

MONIDOR

IV SCREEN™ USER MANUAL



For software version 1.8.2

CE0598

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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. A free paper version of this guide can be obtained by sending an email to Info@monidor.com. A copy will be sent within 5 days of receipt of the request.

This software can only be used with Monidrop® W Infusion meter 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 is intended for use in patients receiving gravity infusion therapy.

IV Screen is intended for use by medical staff who are authorised to administer gravity infusion therapy.

IV Screen application shows infusion data of the connected infusion meters on a mobile device or a PC screen. Multiple Monidrop W infusion meters 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 meters:

- 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 meter, 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, hospital wards, hospital theatres, surgeries, health centres, doctor's offices, clinics
- Indoors use
- At 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, Android or iOS, 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 such as notification threshold or device control parameters.

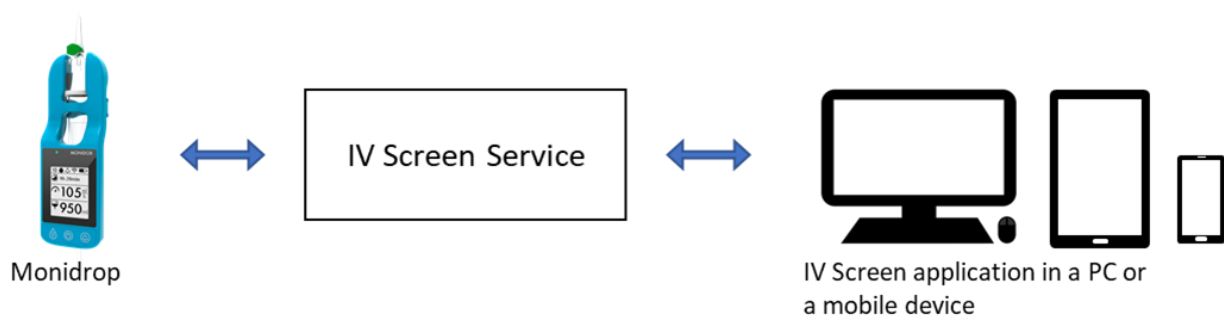


Figure 1: IV Screen Data flow

1.4. Medical device classification

IV Screen software service is classified

- Class Im according to Directive 93/42/EEC (MDD)
- Class IIa according to Regulation 2017/745 (MDR),

EUDAMED: The device is registered in the European Register of Medical Devices.

BASIC-UDI-DI code: 643006695V0046S

1.5. System requirements

Mobile device:

- Display: min 5 inches. HD colour (720x1280)
- CPU: 1.4 GHz 4 cores
- Camera: 2 MP
- Memory: 2 GB
- Operating System: Android 9 or later
- Network connectivity: Wi-Fi or mobile data (4G or 5G)

Computer:

- Display: min 14 in. 14 min HD color (1280 x 720)
- CPU: 1.5GHz 4 cores
- Memory: 4 GB
- Operating System: Windows 10, 11
- Network connectivity: Ethernet, Wi-Fi or mobile data (4G or 5G).

Supported browsers

- Chrome version 78 or later
- Microsoft Edge version 97.0.1072.55 or newer
- Firefox version 70 or newer
- IV Screen application for Android 2.0.0 or newer
- IV Screen application for Windows 1.5.0.0 or newer
- IV Screen application for iOS 18.3.2 or newer






Other browsers may also be supported.

1.6. Service life

IV Screen's software service lifetime is 5 years.

1.7. Symbols used for marking the device

The symbols used on the device comply with EN ISO 15223-1;2021.

Symbol	Explanation of symbols
	Please refer to the user manual or the electronic instruction manual.
	Medical device
	CE marking, includes the reference number of the notified body.
	Unique device identifier (01) UDI-DI Product identification number (11) UDI-PI/release date: release date of the software version, (year, month, day) (10) UDI-PI/batch number: version number Note
	The use of a device or control requires caution or that the situation requires the user to exercise care or to take action to avoid undesirable consequences.

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 meter DOES NOT ADJUST the infusion rate. ALWAYS use gravity IV administration set to adjust the infusion rate.

WARNING: Modifying this device is prohibited.

Incidents related to the device that have led to or could have led to a risk to the health of the patient, user or other person should be reported to your local competent authority and Monidor at info@monidor.com. The list of competent authorities is in Chapter 6.

2.1. Safety standards

- MDR 2017/745 EU Medical Device Regulation
- 719/2021 Medical Devices Act (FIMEA)
- 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.

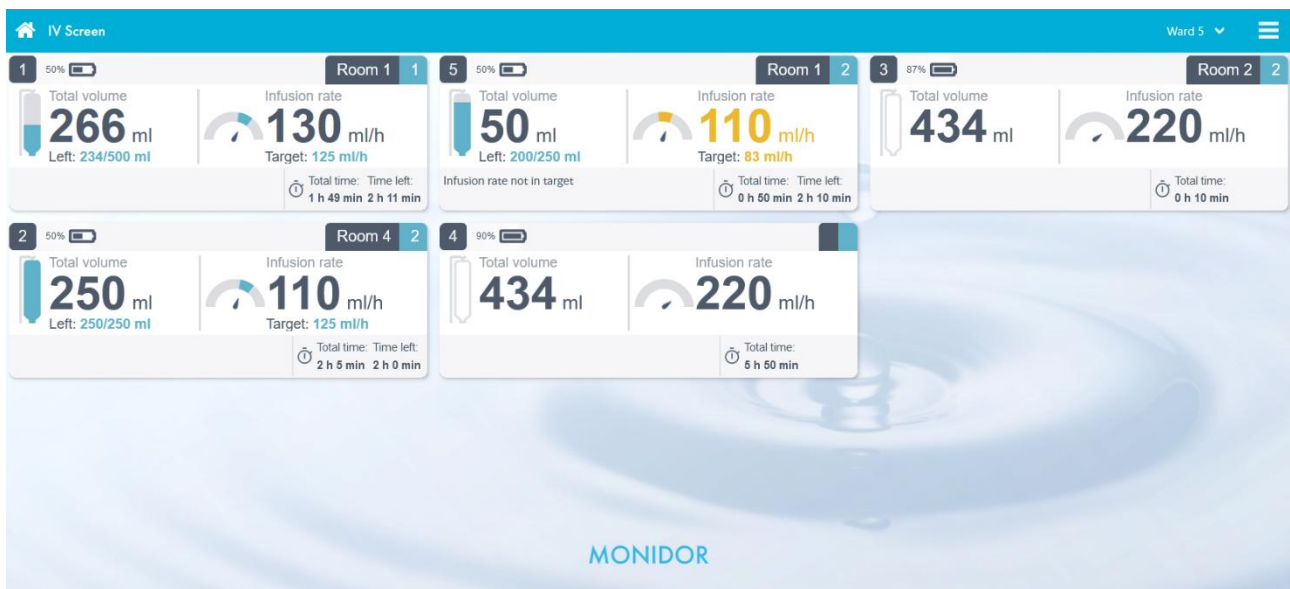


Figure 2: IV Screen monitoring view

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

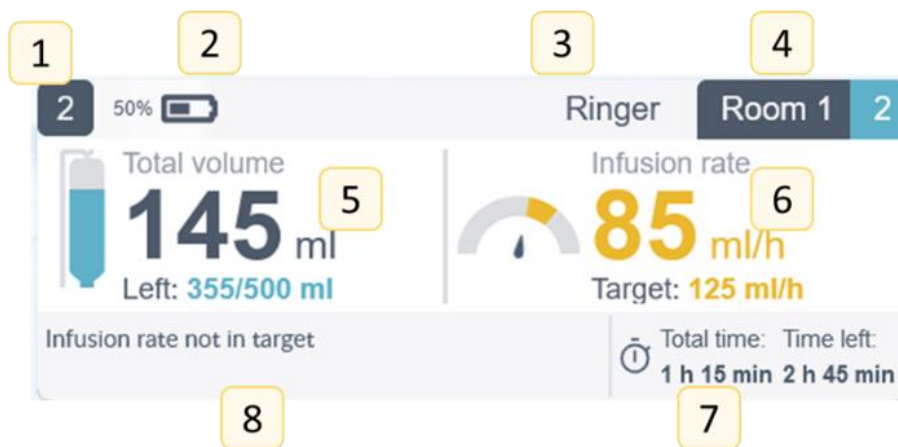


Figure 3: Device card elements

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"

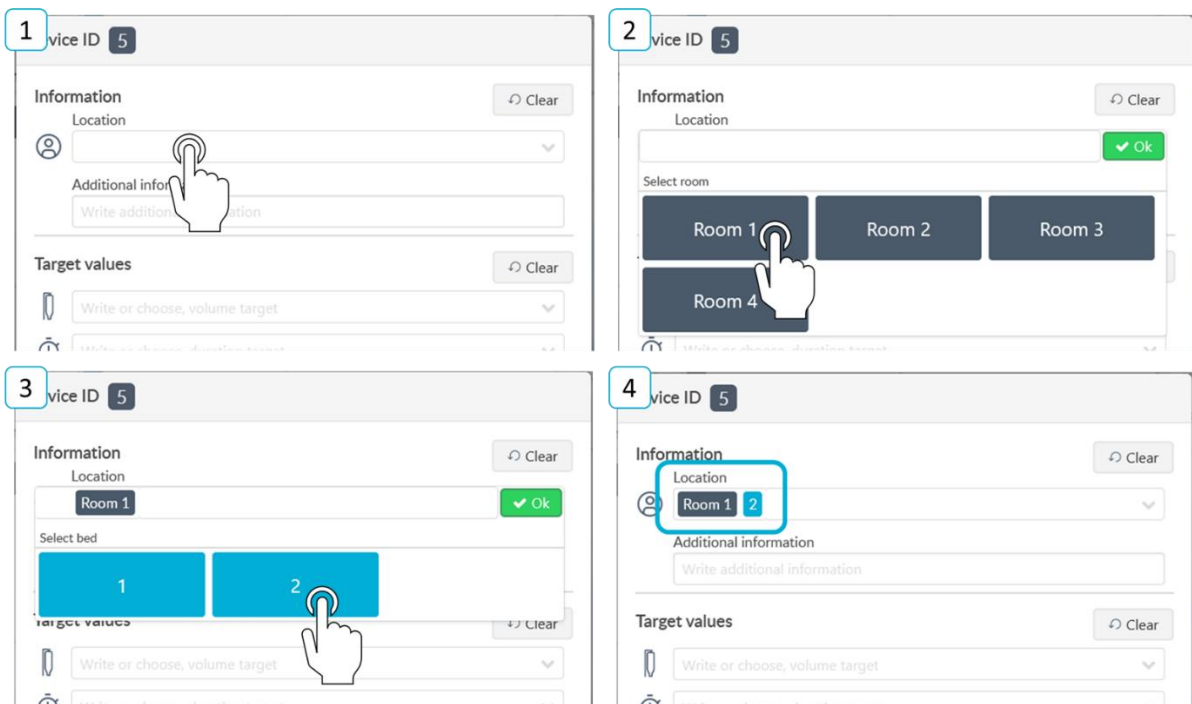


Figure 5: Assign device to room and bed location

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	Sound notification (Not available in the browser and the iOS app)	Acknowledgment
Infusion rate under 6 ml/h	X	X	Automatic once the reason for the notification has been removed
Infusion rate over 1200 ml/h	X	X	
Infusion rate not in target ¹	X		
Total volume nearly reached ²	X	X	
Total volume reached ²	X	X	
Duration nearly reached ³	X		
Duration reached ³	X		
Battery charge under 20	X	X	
Battery charge under 5%	X	X	
Last connection was 5 min ago	X		

1. If both target volume and target duration are set
2. If Target volume is set
3. If Target duration is set

4.1. Infusion rate notifications

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

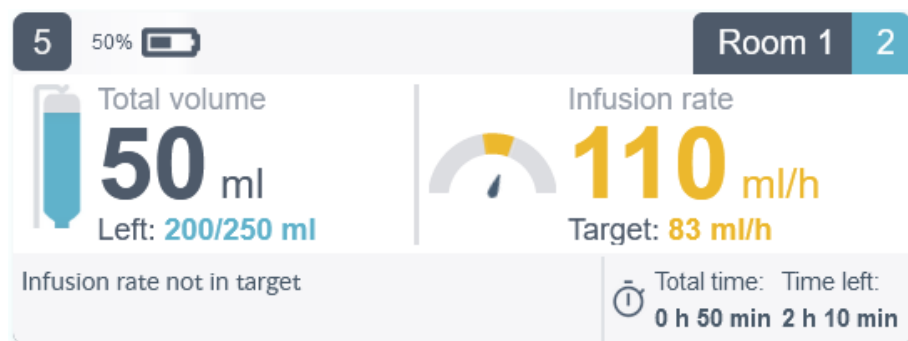


Figure 6: Infusion rate notification

4.2. Total volume

When the total volume is completed, the notifications will appear yellow in the card, 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.

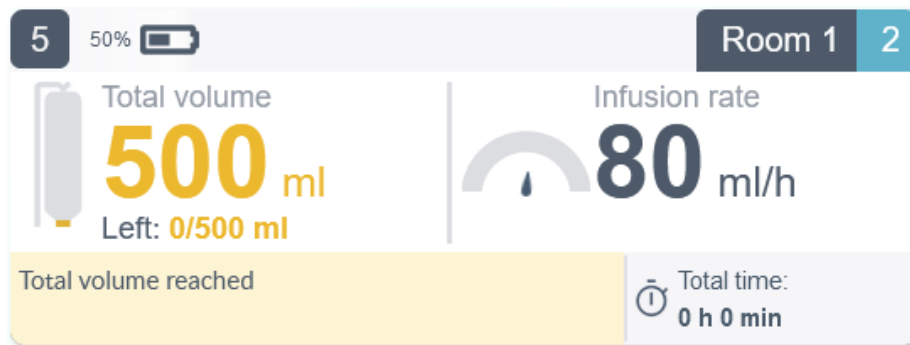


Figure 7: Total volume notification

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.

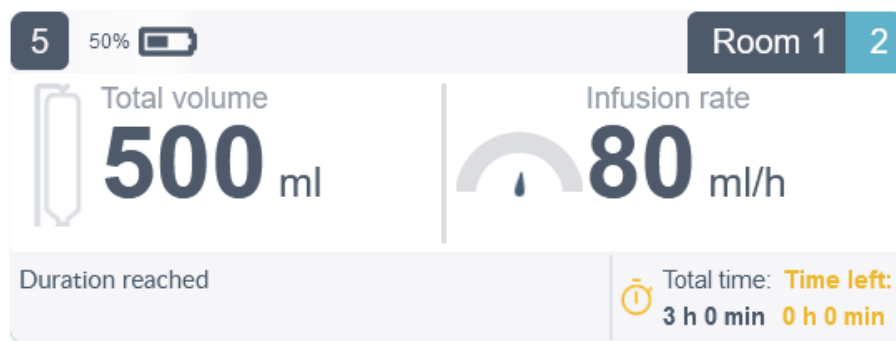


Figure 8: Duration reached notification

4.4. Battery notifications

The Monidrop W Infusion Meter 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.

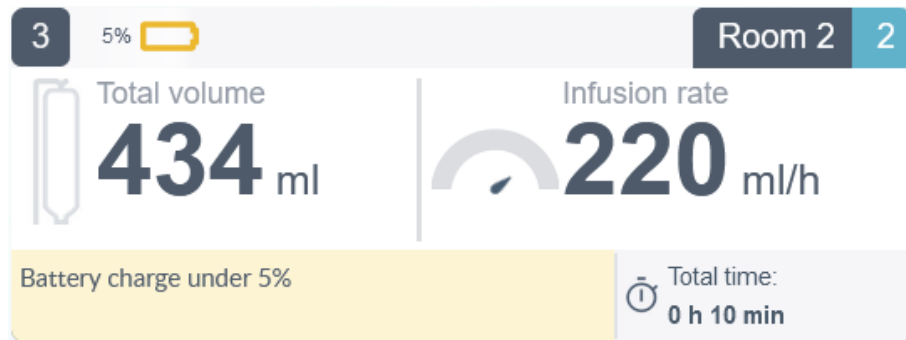


Figure 9: Low battery charge notification

4.5. Sound notifications

Sound notifications are not available in the browser and the iOS application. Sound notifications are automatically activated on the smartphone or tablet on which the information or target values are set. When sound notifications are activated on a specific phone or tablet, they are not activated on other devices unless they are used to set information or target values.

Device ID 21

Information Clear

Location

Additional information Write additional information

Target values Clear

500 ml

4 h 0 min

Calculated desired infusion rate

125 ml/h

Sound notifications ☒

Daily monitoring show

Cancel Save

Serial number: F21A10010000

Figure 10 Activation of sound notifications

Active sound notifications appear on the device card as a bell symbol in the upper-right corner of the card to the left of possibly set room and bed information.

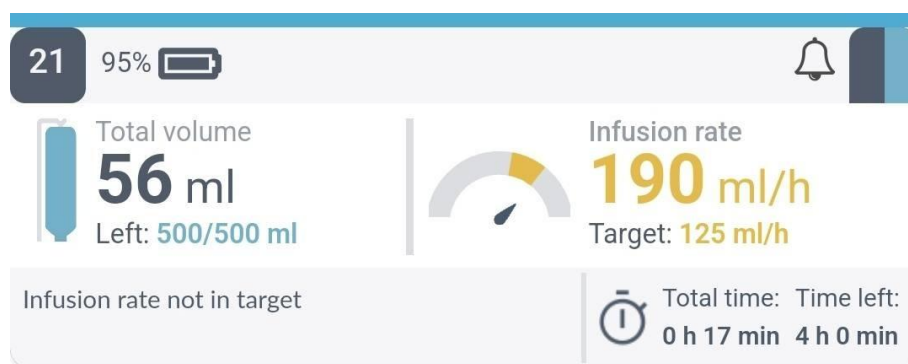


Figure 11 Active sound notifications appear on the device card as a bell symbol.

4.6. Notifications displayed on the Monidrop W infusion meter

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

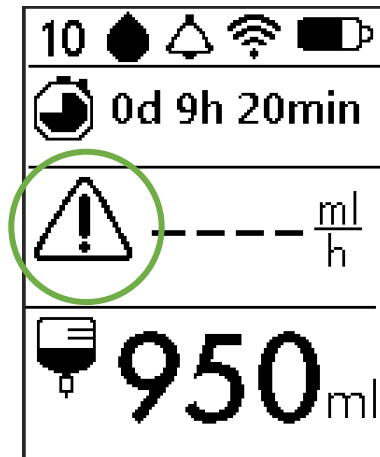


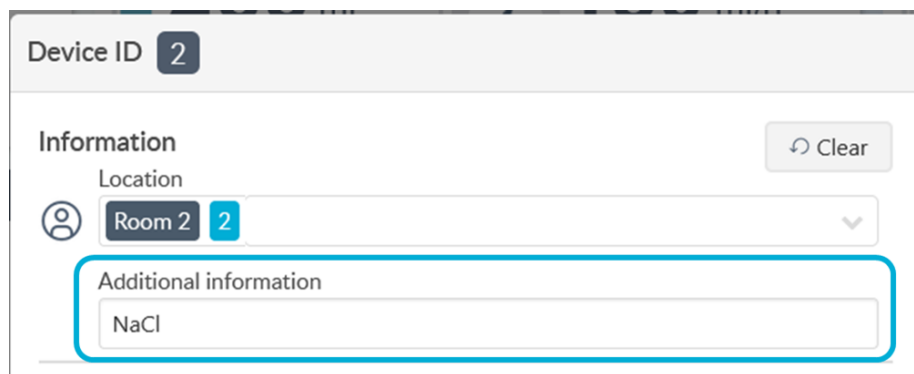
Figure 12 Notification displayed on the Monidrop W infusion meter

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.

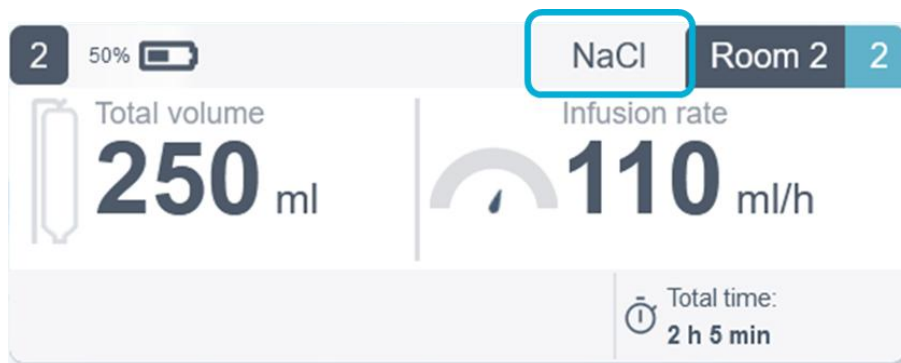
1. Open the device settings window by clicking the device card
2. You can either write the type of liquid you use in the text field or select a suitable liquid type from the list that opens by clicking the text field (optional feature).
3. Confirm the added information by clicking "Save".



The screenshot shows a settings window for 'Device ID 2'. Under the 'Information' section, there is a 'Location' field with a dropdown menu showing 'Room 2' and a '2' in a blue box. Below this is an 'Additional information' text field containing 'NaCl'. A 'Clear' button is visible in the top right corner of the settings area.

Figure 13 Selection of the liquid type

The additional information is shown next to the location fields.



The screenshot shows the IV Screen device card for 'Device ID 2'. At the top, there is a status bar with '2', '50%', and a battery icon. Below this, the 'NaCl' text is highlighted in a blue box, positioned next to the 'Room 2' and '2' location fields. The main display area shows 'Total volume' as '250 ml' and 'Infusion rate' as '110 ml/h'. At the bottom right, a clock icon indicates 'Total time: 2 h 5 min'.

Figure 14 Additional information in device card

5.2. Setting notification threshold for the volume of IV fluid

You can set the volume 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"

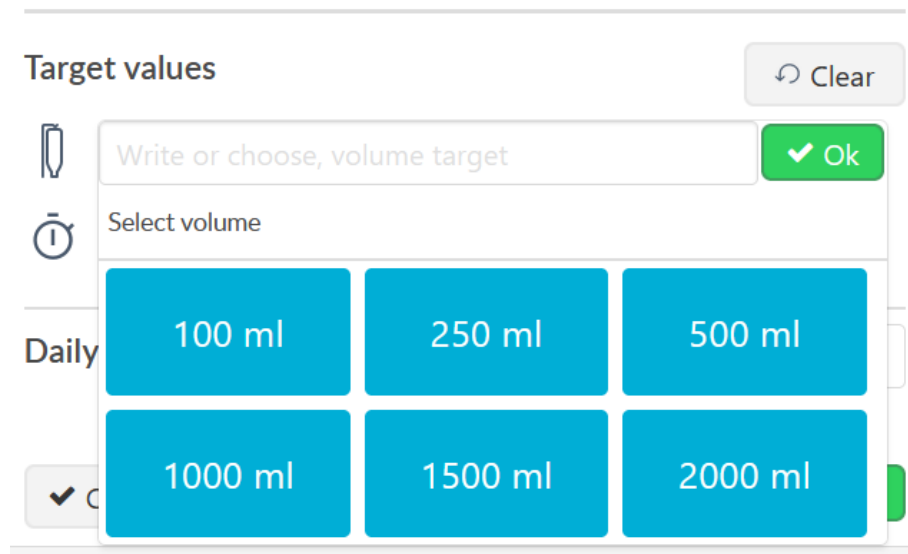


Figure 15 Setting volume of liquid

The set volume 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).

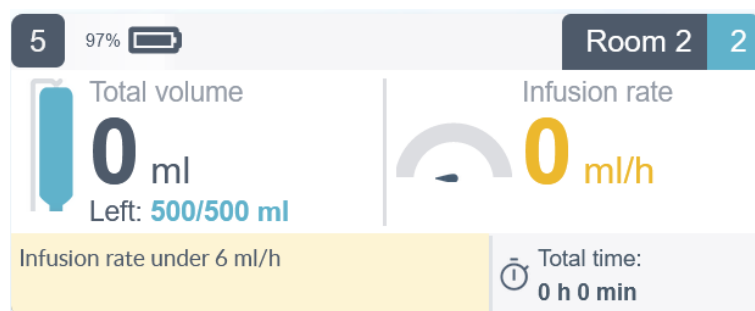


Figure 16 Set volume of liquid is shown on device card.

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"

The screenshot shows a 'Target values' dialog box. At the top, there is a 'Clear' button. Below it is a text input field with a syringe icon and the placeholder text 'Write or choose, volume target'. Underneath is a time selection section with a clock icon and a 'D' (days) field. To the right of the 'D' field are 'h' (hours) and 'min' (minutes) fields. A green 'Ok' button is to the right of the 'min' field. Below the time fields is a 'Select infusion time' section with a 'Dail' (daily) tab selected. A grid of blue buttons contains pre-set durations: 30 min, 1 h, 2 h, 3 h, 4 h, 5 h, 6 h, 12 h, and 24 h. A 'Serial' tab is partially visible on the left.

Figure 17 Setting the target duration of the treatment

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.

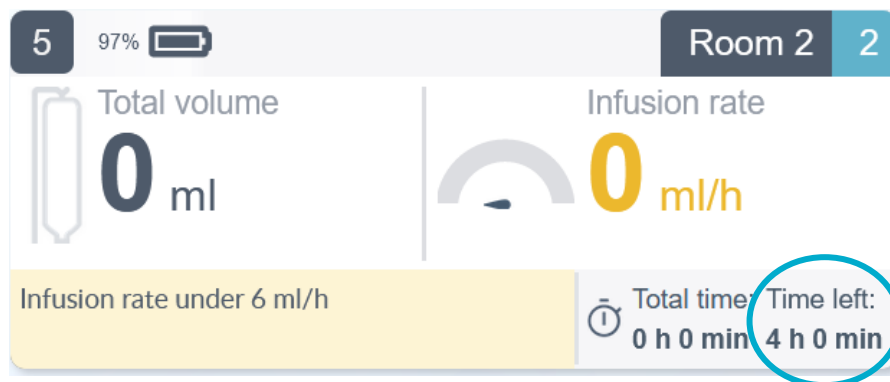


Figure 18 Time left shown on device card

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.

The form shows the 'Target values' section with a 'Clear' button. Below are two input fields: '500 ml' for volume and '4 h 0 min' for duration. Below these fields, the 'Calculated desired infusion rate' is displayed as '125 ml/h' in large blue text.

Figure 19 Simultaneous setting of liquid volume and duration of treatment

The target infusion rate is shown below current infusion rate.

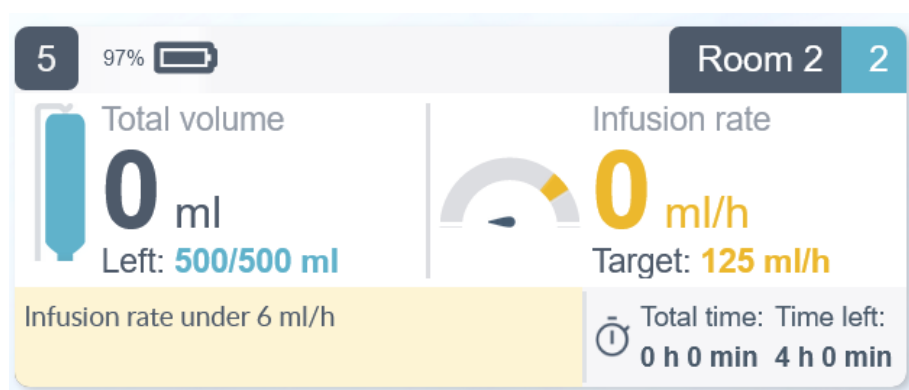


Figure 20 Target infusion rate is shown below current infusion rate

5.5. Daily monitoring

Total volume 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”

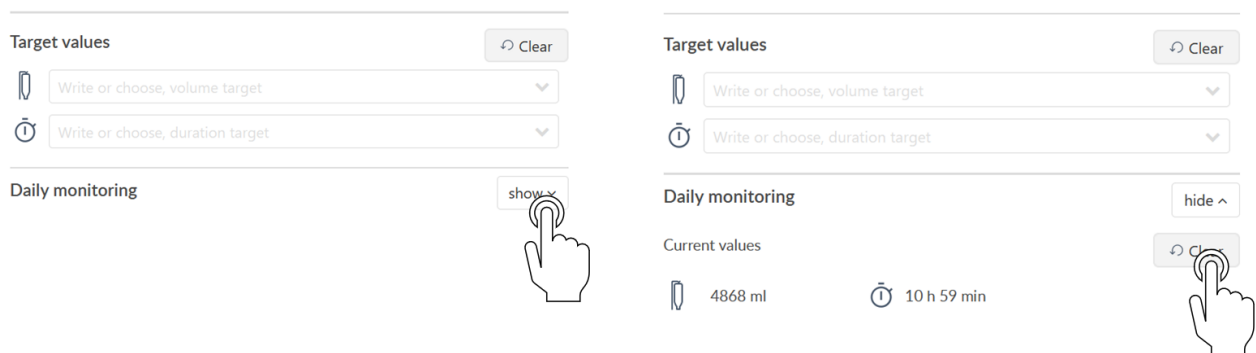


Figure 21 Resetting of daily monitoring values

5.6. Settings displayed on the Monidrop W infusion meter

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

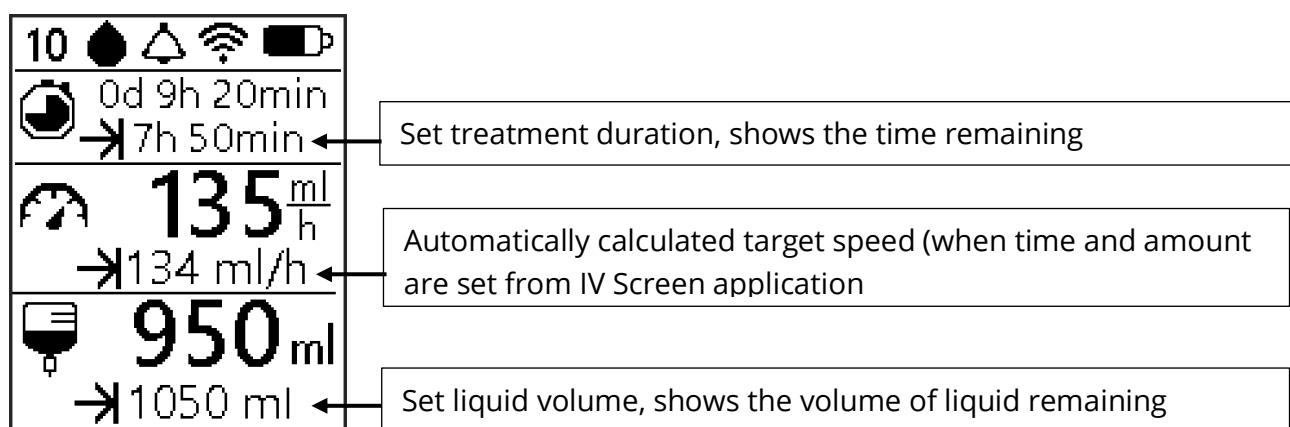


Figure 22 Screen of Monidrop W infusion meter

6. LIST OF COMPETENT AUTHORITIES

Denmark	Danish Medicines Agency Axel Heides Gade 1, 2300 København S, Denmark Tel. +45 7222 7400 E-mail: dkma@dkma.dk, www.laegemiddelstyrelsen.dk
Estonia	State Agency of Medicines 1 Nooruse Street, 50411 Tartu, Estonia Tel. +372 737 41 40 Fax +372 737 41 42 E-mail: info@ravimiamet.ee, www.ravimiamet.ee
Finland	Finnish Medicines Agency P.O. Box 55, FI-00034 FIMEA, Finland Tel. +358 29 522 3341 Fax +358 29 522 3002 www.fimea.fi
France	National Agency for the Safety of Medicine and Health Products 143-147 bd Anatole France, 93285 Saint Denis cedex, France Tel. +33 1 55 87 30 00 www.ansm.sante.fr
Germany	Paul Ehrlich Institute Paul-Ehrlich-Straße 51-59, 63225 Langen, Germany Tel. +49 6103 77 0 Fax +49 6103 77 1234 E-mail: pei@pei.de , www.pei.de/
Greece	National Organization for Medicines Messogion Avenue 284, 15562 Athens, Greece Tel. +30 213 2040 200 Fax +30 210 6545 535 E-mail: relation@eof.gr , www.eof.gr
Hungary	National Institute of Pharmacy and Nutrition Zrínyi U. 3, 1051 Budapest, Hungary Tel. +36 1 88 69 -300 Fax +36 1 88 69-460 E-mail: ogyei@ogyei.gov.hu , www.ogyei.gov.hu

Iceland	<p>Icelandic Medicines Agency Vínlandsleið 14, 113 Reykjavík, Iceland Tel. +354 520 2100 Fax +354 561 2170 E-mail: ima@ima.is, www.ima.is</p>
Ireland	<p>Health Products Regulatory Authority (HPRA) Kevin O'Malley House, Earlsfort Centre, Earlsfort Terrace, Dublin 2, Ireland Tel. +353 1 676 4971 Fax +353 1 676 7836 E-mail: info@hpra.ie, www.hpra.ie</p>
Italy	<p>Italian Medicines Agency Via del Tritone, 181, 00187 Roma, Italy Tel. +39 06 5978401 Fax +39 06 59784312 www.aifa.gov.it</p>
Latvia	<p>State Agency of Medicines 15 Jersikas Street, 1003 Riga, Latvia Tel. +371 7078424 Fax +371 7078428 E-mail: info@zva.gov.lv, www.zva.gov.lv</p>
Liechtenstein	<p>Office of Health / Department of Pharmaceuticals Äulestr 512, 9490 Vaduz, Liechtenstein</p>
Lithuania	<p>State Medicines Control Agency Žirmūnų g. 139A, 09120 Vilnius, Lithuania Tel. +370 5 263 9264 Tel +370 5 263 9265 E-mail: vvkt@vvkt.lt, www.vvkt.lt</p>
Luxembourg	<p>Ministry of Health Allée Marconi, 2120 Luxembourg, Luxembourg E-mail: ministere-sante@ms.etat.lu, www.ms.etat.lu</p>

Malta	Malta Medicines Authority (MMA) Sir Temi Żammit Buildings, Malta Life Sciences Park San Ġwann, SĠN 3000, Malta Tel. +356 23439000 Fax +356 23439161 E-mail: info.medicinesauthority@gov.mt www.medicinesauthority.gov.mt
Netherlands	Medicines Evaluation Board Graadt van Roggenweg 500, 3531 AH Utrecht The Netherlands Tel. +31 (0) 88 224 8000 Fax +31 (0) 88 224 8001
Norway	Norwegian Medicines Agency Postboks 240 Skøyen, 0213 Oslo, Norway Tel. +47 22 89 77 00 E-mail: post@noma.no , https://legemiddelverket.no
Poland	Office for Registration of Medicinal Products, Medical Devices and Biocidal Products Al. Jerozolimskie 181C, 02-222 Warsaw, Poland Tel. +48 (22) 492 11 00 Fax +48 (22) 492 11 09 www.urpl.gov.pl
Portugal	National Authority of Medicines and Health Products Parque de Saúde de Lisboa - Avenida do Brasil, 53 1749-004 Lisboa, Portugal Tel. +351 217987100 Fax +351 217987316 E-mail: infarmed@infarmed.pt , www.infarmed.pt
Romania	National Authority of Medicines and Medical Devices of Romania Str. Aviator Sanatescu 48, 011478 Bucharest, Romania Tel. +4021 317 11 00 Fax +4021 316 34 97 www.anm.ro

Slovakia	State Institute for Drug Control Kvetná 11, 825 08 Bratislava 26, Slovakia Tel. +421 2 5070 1111 Fax +421 2 5556 4127 E-mail: sukl@sukl.sk , www.sukl.sk
Slovenia	Agency for Medicinal Products and Medical Devices of the Republic of Slovenia Slovenčeva ulica 22, 1000 Ljubljana, Slovenia Tel. + 38 6 8 2000 500 Fax + 38 6 8 2000 510 E-mail: info@jazmp.si , www.jazmp.si
Spain	Spanish Agency for Medicines and Health Products Parque Empresarial, Las Mercedes Edificio 8C/ Campezo, 1, 28022 Madrid, Spain www.aemps.gob.es
Sweden	Swedish Medical Products Agency Dag Hammarskjölds väg 42 / Box 26, 751 03 Uppsala Sweden Tel. +46 18 17 46 00 / Fax +46 18 54 85 66 E-mail: registrator@mpa.se , www.lakemedelsverket.se
UK	Pentland Medical Ltd. 48 Craighall Road, Edinburgh, EH6 4RU, UK Tel. 0131 467 5764 Fax 0131 467 1574 E-mail: mail@pentlandmedical.co.uk www.pentlandmedical.co.uk

7. MANUFACTURER'S INFORMATION AND DEVICE LABEL

Manufacturer :



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Elektroniikkatie 3
90590 Oulu
Finland
+358 10 295 9063

Version 9.0
Approved: 10/2025

www.monidor.com

Device label:

IV Screen

Version 1.8.2

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