch to WiFi.
	The Hillrom Connex App was closed before the data was sent	Make sure the smartphone is connected to either a WiFi or a cellular connection and open the Hillrom Connex App.
How do I know my data is going to my healthcare provider?	Varies	In the Hillrom Connex App, go to Settings > Account , and look at the Last Sync time and date. If it is old, make sure the smartphone is connected to either a WiFi or a cellular connection and open the Hillrom Connex App.
		Force a sync using the pull-to-refresh method on your smartphone's screen.
l'm not sure my readings were saved	Varies	In the Hillrom Connex App, select one of the <i>Previous Vitals</i> options and check the date and time of the readings.
My Hillrom Connex App is not working properly	The smartphone or app is in a bad state	Close and reopen the Hillrom Connex App.
		Refer to the smartphone manual. Restart the smartphone.
		Uninstall and re-install the Hillrom Connex App, following your smartphone's manual.
No data transferred from the device to the Hillrom Connex App	Bluetooth for the device is not properly turned on, connected, or programmed	Make sure Bluetooth pairing is properly set up.
		Open the Hillrom Connex App before taking vitals readings.
		NOTE The Hillrom Connex App must be open to successfully

lssue	Possible cause	Suggested action
Unexpected operation or events	Varies	In the Connex App, go to Settings > Help . If the Help does not answer your questions, contact Hillrom Technical Support.
The device or Connex App malfunctions		

24 Troubleshooting

Appendix

Terms and conditions

HILLROM™ CONNEX® MOBILE SOFTWARE APPLICATION TERMS OF USE

DATED MAY 1, 2020

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