

User Manual for spencer™

(insert copyright materials)

DRAFT

This device is pending compliance with Part 15 of the FCC Rules and with Industry Canada licence-exempt RSS standard(s). Operation is subject to the following three conditions: (1) this device may not cause harmful interference, (2) this device must accept any interference received, including interference that may cause undesired operation, and (3) Changes or modifications made to this equipment not expressly approved by HAP Innovations, LLC may void the FCC authorization to operate this equipment.

Le présent appareil est conforme aux CNR d'Industrie Canada applicables aux appareils radio exempts de licence. L'exploitation est autorisée aux trois 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. (3) Les changements ou modifications apportées à cet équipement non expressément approuvée par HAP Innovations, LLC peuvent annuler l'autorisation FCC d'utiliser cet équipement.

This device has a single port, a USB port, in the back, adjacent to where the power cord is attached. The spencer device does not come with any accessories that can be connected. However, it will have Bluetooth functionality.

The device has a rechargeable battery that is not removable. If the battery is in use due to no electrical power, the system continues to dispense medication until the battery charge is exhausted. Since the battery is not removable, there are no user instructions for maintenance, other than to check the battery periodically to ensure it is working. In case of an extended emergency that causes the battery charge to run out, the lid to the device opens automatically, enabling the end user to remove necessary medications.

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Getting Started

Overview of spencer

An in-home medication dispenser, spencer is a new way to connect you with your pharmacist and care teams to help you stay on track with your medication and health goals. It makes taking multiple medications simple.

A working health hub, spencer records your adherence to your medication regimen and provides this information to your caregiver and pharmacist. Spencer also enables you and your pharmacist to communicate about your health. The pharmacist can leave reminders, and you can let the pharmacist know your progress or concerns.

Important safety information

- Place spencer in an indoor living area, on a hard, dry, flat surface.
- Do not place spencer on a radiator or other heated surface.
- Do not plug spencer into an electrical outlet that is controlled by a wall switch, as someone could accidentally switch off the power.
- To reduce the risk of electrical shock or fire, do not place spencer in or near water or other liquids.
- Do not spray cleaners directly onto spencer because moisture could get inside and cause damage. Wipe with a dry or slightly damp cloth; do not use harsh cleaners.
- spencer has a rechargeable battery that is not removable. If the battery is in use due to no electrical power, the system continues to dispense medication until the battery charge is exhausted.

A green light in the top right corner of the front face flashes to indicate that battery power is on.



Support

When spencer directs you to call your pharmacist for medication-related questions or issues, the pharmacy number is provided on spencer's screen. Touch **Settings & Help > Contact Pharmacist**.

For help with the device itself, call the HAP Innovations support number: xxx-xxx-xxxx.

Features

Need pictures here. Check what is available in this release.

Feature	Description
Refills containing medication pouches	Spoiled specifically for you by your pharmacist Easy to load into spencer
Usability	Large, easy-to-read font; clear, to-the-point instructions; colors that indicate certain statuses
Design	Sleek design that fits on countertop
Dispense reminders	- Alert tone with adjustable volume; sound intensifies for missed dose - Flashing light that increases in frequency

Feature	Description
	for missed dose Change in screen color from blue (normal) to amber (late) to red (missed).
Secure data storage for each user ¹	Records of your spencer transactions and communications with care team and pharmacy; these are encrypted so that they are secure and only visible to designated individuals.
Training Videos	Short videos explaining how to use spencer. Touching Settings & Help > Video Tutorials displays a list of the different videos. (See “Video Tutorials” section.)
Meds to Go	Option that lets you dispense medications for specific dates and times that you are going to be away from spencer.
Child Lock	Option to lock the system for anyone who does not know the personal identification number (PIN) or password. You set the password.

¹ **Note:** Your personal information is put into code form (“encrypted”) to limit who can see it. The information is protected and adheres to the Federal Health Insurance Portability and Accountability Act (HIPAA).

Prerequisites

Signing up on the HAP Web site (onboarding).

Obtaining spencer and refill(s).

Training

spencer terms/components

Component	Description
Barcodes	Small box-shaped patterns of varying black lines that can be read by a computer. Individual pill pouches and refill covers have barcodes to identify end user and medication specifics.
Brake	Small metal wire in the lower right of refill that holds the strip in place when needed.
Cloud	When the end user is onboarded, the relevant identifying and medical information is encrypted and sent to the Cloud, where it will be stored securely and accessed only according to HIPAA specifications. The Cloud in turn sends the necessary information for pouches and refill barcodes to be generated for the end user.

Component	Description
Dispense Index	The sequential position of each pouch within a single dispense window. For example, 1 of 3, 2 of 3, 3 of 3, 1 of 1, etc..
End User	For the purpose of this document, the person registered to receive medications from the spencer dispensing device.
HIPAA	Health Insurance Portability and Accountability Act; Federal law requiring security and privacy for an individual's health information.
Lid	Door-like panel at the top of the spencer device that opens and closes for inserting, securing, and removing the refill.
Menu	List of options on the touch screen. Examples are Meds to Go and Settings & Help .
Mouth	The slot (located beneath the touch screens for both spencer and the spooler) where the pouches are delivered to the end user.
Pouch	Plastic package containing pills and identifying information as produced by the packaging system.
Parata Adherence Strip System (PASS)/ Strip Packager	A type of pill-packaging device that fills pouches with the end user's individual doses of medications; also sends clinical data for the end user and medications to the HAP Cloud.
Portal	Web pages containing essential information about spencer's end users, each user's transactions within spencer, pharmacies in the spencer network, etc; the information is subject to HIPAA privacy specifications.
Pouch/Package	Plastic package containing medications and identifying information as produced by a strip packaging system.
Refill	The device on which the medication pouches are spooled. This device fits inside a cover, which in turn fits inside spencer.
Refill Cover	HAP Innovations design for the spooler's housing. The cover is made of cardboard, so it is lightweight and easy to assemble, carry, and insert into spencer. A barcode on the exterior of the cover contains the essential identifying information for the end user and end user's medications.
Spooler	Tool (separate from spencer) that winds the strip, validates strip information, and prints labels.
Strip	Series of pill pouches attached from end to end and

Component	Description
	used for spooling in the spencer Refill.
Touch Screen	Front display panel that enables you to interact with spencer by touching with your finger. (Touch screens are also used on cell phones and computer tablets.)

Screens and Navigation

Touch Screen

The spencer Touch Screen guides you through the dispensing process and enables you to take action by touching certain buttons on the screen. For example, touching **Dispense** with your finger tells spencer you are ready to receive your current medications. Touching **Help** displays a Help menu with instructions on how to use spencer and answers to frequently asked questions (FAQs).

If spencer goes to sleep (menu items are not available), just touch the screen to wake spencer and display the home screen.

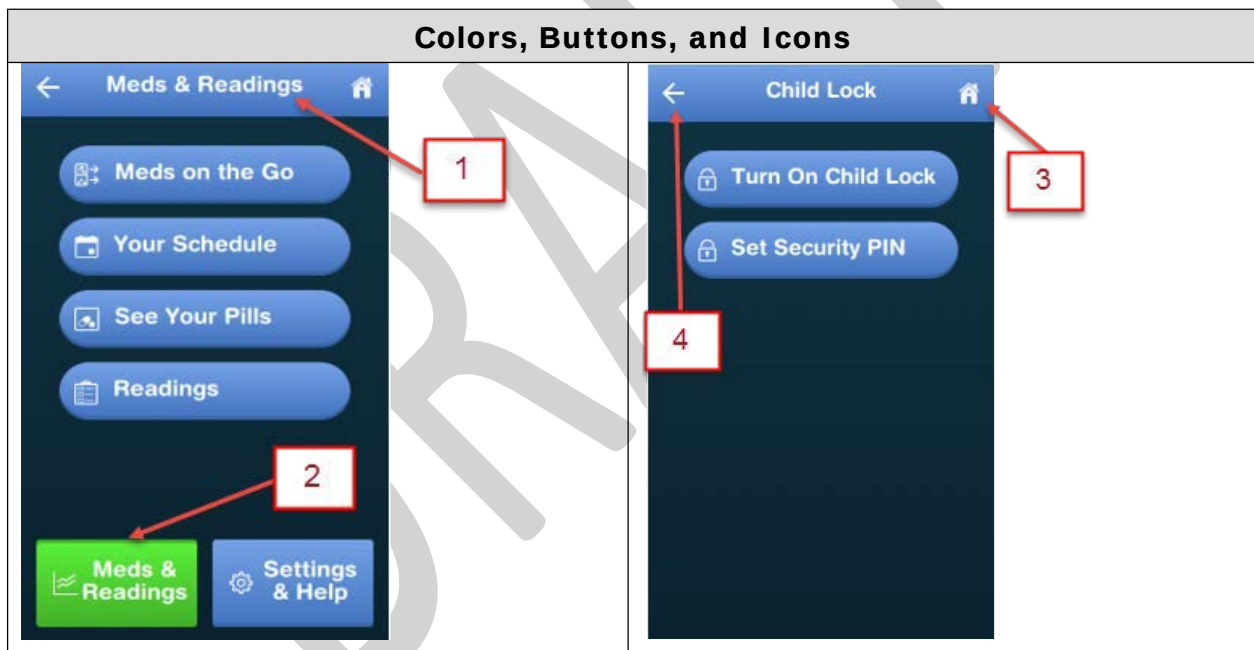
Spencer rotates through various screen savers when it is in idle state. (Give example.)

Navigation

Number	Description	Function
nn	Home screen	Displays the date, time, and Main menus (Meds & Readings and Settings & Help). Additionally, - With no refill inserted, says "Ready for Refill" - With refill inserted, shows time of next dose,
1	Box or label at top of screen	Shows the screen you are currently on
2	Green button	Indicates that the named screen is currently active
3	House icon	Takes you to the Home screen
4	Back arrow	Takes you to the previous screen
15	Grey button	Is not active (function cannot be performed until another one is complete)
10	Blue button	Is active (enables you to perform the named function when you touch it)

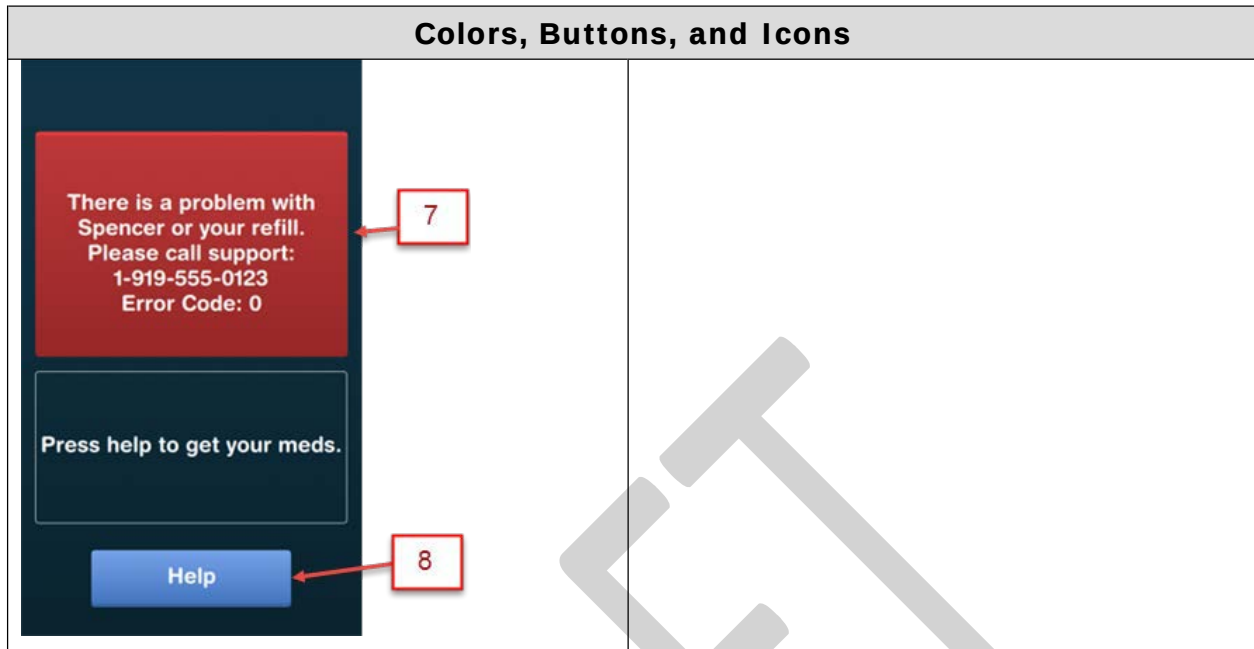
Number	Description	Function
5	Blue normal-dispense screen	Reminds you to take meds during normal dispense time
5	Amber warning screen	Warns you that your dispense time is almost past
6	Red missed-meds screen	Warns that you have missed your medications
7	Sample error screen	Tells you of system error and provides some means of help
8	Help button	Opens screen that explains how to get your medications or otherwise correct an error

Need new screens and new numbering.



Colors, Buttons, and Icons





Note: Error Messages are explained in the Error messages section of this manual.

To see “wrong user” Errors – wrong user (pouch and barcode don’t match – or just say no when asked

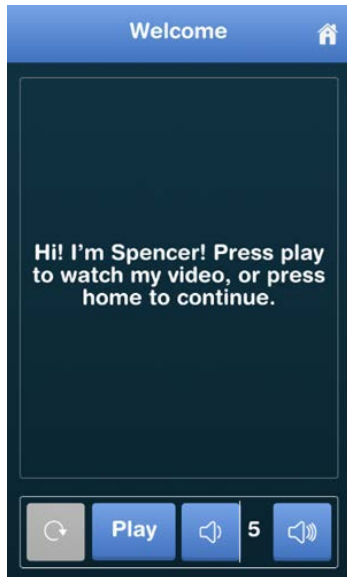
How does a user shut spencer down if something is going wrong?

Setting Up

1. Take spencer out of the carrying case.
2. Set it on a flat, dry surface.
3. Plug it in.

It automatically powers on. (Do not turn on using the power button.) An internal cellular module automatically connects spencer to a cellular network.

The Welcome screen is displayed, giving you the option to watch a tutorial video or go to the Home screen.



4. To watch the instructional video, touch **Play**. See the “Video Tutorial^s” section.



5. To go to the home screen, touch the Home icon. See or go to ?xxxxx. Does this take you home of to the Hi, I'm Spencer. I'm here to help



Loading the Refill

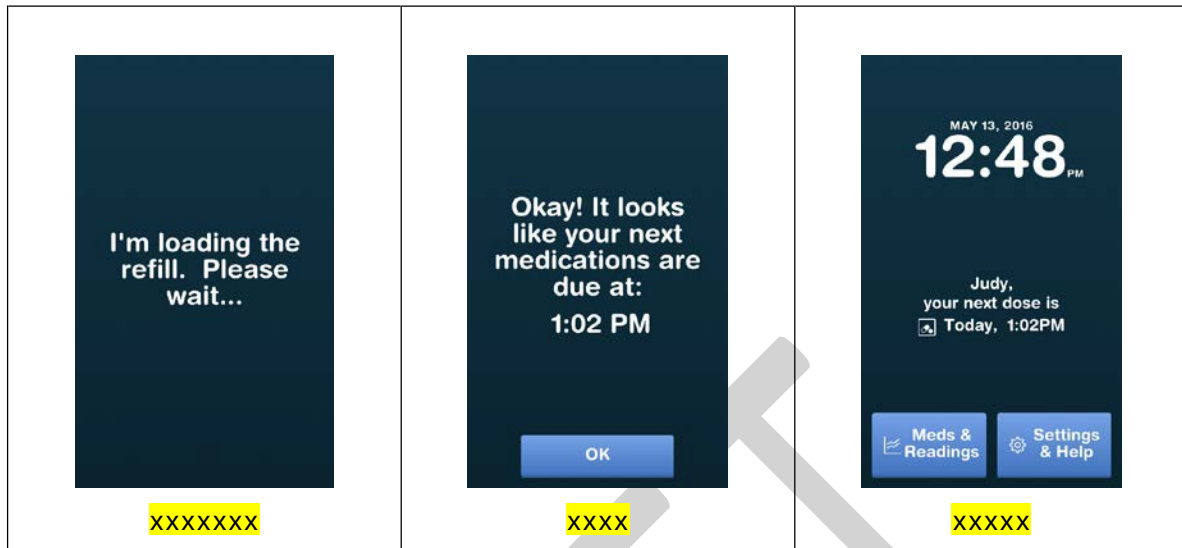
1. Align the front of the refill with the front of spencer. (The barcode and mouth are on the front at the bottom. Also, check for the blue arrows.)
2. Insert the refill into spencer, ensuring it is seated securely.
3. Gently close the lid until it “catches” and finishes closing itself.

A spencer greeting is displayed.

- This section totally is guess work and needs attention. If this is the first time you have used spencer: Message?? User confirmation?

 Should be lower case Spencer xxxxxxxx	 xxxx	 xxxxxx
 xxxx	xxxxxx	

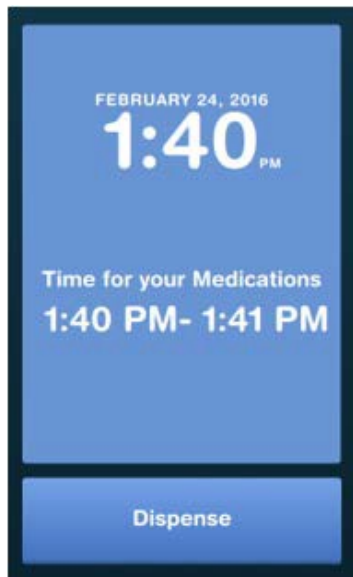
- If this is for a new refill but you have used spencer before: Message??
- If this is to re-start a refill that was interrupted for some reason: Message??



Dispensing Your Medications (Meds)

Normal Dispense

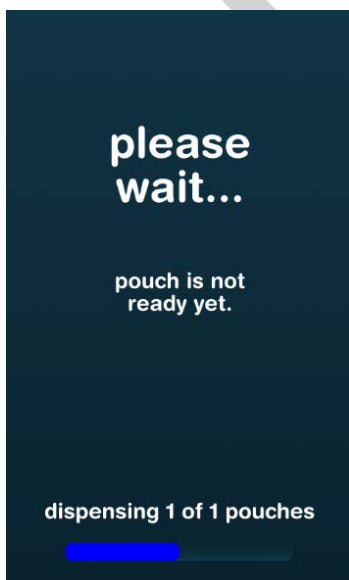
When the dispense time arrives, a blue screen is displayed to tell you it's time for your medications, the dispense button blinks, and an alert is played.



4. Touch **Dispense**.

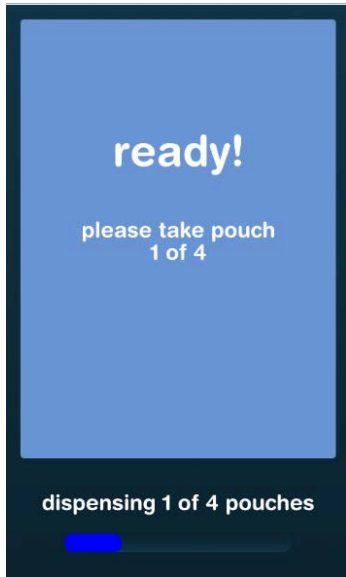


A screen similar to the following is displayed. The blue status bar tells you the status of the dispense. **Note:** you should not touch the pouch until it is ready.



When ready, spencer displays a screen similar to the following. The mouth flashes blue to let you know the meds are ready.

The screen below shows that 1 pouch out of 4 is ready. The number of pouches will vary per end user and per dispense schedule.



5. Remove the pouch or pouches of medications from the mouth.

Any reminders, questions, or other messages from your pharmacist may be displayed at the end of a dispense time. An example is shown below:



6. If the message requires a response, touch the appropriate button on the screen. In this example, touch **OK**.

Late Dispense

If the normal reminder goes unnoticed for a period of time, an amber screen is displayed to tell you that limited time is left to take your medications; the dispense button blinks, and a louder alert is played.

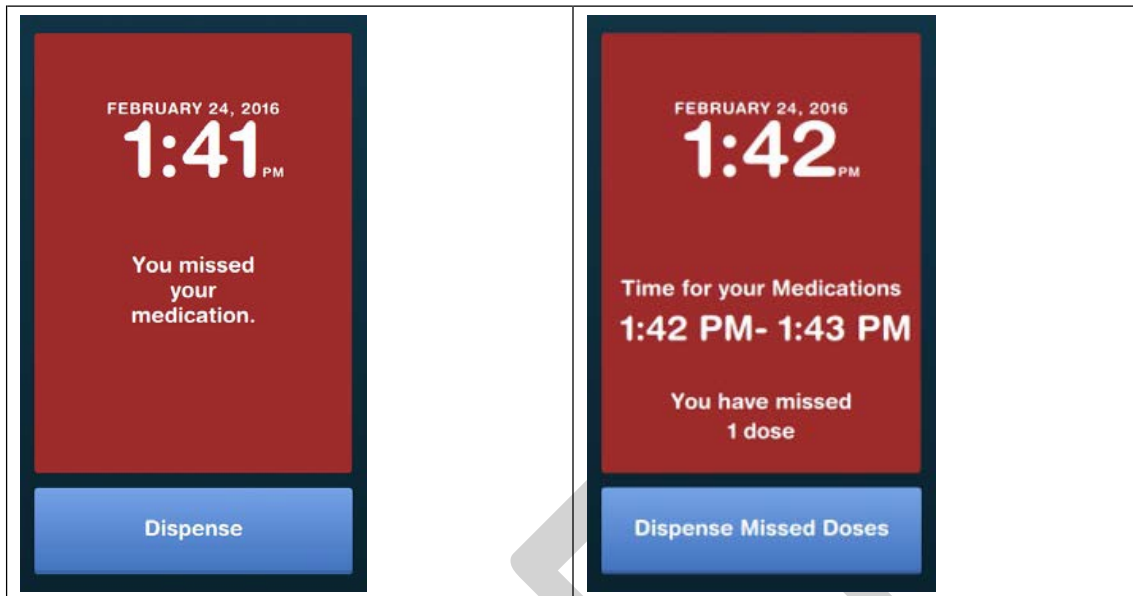


1. To dispense your meds, follow the steps above under “Normal Dispense,” starting with step 4.

Missed Dispense

If the late dispense reminder expires, a red screen is displayed to tell you that you have missed 1 or more doses. The light flashes red.

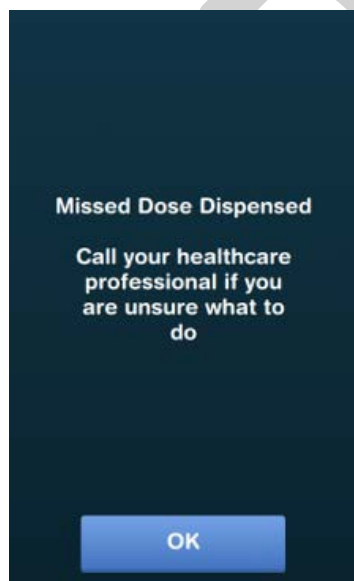
A screen similar to the following is displayed when you have missed a dose (or doses).	A screen similar to the following is displayed to tell you when you have missed a dose (or doses) AND that your next dose is now due.
--	---



1. Touch **Dispense** or **Dispense Missed Doses** to dispense all missed doses.

Dispense Missed Doses

A screen similar to the following is displayed. Replace screen below with newer red one.



2. Touch **OK** and contact your healthcare professional as needed.

OK

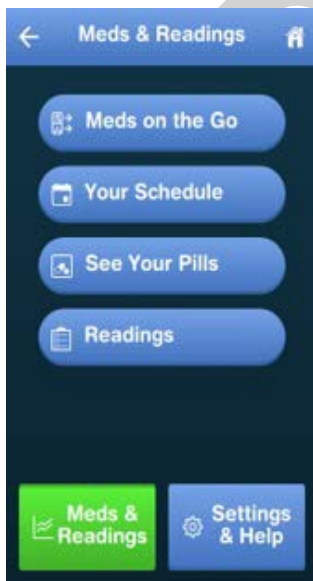
Meds and Readings

1. On the home screen, touch **Meds & Readings**.



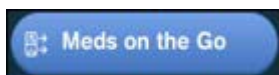
The Meds & Readings screen is displayed, showing the following menu options. These are explained in detail in the subsections below.

Menu Option	Description
Meds on the Go	Enables you to dispense meds to take with you for a time period that you define.
Your Schedule	Shows past and upcoming dispense times.
See Your Pills	Displays pictures of your pills with their names and dosage.
Readings	Lets you view graphs tracking your blood sugar, weight, adherence to your meds schedule, and other health information entered in spencer.

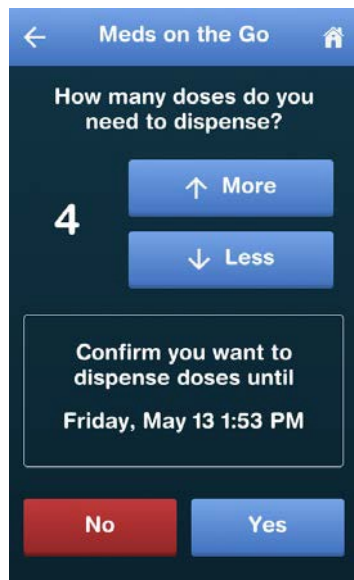


Meds on the Go

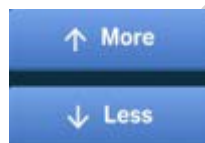
1. On the Meds & Readings screen, touch **Meds on the Go**.



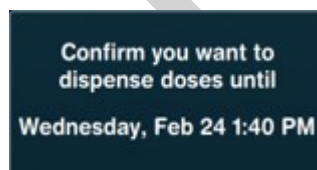
The Meds on the Go screen is displayed. The default number of doses to dispense is 1. The maximum is based on the number of doses you have left in your refill.



2. Touch **More** or **Less** to change to the number of doses you want.



A message is displayed below the number asking you to confirm the date and time for the last to-go dose. (The first to-go dose is the next one on your schedule.)



3. Touch **No** if the date and time are not correct and **Yes** if they are.



4. (a) If you touch **No**, you are returned to the Meds & Readings screen.
- (b) If you touch **Yes**, the Confirm Dates screen is displayed. The Dispense button flashes.



5. Review the dates and times to be sure they are accurate.
6. (a) If accurate, touch **Dispense**.



The doses are dispensed and recorded with spencer as being “manual.”

- (b) If not accurate, touch the back arrow and adjust the dates and times on the Meds to Go screen.



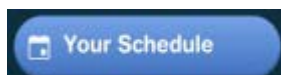
(For instructions on adjusting dates and times, start with step 2 in this section, “Meds on the Go.”)

Optionally, touch the Home icon to return to the Home screen.

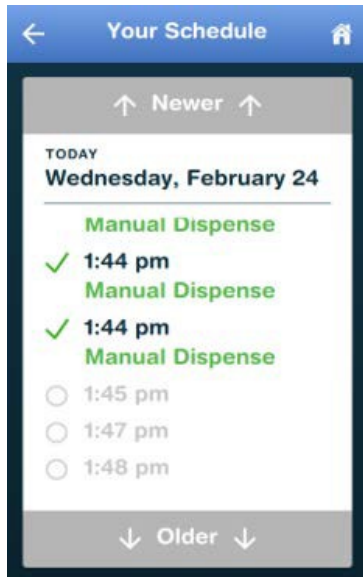


Your Schedule

1. On the Meds & Readings screen, touch **Your Schedule**.



The Your Schedule screen is displayed, showing the history of previous dispenses and the schedule for pending dispenses.

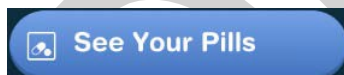


2. Touch the **Newer** and **Older** arrows to see the schedule for today in ascending or descending order, respectively. You can also scroll by moving your finger up and down on the screen ("swiping"). Note: Today means xxxxx.



See Your Pills

1. On the Meds & Readings screen, touch **See your Pills**.



The See your Pills screen is displayed, providing the names and strengths of your meds. Pictures and/or descriptions are also provided.



2. Use the Up arrows to scroll the screen up and the Down arrows to scroll down. You can also scroll by moving your finger up and down on the screen ("swiping").

Note In this example, the Up arrow button is grey, indicating that the button is not active (i.e., Synthroid is the top of the list). You can scroll down but not up.



Readings

1. On the Meds & Readings screen, touch **Readings**.



The Readings screen is displayed, showing the following menu option. These are explained in detail in the subsections below.

Menu Option	Description
Blood Sugar	Which will be on this release?

Blood Sugar



Settings & Help

1. On the home screen, touch **Settings & Help**.

The Settings & Help screen is displayed, showing the following menu options. These are explained in detail in the subsections below.

Menu Option	Description
Contact Pharmacist	Displays contact information for your pharmacy.
Video Tutorials	Enables you to view videos explaining how to use spencer. What is status of these?
Help	Provides help/instructions for replacing the refill and shutting spencer down. Also gives information about the hardware and software versions for your particular spencer.
Alert Volume	Enables you to set the volume for spencer – for alerts and other audio features.
Child Lock	Provides guidance in setting up a Personal Identification Number (PIN) or password so that you can restrict spencer access. This feature is optional.

Contact Pharmacist

1. On the Settings & Help screen, touch **Contact Pharmacist**.

The Contact Pharmacist screen is displayed, showing pharmacy name, contact information, and hours of operation.

Video Tutorials

1. On the Settings & Help screen, touch **Video Tutorials**.

Need screen for this. (Not greeting screen with tutorials, but the one you access via settings & Help)

1. Touch the volume control button on the right to increase the volume.



2. Touch the volume control button on the left to decrease the volume.



3. Touch **Play** to display the menu for video selection.



The refresh button is grey (inactive) until you start playing a video. It then becomes blue (active) so you can rewind the video to view again.



Help

1. On the Settings & Help screen, touch **Help**.

The Help screen is displayed, showing the following menu options. These are explained in detail in the subsections below.

Menu Option	Description
Replace Refill	Provides instructions for replacing the refill.
Shutdown	Provides instructions to shut spencer down.
Version	Shows the software and hardware versions and spencer's serial number.

Replace Refill

Add steps for removing child lock where applicable.

1. On the Help screen, touch **Replace Refill**.

The Replace Refill screen is displayed.



2. Touch **Unlock Lid**.

A confirmation screen is displayed.



Are you sure you want to replace the refill?

3. (a) If yes, touch **Yes** and go to the next step.

(b) If no, touch **Cancel** to go back to the confirmation screen or touch the Home icon to go the Home screen. Skip steps 4 and 5.

If Child Lock is on, a screen is displayed asking for your security PIN.

4. Enter your 4-digit PIN and touch **Unlock.** (If Child Lock is off, skip this step.)

If you chose **Yes**, the Ready for Refill screen is displayed, and the spencer lid is opened slightly. Go to step 4.

If you chose **Cancel**, the **xxx** page is displayed.

(returns you to the confirmation screen and not to home page)

5. To replace the refill (meaning you touched **Yes** in the previous step), open the lid, remove the current refill, and insert the new refill.

Shutdown

See if child lock interferes with this.

1. On the Help screen, touch **Shutdown**.

A confirmation screen is displayed.

2. Touch **Shutdown** to power down the spencer device or **Cancel** if you do not want to power down.

If you chose **Shutdown**, spencer is turned off. If you chose **Cancel**, the **xxx** screen is displayed.

Version

1. On the Help screen, touch **Version**.

The Version screen is displayed, showing the

- Versions for software, hardware, and firmware
- Serial number for your spencer and its Internet Protocol (IP) address
- WiFi Network to which your spencer is attached.



2. Touch **Refresh** to update the screen, in case any changes have been made recently.

Refresh

Alert Volume

1. On the Settings & Help screen, touch **Alert Volume**.

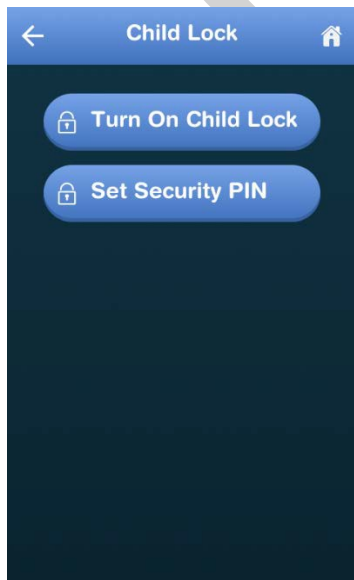
Child Lock

Walk through this again.

1. On the Settings & Help screen, touch **Child Lock**.

The Child Lock screen is displayed, showing the following menu options. These are explained in detail in the subsections below.

Menu Option	Description
Turn On Child Lock/ Turn Off Child Lock	Provides instructions for turning Child Lock off or on, depending on the current setting.
Set Security PIN	Provides instructions to enter a new PIN or change an existing PIN.



Set Child Lock

If you need to set or change a PIN, see the “Set Security PIN” section.

1. On the Child Lock screen, touch **Turn On Child Lock** or **Turn Off Child Lock**.

The appropriate screen is displayed (depending on your choice).

2. Enter your 4-digit PIN number and touch **Unlock** or **Lock** (depending on your choice).

Note: When Child Lock is ON, you must enter your PIN to dispense medicines, replace refill, or turn Child Lock off.

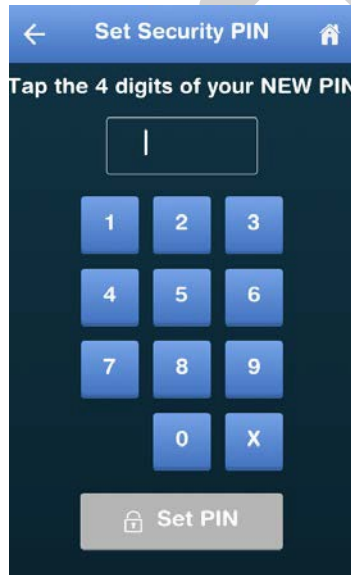
Set Security PIN

1. If you want to change the existing Security Personal Identification Number (PIN) or add a PIN for the first time, touch **Set Security PIN**.



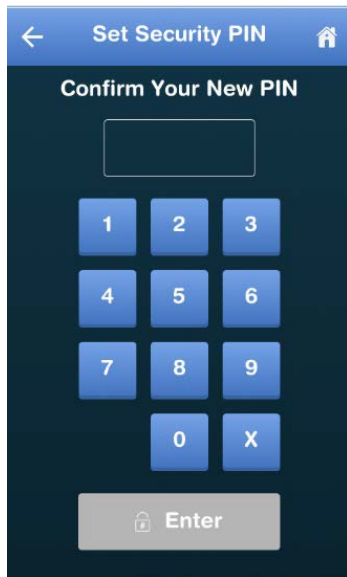
The Set Security PIN screen is displayed, asking you to enter your existing PIN and/or enter a new one.

2. If you are changing your existing password, enter the existing 4-digit password and touch **Enter**. If you are entering a brand new password, skip this step.
3. In the Set Security PIN screen, touch the 4 numbers on the screen for your new PIN and touch **Set PIN**.



4. Touch **Set PIN**.

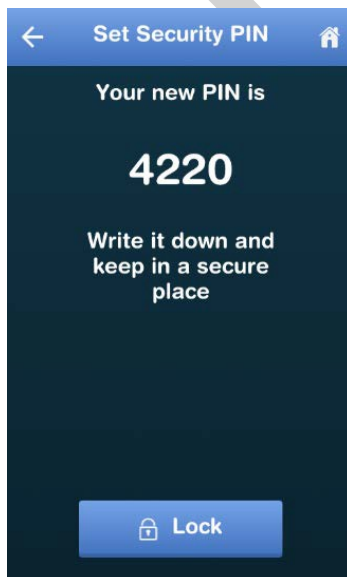
Another screen is displayed, asking you to confirm the new PIN.



5. Touch the PIN numbers again and touch **Enter**.



A screen is displayed showing the new, confirmed PIN and reminding you to write it somewhere.

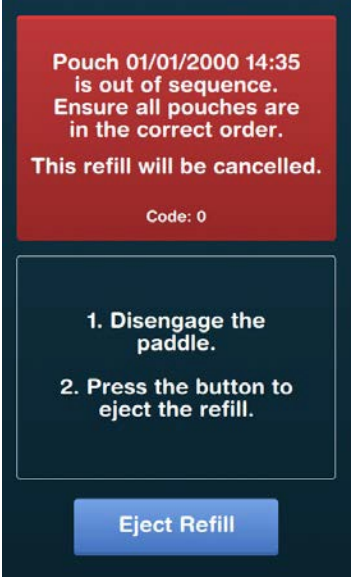
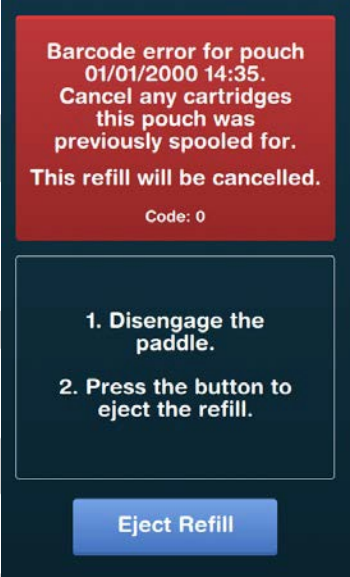


6. Write the number on a notepad, spreadsheet, etc., and store it somewhere secure.

7. Touch **Return**.

You are returned to the Settings & Help screen. The Home screen displays a note that dispensing is locked.

Error messages

Add error here	Add error here
The blah, blah  Pouch 01/01/2000 14:35 is out of sequence. Ensure all pouches are in the correct order. This refill will be cancelled. Code: 0 1. Disengage the paddle. 2. Press the button to eject the refill. Eject Refill	A pouch barcode has scanned that is not in the list from the Cloud. The pouch may have been spooled already but not cancelled.  Barcode error for pouch 01/01/2000 14:35. Cancel any cartridges this pouch was previously spooled for. This refill will be cancelled. Code: 0 1. Disengage the paddle. 2. Press the button to eject the refill. Eject Refill