

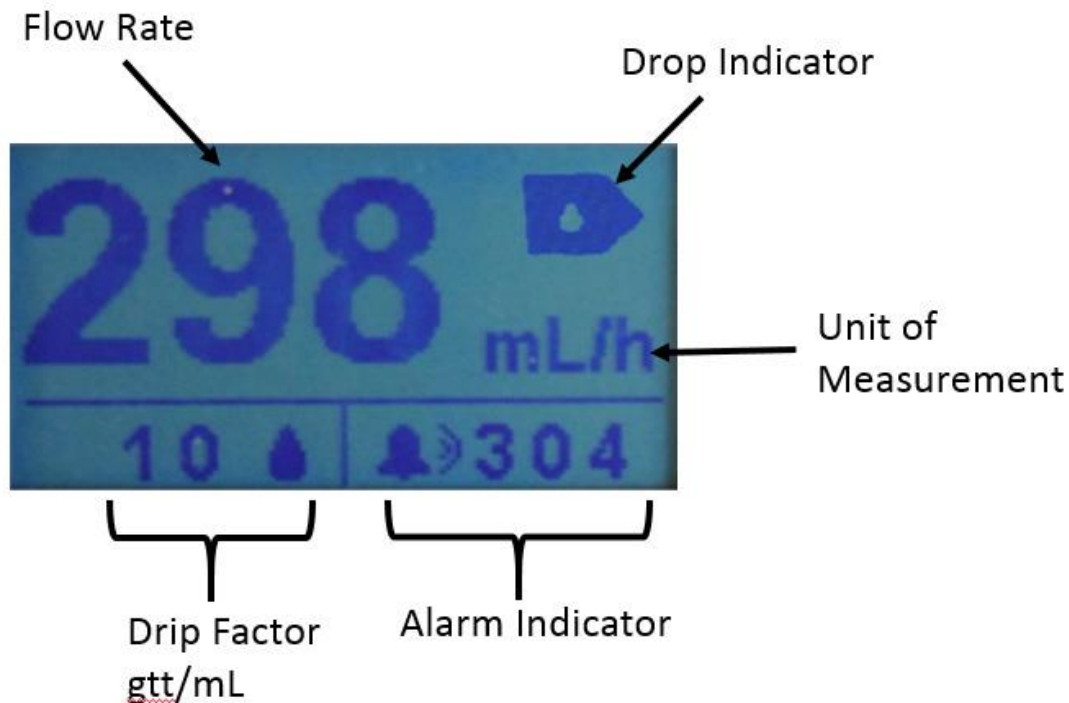
Section 11 – Device Description

The DripAssist device is intended to be used as a supplementary monitoring system for monitoring the flow rate of intravenous fluids. The DripAssist is a passive device. It does not control the flow rate of fluids passing through a drip chamber. The device operates by monitoring the drops through the drip chamber of a standard IV administration set. By tracking the intervals between drops, the device calculates the flow rate through the chamber and displays the flow rate on an LCD screen.

There is an alarm functionality that can be activated once a desired flow rate, or “set point,” is reached. The alarm, when activated, will sound when the flow rate deviates from a fixed percentage from the “set point.”

The device can be used with drip sets of 10, 15, 20, and 60 gtt/mL. The device is powered by one AA battery. The device can display the flow rate in drops per minute or mL per hour. The unit of measurement being displayed can be changed while the device operates. The device can also display the total volume that has dispensed through the drip chamber. The device is designed to be used with drip rates slow enough to be calculated by the human eye; a steady stream of fluid is outside the operating parameters.

There are five primary display elements on the DripAssist screen.

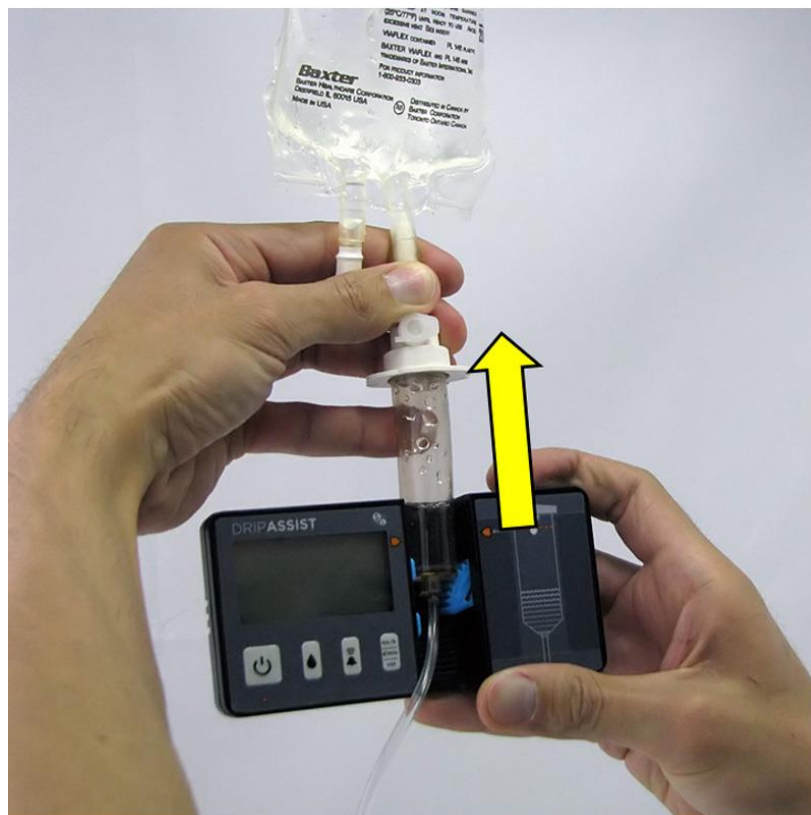


The first, and largest, is the display of flow rate which is the middle of the screen. The second is in the bottom left corner of the screen which displays the selected tubing size. The

third is the bottom right corner of the screen which displays the alarm status: alarm off or the rate at which the alarm was set to. The fourth element [REDACTED]

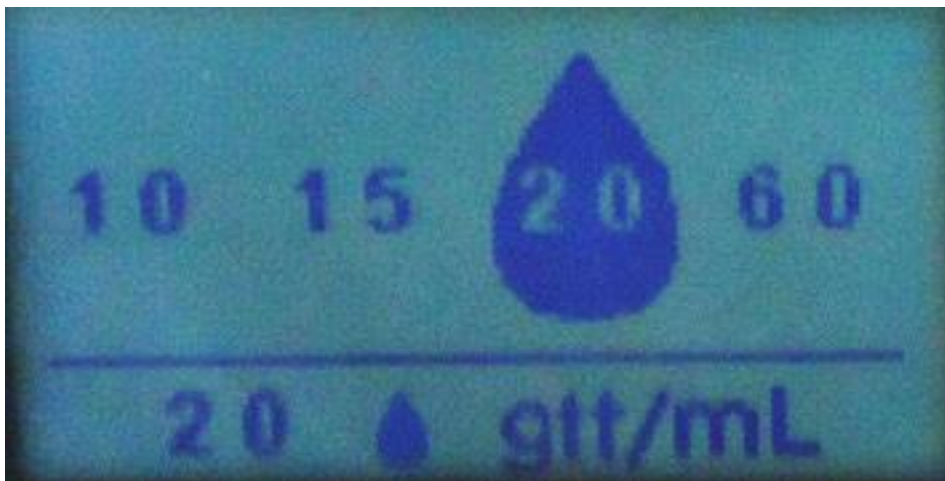
[REDACTED]. The fifth element appears to the right of the displayed flow rate, and that is the units of measurement in which the user is seeing the flow rate: drops per minute, mL per hour, or total volume.

The device operates by tracking drops using [REDACTED] chamber is situated. The DripAssist is positioned on the drip chamber by sliding the device upwards so the rotating cam moves downward and [REDACTED] s [REDACTED].





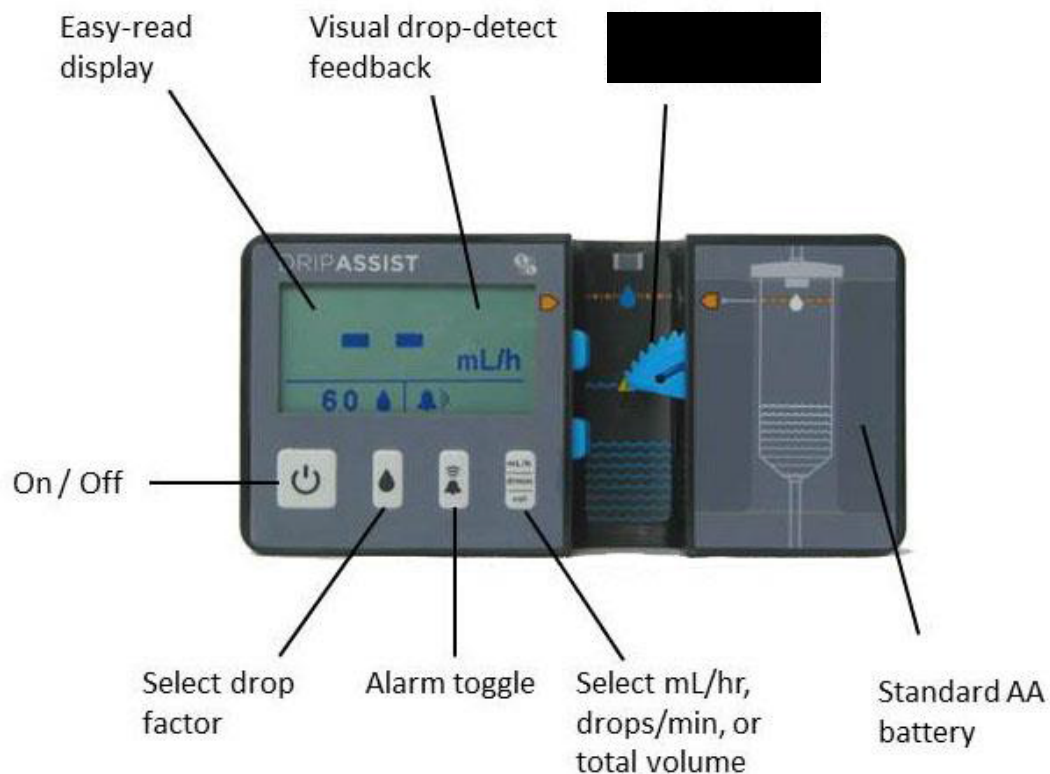
There are four buttons on the device. The first button is the power button. The device can be turned on either before the device is positioned on the drip chamber or after positioning. When the device is turned on, the screen comes to life and four numbers are displayed: 10, 15, 20, 60. These represent the possible tubing sizes and serve as a prompt for the user to select the correct one. Once the device is positioned on the drip chamber, the size of the tubing set is selected using the second button. That second button allows the user to toggle among the four tubing sizes, displayed on the screen by the numbers 10, 15, 20 and 60.



The device will not begin calculating until the tubing size gtt/mL is selected. The correct size is selected by pushing the second button once. Once the size is selected, the bottom left side of the screen displays the selected tubing size as user feedback and confirmation that their intended selection registered with the device.

Once the user begins the fluid administration through means not involving the DripAssist, the device begins to calculate the flow rate. The device [REDACTED]. Until that time, [REDACTED]. Once the flow rate stabilizes, the user can elect to activate the alarm. This is done by pressing the alarm button once to create a 'set point.' That 'set point' is then [REDACTED]. The alarm is deactivated by pressing the alarm button again. When the alarm is not activated, the bottom right hand sector of the screen displays an alarm icon with a line through it. Whenever the flow rate is displayed, the user can use the fourth button to select the unit of measurement they wish to see. The user changes the unit of measurement by pressing the fourth button which cycles through drops per minute, mL per hour, and total volume.

While the device is in use and calculating a flow rate, [REDACTED]. This serves as [REDACTED].



[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

Based [REDACTED] DripAssist, which are shown in Table 1.

Drip Set	mL / drip	Max Drips / Minute	Max mL / minute	Max mL / hour
10 drops / mL	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
15 drops / mL	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
20 drops / mL	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
60 drops / mL	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]

Table 1: [REDACTED] the DripAssist

Flow Rate Calculations:

The flow rate of [REDACTED]

Interval Calculation

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

Milliliters per Hour:

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

Total Volume:

[REDACTED]

[REDACTED]

Limitations

The reported or displayed flow rate is limited by the number of characters available on the LCD screen.

Table 2 shows the differences between

Drip Set	Max Detectable mL / minute	Max Detectable mL / hour	Max Displayable ml/hour	Effective Maximum flow rate for a given Drip Set
10 drops / mL				
15 drops / mL				
20 drops / mL				
60 drops / mL				

Table 2:

The microprocessor also monitors the AA battery to ensure the device is able to continue accurate calculations. When the device battery runs low, When the voltage level of the battery and the s The device will not operate when the power to the microprocessor is inadequate to guarantee accurate measurements.

The power management component of the software allows the device to operate for approximately

Bench testing indicates that the DripAssist measurements