WISEPILL RT3000

MEDICATION MONITORING

AND

REMINDER SYSTEM

PRODUCT HANDBOOK

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Wisepill Technologies is an electronic manufacturer and software company, foundered in 2008 to address the serious problem of non-adherence to medication. Wisepill provides tools and solutions for clinical trials, medical research, disease management and everyday medication management.

Figure 1.1. The Wisepill RT3000 pill dispenser

Figure 1.2   USB charger and cable

The Wisepill RT3000 is a portable medication monitoring and reminder system.

Every time a pill dispenser is opened, the Wisepill RT3000 stores the date and time of the opening. The data is then transmitted to the Wisepill Cloud Server using mobile cellular technology. A patient's prescription can be loaded on the Wisepill Cloud Server and interventions can be created and configured to remind patients if they forget to take their medication.

Adherence data and reports can be viewed on the Wisepill Cloud Server and on the mobile friendly browser application.
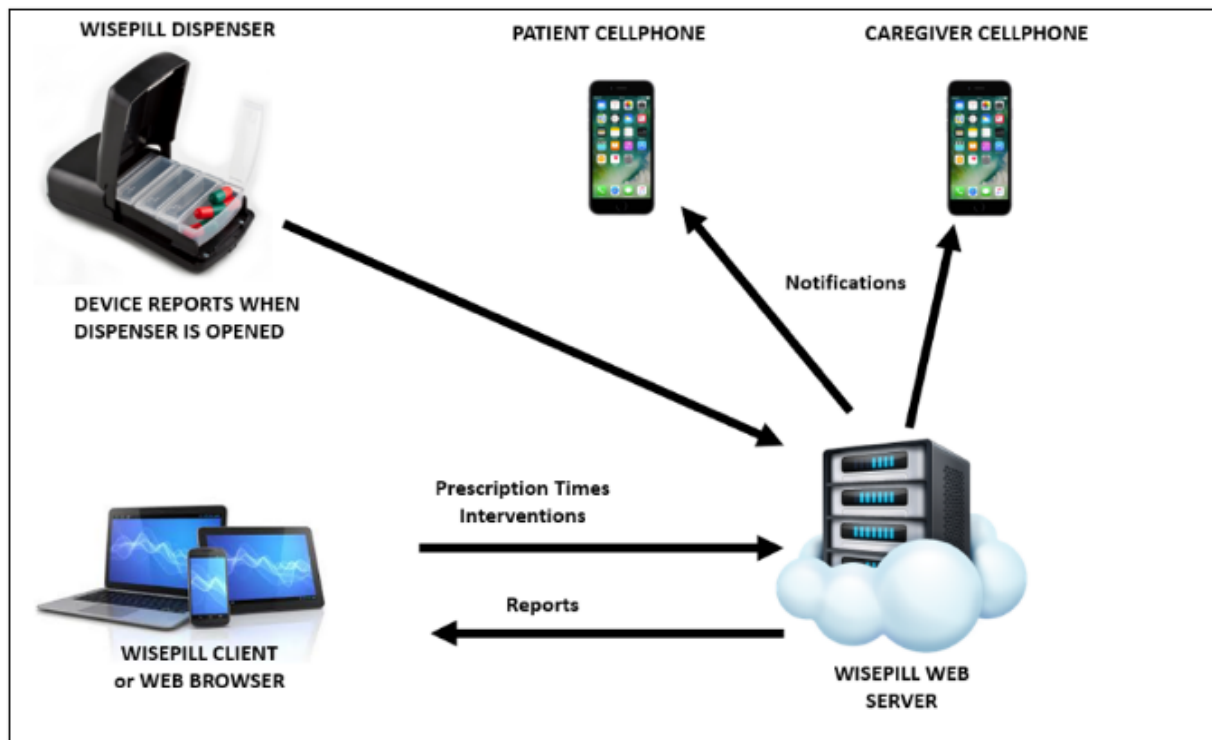
The Wisepill System

The Wisepill RT3000 dispenser consists of two components, namely the medication dispenser and the pill cartridge. The pill cartridge comes in two options. a) the AM-PM cartridge with two compartments b) the 7-day-week version with seven compartments.

Pill Dispenser

Pill Cartridge

USB Cover

Red LED   **Green LED**

Figure 3.1   Wisepill RT3000 Dispenser

Figure 3.2   Seven Day Week Pill Cartridge

Figure 3.3   AM/PM Pill Cartridge

Figure 3.4 Opening the dispenser

3.1 Pill Dispenser identification (IMEI Number)

The Wisepill RT3000 has a unique 15-digit number which is located inside the dispenser lid.
The IMEI number is used to link the device to a patient.

3.2 USB Data/Charging Port

The electronic module has a USB port for downloading data, charging the battery and for configuration of the unit. The Wisepill RT3000 dispenser can be charged directly via the USB port with a standard USB charger. Optionally, the batteries can also be charged externally with a battery charger.

3.3 Indicator LEDs

The primary function of the LEDs are as follows:

Green   – Daily Alarm
Red   – Low battery warning

The LEDs can be enabled/disabled remotely via the server software or via the PC Application.

The Green LED (Alarm/LID Open/Communication indicator)

- o will flash once when the container is opened and again once when the container is closed
- o will quickly flash three times when the container is opened and closed quickly
- o will flash in sequence during the (daily) Medication Alarm
- o will flash during the GSM data communications
- o will be on solid, while connected via USB to the computer

The Red LED (Low battery/Charging)

- When the battery is low, the red LED
  - o will flash at the time of the alarm
  - o will be on solid when the container is opened
  - o will flash while the battery is on charge (when fully charged the red LED will stop flashing).

- A personal USB charger can be used to charge the battery.

3.4 Buzzer

The buzzer is activated during the ALARM sequences. The dispenser emits a soft tone when the container is opened or closed. The alarm and lid buzzer sounds can be enabled or disabled remotely via the server software or the evriMED PC application.

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4 KEY TERMS AND FEATURES

4.1 Medication intake event

A medication intake event is an electronic record that is created when a patient opens the device to take his or her medication. It consists of a date-and-time stamp.

4.2 Heartbeat

The heartbeat is automatically recorded daily by the device and is sent periodically to the Wisepill Cloud Server to indicate that the device is operating properly (reporting battery life and signal strength).

4.3 Data transmission, storage, and delayed data

There may be times when the RT3000 dispenser is not able to transmit its data to the Wisepill Cloud server because of bad mobile network coverage or low battery. When the RT3000 dispenser is again able to connect to the Wisepill server, it will transmit all unsent medication events and heartbeat information.

4.4 Signal strength and battery status

Every time a device connects to the Wisepill Cloud Server, the strength of the cellular connection and the battery status is recorded.

4.5 Event lapse

An event lapse is said to occur where no events appear on the Server for a period of time.

The cause of an Event Lapse may either be caused by

- technical reasons (e.g. low battery power, SIM card error or faulty device)

OR

- user behavior (e.g. forgetting, intentional non-adherence)

The cause of an event lapse can be determined after a successful data transmission by checking for the presence of heartbeat data.

4.6 The Alarms

The alarm period is 30 minutes in length and consists of three alarm cycles. The alarm cycles are 10 minutes each and made up of two parts. These alarms apply regardless of the type of reminder selected.

- The first three minutes of the alarm cycle is the active alarm. During the active alarm, the buzzer will sound, and the green LED will flash in the following sequence: short, short, long.

- The last 7 minutes of the alarm cycle is the passive alarm. During the passive alarm, the buzzer will not sound, and the green LED will not flash.

- Opening the container will cancel the active alarm

  o If it is opened within four hours before the scheduled alarm or
  o If it is opened during the alarm period.

- Opening and closing the container quickly (i.e., a "quick open") will "mute" the alarm. A quick open is configured as less than or equal to 2 seconds. A quick open event will stop the current active alarm, but not the alarm period. The alarm will again be active during the next alarm cycle. A quick open is assumed to not indicate a medication dosing event.

4.7 Battery Capacity

The battery for the RT3000 is the 1100 or 1700 mAh LIPO battery which will provide 3 – 6 months of battery life.

4.8 Storage Capacity

The Wisepill RT3000 can store more than 12,000 records or events.

The Wisepill RT3000 devices will be delivered with the lithium battery disconnected and partially charged. Airfreight regulations will not allow for shipment of fully charged batteries

Use the Mini USB cable and wall charger to charge the battery. The red LED will stop flashing once the charge is complete

Accessing the battery

- Open the Wisepill Dispenser and using the supplied Torx screwdriver, remove the 4 screws.
- The top part of the dispenser will slide off exposing the electronic board and the battery.
- Connect the battery and reassemble the dispenser (to disconnect the battery grip all 3 wires together and gently tug to disconnect).
- Align the plastic slots and slide (See below).
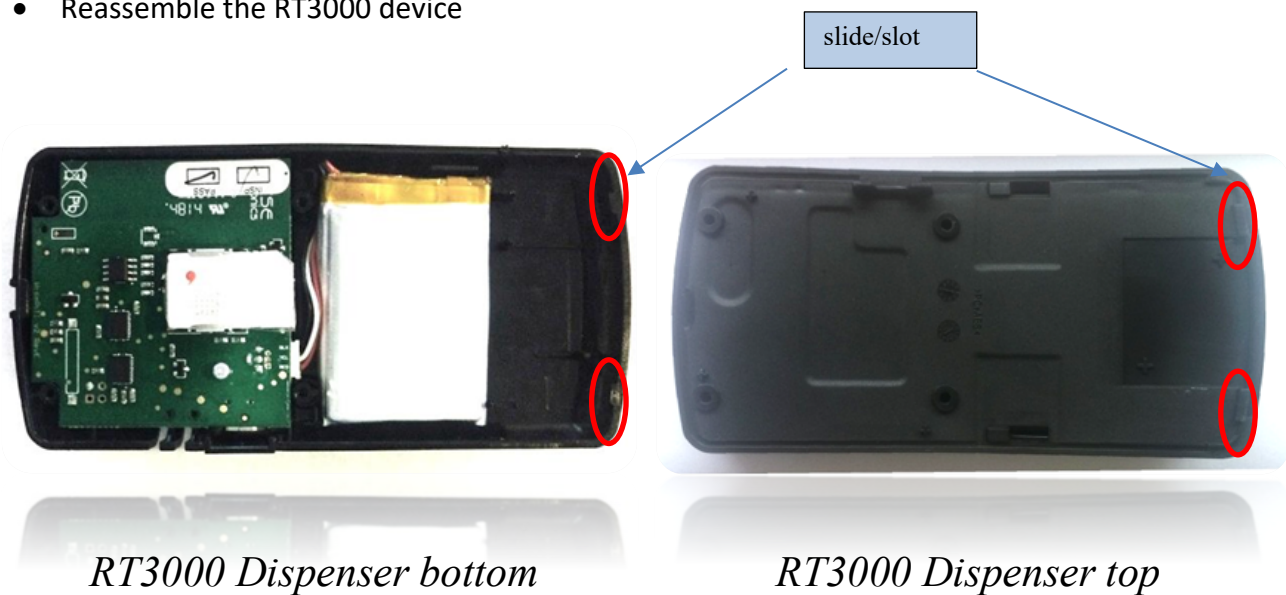- Reassemble the RT3000 device

slide/slot

RT3000 Dispenser bottom   *RT3000 Dispenser top*

Figure 1.3. T6 Torx screwdriver

Wisepill Technologies provides data services for the RT3000 pill dispenser by means of mobile cellular communications. A SIM chip is integrated with the electronics of the Wisepill RT3000 module. The Wisepill RT3000 is available with either a SIM chip or a standard SIM card.

6   CONFIGURING THE WISEPILL RT3000

The RT3000 dispenser can either be configured by the evriMED PC Application OR remotely by the Wisepill Cloud Server Application or Partner Web Application (e.g. 99DOTS Web Application).

Note: If Automatic configuration has been enabled on the Server for a particular device, the remote configuration will always have precedence over the PC application settings. The Web application will push its configuration down to the unit every time the unit connects.

6.1   Automatic Configuration

If Automatic configuration has been enabled on the Wisepill Cloud Server Application, the device can be setup automatically.

When the RT3000 dispenser is powered up for the first time (or when the date and time is not set), both LEDs will flash to indicate that the date and time is not set. Please refer to section 12.0 for additional information on LED flash codes.

By cycling the power on the device, one can force the device to connect to the server and self-configure. The time and date of the device will also be updated.

6.2 Manual Configuration

6.2.1.1 The evriMED PC Application

The evriMED PC application is available for download from the Wisepill website and is useful for local/offline visualization of the Wisepill RT3000 data.
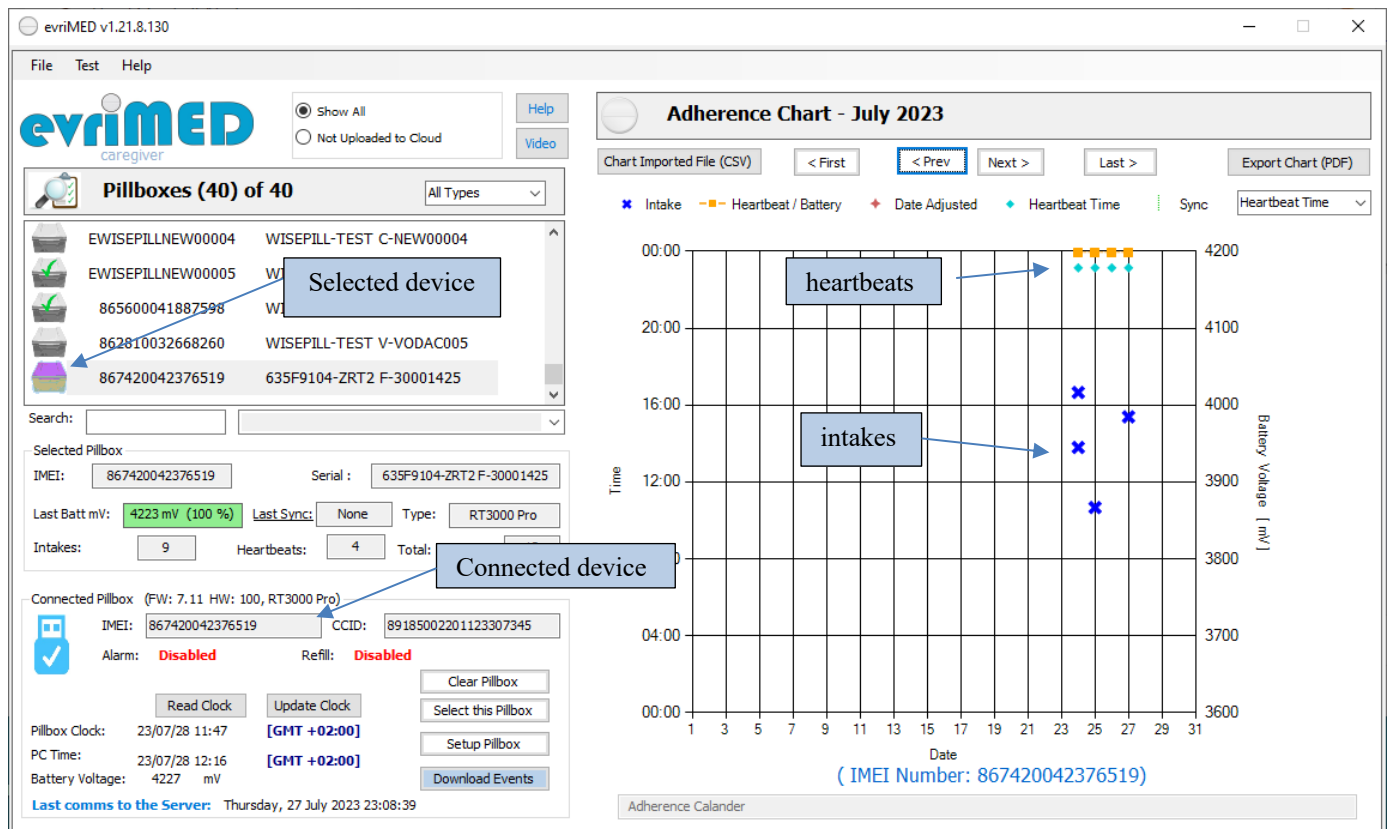
The evriMED PC application allows a direct connection to the pill dispenser device via a USB cable.

Manual configuration is useful when Automatic configuration has not been enabled on the Wisepill Cloud Server Application. The device can be configured by means of the evriMED PC application and the values will then not be overwritten by the server.

Click the "Setup Pillbox" button on the on the lower left of the main window.

6.2.1.2   Daily Alarm Setup

An audible/visual alarm on the dispenser can be enabled and disabled (Enable Medication Alarm) Note: By default, the Medication Alarm is not enabled.

Alarms can be enabled or disabled for each day of the week ("Repeat Alarm on these days").

- Medication Alarm (Which provides reminders for each medication dose)
  - Daily reminder for the user to take his/her medication
  - Format: HH:mm & "Enable Medication Alarm" check box
  - Sample: 10:00 & "Enable Alarm" on weekdays

6.2.1.3 Lid Setup

- The lid open/close buzzer tone can be enabled or disabled
- The lid open/close LED flash can be enabled or disabled

6.2.1.4 Time Setup

- Select the correct Time Zone from the dropdown list.
- Tick the "Assign Time Zone and Set to PC Time" checkbox and then click on the apply button to synchronize with the local computer date and time.

6.2.1.5 Connecting to Server

The "Connect to the Server" setting determines the frequency of the server updates, how often the device will connect to the cellular network and upload the events, in number of days. This setting is done on the Wisepill Server for a group of devices.

- Normal Mode: The device will attempt to connect live to the server the first time the device is opened on a given day. The device will connect to the server to send unsent heartbeats or Intake events at least once every 24 hours.

- Test Mode: The device will attempt to connect live to the Server every time the device is opened or at least once every 24 hours.

- Battery Saving Mode: The device will attempt to connect to the Server every x days.

- The Wisepill Dispenser is a pill box with a built-in cellphone modem. The pill box and electronics module should therefore be treated as you would treat a regular cell phone. I.e., keep it clean and dry.

- You can clean your Wisepill Dispenser using a damp cloth. As with a regular cellphone, the dispenser should be kept as dry as possible.

8   SAFETY WARNINGS

8.1   Battery Safety

A lithium-ion battery is used in this device. If these guidelines are not followed, batteries may experience a shortened life span or may present a risk of damage to the device, fire, chemical burn, electrolyte leak, and/or injury.

- Do not immerse or expose the device to water or other liquids
- Do not disassemble, modify, remanufacture, puncture or damage the device or batteries
- Do not remove or attempt to remove the non-user-replaceable battery
- Do not expose the device or batteries to fire, explosion, or any other hazard
- Store the box and device in a place within the following temperature range: 0 °C to 35 °C
- Keep box and device away from high-humidity areas
- For charging, only use the power cable that was provided with the device
- Keep out of reach of children

8.2   Magnet Safety

Both the device and the box may contain magnets. Under certain circumstances, magnets may cause interference with some internal medical devices, including pacemakers and insulin pumps. Devices that contain magnets should be kept away from such medical devices.

The Wisepill RT3000 contains a battery charging circuit and can be charged by using a standard USB battery charger.

Item	Specification
Weight of the Device	130g
Dimensions of the Device	30 x 60 x 130 mm
Data Storage	12000 records
Battery Life, Normal Mode	1100 or 1700 mAh (3-5 months)
Battery Life, Battery Saving Mode	1100 or 1700 mAh (4-6 months)
Power requirements	3.7 V Li-Polymer battery capacity 1100/1700 mAh
Weight: Module + LiPo Battery and Standard Container	300g
Material	Polypropylene Copolymer
SIM	• eSIM • SIM card
Cellular Network type	• G510: GPRS/GSM:850/900/1800/1900MHz • MA510: LTE CAT M1/NBIoT/GPRS Cellular networks supported: LTE & 2G
Modems Approvals	Fibocom G510 / MA510 Modem. CE-RED/GCF/RoHS/REACH Anatel/CCC/SRRC/NAL
Temperature range	The Operating range is 0 to +50°C The storage temperature is 0 to +70°C
Relative Humidity	20% to 65% non-condensing
Shock Resistance	Withstands a one meter drop onto a solid surface
Electromagnetic Compatibility/Interference	As Specified for FCC, CE and R&TTE compliance
Protection from Liquids and Dust	Dust and splash resistant
Vibration	10 ~ 55Hz and amplitude 0.35mm
Safety	IEC 60950-1:2013

This functionality is only available in devices with Firmware Version 4.17 or later. The evriMED PC application can be used to place the Wisepill RT3000 into shipping mode.

Shipping mode is provided so that modules can be safely shipped with their batteries connected.

- o   While in shipping mode, the device is in deep sleep
- o   Shipping mode is only exited when the RT3000 is connected to a PC USB port, or if the power is cycled or on a LID OPEN

11   TROUBLESHOOTING AND LED FEEDBACK

11.1 PERSISTANT ISSUE CODES

Persistent issues are issues that need to be rectified before a device can be given to a user:

- Date and Time is not set (both LEDS flash together). This may be because that the device has not connected to the network and has not received a Time synchronization. Time/Date can also be set on the evriMED PC App.
- The device has never connected to the Network
- When triggered, the LEDs flash for 30 minutes and then the RT3000 enters sleep mode.
- The display of the Persistent codes is triggered when the lid is opened or on reset.

Green	Red	Description
FLASH (sync)	FLASH (sync)	Time/Date has not been set or Device has never connected to the Application Server

11.2 NON PERSISTANT ISSUE CODES

Non-persistent issue codes are visual indications of a temporary problem (e.g. no, or poor network coverage). The LEDs flash ten times and then the RT3000 enters sleep mode.

These codes are useful for support and debugging purposes.

- Device did not connect to the GSM
- Device did not connect to the Application Server
- Device configuration could not be updated
- The non-persistent codes are displayed as follows: Ten flash cycles at end of connection attempt cycle.

Green	Red	Description
Alt	Alt	Device did not connect to Network
Alt x 2	Alt x 2	Device did not connect to Server

11.3 CONNECTION STATUS

Note: This functionality is only available in devices with Firmware Version 4.17 or later.

When the RT3000 attempts to transmit events to the Server, it flashes the green LED as follows:

Green	Red	Description
FLASH (quick on, long off)	OFF	Modem is powered on but off network
FLASH (long on, long off)	OFF	On Network
FLASH (quick on, quick off)	OFF	Transmitting
OFF	OFF	Sleeping

The RT3000 usually will be seen doing this when the lid is opened.

11.4 POWER UP BATTERY INDICATOR

Note: This functionality is only available in devices with Firmware Version 4.17 or later.

This feature is useful for checking in the field whether a device is fully charged. If power is removed from the module by plugging the battery out and then in again, the following sequence will be seen:

The LEDs will run in sequence (red, green) about 7 times

Depending on the battery charger, the following indicators will apply:

11.4.1 Low battery
The red LED will come on for about 5 seconds and three long low pitch tones will be heard.
11.4.2 Medium battery
The LEDs will be off and three long low pitch tones will be heard.
11.4.3 Full battery
The green LED will come on for about 5 seconds and three long high pitch tones will be heard.

In firmware versions 7.11 and later, the power up indicator is also activated when the USB cable is unplugged from a charger or PC.