

evriMED1000C

MEDICATION MONITORING

AND

REMINDER SYSTEM

AN INTRODUCTION

Version: 1.48, Date: 30 July 2020





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1.0 ABOUT WISEPILL TECHNOLOGIES

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.



The evriMED1000C Electronic Module



2.0 ABOUT THE evriMED1000C SYSTEM

The evriMED1000C is a desktop medication monitoring and reminder system.

Every time a pill dispenser is opened, the evriMED1000C 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.





3.0 ABOUT THE evriMED DISPENSER

The evriMED1000C dispenser consist of two hardware components, namely the electronic module and the medication container. This modular design allows the electronic module to be reused and the container to be replaced if needed. The electronic module slots into the container so that the indicator LEDs are visible through the front of the container (see figure below). A USB port can be accessed by opening the container.



evriMED1000C Dispenser



a) USB Data/Charging Port

The electronic module has a USB port for downloading data, charging the battery and for configuration of the unit. The evriMED1000C 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.

b) Indicator Lights/LEDs

The primary function of the three lights or LEDs are as follows:

- Green Daily Alarm
- Yellow Time to Refill Medicine Dispenser
- Red Low battery warning

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

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

- The green LED
 - \circ 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
 - will flash during the GSM data communications
 - \circ $\;$ will be on solid, while connected via USB to the computer $\;$

The Yellow LED (Refill Indicator)

- When it is time to refill medication, the yellow light
 - will flash with the green LED at the time of the medication alarm. If the Medicine Alarm is not enabled, only the yellow LED will flash
 - will be on solid when the container is opened.
 - \circ In the event of poor GSM communications, the yellow LED may flash for a brief period

<u>The Red LED</u>

- When the battery is low, the red LED
 - will flash at the time of the alarm
 - will be on solid when the container is opened
 - $\circ\;$ 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.
- c) 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 PC evriMED application.



4.0 KEY TERMS AND FEATURES

a) 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.

b) 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).

c) Data transmission, storage, and delayed data

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

d) 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.

e) 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.



f) 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 yellow LED will flash if the "Refill Alarm" is configured and the date is less than or equal to the current date.
- 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. The yellow LED will continue to flash if the "Refill Alarm" is configured and the date less than or equal to today.
- Opening the container will cancel the active alarm
 - If it is opened within four hours before the scheduled alarm or
 - 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.
- g) Battery Capacity

The battery for the evriMED1000 is the 2100 mAh LIPO battery which will provide 3 - 5 months of battery life in normal mode and 6 - 8 months battery life in Battery Saving mode.

h) Storage Capacity

The everiMED1000C can store more than 12,000 records or events.



5.0 INSTALLING THE BATTERY



Step 1. Open the battery bay door and back cover and remove the battery



Step3. Align the connector on the battery with the connector on the Printed Circuit Board.



Step 5. Ensure that the battery connector is securely connected, as shown above.



Step 2. Position the module so that the battery connector is exposed



Step 4. Feed the battery connector through the hole in the battery bay, as shown above.



Step 6. Close the back cover, insert the battery and close the battery bay door.



6.0 THE SIM CARD

The SIM chip is integrated with the electronics of the evriMED1000C module. For any queries please contact <u>support@wisepill.com</u>.

The evriMED1000C is also available with a standard SIM card.

7.0 CONFIGURING THE evriMED1000C

The evriMED 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.

a) Automatic Configuration

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

When the evriMED dispenser is powered up for the first time (or when the date and time is not set), all three 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.



b) Manual Configuration

The evriMED PC Application

The evriMED application is available for download from the Wisepill website and is useful for local/offline visualization of the evriMED data.



The evriMED application allows a direct connection to the evriMED 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.

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

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)
 - \circ $\;$ 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



Refill Alarm Setup

- Future dated reminder for the user to refill their medication
- Format: yy/mm/dd HH:mm:ss & "Enable Refill" check box
- Sample: 20/07/01 09:00:00 & "Enable Refill" check box

Lid Setup

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

<u>Time Setup</u>

- 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.

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.



8.0 CARING FOR THE evriMED DISPENSER

- 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.

9.0 WARNINGS

a) Battery Warnings

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

b) Magnet Warning

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.



10.0 SPECIFICATION FOR THE evriMED1000

The evriMED1000C contains a battery charging circuit and can be charged by using a standard USB battery charger.

Item	Specification
Data Storage	12000 records
Battery Life, Normal Mode	2100 mAh 3-5 months
Battery Life, Battery Saving Mode	2100 mAh 6-8 months
Power requirements	One 3.7 V Li-Polymer battery capacity 2100 mAh
Weight: Module + LiPo Battery and	300g
Standard Container	
Dimension: Standard Container	166.9 mm x 129 mm x 71.4 mm
Dimension: Module	119.8 mm x 60.6 mm x 19.5 mm
Material	Polypropylene Copolymer
SIM Card	• eSIM
Cellular Network type	 Mini SIM (= 2FF): 25 x 15 mm GPRS/GSM:850/900/1800/1900MHz
	Cellular networks supported: 26
Modem	Fibocom G510 GSM Modem.
Approvals	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



11.0 SHIPPING MODE

Note: This functionality is only available in devices with Firmware Version 4.17 or later. The evriMED PC application can be used to place the evriMED1000C into shipping mode.

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

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

12.0 TROUBLESHOOTING AND LED FEEDBACK

a) 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 (All LEDS flash together). This may be because that the device has not connected to the network and has not received a Time syncronisation. Time/Date can also be set on the evriMED PC App.
- The device has never connected to the Network (Flashing green and yellow together).
- When triggered, the LEDs flash ten times and then the evriMED enters sleep mode.
- The display of the Persistent codes is triggered when the lid is opened or on any reset.

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

b) NON PERSISTANT ISSUE CODES

Non-persistent issue codes are visual indications of a temporary problem (e.g. no, or poor network coverage). These codes are useful for support and debugging purposes.

- Device did not connect to the GSM network (Alternate flashing of green and red LED).
- Device did not connect to the Application Server (Alternate flashing of the red and yellow).
- Config could not be updated (Alternate flashing of the green and yellow).
- The non-persistent codes are displayed as follows: Ten flash cycles at end of connection attempt cycle.

Green	Yellow	Red	Description
Alt	OFF	Alt	Device did not connect to Network
OFF	Alt	Alt	Device did not connect to Server
Alt	Alt	OFF	Config was not read



c) CONNECTION STATUS

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

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

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

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

d) 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 orange light will come on for about 1 second
- The LEDs will then run in sequence (red, orange, green) about 7 times
- Either the RED, Orange or green LED will then come on its own for about 5 seconds to indicate battery status (green = full, orange = half, red = flat) with the following tones:
- Three short high pitch tones together with the green LED indicates that the battery is fully charged.
- Three long low pitch tones together with the ORANGE or RED LED indicates that the battery is not Fully charged.