

MONIDOR

Monidrop[®] W Infusion monitor

Operating manual

Software version 1.3.X-1.6.X

CE 0598

EN

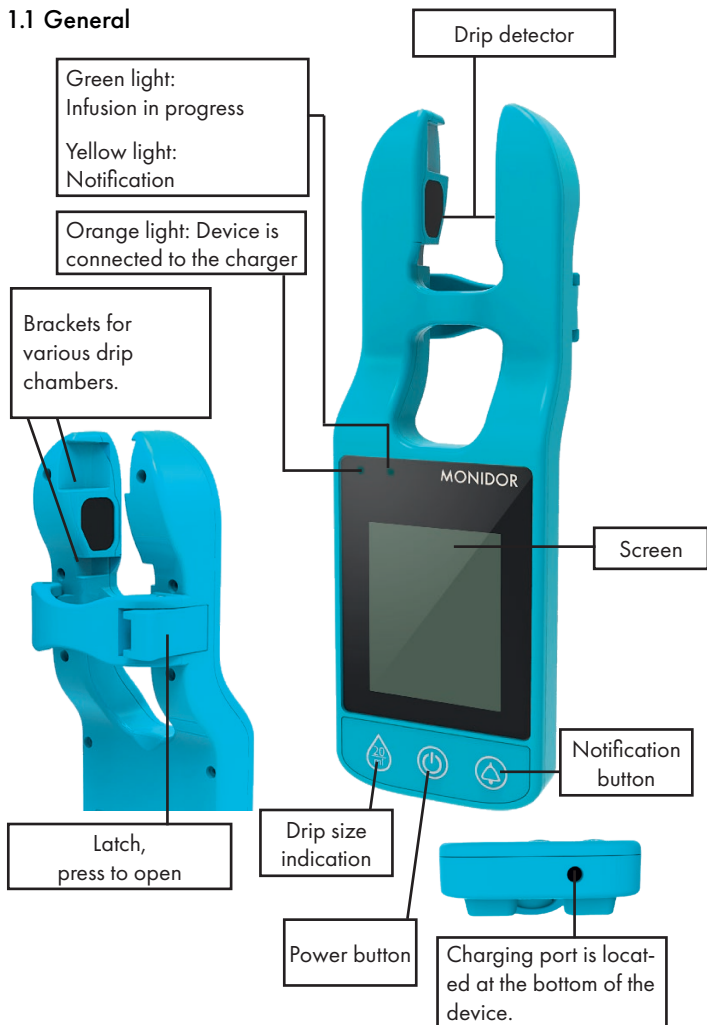


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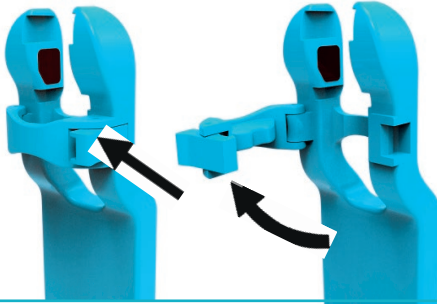
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1 Monidrop® W infusion monitor / General

1.1 General



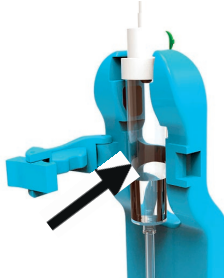
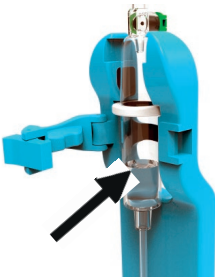
1.2 Attaching Monidrop to a drip chamber



1. Open the locking mechanism by pressing the locking lever and open the latch.

With collar

Without collar



2. Put the drip chamber into place as shown in the figures.

Note the correct positioning of different types of drip chamber models! More detailed instructions on page 6.

With collar

Without collar



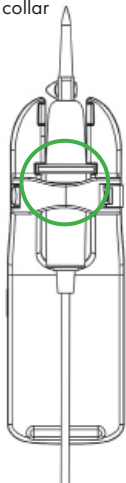
3. Close the latch by returning it to the locking position.

Note! If the lock feels too tight, check the correct position of the drip chamber.

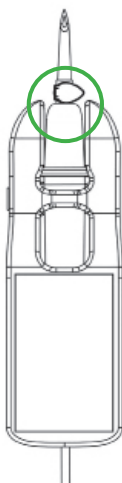
1 GENERAL

Correct positions of drip chambers:

Figure 1. Drip chamber with a collar

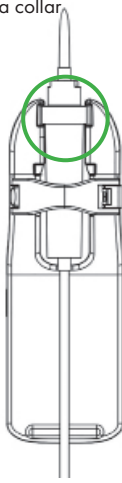


Back

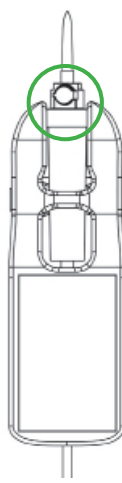


Front

Figure 2. Drip chamber without a collar



Back



Front

Place the drip chamber in the Monidrop® W device so that the air intake cap points forwards or backwards. If the drip chamber has a collar, guide the edge of the collar to the lower slot (Figure 1). If the drip chamber does not have a collar, guide the drip chamber to the upper slot (Figure 2).

1.3 Patient safety

1.3.1 Purpose of use

The Monidrop® W infusion monitor is intended for the periodic or continuous measurement of parenteral fluids via an intravenous route. The Monidrop® W infusion monitor is used for dosage measurements in intravenous therapy. The device DOES NOT set the IV dosage. Instead, the dosage is set using a roller clamp or a flow regulator of the infusion set. The device is intended for use by healthcare professionals at hospitals and health care centres and in home healthcare. The medical staff must determine the suitability of the device for the intended purpose of use

on the basis of device properties and technical specifications.

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 11.



Monidrop® W DOES NOT ADJUST the infusion rate. ALWAYS use a roller clamp or a fluid regulator to adjust the infusion rate.

1.3.2 Use

- Users of the Monidrop® W infusion monitor must read this operating manual before using the device. A Monidor salesperson or another authorised person must provide the first guidance of use.
- Make sure that the device is firmly in place during its use.
- Before use, check the device and its fastening mechanisms in case of damage or any missing parts.
- Do not fully open the roller clamp or the fluid regulator or so that a continuous stream drips into the drip chamber.
- The device is intended for use indoors in a stable operating environment. The device is not suitable for use on vehicles.
- The use of the device is not recommended for children under 10 years of age or patients of less than 20 kg, or in such situations where the measurement accuracy should be better than $\pm 11,8\%$.
- The device must not be used under direct sunlight, a powerful spotlight or a flashing fluorescent tube. In this case, the measurement accuracy cannot be guaranteed.
- The device must not be used during magnetic resonance imaging (MRI).
- The Monidrop® W infusion monitor is designed as a measuring device for the administration of maintenance fluids, nutritional solutions, blood products or antibiotics. The device is not applicable for use together with strong medicinal substances requiring high accuracy.
- Only use infusion set suitable for the device, with a drip size ALWAYS of 20 drops (gtt)/ml and accuracy of at least $\pm 10\%$. Before use,

1.3 PATIENT SAFETY

check that the infusion set is attached correctly to the device.

- The Monidrop® W infusion monitor always uses ml/h (millilitres per hour) as the measuring unit for the infusion rate.
- Make sure that fluids can flow freely by straightening all lines.
- The height of the IV bag should be suitable for gravity infusion. The height should be about 60 ... 90 cm above the patient.
- Make sure that the level of the drip chamber does not reach the measurement range. Fill the drip chamber halfway at the most.
- When replacing infusion sets, follow the infusion set manufacturer's recommendations (note country-specific hygiene regulations).
- The operating conditions of the device must fulfil proper requirements (e.g. VDE 0100, VDE 0107 or IEC regulations). Note country-specific guidelines and differences.
- The device has also been approved for home healthcare in accordance with standard 60601-1-11.
- Do not use the device in a room containing explosive substances.
- Protect the charger against moisture.
- If the device drops or suffers a heavy impact, it must be sent to a service point for inspection.
- Only use the charger delivered with the Monidrop W device. The use of chargers other than the one supplied with the Monidrop W device is prohibited, as they may result in increased electromagnetic emissions or reduced immunity to electromagnetic interference, which may lead to malfunction of the device. For the same reason, no other devices using radio frequencies, such as NFC/RFID tags, may be attached to the device.
- Do not tilt the device heavily when using it. If the device is tilted by more than 20 degrees, its measurement accuracy cannot be guaranteed.
- 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.
- The buttons on the Monidrop must not be pressed with sharp objects, but only with your fingers.

WARNING: The device does not identify any air or bubbles in the IV line.

WARNING: The device does not identify any significantly high flows (continuous drip) if the roller clamp or the fluid regulator is fully opened. In these cases, the device may not give a direct notification.

WARNING: Modifying this device is prohibited.

WARNING: The charger cable causes a choking hazard for small children.

WARNING: Do not use the device if its charger or cable is damaged.

1.3.3 Blood transfusion

- The Monidrop® W infusion monitor can be used to monitor infusion of blood products. Only use disposable products intended and indicated for blood products. The drip size of the blood line must be 20 drops (gtt)/ml.

1.3.4 Other infusion factors

- Check the compatibility of the products and medicine used from the manufacturers' specifications.

1.3.5 Safety standards

- The Monidrop® W infusion monitor fulfils all safety regulations of standards IEC/EN 60601-1 and EN 60601-1-11:2015 on medical electrical equipment.
- The device fulfils electromagnetic compatibility (EMC) requirements in accordance with EN 60601-1-2:2015 + A1:2021 (Medical

1.3 PATIENT SAFETY

electrical equipment - Electromagnetic disturbances - Requirements and tests).

- This product is compliant with Directive 2014/53/EU. The relevant Declaration of Conformity is available at www.monidor.com.
- If the device is used in the proximity of other devices that may cause significant interference (e.g. high-frequency surgical equipment, computed tomography equipment, infrared transmitters, etc.), follow the safe distances recommended for such equipment.
- If the Monidrop® W infusion monitor is used at temperatures lower than the indicated operating conditions, it must be kept at room temperature for at least one hour before use. If the Monidrop® W infusion monitor is used at temperatures higher than the indicated operating conditions, it must be kept at room temperature for at least 30 minutes before use.

1.3.6 Electromagnetic compatibility (EMC) safety information

WARNING: Avoid using this equipment directly adjacent to, or stacked with, other equipment because this may cause improper operation. If adjacent or stacked use is necessary, observe both devices to confirm that they operate normally.

WARNING: Use only accessories, transducers and cables specified or provided by Monidor for Monidrop® W. Using other accessories/cables may increase electromagnetic emissions or reduce electromagnetic immunity and may cause improper operation.

WARNING: Keep portable RF communications equipment (including items such as antenna cables and external antennas) at least 30 cm (12 inches) away from any part of Monidrop® W, including the cables specified by Monidor. Using RF equipment closer than 30 cm may degrade performance.

If electromagnetic interference is suspected (e.g. unstable or unexpected values/notifications or abnormal behaviour), increase the distance between Monidrop® W and potential sources of electromagnetic disturbance, and/or turn the source off if possible. If abnormal operation continues, stop using the device and contact Monidor technical service.

2 Symbols / Menu structure

Device symbols:

Power switch On/Off



Notification button



Display symbols:



Battery status



Battery status (charger connected)



Mute



Sound on



Drip indicator



Remotely set target limit

or limit (if used with IV Screen)



Liquid volume



Treatment duration



Infusion rate



Notification



Not connected to network










Wireless cloud communication problem

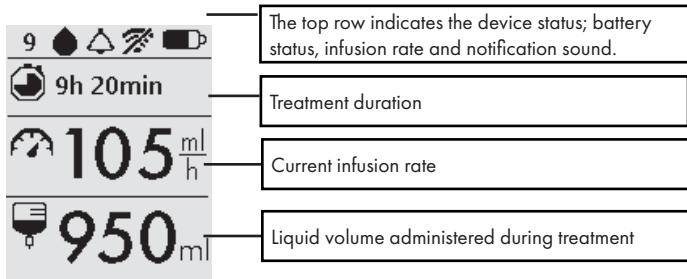


Connected to wireless network

Label:

Symbol	Description of symbols
	Note: Read the instructions delivered with the product.
	Drip size: 20 drops (ggt)/ml
	Markings of electrical and electronic equipment in accordance with directive 2002/96/EC (waste electrical and electronic equipment)
CE 0598	CE marking in accordance with directive 93/42/EEC
	Temperature limit
	Humidity limit
	Air pressure limitation
	Non-ionising electromagnetic radiation (IEC 60417-5140)

Main screen (measurement view)



If the line in the adjacent figure is shown for the current infusion rate, the measurement result is uncertain or the drip cannot be detected. Check that the drip chamber and device are straight and correctly attached. Remove any foam from the drip chamber.

3 Using the device

3.1 Activation and start of infusion


3.1.1 First start-up of a new device

Connect the device to the charger for a few seconds before pressing the power button.

3.1.2 Preparations

1. Insert the pointed tip of the IV line into the bottle in an upright position. Fill at most 1/2 of the drip chamber to keep the drip detection function operational.
2. Fill the drip chamber and close the roller clamp or the fluid regulator.
3. Check that the Monidrop® W device is undamaged and contains all the necessary parts.

3.1.3 Starting the device

Start the device by pressing the power button.  If the device is connected to the charger, a battery charge symbol will be displayed on the screen and an orange light will indicate that the device is being charged.

Note the self-test program: The device performs a self-test program during start-up.

3.1.4 Starting infusion monitoring

1. Attach the Monidrop® W device to the drip chamber as instructed.
2. Make sure that the device is firmly in place and in an upright position.
3. Use the roller clamp or the fluid regulator to set the infusion rate. The measurement result is shown by the Monidrop® W device.
4. The Monidrop® W device gives notification if the infusion rate is over 1200 ml/h or the battery status is low.
5. Press the notification button on the front of the unit if you want to


activate or deactivate notifications when infusion rate is less than 6 ml/h or when battery status is low.

Note: Attaching different types of infusion sets to the Monidrop® W device must be done in accordance with the instructions.

WARNING: Do not apply any force when attaching the drip chamber to the Monidrop® W device. If the fastening mechanism seems stiff, check that the position and installation of the infusion set and clamp is correct.

- Only use infusion sets suitable for the device, with a drip size ALWAYS of 20 drops (gtt)/ml and accuracy of at least $\pm 10\%$. Before use, check that the line is attached correctly to the device.


3.2 Starting a new treatment

To start a new treatment, reset the previous treatment by turning the power off for three (3) consecutive seconds . Then, restart your device to be ready to use again.

3.3 Ending an infusion treatment

You can stop monitoring the treatment in progress by switching off the device by pressing the power button  for three (3) seconds.

3.4 Shutting down the device

Shut down the device by pressing the power button  for three (3) seconds. When the device is switched off, any previously set data and settings will be reset.


4 Notifications

The Monidrop® W infusion monitor is equipped with its own notification system (notification sound and optic notification).

Notification type	Notification tone	Optic notification			Acknowledgment
		Yellow LED	Red LED	Text/image	
Visual notification	No	Blinking		Blinking triangle	Automatic once the reason for the notification has been removed
Sound notification	Yes	Blinking		Blinking triangle	Automatic once the reason for the notification has been removed

4.1 Notifications

4.1.1 Infusion rate is less than 6 ml/h

You can activate the notification by pressing the notification button on the front of the device . The message is displayed with a flashing yellow light and sound and the screen displays a flashing notification triangle at the infusion rate symbol.

- Notification when infusion rate is less than 6ml / h

4.1.2 Battery low

The device gives notification with a blinking yellow light, a notification tone and a flashing triangle at the infusion rate symbol. The message is automatically cleared when the device is connected to the charger.

- The device gives notification when the battery status is down to 10%.

4.1.3 Infusion rate is over 1200 ml/h

The message is displayed with a flashing yellow light and sound and the screen displays a flashing notification triangle at the infusion rate symbol.


- Notification when infusion rate is more than 1200 ml/h


4.1.4 Self-test program and forced restart

The device performs a self-test program during start-up. If there are any problems during the test, the device will give an notification by emitting a continuous red light and tone, and all device functions will be locked. The device can be switched off and restarted, in which case the device will perform self-test program again.

If the device freezes, it may be forced to restart by pressing the power button for an continuous period of eight 8 seconds. Contact maintenance if the device does not start regardless of the restart.

4.2 Managing audio notifications

Audio notifications can be muted and activated using the notification button.  The mute symbol is displayed at the top of the display, when the "less than 6ml/h notification" is set to mute.

 By default, the notification for an infusion rate below 6 ml/h is muted each time the device is turned on.

Pressing the audio notification button a second time activates the audio notifications if the infusion rate falls below 6 ml/h.

5 Battery charge and maintenance

The Monidrop® W infusion monitor is equipped with a rechargeable lithium ion polymer battery. A new battery can be used for 40 hours on one charge. To ensure optimal use, the device is equipped with a protective function against overcharging and excess battery discharge (prevention of deep discharge).

At the top of the screen, the battery status is indicated in percentage, and the battery symbol indicates the battery status in steps. Symbols indicate the battery status as shown below. On the left, the battery is fully discharged and on the right, the battery is fully charged. The percentage displayed below indicates the battery status on a rough level.



The Monidrop® W infusion monitor can also be used when its battery is being charged, and it will operate normally. When the device is connected to the charger, the middle LED at the top of the screen will be orange when the battery is being charged and the symbol shown below will be displayed in place of the battery status symbol.



If the battery is fully discharged, the device will go off automatically. If the battery is fully discharged, keep the charger plugged up to one hour until the charging light comes on. The battery can then be fully charged.

Note: Only use the charger delivered with the device to charge the Monidrop® W infusion monitor. Note that the device has a limited movement range when the charger is connected.

Instructions for the optimal use of the battery:

- Charge the battery at least once every three months.
- At the regular operating temperature, the battery can be charged and discharged approximately 500 times before its capacity decreases below 80% of the maximum value.
- The battery will slowly discharge if the infusion monitor is not connected to the power grid and even if the device is not in use.
- The full operating period of the battery can only be achieved when the device is operated uninterrupted at room temperature and the battery is fully charged. The battery capacity displayed is indicative. If the battery is older, the actual operating period may differ from that shown on the screen.

Note: The battery may explode or leak if it is opened or burned/heated. Note waste handling guidelines.

Note: While the device is charged, disconnection from the mains supply occurs by removing the charger from the AC power socket.

WARNING: While charging Monidrop during use, ensure that access to the mains plug is not blocked so that the charger can be disconnected from the mains power receptacle in the event of an emergency.

Battery maintenance and warranty:

The device manufacturer provides the battery with a warranty of two (2) years. This is the typical service life of the battery (without causing any significant reduction in the operating period). After two years, the battery will be replaced during scheduled maintenance.

The battery can only be replaced by a service provider authorised by Monidor.

6 Cleaning

Wipe the surface clean using a piece of cloth and a mild soap-water solution. If required, disinfect the device using ApoWipe or a similar product.

The device can also be disinfected as follows:

- 80% isopropanol
- OR
- Mild alkaline disinfectant
- OR
- Phenoxyethanol + quaternary disinfectant, dilution 1:10
- OR
- Chlorine-containing disinfectant, with an active chlorine content of up to 2%, dilution 1:10

Note: Do not immerse the device in any fluid or spray any water or cleaning agent on the device.

Note: Do not use a cleaning stick to touch or press the protective film behind the speaker holes and bars.

7 Warranty / Inspection and maintenance / Training

The manufacturer's liability: The manufacturer, assembly or installation company or importer is only responsible for device safety when:

- An authorised person has installed the device or made expansions, additions, modifications or repairs.
- Electrical installations in the operating facilities are in accordance with regulations (e.g. VDE 0100, 0107 and/or IEC standards), taking any country-specific requirements into account.
- The device is used in compliance with the operating manual.
- Regular maintenance has been performed regularly.

Warranty

- Monidor provides all Monidrop® W infusion monitors and accessories it has manufactured with a warranty of 12 months. The warranty covers installation and the replacement of defective parts if the defect is caused by a structural, manufacturing or material error. The warranty becomes void if the owner/user or any third party makes modifications to the device.
- The warranty does not cover any defects caused by an incorrect or improper use or regular wear and tear.
- The device must be disposed of as electrical and electronic waste (currently in EU area only).

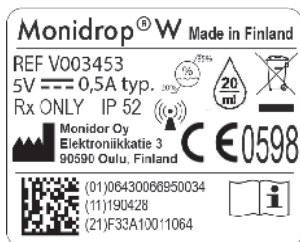
Technical inspection and maintenance:

- It is recommended that a technical safety inspection and scheduled maintenance be performed every two years. Any markings in accordance with the checklist must be entered in the device maintenance register. Maintenance can only be performed by maintenance employees trained/authorised by Monidor or its distributor.
- Monidor will provide authorised maintenance organisations with maintenance instructions at request.

Periodic inspections:

Check that the device is clean, undamaged and in an operating condition. Only use the device in accordance with this operating manual.

The areas at the back of the device inside the white frames in the figure below are intended for the labels of hospitals or health care centres.



Device serial number
(the serial number in the image is
an example and does not corres-
pond to the correct serial number
of the device)

Training

Training for the use of the Monidrop® W infusion monitor is available. Contact the device seller for more information.

8 Content of the delivery and inspecting the content / Recycling

Content of the delivery

Monidrop® W infusion monitor, charger, quick user guide

Inspecting the content of the delivery

Regardless of protective packaging, there may be transportation damage. Check that nothing is missing from the delivery. Do not use the device if it is damaged. Contact device maintenance.

Test that the device works correctly before its first use. This is a statutory procedure in many countries.

Recycling

The device and battery must be disposed of as electrical and electronic waste.



Note any hygiene and waste handling guidelines related to disposable products and IV fluids.

9 Technical specifications

Device type	Infusion monitor
Classification (according to EN 60601-1)	Internally powered medical device. Charger and device complies with class II requirements while connected to mains supply.
Class (Directive 93/42/EEC)	Im
Moisture protection	Monidrop® W IP 52 (dustproof, protection against water dropping vertically or at a maximum angle of 15 degrees) (Charger IP 22)
External power source:	5 V Sinpro: 100–240V ~47–63Hz 0.30–0.15 A Globtek: 100-240V~50-60 Hz 0.30 A Using the charger delivered with the Monidrop® W device
Operating principle	Device is attached mechanically directly to the drip chamber of the infusion administration set. It calculates drops that are dropping inside the drip chamber. Drop detection is based on transmitting IR light through a drip chamber. When drop breaks the light, the event can be measured by receiving light sensor. Result are calculated and showed to user in convenient units (ml/h and ml).
Interference protection EMC	IEC/EN 60601-1-2
Operating rate	100% (continuous operation)
Operating conditions	<ul style="list-style-type: none"> • Relative humidity, % 20 % ... 85 % (of air humidity condensation) • Temperature +5 ... +40 °C • Air pressure 80 kPa ... 106 kPa

9 TECHNICAL SPECIFICATIONS

Storage conditions: <ul style="list-style-type: none"> • Relative humidity, % • Temperature • Air pressure 	20 % ... 85 % (of air humidity condensation) -20 ... +55 °C 80 kPa ... 106 kPa
Battery type	Li-ion-polymer
Operation time	Approx. 40 hours
Charge time	Approx. 2 hours
Weight	Approx. 110 g
Dimensions (W × H × D)	54 x 166.1 x 43.4 mm
Measurement range	6 ml/h ...1200 ml/h
Volume range	0 ml ... 9999 ml
Treatment duration limit	99 hours 59 minutes
Measurement accuracy	Typical measurement accuracy ± 1.8% Furthermore, the measuring accuracy is affected by the accuracy of the IV infusion set, which is 0% ± 10% while connected to the Monidrop
Regular maintenance (operating safety)	Recommended once in two years
Expected service life	10 years
Radio module (optional)	Compatible with WiFi protocols 802.11 b/g/n Frequency range 2.4 GHz ~ 2.5 GHz (2400M ~ 2483.5M) Standards FCC/CE

9 TECHNICAL SPECIFICATIONS

Intended electromagnetic environment

Monidrop® W is intended for use by healthcare professionals in hospitals and healthcare centres, and in home healthcare. It is intended for indoor use in a stable operating environment. Do not use the device in MRI environments.

Essential performance related to EMC

For the purpose of electromagnetic compatibility, the essential performance of Monidrop® W is the ability to measure and display infusion rate (ml/h) and infused volume (ml) within the specified operating range, and to provide the notifications described in this manual.

If electromagnetic disturbances cause abnormal operation, the user must verify the infusion situation by clinical means and take appropriate action (e.g. adjust the infusion set using the roller clamp/flow regulator). Increase separation distance from RF sources or switch them off if possible, and avoid using the device adjacent to or stacked with other equipment. If abnormal operation persists, discontinue use and contact Monidor.

Manufacturer's instructions and declaration of electromagnetic compatibility

Disturbance test	Compatibility	Electromagnetic environment – instructions
RF emissions CISPR 11	Group 1	Monidrop® W only uses RF energy in internal functions. Therefore, it only has very low emissions, and probably does not disturb any nearby electrical devices.
RF discharge CISPR 11	Class B	Monidrop® W and its parts are suitable for use in all facilities, including households and residential buildings connected to the public low-voltage grid.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage changes/flicker emissions IEC 61000-3-3	Compatible	

Note: Maximum emissions were measured with a complete system. (Monidrop® W and its parts)

Cables and accessories relevant to EMC

Use only cables/accessories supplied with the device. Use of other accessories/cables may result in increased emissions or reduced immunity and may cause improper operation.


Manufacturer's instructions and declaration – electromagnetic interference tolerance

The Monidrop® W infusion monitor is intended for use in the electromagnetic environments defined below. The owner or user of the Monidrop® W infusion monitor and its parts must ensure that the device is used in such an environment.

Interference tolerance test	Test level IEC 60601-1-2	Compatibility level	Electromagnetic environment – instructions
Electrostatic discharge (ESD) IEC/ EN 60601-1-2	Contact: ± 8 kV Air: ± 2 kV ± 4 kV ± 8 kV ± 15 kV	± 8 kV no interference ± 2 kV no interference ± 4 kV no interference ± 8 kV no interference ± 15 kV no interference	The floor must be made of wood, concrete or ceramic tiles. If the floor is covered with a synthetic material, the relative humidity must be at least 30%.
Electrostatic transient/burst in accordance with standard IEC 61000-4-4	± 2 kV power supply lines ± 1 kV input/output lines	± 2 kV ± 1 kV	The quality of supply current must correspond with the quality in a typical commercial environment or hospital environment.
Surge in accordance with standard IEC 61000-4-5	± 1 kV differential mode ± 2 kV common mode	± 2 kV ± 1 kV	The quality of supply current must correspond with the quality in a typical commercial environment or hospital environment.
Voltage decreases, brief interruptions and voltage changes in power supply lines in accordance with IEC 61000-4-11	<5 % U_T (>95% decrease in U_T) For 0.5 periods 40 % U_T (60% decrease in U_T) For 5 periods 70 % U_T (30% decrease in U_T) For 25 periods <5 % U_T (>95% decrease in U_T) For five seconds <5% U_T for five seconds (>95% decrease)	Compatible when using an internal battery	The quality of supply current must correspond with the quality in a typical commercial environment or hospital environment.

9 TECHNICAL SPECIFICATIONS

Note 1: Different testing values of standard IEC 60601-2-24 are indicated in the table. These testing values do not permit any hazardous interference, while interference is permitted using the lowest testing values of standard IEC 60601-1-2.

Magnetic field at a network frequency (50/60 Hz) in accordance with standard IEC 61000-4-8	IEC 60601-2-24: 400 A/m	400 A/m	Magnetic fields at a network frequency must be at a level characteristic to a typical commercial environment or hospital environment.
<p>Radiated electromagnetic HF fields in accordance with standard IEC 61000-4-6</p> <p>Radiated electromagnetic HF fields in accordance with standard IEC 61000-4-3</p>	<p>IEC 60601-1-2: 3V_{eff} normal and 10V_{eff} Within ISM frequency range</p> <p>IEC 60601-2-24: 10V_{eff} 150 kHz – 80 MHz</p> <p>10 V/m 80 MHz – 2.5 GHz</p>	<p>10V_{eff} 150 kHz – 80 MHz</p> <p>10 V/m 80 MHz – 3 GHz</p>	<p>Mobile and movable RF communications devices cannot be used at a distance closer to Monidrop and its parts than the distance calculated using the formula applied to the transmitter frequency.</p> <p>Recommended distance</p> <p>$d = 1.2 \sqrt{P}$ Field intensity must be less than 10V/m</p> <p>$d = 1.2 \sqrt{P}$ 800 MHz – 2.5 GHz</p> <p>where P is the maximum output of the transmitter in watts (W) in accordance with the transmitter manufacturer and d is the recommended distance in meters (m).</p> <p>The field intensity caused by fixed RF transmitters which can be determined by means of an electromagnetic survey must be lower than the compatibility level at each frequency range.</p> <p>There may be interference close to devices furnished with the following symbol:</p> 

Note 2: A higher frequency range is applied to 80 MHz and 800 MHz.

Note 3: These instructions may not apply to all situations. Electromagnetic spreading is also affected by absorption to structures, objects and people, and reflection from them.

Note 4: Different testing values of standard IEC 60601-2-24 are indicated in the table. These testing values do not permit any hazardous interference, while interference is permitted using the lowest testing values of standard IEC 60601-1-2.

Recommended distance between mobile and movable RF communications devices and the Monidrop® W infusion monitor

The Monidrop® W infusion monitor is intended for use in electromagnetic environments where radiated RF emissions are controlled. The owner or user of Monidrop® W and its parts can help to prevent electromagnetic interference by keeping the minimum distance between mobile and movable RF communications devices (transmitters) and Monidrop® W as defined in the following recommendations in accordance with the maximum output of the communications device.

WARNING: Keep portable RF communications equipment (including antenna cables and external antennas) at least 30 cm (12 inches) away from any part of Monidrop® W, including Monidor-specific cables. Using RF equipment closer than 30 cm may degrade performance.

If interference is observed, increase the distance to the RF source, reposition the equipment, or switch the RF source off if possible.

10 Operating instructions for accessories

Charger

The Monidrop® W infusion monitor is equipped with a charger, with which the battery can be charged during the use of the device and when the device is not in use.

The Monidrop® W infusion monitor can only be charged using the charger delivered with the package. Always check that the correct charger is used. Use of other accessories/cables may result in increased emissions or reduced immunity and may cause improper operation.

Technical specifications:

Sinpro

100–240 V ~47–63 Hz 0.30–0.15 A

Manufacturer: Sinpro, made in Taiwan

Model number: HPU10C-102 or HPU10B-102

IP 22

Charger cable (supplied with the charger / device package)

Maximum length: 2,6 m

Globtek

100-240V~50-60 Hz 0.30 A

Manufacturer: Globtek, made in China

Model number: GTM46101-1005-USB

IP 20

Charger cable (supplied with the charger / device package)

Maximum length: 3 m

Important charger safety instructions:

This product is intended for indoor use only. When using an electrical appliance, basic safety precautions should always be followed, including the following: Read all instructions before using power supplies.

DANGER - To reduce the risk on electric shock: A power supply should

10 OPERATING INSTRUCTIONS FOR ACCESSORIES

never be left unattended when plugged in. Always unplug this power supply from the electric outlet immediately after using.

WARNING - To reduce the risk of burns, fire, electric shock, or injury to persons:

1. Do not allow to be used as a toy. Pay close attention when this power supply is used by or near children.
2. Use this power supply only for its intended use as described in this manual. Use only attachments recommended by the manufacturer as contained in this manual.
3. Never operate this power supply if it has a damaged cord or plug, if it is not working properly, if it has been dropped or damaged, or fallen into water. In such cases, return the appliance to the nearest authorized dealer or service center for examination, repair, electrical or mechanical adjustment.
4. Never drop or insert any object into any openings.
5. Do not use outdoors.
6. Do not operate where aerosol (spray) products are being used or where oxygen is being administered.
7. The socket-outlet should be installed near the power supply and should be easily accessible.
8. Do not unplug by pulling on cord. To unplug, pull on the plug, not on the cord.
9. Units without level V Efficiency may no longer be used for electronic household and office equipment.
10. Manufacturer can be contacted: Sinpro Electronics Co.,Ltd. No.5, Yanxi St. P.E.P.Z. Pingtung City, Pingtung County 90093, Taiwan, Globtek Inc. 186 Veterans Dr, Northvale NJ 07647, USA.
tel 1-201-784-1000

11 LIST OF COMPETENT AUTHORITIES

Country	Name and contact details
Austria	Austrian Agency for Health and Food Safety Spargelfeldstraße 191, 1220 Wien, Austria Tel. +43 5 0555-0 Fax +43 5 0555-22019 www.ages.at
Belgium	Federal Agency for Medicines and Health Products Eurostation building, block 2, place Victor Horta, 40/ 40 1060 Brussels, Belgium Tel. +32 2 524 7111 E-mail: info.medicines@fagg-afmps.be, www.famhp.be
Bulgaria	Bulgarian Drug Agency 8 Damyán Gruev Str. Sofia 1303, Bulgaria Tel. +359 2 890 35 55 Fax +359 2 890 34 34 E-mail: bda@bda.bg, www.bda.bg
Croatia	Agency for medicinal products and medical devices of Croatia Ksaverska cesta 4, 10 000 Zagreb Tel. +385 1 4884 100 Fax: +385 1 4884 110 E-mail: halmed@halmed.hr, www.halmed.hr
Cyprus	Ministry of Health - Pharmaceutical Services 1475 Nicosia, Cyprus Tel: +357 22608620 Fax: +357 22608649 E-mail: phscentral@phs.moh.gov.cy, www.moh.gov.cy/phs
Czechia	State Institute for Drug Control Srobarova 48, 100 41 Praha 10, Czechia Tel. +420 272 185 333 Fax +420 272 185 756 E-mail: infs@sukl.cz, www.sukl.cz

11 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
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Fax +30 210 6545 535
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11 LIST OF COMPETENT AUTHORITIES

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- Iceland Icelandic Medicines Agency
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E-mail: ima@ima.is, www.ima.is
- Ireland Health Products Regulatory Authority (HPRA)
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- Italy Italian Medicines Agency
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Fax +39 06 59784312
www.aifa.gov.it
- Latvia State Agency of Medicines
15 Jersikas Street, 1003 Riga, Latvia
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Fax +371 7078428
E-mail: info@zva.gov.lv, www.zva.gov.lv
- Liechtenstein
Office of Health / Department of Pharmaceuticals
Äulestr 512, 9490 Vaduz, Liechtenstein

11 LIST OF COMPETENT AUTHORITIES

- Lithuania State Medicines Control Agency
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Tel. +370 5 263 9264
Tel +370 5 263 9265
E-mail: vvkt@vvkt.lt, www.vvkt.lt
- Luxembourg Ministry of Health
Allée Marconi, 2120 Luxembourg, Luxembourg
E-mail: ministere-sante@ms.etat.lu, www.ms.etat.lu
- Malta Malta Medicines Authority (MMA)
Sir Temi Żammit Buildings, Malta Life Sciences Park
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- Netherlands Medicines Evaluation Board
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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
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11 LIST OF COMPETENT AUTHORITIES

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E-mail: infarmed@infarmed.pt, www.infarmed.pt
- Romania National Authority of Medicines and Medical Devices of
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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
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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
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