

MONIDOR

IV SCREEN™ USER MANUAL



For software version 1.7.0

CE 0598

Contents

1. Introduction	3
1.1 Intended use.....	3
1.2 Intended conditions of use	3
1.3 Operating principle	4
1.4 Medical device classification	4
1.5 Supported browsers	4
1.6 Service Life.....	5
2. Safety instructions.....	5
2.1 Safety standards	5
3. Basic use	6
3.1 Main view.....	6
3.2 Assigning the Monidrop location.....	7
4. Notifications.....	9
4.1 Infusion rate notifications	9
4.2 Total volume.....	10
4.3 Treatment duration	10
4.4 Battery notifications.....	10
4.5 Mobile phone notifications	11
4.6 Notifications displayed on the Monidrop W Infusion Monitor	12
5. Other Functions.....	13
5.1 Infusion additional information, such as type of IV fluid.....	13
5.2 Setting notification threshold for the amount of IV fluid	14
5.3 Setting notification threshold for treatment duration.....	15
5.4 Simultaneous setting of liquid volume and duration of treatment.....	16
5.5 Daily monitoring.....	17
5.6 Settings displayed on the Monidrop W Infusion Monitor	17

1. INTRODUCTION

This document is the user manual for IV Screen infusion remote monitoring, a software designed by Monidor Oy.

It is recommended that you read this user manual carefully before use.

This software can only be used with Monidrop® W Infusion monitor delivered by Monidor Oy. The use of the software with any other monitoring device is forbidden.

1.1 Intended use

IV Screen is a cloud-based software service. Monidrop® W infusion meters connect to the IV Screen service and send infusion and device information to the IV Screen service and receive infusion-related reference values as shown in Figure 1.

IV Screen application shows infusion data of the connected infusion monitors on a mobile device or a PC screen. Multiple Monidrop W infusion monitors can be connected to IV Screen simultaneously.

The intended purpose of the IV Screen is to remotely show current IV infusion status of above-mentioned IV infusion monitors:

- infusion flow rate
- infusion volume
- infusion time
- notification status
- battery status

IV Screen application gives visual notifications. It shows the identification information of each infusion monitor, which are connected to the IV Screen cloud. Remote monitoring of all infusions from one screen helps nurses to evaluate and follow IV infusions.

1.2 Intended conditions of use

Application is intended to be used in the following conditions:

- In hospitals, hospitals wards, hospital theatres, surgeries, health centres, doctor's offices, clinics
- Indoor use
- In the home
- It is possible, but not recommended, to use the application in outdoor environment.

1.3 Operating principle

IV Screen receives and stores the remote monitoring data from the remote devices and shows the remote monitoring data and notifications to the users.

IV Screen service is run on secure cloud server or on a locally hosted server, and it is used with IV Screen application for Windows or Android, or with a Web browser.

Monidor remote monitoring service consists of three parts. See figure 1:

- 1) Monidrop infusion meters, that measure status of IV infusion therapy and send data, such as current infusion rate and infused total volume to IV Screen.
- 2) a cloud or server software service which receives and stores the remote monitoring data from the Monidrop devices, and
- 3) a user interface to show the remote monitoring data to the users. It may include audible/visual notifications to the user. It may allow pre-setting of monitoring related parameters. These parameters may be e.g., notification threshold or device control parameters.

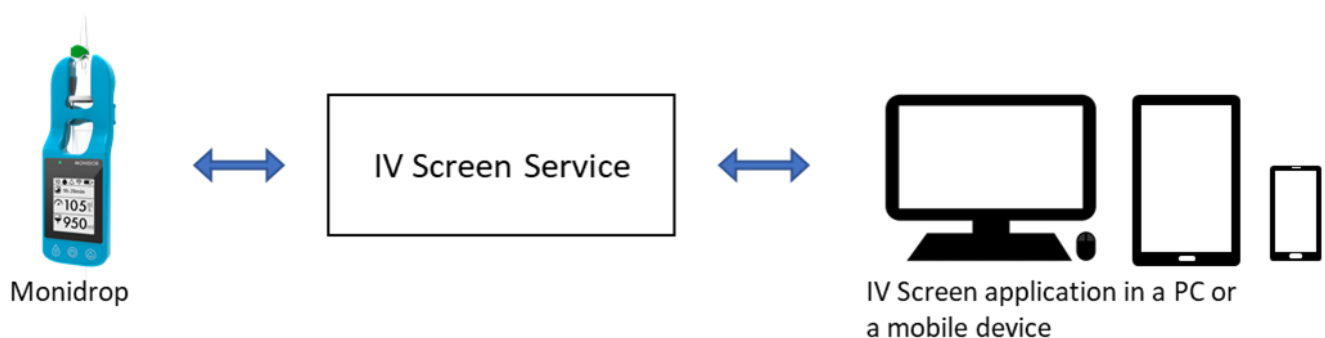


Figure 1: IV Screen Data flow

1.4 Medical device classification

IV Screen software service is classified class Im (according to Directive 93/42/EEC).

1.5 Supported browsers

- Chrome version 78
- Microsoft Edge version 97.0.1072.55
- Firefox version 70

Other browsers may also be supported.

1.6 Service Life

IV Screens software service lifetime is 5 years.

2. SAFETY INSTRUCTIONS

- Monidor is not responsible for the safety of the user's remote display devices (e.g. PC or mobile phone).
- Stable internet connection is required to use remote monitoring software
- The device has also been approved for home care in accordance with standard 60601-1-11.
- The user must always evaluate the correctness of the information displayed before making any treatment decisions.
- Regardless of recommended limits, the values selected for treatment must be medically correct.
- The user must ensure that patient information is correct and the selected target concentrations and measured dosage rates comply with the regulations of the country in question.
- Connection is permitted only to devices that Monidor Oy has approved.
- Regardless of the use of IV Screen, the care personnel need to regularly observe the patients according to local practices and policy.

WARNING: Monidrop® W infusion monitor DOES NOT ADJUST the infusion rate. ALWAYS use gravity IV administration set to adjust the infusion rate.

WARNING: Modifying this device is prohibited.

2.1 Safety standards

- 93/42/EEC Medical Devices Directive (MDD)
- IV Screen satisfies all safety standards for medical device software in compliance with EN 60601-1.

3. BASIC USE

3.1 Main view

User can monitor multiple infusion therapies on the same screen. Each Monidrop device appears as a separate card on the screen.

The device cards show the measured infusion data and possible notifications. Some of the notifications are based on parameters defined by the user, see chapter 4. If there is an active notification in the card, it's emphasized with yellow colour, and the reason for the notification is written in text at the bottom of the card.

The notification is automatically cleared off the screen after the cause of the notification has been corrected.



Figure 2: IV Screen monitoring view

Card View:

1. Device number
2. Battery charge status
3. Optional text field
4. Room and patient location
5. Amount of fluid administered and the remaining/target fluid amount (ml)
6. Infusion rate and target infusion rate (ml/h)
7. Duration of the treatment and the remaining time of the target duration (h, min)
8. Reason for the notification in text

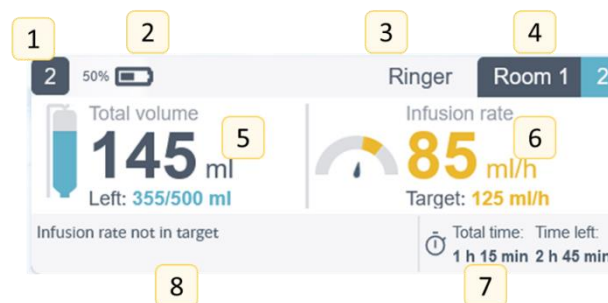


Figure 3: Device card elements

3.2 Assigning the Monidrop location

Device card in IV Screen can be identified by the ID number in the top-left corner of the device card. That ID number matches the number in the top-left corner of the Monidrop infusion meter's screen.



Figure 4: Device number

Assign the device location by clicking the device card that matches the Monidrop device in the remote monitoring screen. The room and location can be chosen from the pre-defined choices.

- open device options by clicking the device card
- Tap location field (1)
- Select room and location where Monidrop infusion meter is being used (2,3)
- save the selected values by clicking "Save"

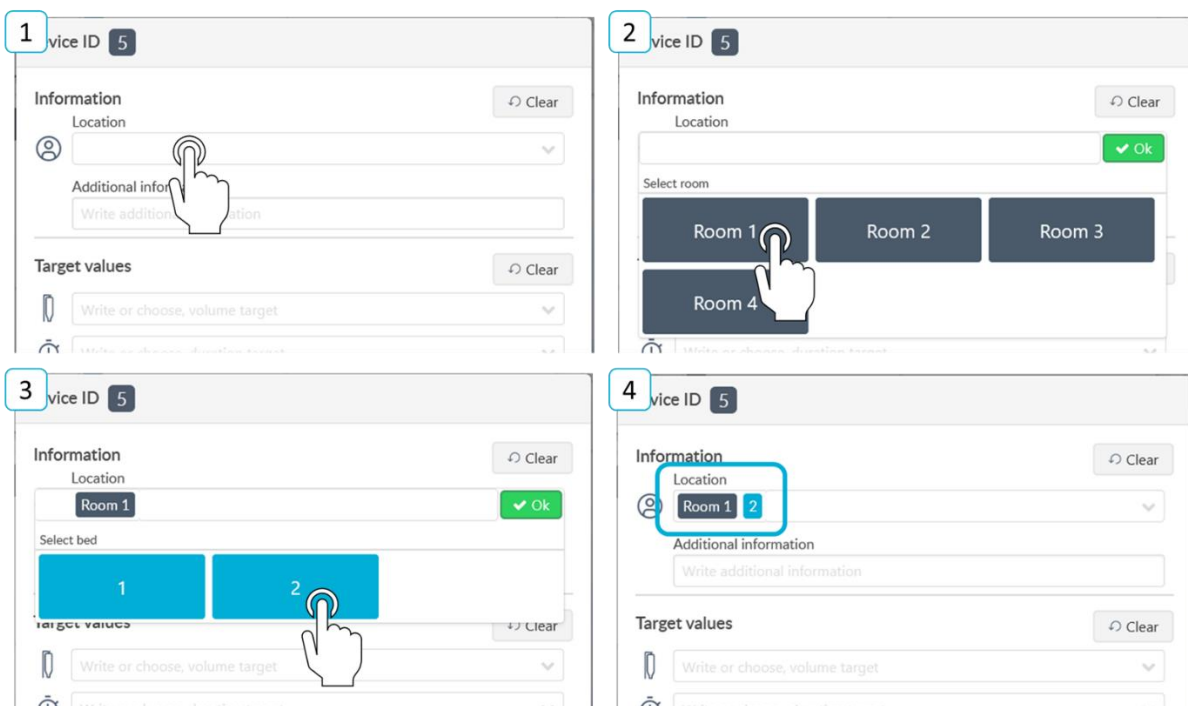


Figure 5: Assign device to room and bed location

4. NOTIFICATIONS

IV Screen provides notifications for both treatment-related and software-related parameters. The messages are also displayed on the Monidrop W display and LED lights.

Notifications:

Notification	Visual notification	Phone notification	Always enabled notification	Acknowledgment
Infusion rate under 6 ml/h	X	X	X	Automatic once the reason for the notification has been removed
Infusion rate over 1200 ml/h	X	X	X	
Infusion rate not in target	X			
Total volume nearly reached	X	X		
Total volume reached	X	X		
Duration nearly reached	X			
Duration reached	X			
Battery charge under 20%	X	X	X	
Battery charge under 5%	X	X	X	
Last connection was 5 min ago	X		X	

4.1 Infusion rate notifications

Infusion rate notifications are shown using yellow colour, and the reason for the notification is shown also in text. The messages will automatically disappear once the cause has been corrected.

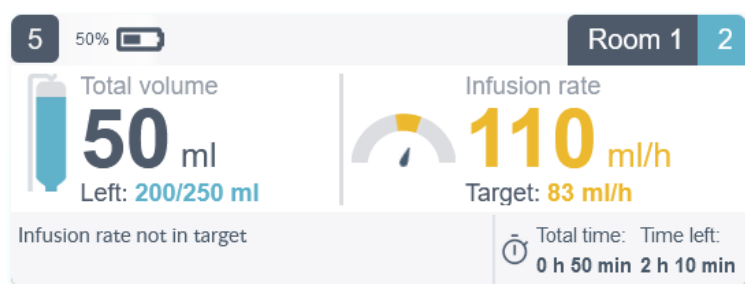


Figure 6: Infusion rate notification

4.2 Total volume

When the total volume is completed, the notifications will appear in the card in yellow colour, and the reason for the notification is shown as text on the bottom of the card.

The notification is removed when the volume target is cleared in the device settings window, or new target is set e.g. when starting a new infusion bag.

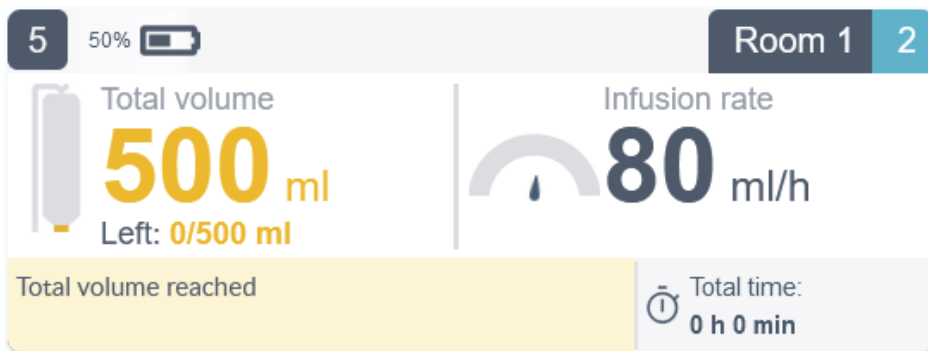


Figure 7: Total volume notification

4.3 Treatment duration

When the treatment duration is reached, the notification is shown in yellow, and the reason for the notification is shown as text on the bottom of the card.

The notification is removed when the duration target is cleared in the device settings window, or new target is set e.g., when starting a new infusion bag.

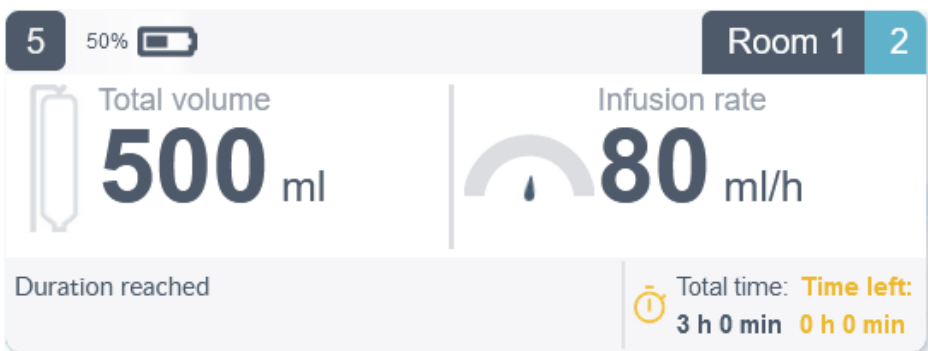


Figure 8: Duration reached notification

4.4 Battery notifications

The Monidrop W Infusion Monitor battery status notification is shown as yellow battery indicator icon. The reason for the notification is shown as text on the bottom of the card. The first notification is shown when 20% of the charge status is left and the second notification when the charge status is 5%. The message disappears when the device is charged.

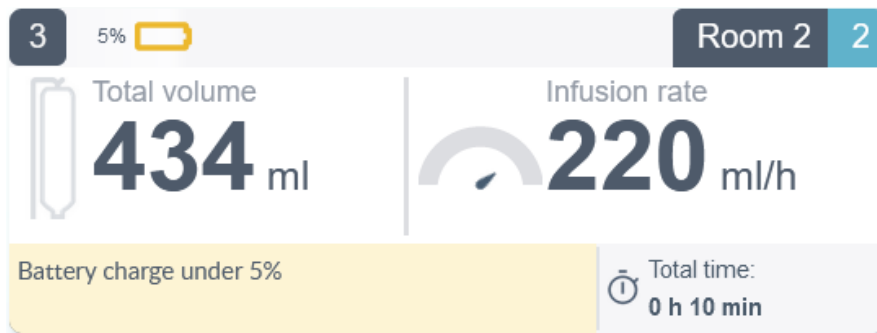


Figure 9: Low battery charge notification

4.5 Mobile phone notifications

User can activate mobile phone notifications by clicking the slider button in the device settings dialog. When activating mobile phone notifications in specific smart phone, they are not activated automatically in other phones.

Device ID 7

Information Clear

Location ▼

Additional information
Write additional information

Target values Clear

Write or choose, volume target ▼

Write or choose, duration target ▼

Mobile notifications Toggle switch (highlighted)

Daily monitoring show ▼

Cancel Save

Serial number: ETU00760299

4.6 Notifications displayed on the Monidrop W Infusion Monitor

When you set target values via the IV Screen, the values you set are transmitted over the wireless network to the Monidrop W Infusion Monitor screen.

For example, if the infusion rate is less than 6 ml/h or if it deviates from the set notification limits, a flashing triangle will appear next to the infusion rate icon.

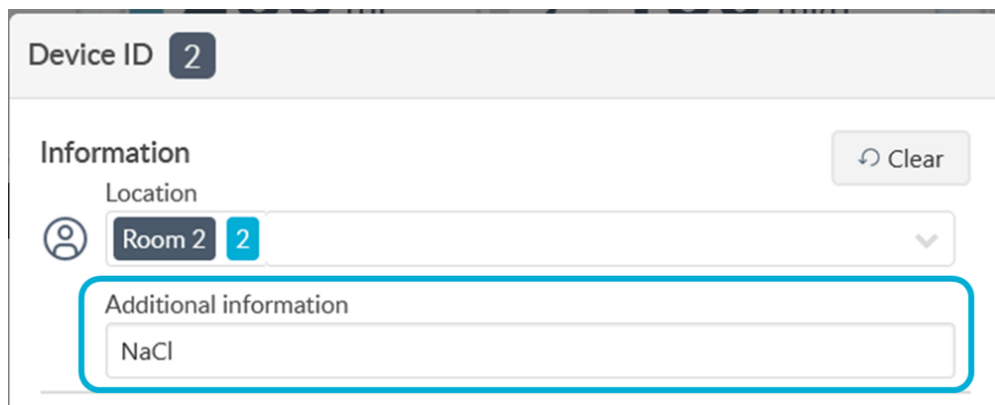


5. OTHER FUNCTIONS

5.1 Infusion additional information, such as type of IV fluid

If you want the liquid type used for treatment to be displayed on IV Screen, you can name it at the patient Room and patient place setting.

1. Open the device settings window by clicking the device card
2. Enter the type of the used IV fluid into the Additional information field. Optionally some other additional information may also be entered in this field
3. Confirm the added information by clicking "Save".



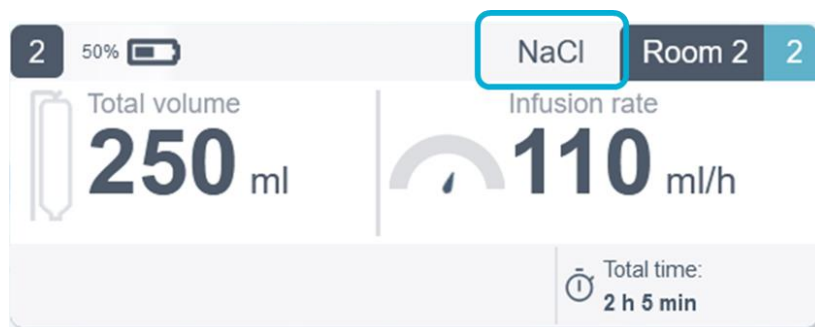
Device ID 2

Information Clear

Location Room 2 2

Additional information NaCl

The additional information is shown next to the location fields.



2 50% NaCl Room 2 2

Total volume **250** ml

Infusion rate **110** ml/h

Total time: 2 h 5 min

5.2 Setting notification threshold for the amount of IV fluid

You can set the amount of infusion fluid you will be using.

1. Open the device settings dialog by tapping the device card
2. Tap the volume target field, which opens a drop-down menu
3. Choose one of the pre-set options or type in a custom value
4. Confirm your choice by clicking "Save"

The screenshot shows a dialog titled "Target values" with a "Clear" button in the top right. Below the title is a text input field with the placeholder "Write or choose, volume target" and a green "Ok" button. Below this is a section labeled "Select volume" with a list of pre-set options: 100 ml, 250 ml, 500 ml, 1000 ml, 1500 ml, and 2000 ml. The options are arranged in two rows of three. A "Daily" label is on the left, and a "Save" button is at the bottom left.

The set amount of liquid is shown next to the IV bag icon. The first number shows how much fluid is left (ml), and the second number shows the original target value (ml).

The screenshot shows the IV screen with a status bar at the top displaying "5", "97%", and a battery icon. The main area is divided into two sections: "Total volume" and "Infusion rate". The "Total volume" section shows a blue IV bag icon, "0 ml", and "Left: 500/500 ml". The "Infusion rate" section shows a yellow "0 ml/h" and a gauge. At the bottom, there is a yellow bar with "Infusion rate under 6 ml/h" and a grey bar with "Total time: 0 h 0 min".

5.3 Setting notification threshold for treatment duration

You can set the target duration of the treatment in hours and minutes, and the program will notify you when the time is about to be reached and when it is reached.

1. Open the device settings dialog by tapping the device card
2. Tap the duration target field, which opens a drop-down menu
3. Choose one of the pre-set options or type in a custom value as days, hours and minutes
4. Confirm your choice by clicking "Save"

Target values Clear

Write or choose, volume target

Select infusion time

Dail

30 min 1 h 2 h

3 h 4 h 5 h

6 h 12 h 24 h

Serial

The set time will appear on the right side next to the total elapsed time. The reading shows how much time is left from the target value.

5 97%

Room 2 2

Total volume 0 ml

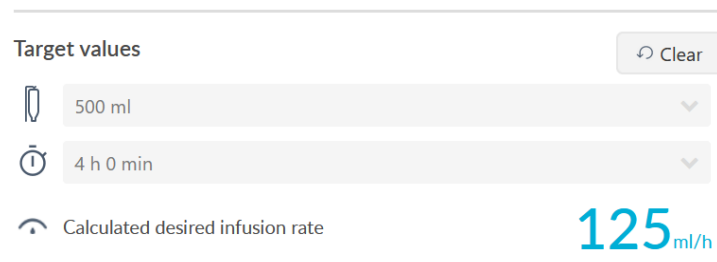
Infusion rate 0 ml/h

Infusion rate under 6 ml/h


Total time: Time left: 0 h 0 min 4 h 0 min


5.4 Simultaneous setting of liquid volume and duration of treatment

If both liquid volume and duration of treatment are set, IV Screen calculates the target infusion rate automatically. If the speed deviates from the set value more $\pm 30\%$, IV Screen will show a notification.



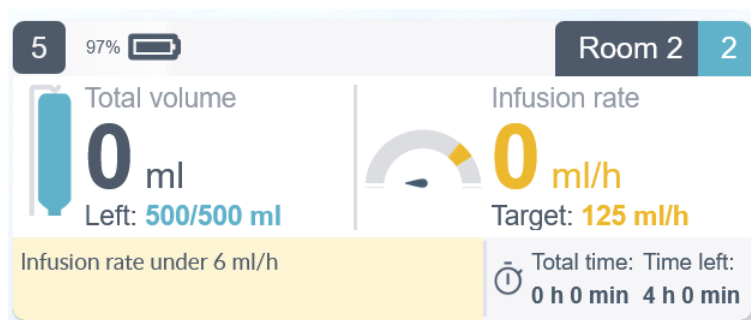
Target values ↺ Clear

 500 ml ▼

 4 h 0 min ▼

 Calculated desired infusion rate **125_{ml/h}**

The target infusion speed is shown below current infusion speed.




5 97% Room 2 2

Total volume **0 ml**
Left: 500/500 ml

Infusion rate **0 ml/h**
Target: 125 ml/h

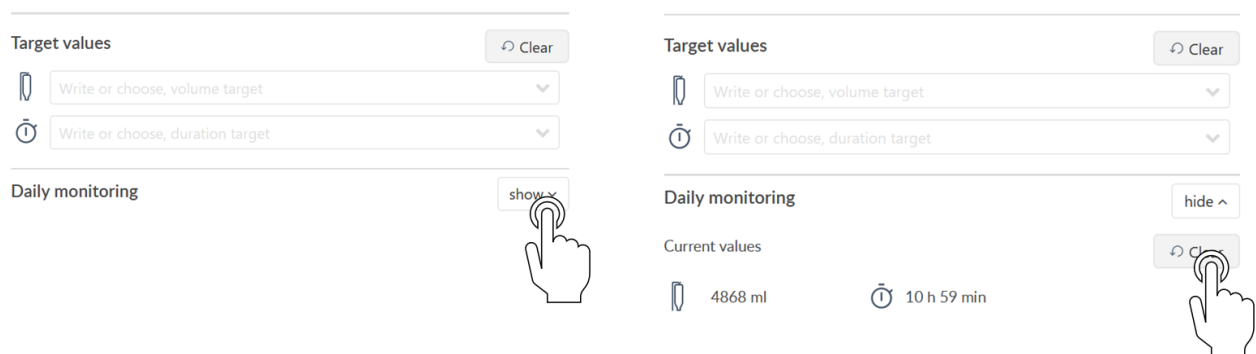
Infusion rate under 6 ml/h

 Total time: Time left:
0 h 0 min 4 h 0 min

5.5 Daily monitoring

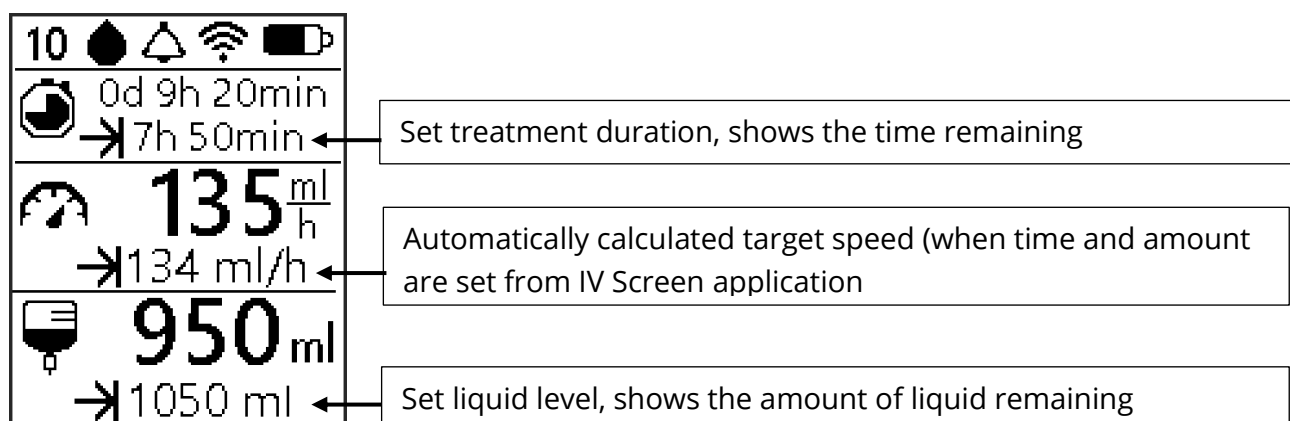
Total amount of infused fluid and the duration can be reset to zero e.g. once a day. After resetting the values, the previous values are shown in the dialog until next reset or until Monidrop device is restarted. Resetting the values does not affect the target or remaining amount of IV fluid or time.

1. Open the device settings dialog by tapping the device card
2. Show the daily monitoring section by clicking the "show" button
3. Click "Clear"



5.6 Settings displayed on the Monidrop W Infusion Monitor

When you make infusion therapy settings through the IV Screen application, the settings appear on the screen of your Monidrop W infusion monitor.





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