

Description of EUT and its intended use:

The Medesto Connect is intended to:

1. Provide alerts to patients for pre-determined medication dosing schedules and record usages taken when inserted on to Medesto Pod medication container and a cell has been punctured to receive the medication.

Device interaction:

1. With the Medesto Go inserted onto the Medesto Pod, the user / caregiver (if one is required by the user) will receive a series of alerts via chimes and lights for predetermined medication schedule.
2. The patient / caregiver then can puncture a cell(s) containing medication for that patient.
3. The Medesto Go recognizes the punctured cell and sends the recorded usage to the Medesto Dashboard via a cellular network.

Use condition:

- This device is intended for single user only.
- This is used in indoor living area.
- Device is unsterile.
- Reusable Medical Device. Device can be used a few times in a week to multiple times in a day based on the patient dosing schedule.
- This device is for external use only.

Selected Operational Mode(s)

1. Verifying – Test Firmware

- Step 1 – Ensure the Medesto Go is fully charged
- Step 2 – Insert the Medesto Go on to a Medesto Test Pod
- Verify: The device will display 3 flashes of green and white lights confirming the device recognizes the Medesto Pod by scanning the NFC tag
- Step 2 – Hold the center button down for 3 seconds to start a Status Sequence mode
- Verify:
 - Cell Signal – Light Blue + White Lights (0 to 15 depending on cell signal)
 - Battery Charge – Orange Light + White Lights (0 to 15 depending on charge level)
 - Cells Available – Purple Light + 15 White Lights

2. Verifying – Schedule / AWS Connection

- Step 1 – Ensure the Medesto Go is fully charged
- Step 2 – Insert the patient's Medesto Go on to a patient's Medesto Pod
- Verify:
 - The device displays 3 flashes of green and white lights confirming the device has read the NFC tag
 - The device displays either a Green Light or Red Light along with a radiation UI with the white lights
- Step 3 – Puncture a cell
- Verify:
 - The devices UI will indicate which cell was punctured with a white light along with a green center button and beep verifying the punctured cell was acknowledged.
- Step 4 – Press the center button one time to wake the device up
- Verify – That the device shows a Yellow Light along with a radiation UI

3. Verifying No Cellular Connection

- Step 1 – Ensure the Medesto Go is fully charged
- Step 2 – Hold down the center button for 3 seconds to initiate a Status Sequence mode
- Verify:
 - Cell Signal – Light Blue + Zero White Lights
- Step 3 – With the device inserted on to the correct pod, press the button one time to wake the device up
- Verify:
 - Device takes 30 seconds and times out with a red flashing light with no white lights