

MONIDOR

IV SCREEN INSTRUCTIONS FOR USE

For software version 1.0.0



CE0598

Sisällys

1. Introduction	2
1.1 Intended use.....	2
1.2 Intended conditions of use	3
1.3 Operating principle	3
1.4 Medical device classification	3
1.5 Supported browsers	3
1.6 Service Life.....	3
2. Safety instructions.....	4
2.1 Safety standards	4
3. Basic use	5
3.1 Main view.....	5
3.2 Assigning the patient place	6
4. Notifications.....	8
4.1 Infusion rate notifications	8
4.2 Total volume.....	9
4.3 Treatment duration	9
4.4 Battery notifications.....	10
4.5 Notifications displayed on the Monidrop W Infusion Monitor	11
5. Other Functions.....	12
5.1 Naming administrated liquid type.....	12
5.2 Setting notification threshold for amount of liquid	13
5.3 Setting notification threshold for treatment duration.....	14
5.4 Simultaneous setting of liquid volume and duration of treatment.....	15
5.5 Managing device view.....	16
5.6 Settings displayed on the Monidrop W Infusion Monitor	16
6. Manufacturer Contact Information	17

1. INTRODUCTION

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

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

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

1.1 Intended use

“IV Screen” is a cloud SW application. IV infusion monitors (e.g. Monidrop® W) connect to the IV Screen cloud application and send infusion and device data to it and receive some infusion related reference values. from IV Screen.

IV Screen shows infusion data of the connected infusion monitors on a web browser window. Multiple Monidrop W infusion monitors can be connected to IV Screen simultaneously.

The “IV Screen” defines both interfaces, from the IV infusion monitor to the “IV Screen” and from the “IV Screen” to the remote display unit.

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 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 centers, Doctor's offices, Clinics
- Interior use
- In the home
- It's possible, but not recommended, to use Application in exterior 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.

The application is run in locally hosted server or in secure cloud server and it is used e.g. with a Web browser.

The application consists of two parts:

1) a cloud or server software which receives and stores the remote monitoring data from the remote devices, and

2) 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.

1.4 Medical device classification

Class Im (according to Directive 93/42/EEC)

1.5 Supported browsers

- Chrome version 78
- Microsoft Edge version 44.18362.1.0
- Firefox version 70

Other browsers may also be supported.

1.6 Service Life

5 years.

2. SAFETY INSTRUCTIONS

- Monidor is not responsible for the safety of the 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 use of IV Screen, the care personnel needs to regularly observe the patients according local practices and norms.

WARNING: Monidrop® W infusion monitor DOES NOT ADJUST the infusion rate. ALWAYS use a roller clamp to adjust the infusion rate.

WARNING: Modifying this device is prohibited.

2.1 Safety standards

- 3/42/EEC Medical Devices Directive (MDD)
- IV Screen satisfies all safety standards for medical device software in compliance with EN 60601-1.

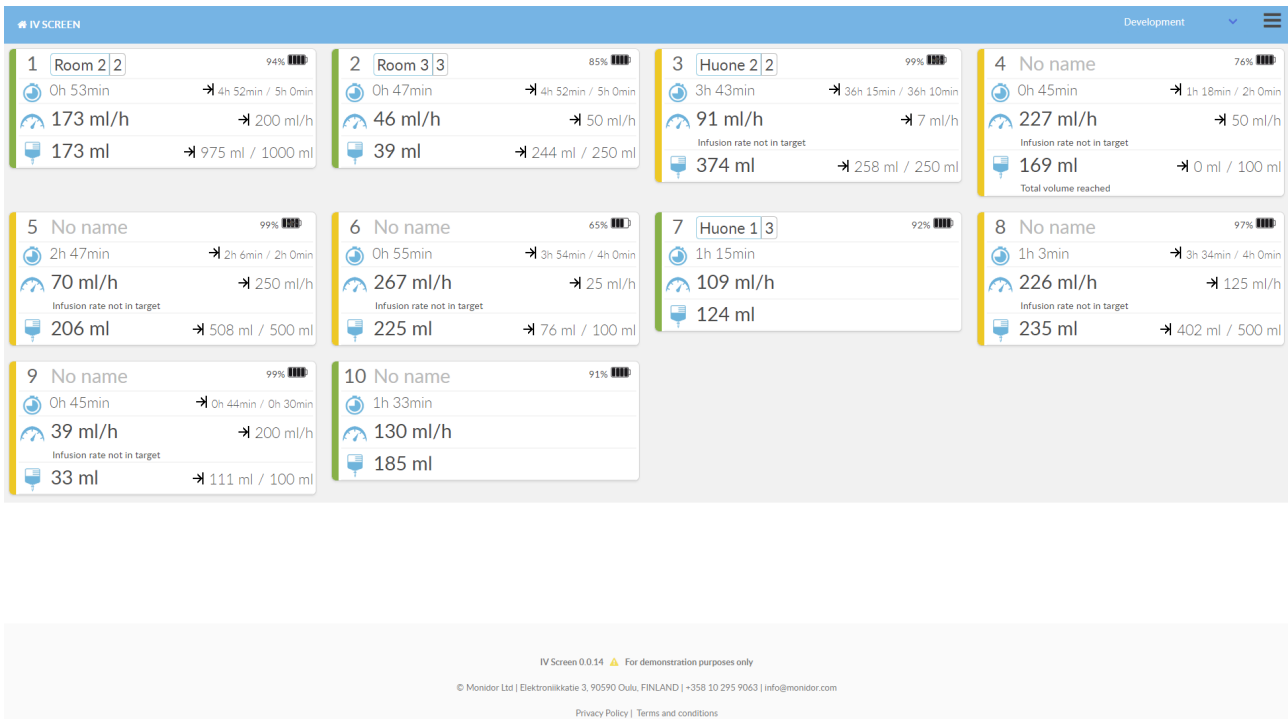
3. BASIC USE

3.1 Main view

In IV Screen main view, all infusion treatments with Monidrop W infusion monitors on the same ward can be viewed on the same screen. Each device appears as a separate card on the screen.

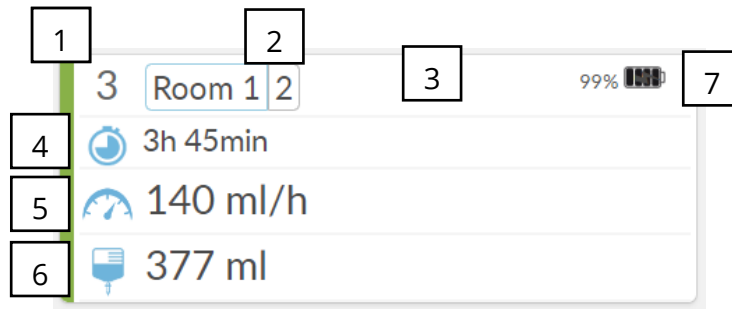
The green color on the left side of the card indicates that there are no active notifications. The color will turn yellow if there is an active notification. Some of the notifications are based on user defined infusion parameters, see Chapter 4. The cause of the notification is highlighted in yellow and the reason for the message appears on the card.

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



Card View:

1. Device Number
2. Room and patient place
3. Optional text field. For example, the type of liquid used can be added.
4. Duration of treatment in hours and minutes.
5. Infusion rate (ml / h)
6. Amount of fluid administrated (ml)
7. Battery charge status



3.2 Assigning the patient place

Name the patient by selecting the card corresponding to the number of the Infusion Monitor you are using. You can choose a room and patient place from the options provided by the software, or type freely in the typing box.

Device Number	Room / Patient Place	Duration	Infusion Rate	Amount of Fluid	Battery Status
1	Room 2 2	0h 53min	173 ml/h	173 ml	94%
2	Room 3 3	0h 47min	46 ml/h	39 ml	85%
3	Room 5 2	3h 43min	91 ml/h	374 ml	99%
4	No name	0h 45min	227 ml/h	169 ml	76%
5	No name	2h 47min	70 ml/h	206 ml	99%
6	No name	0h 55min	267 ml/h	225 ml	65%
7	Room 2 1	1h 15min	109 ml/h	124 ml	92%
8	No name	1h 3min	226 ml/h	235 ml	97%
9	No name	0h 45min	39 ml/h	33 ml	99%
10	No name	1h 33min	130 ml/h	185 ml	91%

IV Screen 0.0.14 For demonstration purposes only
© Monitor Ltd | Elektronikkatie 3, 90590 Oulu, FINLAND | +358 10 295 9063 | info@monitor.com
Privacy Policy | Terms and conditions

1. Select the top row of the card you are using.
2. Select the room and location where the Monidrop W Infusion Monitor is used. You can also type any text you like in the open text box, for example the type of fluid you are using. Select "OK" to confirm.
3. Confirm your selection by selecting "Save".

F21A10010009

Write or choose, name/place

Write or choose, volume target ml

Write or choose, duration target

Save Cancel

F21A10010009

Write name Ok

Room 1	Room 2
Room 3	Room 4
Room 5	Room 6

4. NOTIFICATIONS

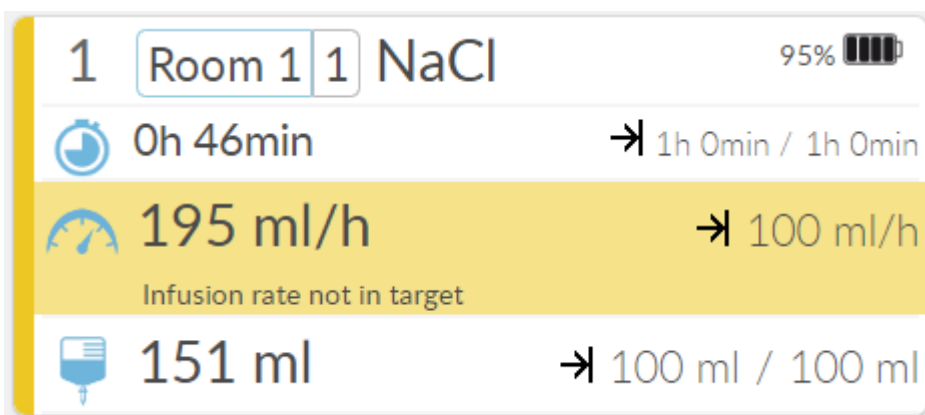
IV Screen provides notifications for both treatment-related and software-related parameters. The messages are also displayed on the Monidrop WLAN Infusion Monitor display and LED lights.

Notifications:

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

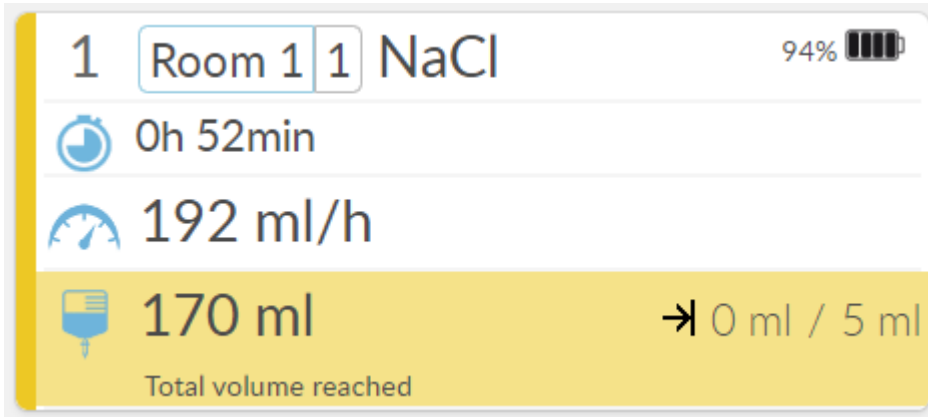
4.1 Infusion rate notifications

Infusion rate notifications appear in the infusion rate card view on the same line as the infusion rate readings. The messages will automatically disappear once the cause has been corrected.



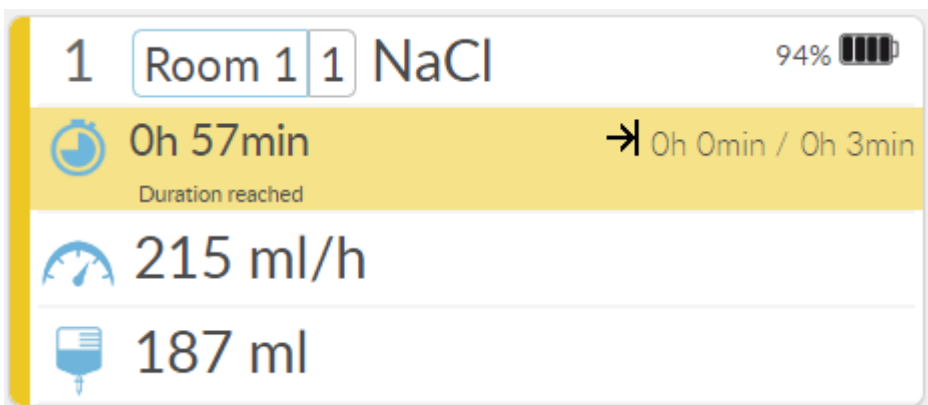
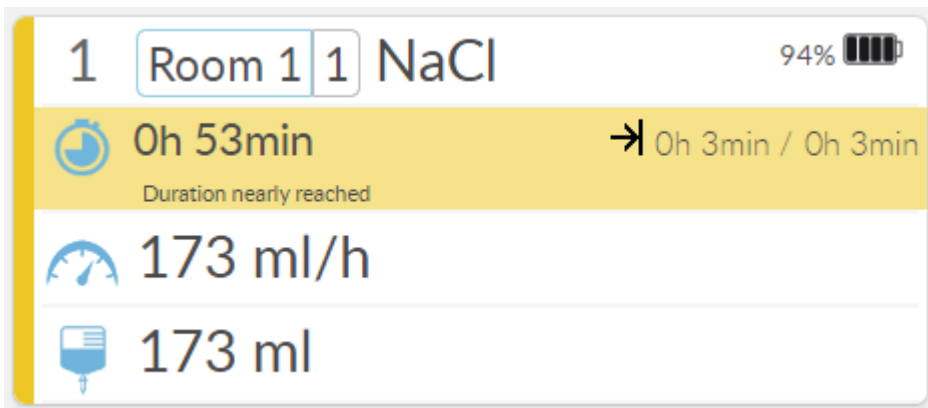
4.2 Total volume

When the total volume set is full, the notifications will appear in the card view on the same line as the total volume already dripped. The messages will automatically disappear once the cause has been corrected.



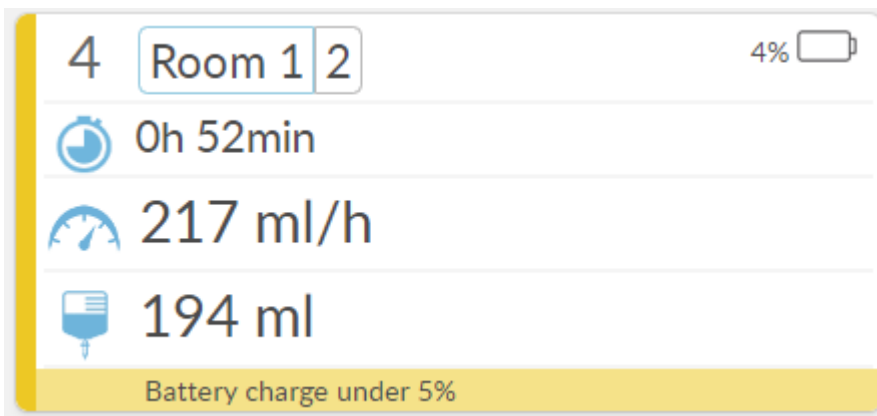
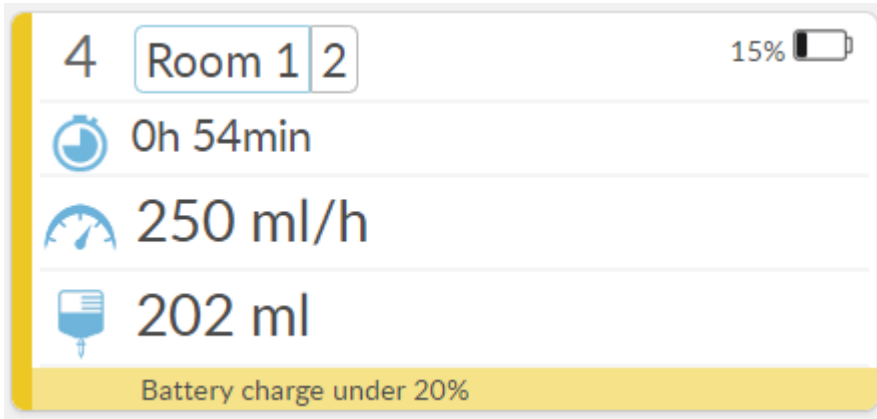
4.3 Treatment duration

When the treatment duration is reached, the notifications appear in the treatment duration card view on the same line as the real-time treatment duration readings. The messages will automatically disappear once the cause has been corrected.



4.4 Battery notifications

The Monidrop W Infusion Monitor battery status message appears on the bottom line of the card. The first notification comes 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.



4.5 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 deviates from the set notification limits, a flashing triangle will appear next to the infusion rate icon.

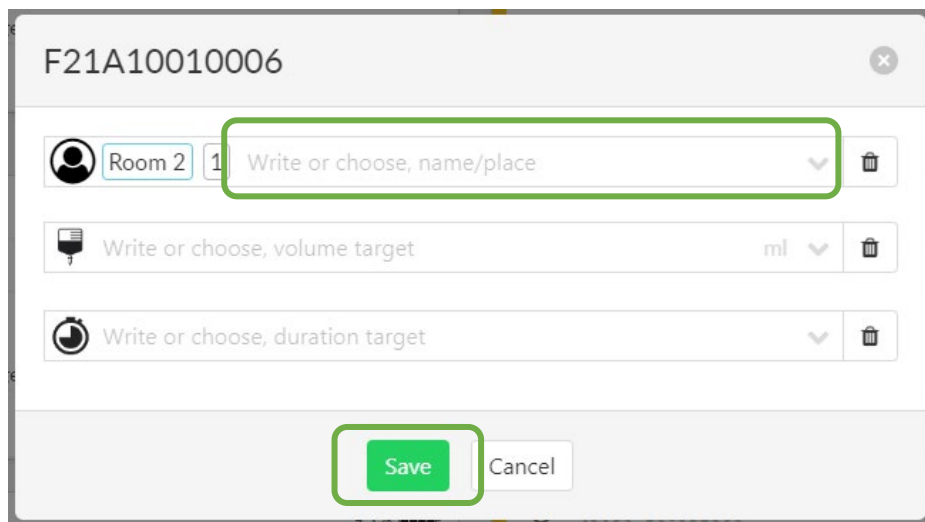


5. OTHER FUNCTIONS

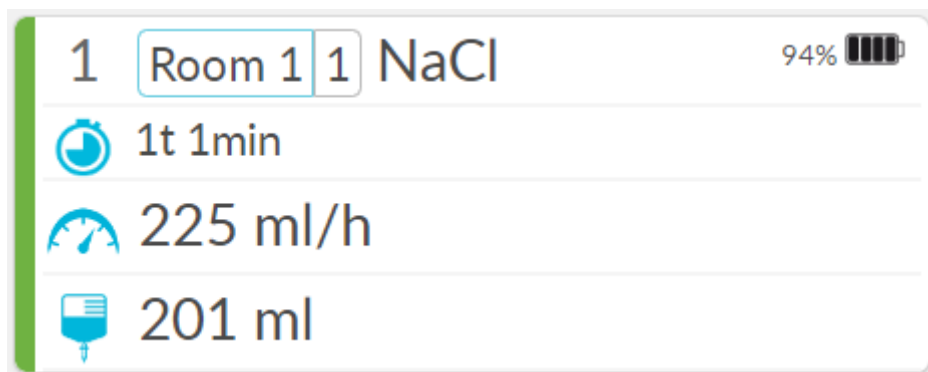
5.1 Naming administrated liquid type

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. Tap the place naming box with to open the menu.
2. Write down the type of liquid you are using in the open text box. You may also enter here any additional information you may need during treatment. Select "Ok" to confirm.
3. Confirm your selection by selecting "Save".



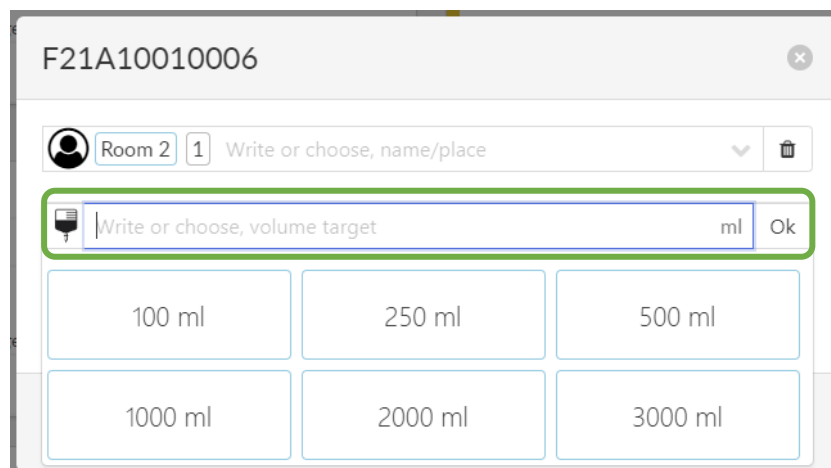
The amount of fluid written in the free writing field (NaCl as shown below) is now displayed to the right of the room and location information.



5.2 Setting notification threshold for amount of liquid

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

1. Tap the fluid volume naming box to open a drop-down menu.
2. Enter the amount you use in milliliters or select one of the options provided by the program. Select "Ok" to confirm.
3. Confirm your selection by selecting "Save".



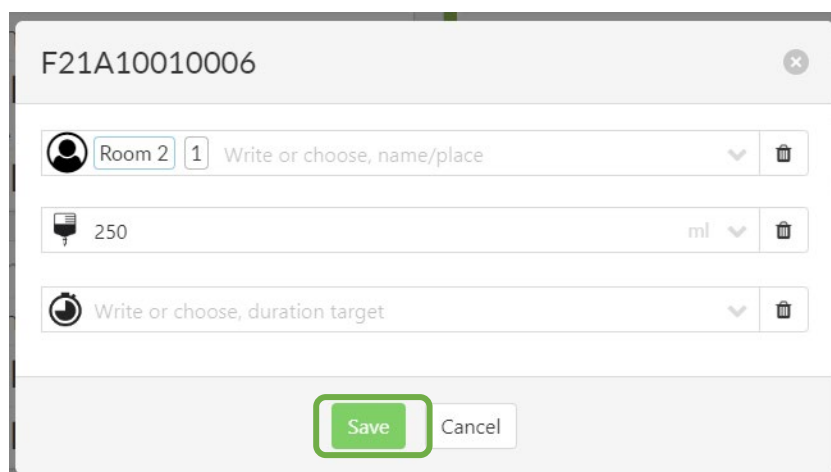
F21A10010006

Room 2 1 Write or choose, name/place

Write or choose, volume target ml Ok

100 ml 250 ml 500 ml

1000 ml 2000 ml 3000 ml



F21A10010006

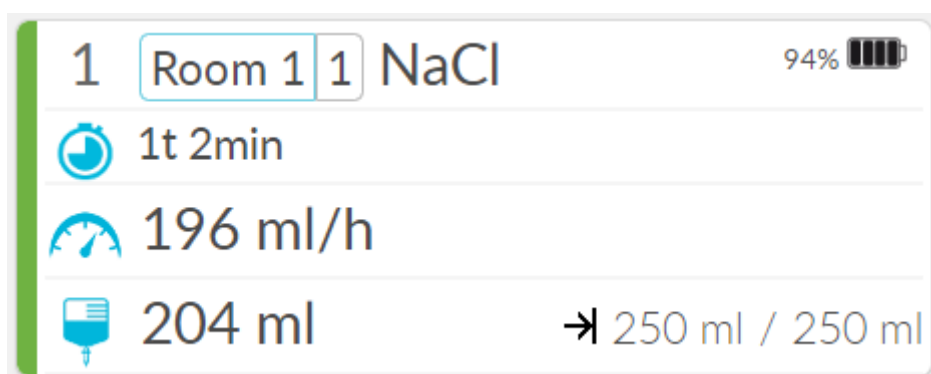
Room 2 1 Write or choose, name/place

250 ml

Write or choose, duration target

Save Cancel

The set amount of liquid appears on the right side of the liquid level line. The first reading tells you how much liquid is left, and the second reading shows the amount of liquid initially set.



1 Room 1 1 NaCl 94%

1t 2min

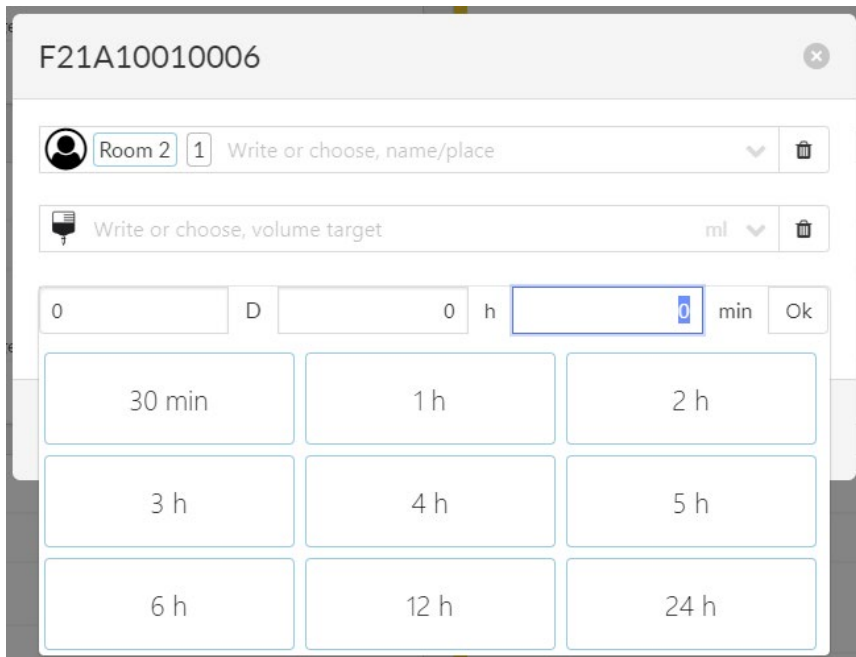
196 ml/h

204 ml → 250 ml / 250 ml

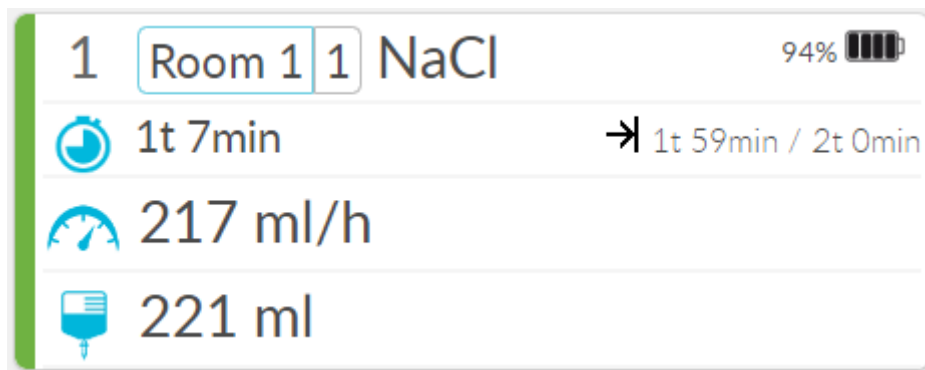
5.3 Setting notification threshold for treatment duration

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

1. Tap the fluid volume naming box. This will bring up the dropdown menu.
2. Type the duration of your treatment in the boxes or select one of the options provided by the program.
3. Confirm your selection by selecting "Save".

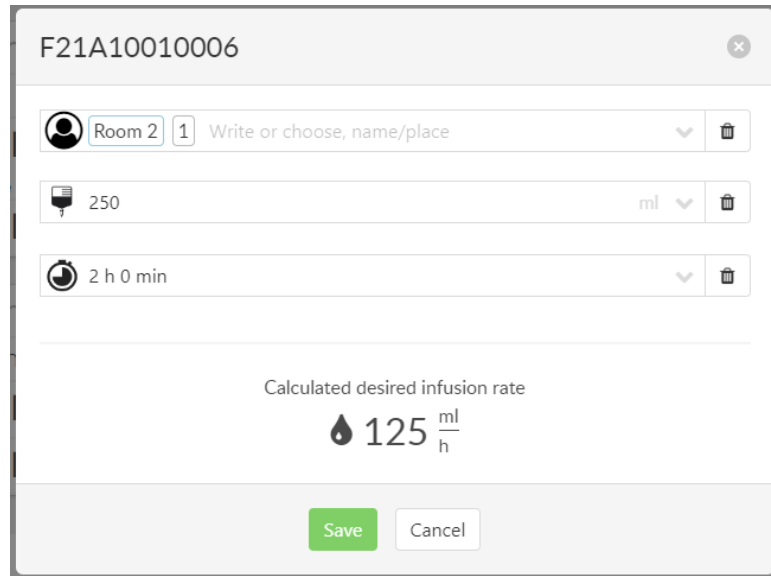


The set time will appear on the right side. The first reading tells you how much of the set time is left and the second reading shows the original time set.



5.4 Simultaneous setting of liquid volume and duration of treatment

If you set both liquid volume and duration of treatment, the program automatically calculates the target infusion rate for the treatment that appears on the screen and on the Monidrop W infusion monitor. If the speed deviates from the set value +/- 30%, the IV Screen will notify.



The screenshot shows a user interface for setting infusion parameters. At the top, the identifier 'F21A10010006' is displayed. Below this, there are three input fields: a location field set to 'Room 2' with a quantity of '1', a volume field set to '250 ml', and a duration field set to '2 h 0 min'. Each field has a trash icon for deletion. Below the input fields, the text 'Calculated desired infusion rate' is shown, followed by a large display of '125 ml/h' with a drop icon. At the bottom, there are 'Save' and 'Cancel' buttons.

F21A10010006

Room 2 1 Write or choose, name/place

250 ml

2 h 0 min

Calculated desired infusion rate

125 $\frac{\text{ml}}{\text{h}}$

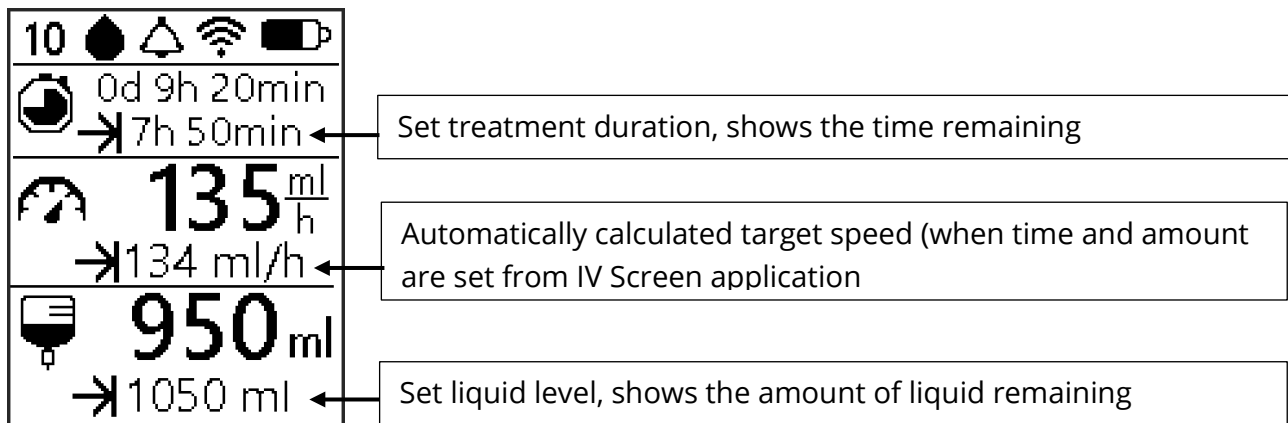
Save Cancel

5.5 Managing device view

You can select which department devices are displayed in the IV Screen if there are more than one department in your organization that you are working with.

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.



The image shows a screenshot of the Monidrop W Infusion Monitor display. The display is divided into four horizontal sections, each with a callout box explaining the settings:

- Top section:** Shows the number '10' and icons for a drop, a triangle, a Wi-Fi signal, and a battery level. Below this, it displays '0d 9h 20min' and '→7h 50min←'. A callout box points to the '7h 50min' and says: "Set treatment duration, shows the time remaining".
- Second section:** Shows a speedometer icon, '135 ml/h', and '→134 ml/h←'. A callout box points to the '134 ml/h' and says: "Automatically calculated target speed (when time and amount are set from IV Screen application)".
- Third section:** Shows a liquid level icon, '950 ml', and '→1050 ml←'. A callout box points to the '1050 ml' and says: "Set liquid level, shows the amount of liquid remaining".

6. MANUFACTURER CONTACT INFORMATION



Monidor Oy
Elektroniikkatie 3
90590 Oulu
Finland
Contact Phone

Version 2.0
Approved: 12/2019

MONIDOR