




Instructions for use and technical specifications

1 Introduction

The intended use for Dripmate is to regulate the dosage of the medication administered by the infusion set. Dripmate is designed to control a continuous flow. The system is intended for continuous delivery of medication that is usually administered by the infusion set. The system is not suitable for high potent medication or treatments that require flow rates less than 20ml/hr. Dripmate includes a drive system, a tube channel, a lid for fixing the tube in the right position and a power supply. The battery is rechargeable however internal and non-serviceable. Dripmate is designed for use in a hospital environment.

2 Warning

Only to be used with standard 20d/ml infusion set marked with:  with an outer drip chamber diameter of 15 to 21 mm and a tube diameter of 4.1 +/- 0.3 mm according to ISO 8536-4 and ISO 8536-8. Read the Instructions for Use carefully before taking DRIPMATE into use. Do not use Dripmate with highly potential medication. Do not use Dripmate for treatments that require flow rates less than 20ml/hr. Dripmate is only to be used by trained personnel. Use of unsuitable infusion sets may cause malfunction. The loading, priming, changing and reloading of infusion sets must follow the infusion set supplier's instructions for use. Make sure that the infusion set is fully closed (no fluid running) when loading, changing and reloading the infusion set to avoid free flow. Drop size formed by the drop nozzle in the drip chamber may be affected if used in a vibrating environment, e.g. under transportation, as Dripmate calculates the flow by counting drops, this might affect the dose accuracy. Any equipment connected to the infusion line may affect regulation of fluid. Dripmate meets the requirements of EMC. This, however, is no guarantee that the equipment will not be affected by electromagnetic disturbances.

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4 Preparing Dripmate

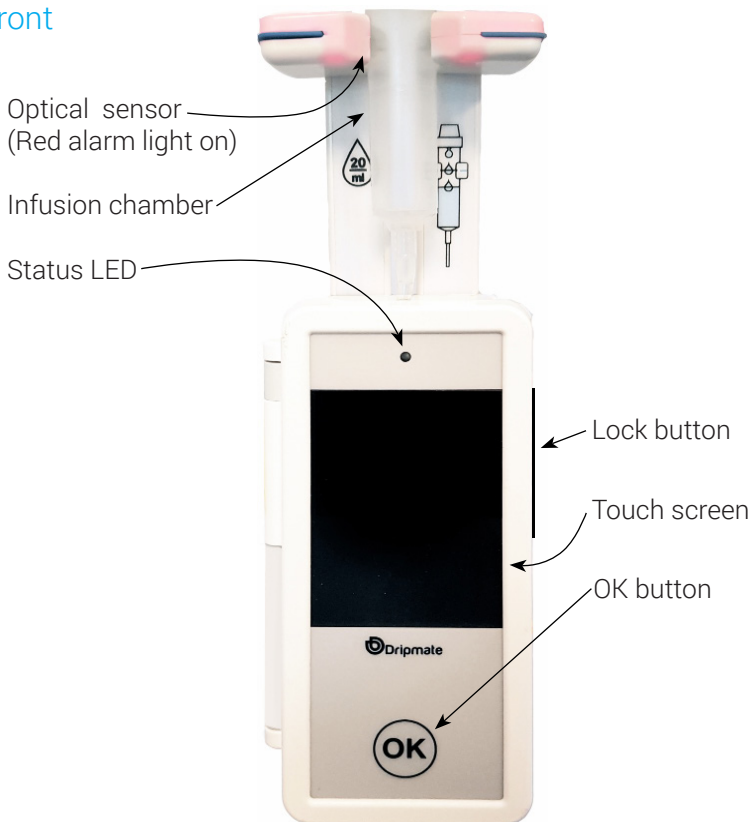
Make sure all items are in the package.

The package contains:

- 1 Dripmate
- 1 Power supply
- 1 IFU mini guide.

4.1 Overview

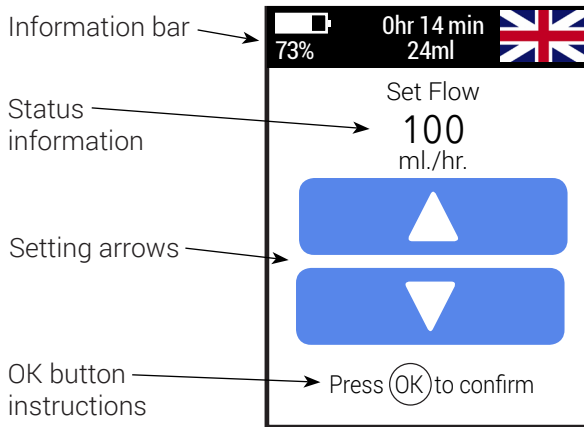
The front



The inside



The display



Status LED

The status LED at the top front of Dripmate will indicate what status Dripmate is in. This is particularly important when the display is off.

During start-up and self-test, the light will change from green to yellow.

Attention: If the status LED does not light up yellow and green, then Dripmate must be returned for service.

When setting the flow rate or when in pause the green light will be continuously lit.

When the flow is running and Dripmate regulates, the green light will flash.

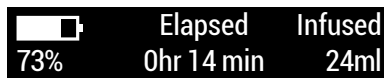
When running in occlusion warning mode, the yellow light will flash.

When Dripmate is charging, the yellow light will flash. The light will change to green when fully charged.

Optical sensor

Next to the IR light transmitter and the IR receiver, the optical sensor will flash a red light during self-test and when in alarm mode.

Information bar



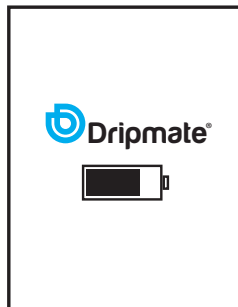
The information bar will at all times show the remaining battery capacity in %, how long the infusion has been running in hr. and min. since start-up or since being reset to zero and how much fluid (ml) that has been infused since start-up or reset to zero.

4.2 Procedure

Prior to using Dripmate for the first time, it must be charged for a minimum of 5 hours by attaching the power supply to a power outlet and plugging in the mini USB to the mini USB connector in Dripmate.



Note: A charging battery icon will be displayed after being connected to a power outlet. The display will then turn off but the status indicator will blink yellow when charging and light up green when fully charged.



Attention: Dripmate must be switched off when charging. Make sure to always fully charge the battery.

5 Use Dripmate

5.1 Attach to infusion set

Prepare the infusion set as when preparing for conventional infusion and close the flow of fluid.

Make sure that the liquid container is placed a minimum of 50 cm and a maximum of 200 cm above the patient's heart.

Attach Dripmate to the tubing just below the drip chamber:

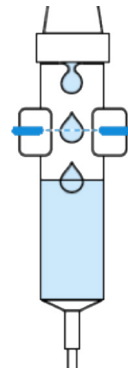
- 1 Hold Dripmate in one hand
- 2 Open the back of Dripmate by pushing the lock button upwards.
- 3 Pull up the optical sensor from Dripmate.
- 4 Fit the tube in the tube guides inside the back of Dripmate.

Attention: Make sure that the tube is correctly fitted into the tube guides.

- 5 Close Dripmate.

Attention: the lock button will automatically slide down and lock the tubing firmly inside Dripmate.

- 6 "Click" the optical sensor onto the drip chamber with the blue line pointing to a position where the drops are falling freely.



Attention: If the optical sensor does not hold onto the drip chamber, return Dripmate for service.

No drops will be detected if the drop sensor is misplaced or not working correctly.

After turning on Dripmate, it will open the flow and search for drops. If no drops are detected Dripmate a "flow stop" alarm will turn on and the flow will be stopped. (If the optical sensor is misplaced or not working correctly, there is a risk that a free flow will occur in the time it takes Dripmate to open and close the flow).

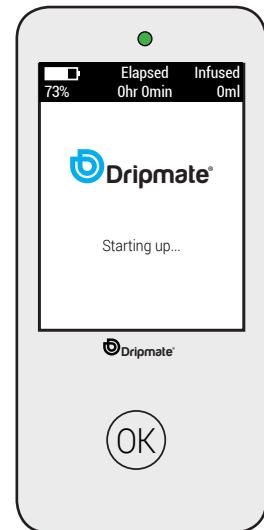
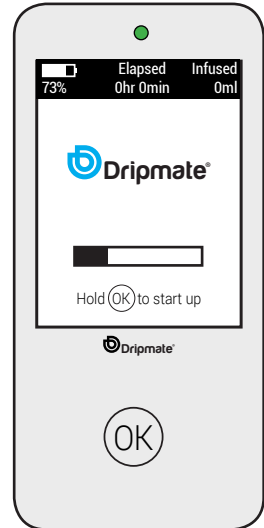
5.2 Turn on

Press and hold the

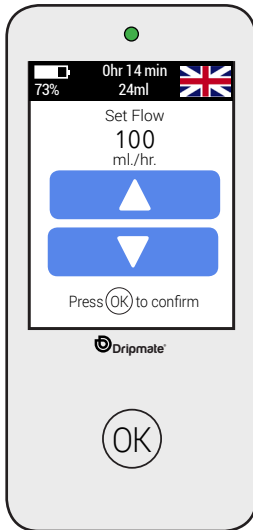
 button for 2 seconds

Dripmate will run a self-test turning on the display. The red alarm light, situated next to the optical sensor, will flash, the motor will start running, the status LED will then turn green followed by yellow and 3 beeps will sound.

Attention: Turn off Dripmate and return it to service if; the display does not work properly, the red alarm light or the status LED is not functioning or the 3 beeps do not sound.



5.3 Set flow rate



After the self-test Dripmate, will ask for a flow rate.

Note: The last used flow rate will be default.

Attention: If the tube guide is locked, Dripmate will close the flow and the roller clamp on the infusion set can be opened. If the tube guide is open Dripmate will open the flow to allow easy replacement of tubing.

When the tube guide is locked and the roller clamp opened some drops might fall. Make sure by inspection that the flow will stop within 5 seconds. If the flow continues close roller clamp and refit the tube in the tube guides by opening the back and taking out the tubing and then refitting it into the tube guides before locking the back of Dripmate.

The flow rate is adjusted by pressing the up and down arrows on the touch sensitive display.

Note: Dripmate can be handled whilst wearing gloves.

When the desired flow rate is displayed press the



button and Dripmate will ask you to confirm the flow rate.

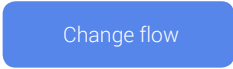
Note: If no buttons are activated, the display will turn off to save power. To turn on the display, press the OK button.



It is possible to change the language by pressing the flag in the upper right hand corner. Find instructions for use in various languages at www.dripmate.eu/IFU

5.4 Start

From the confirm flow screen you can press:

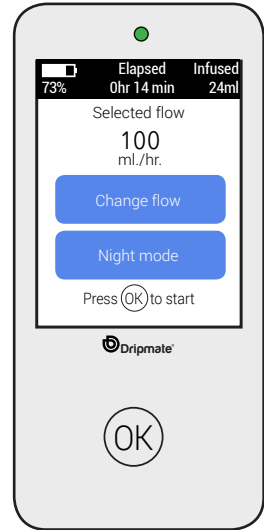


and Dripmate will goto: section 5.3 Set flow rate. Press the



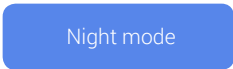
Note: Dripmate will open the flow until the first drop is detected and will then start regulating.

Attention: Check if the drops starts falling in the expected flow.



5.5 Night mode

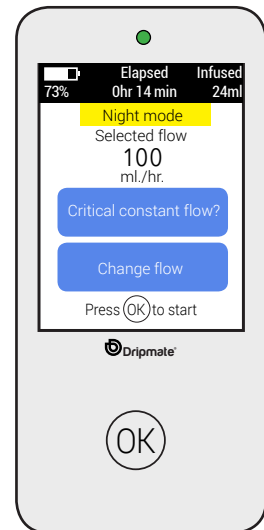
From the confirm flow screen you can press:



Night mode can be used if the low flow alarm is interfering with the patient's sleep.

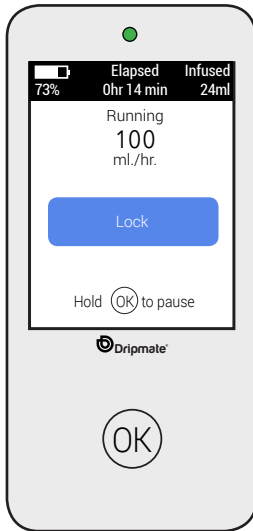
Attention: Night mode should NOT be used if it is critical to sustain a constant flow rate. In night mode the low flow alarm will be activated after 45 minutes of a continuous low flow. This means that the actual flow rate can at times be lower than the selected flow.

Note: In night mode a lower flow rate will activate a warning as described in section 5.7.




5.6 Running

Note: When running, Dripmate will maintain the set flow rate. The display will turn off to save power but the green status indicator will flash. If Dripmate is not able to maintain the set flow rate a warning or alarm will sound.




To pause Dripmate, press and hold the

 button.

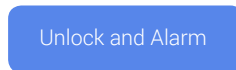
To lock Dripmate, press



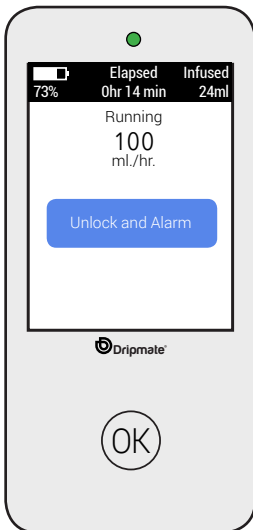
Attention: When Dripmate is locked the

 button is inactive.

To unlock Dripmate, press



and Dripmate will unlock and sound with 3 beeps.



Long term infusion

If an infusion therapy takes longer than the battery's capacity allows, then the Dripmate needs to be replaced with another fully charged Dripmate to continue the infusion.

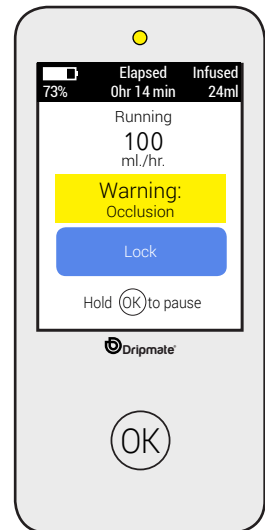
Follow the standard procedure for stopping and starting Dripmate, see section 5.9 and section 5.4.

Attention: The elapsed time and the infused volume will be reset when turning off Dripmate. The fully charged Dripmate will start counting elapsed time and infused volume from zero. If the total elapsed time and infused volume are needed, these must be calculated manually using the numbers from the different Dripmates.

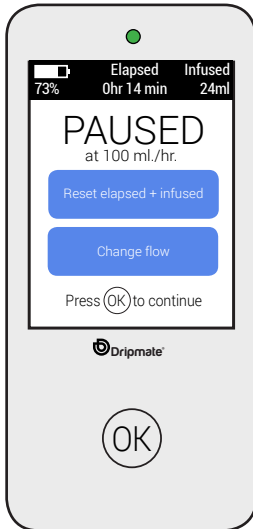
5.7 Warning

Attention: A warning occurs if Dripmate has fully opened the piston but is not able to maintain the set flow rate. Make sure that there is no kinking of the tube, the catheter in the vein is not blocked and that the height, measured from the patient's heart to the medication bag, is big enough.

Note: In warning mode, Dripmate will keep the flow open even though the flow being too slow. If the flow occlusion is fixed by removing any kinking, rearranging the catheter or raising the medication bag, Dripmate will return to normal regulation section 5.6.



5.8 Pause



In running mode, Dripmate can be paused by pressing the

(OK) button for 2 sec.

Once paused, Dripmate will close the flow.

When paused, the time counter (Elapsed) and volume counter (Infused) can be reset to zero by pressing:

Reset elapsed + infused

The flow can be adjusted by pressing:

Change flow

To continue the infusion, press the

(OK) button.

5.9 Turn off

Dripmate can be turned off in “Set flow rate” mode or “Pause” mode by pressing the

 button for 2 sec.

After pressing the

 button for 2 sec

the display will stay on for 5 sec flashing: “Close tube” and the display back light. After the 5 sec Dripmate will open the flow.


Attention: The elapsed time and the infused volume will be deleted when Dripmate is turned off.



6 Alarms

During alarms beeps sounds, the red alarm light flashes and the flow is closed.

The sound of the alarm can be turned off by pressing the

 button.

The alarm itself can be turned off by pressing and holding the

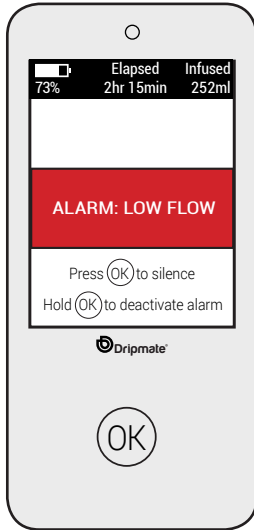
 button for 2 sec

Dripmate will return to “Set flow rate”.

Attention: If a flow is detected in the drip chamber after an alarm has occurred, close the flow manually on the infusion set’s roller clamp and return Dripmate for service.

6.1 Low flow rate

If Dripmate is in occlusion warning for 5 min, a LOW FLOW alarm will turn on.

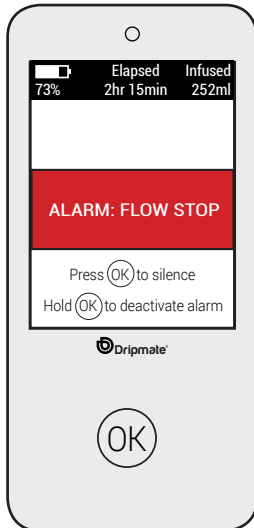


6.2 Flow stop

If no flow is detected at start-up a FLOW STOP alarm will turn on.

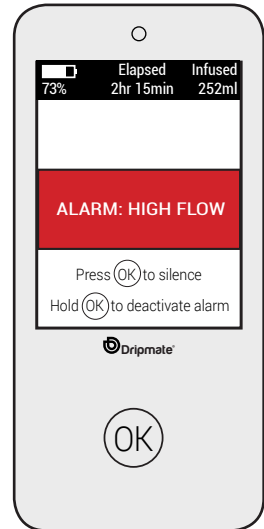
If no drops are detected by Dripmate in the time it takes 15 drops to fall at the set flow rate or maximum 30 secs, a FLOW STOP alarm will turn on.

Note: The 15 drop limit is to avoid the drip chamber from running dry if the medication bag is empty.



6.3 High flow rate

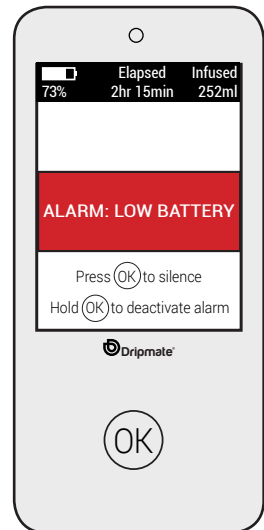
If the drops are falling too fast for a period of 20 drops Dripmate will turn on a HIGH FLOW alarm.



6.4 Low battery level

If the battery is running low on power, then Dripmate will turn on a LOW BATTERY alarm.

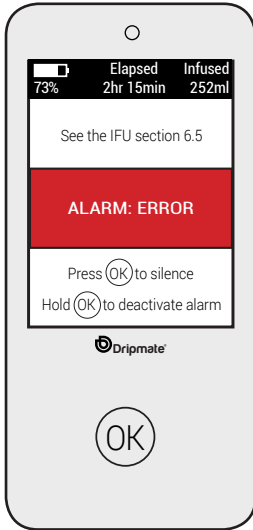
Attention: If a low battery alarm has sounded, Dripmate then must be charged before further use.



6.5 Error alarm

If Dripmate detects an error e.g. during self-test, an ERROR alarm is activated. Restart Dripmate and try again as described in section 5.

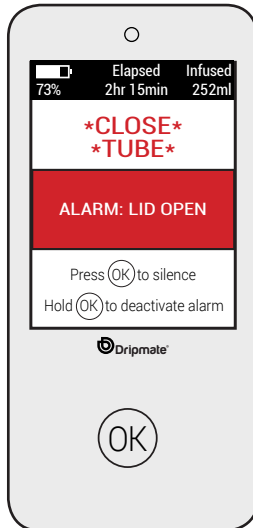
Attention: If ERROR alarm is activated repeatedly, Dripmate must be returned for service.



6.6 Lid alarm

If Dripmate is opened whilst running, a LID OPEN alarm will turn on.

Attention: In case of a LID OPEN alarm, make sure to close the tube to avoid free flow.



7 Cleaning

Dripmate must be cleaned by wiping it with a tissue or cloth moistened in water, commonly used cleaning agents or alcohol.

Cleaning of Dripmate must be performed as a minimum once a year. Cleaning should be performed if any dirt is detected.

8 Service and maintenance

Dripmate is designed as a non-serviceable device.

It is not possible to disassemble Dripmate and the battery is not replaceable.

It is not possible to calibrate Dripmate as there are no sensors that can drift over time.

An annual control of Dripmate can be completed according to the Instructions for Use. Furthermore, a dose accuracy test can be conducted according to IEC 60601-2-24.

In case of questions or complaints please contact your local supplier.

9 Accessories

Battery charger specification:

Friwo Type: FW8002/05 ACDC adapter with mini USB plug.

Voltage: 5V +10%

Current : 1A

10 Technical specifications

Flow rate: 20 to 600 ml/hr. can be adjusted in increments of 1 ml/hr from 20 to 180 ml/hr and in increments of 10 ml/hr from 180 to 600 ml/hr

The infused volume is calculated from the start of a treatment in ml.

The elapsed time is calculated from the start of a treatment in hr. and min.

Dripmate is designed to hang vertically on the infusion tube, however it will not be affected by angular variations of up to +/- 12 degrees.

Altitude: -300 to 10000 feet

Water safe: IP class 42.

Humidity limits: 20 – 90% RH noncondensing.

Temperature limits: +5°C to +40°C.

Avg. battery run time: 24 hours under normal conditions. Heavy use of display may decrease the battery time.

Note: The display is very power consuming and if the display is used very frequently a shorter run time can be experienced. The battery indicator does taker of that as it counts down faster when display is on.

Charging time: max. 5 hours.

Physical dimensions: 14 x 6,6 x 3.5 cm with the extractable optical sensor in its retracted position.

Weight: 210g

Only to be used with standard 20d/ml infusion set according to ISO 8536-4 and ISO 8536-8 with an outer drip chamber diameter of 15 to 21 mm and a tube diameter of 4.1 +/- 0.3 mm.

Dose accuracy:

Volumetric dose accuracy including drip chamber accuracy of +/- 10% is +/- 12% according to IEC 60601-2-24.

Dripmate has a drop rate accuracy of +/-2%.

EMC and ESD tests have been performed according to the following standards:

Emission:

EN/IEC 60601-1-2:2015 Medical electric equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic compatibility – Requirements and tests.

Product family standards:

EN/IEC 61000-3-2:2014 Harmonic

EN/IEC 61000-3-3:2013 Flicker

Immunity:

EN/IEC 60601-1-2:2015 Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic compatibility – Requirements and tests.

Test results

Phenomenon	Used basic standard	Test on	Result
Radiated emission	CISPR 11: 2009 + A1: 2010	Enclosure port	Requirements fulfilled
Conducted emission	CISPR 11: 2009 + A1: 2010	Input AC power port	Requirements fulfilled
Harmonic current emission	EN/IEC 61000-3-2: 2014	Input AC power port	N/A
Voltage fluctuation and flicker emission	EN/IEC 61000-3-3: 2013	Input AC power port	N/A
ESD immunity	EN 61000-4-2: 2009 IEC 61000-4-2: 2008	Enclosure port	Requirements fulfilled
Radiated RF immunity	EN/IEC 61000-4-3: 2006 + A1 + A2	Enclosure port	Requirements fulfilled
Conducted RF immunity	EN 61000-4-6: 2009 IEC 61000-4-6: 2008	Input AC power port Signal ports	Requirements fulfilled
Conducted fast transient immunity	EN/IEC 61000-4-43: 2004 + A1	Input AC power port Signal ports	Requirements fulfilled
Conducted surge transient immunity	EN 61000-4-5: 2014 IEC 61000-4-5: 2014	Input AC power port	Requirements fulfilled
Power frequency magnetic field immunity	EN 61000-4-8: 2010 IEC 61000-4-8: 2009	Enclosure port	Requirements fulfilled
Voltage dips and interruptions immunity	EN/IEC 61000-4-11: 2004	Input AC power port	Requirements fulfilled

N/A: Not applicable

Note: The equipment meets the requirements of EMC. This, however, is no guarantee that the equipment will not be affected by electromagnetic disturbances.

Warranty: 2 years

11 Symbols



Product is CE marked according to EU directive 93/42/EC

SN

Serial number

REF

Product number



Production year and month.



Manufacturer.

IPX 2

Water protection class.



Type BF equipment.



Contain Lithium-polymer battery. Dispose according to local regulation.



Attention, consult ACCOMPANYING DOCUMENTS.



Attention, consult Instructions for Use.



Plastic used.



Refers to drop size in infusion sets to be used with Dripmate.



CE
1370

IPX 2



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