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USER MANUAL

WEARABLE INFUSION PUMP

SORREL medical

For use with Wearable Infusion Pump Software Rev1.2.0

Table of Contents

Important Notice

The Wearable Infusion Pump User Manual is delivered subject to the conditions and restrictions listed in this section. Clinicians and users should read the entire User Manual prior to operating the Wearable Infusion Pump in order to fully understand the functionality and operating procedures of the pump.

Prescription Notice

Federal United States law restricts this device for sale by or on the order of a physician only {21 CFR 801.109(b)(1)}.

The Wearable Infusion Pump is for use at the direction of, or under the supervision of, licensed physicians and/or licensed healthcare professionals who are trained in the use of the pump and in the administration of subcutaneous infusions. The instructions for use presented in this manual should in no way supersede established medical protocol concerning patient care.

Copyright, Trademark and Patent Information

Sorrel (with or without logos) is a trademark of Sorrel Medical Ltd.

The design, pumping mechanism and other features of the Sorrel Wearable Infusion Pump are protected under one or more US and Foreign Patents.

Disclaimer

The information in this manual has been carefully examined and is believed to be reliable. No responsibility is assumed for any inadvertent inaccuracies. Sorrel Medical Ltd. reserves the right to make changes to any of its products in order to improve reliability, design and performance. The instructions presented in this manual should in no way supersede established medical protocol concerning patient care. The text and drawings herein are for the purposes of illustration and reference only; the specifications on which they are based are subject to change without notice.

Warning

Sorrel Medical Ltd. will assume no responsibility for incidents which may occur if the product is not used in accordance with product labeling. Refer to Warnings and Safety Precautions on page 12 for a complete list of warnings and cautions.

Technical Assistance

For technical questions, troubleshooting assistance and reporting of unexpected events, please contact your healthcare provider. You may also contact Sorrel Medical Ltd. support via email to the following address: support@sorrelmedical.com

1. INTRODUCTION

1.1. Product Intended Use and Indications for Use

The Wearable Infusion Pump is intended for use in subcutaneous infusion of prescribed liquid medication of up to 6 hours.

The pump is medication agnostic (no specific medication) and designed for pediatric and adults subcutaneous treatment.

1.2. Terms and Abbreviations

Term/Abbreviation	Meaning
Continuous Infusion	Infusion is continuously administered in one programmable rate
EMC	Electromagnetic Compatibility
EMI	Electromagnetic Interference
FCC	Federal Communications Commission
mL	Milliliters
MRI	Magnetic Resonance Imaging
RH	Relative Humidity
RF	Radio Frequency
ROW	Rest of World (i.e. non-US)
Volume To Be Infused	The amount of fluid programmed or remaining to be infused. The value range is 0.1 to 3 mL

1.3. Document Conventions

The following messages in this manual prompt reader to pay special attention to specific points:

	**Warnings** alert the user about situations to be avoided, the result of which could lead to death or serious injury. They may also describe potential serious adverse reactions and safety hazards.
	**Cautions** caution the user of a potentially hazardous situation which, if not avoided, may result in minor or moderate injury to the user or damage to the equipment or other property. It may also be used to alert against unsafe practices.
	**Notes** provide additional information to help obtain optimal equipment performance.

1.4. Safety and Compliance Information

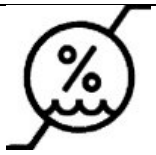
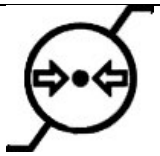
The following section presents important labeling, safety and compliance information:

1.4.1 Symbols and Labeling

The following table describes the symbols that appear on the Wearable Infusion Pump's labels, and identifies their locations on the labels:

Symbol	Description	Location
	CE certification mark	Single unit pack label (ROW) & shipping package (ROW)
	Bluetooth™ logo	Single unit pack label & shipping package
	Do not use if package is damaged	Single unit pack label

	Waste Electrical and Electronic Equipment (WEEE) Disposal This symbol indicates that used batteries and electronic equipment must not be disposed of as unsorted municipal waste, and must be collected separately. Contact an authorized representative for information concerning the decommissioning of your equipment.	Single unit pack label
	Non-DEHP tubing	Single unit pack label & shipping package
	Latex free	Single unit pack label & shipping package
	Do not re-use	Single unit pack label
	Non-pyrogenic	Single unit pack label

	Refer to instruction manual/ booklet	Single unit pack label
	Keep away from sunlight	Single unit pack label & shipping package
	Keep dry	Shipping package
	Storage temperature range	Single unit pack label & shipping package
	Storage humidity range	Single unit pack label & shipping package
	Storage atmospheric pressure range	Single unit pack label & shipping package
IP65	Degree of Protection against Ingress of Water and Dust	Single unit pack label
	Defibrillation proof type CF applied part	Single unit pack label
Rx Only	US federal law restricts this device to prescription only	Single unit pack label (US/Canada)
	Name and address of manufacturer	Single unit pack label & shipping package

	Sterilized using ethylene oxide	Single unit pack label & shipping package
	Serial number	Single unit pack label & pump side label & shipping package
	Catalogue Number	Single unit pack label & shipping package
	Authorized representative in the European Community	Single unit pack label (ROW)
	Sorrel Medical company logo	Single unit pack label & pump top label & shipping package
	Use by date: YYYY-MM-DD	Single unit pack label & pump side label
	Instructions for use regarding RF data (includes a table of relevant countries with English language)	Single unit pack label (ROW)

1.4.2 Compliance and Classification

This manual has been written in conjunction with the requirements of the following International Standards:

- IEC 60601-1 - Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
- IEC 60601-1-2 - Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests
- IEC 60601-2-24 - Medical Electrical Equipment - Part 2-24: Particular Requirements for Safety of Infusion Pumps and Controllers. Data presented in the Technical Specification section reflect specific test

conditions defined in this standard. Other external factors, such as varying back pressure, temperature, head height, set usage, fluid restrictions, solution viscosity, or combinations of these factors may result in deviations from the performance data presented

- IEC 60601-1-8 - Medical electrical equipment -- Part 1-8: General requirements for basic safety and essential performance - Collateral standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems
- IEC 60601-1-11 - Medical electrical equipment -- Part 1-11: General requirements for basic safety and essential performance – Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment
- ISO 11608-1 - Needle-based injection systems for medical use — Requirements and test methods — Part 1: Needle-based injection systems
- FCC: The Federal Communications Commission (FCC) regulates interstate and international communications by radio, television, wire, satellite and cable. The Wearable Infusion Pump complies with Part 15 of the FCC Rules.
- Classification according to IEC 60601-1:
    - Internally powered
    - Type CF
    - Continuous operation
    - Not suitable for use in the presence of flammable aesthetic mixture with air or with oxygen or nitrous oxide
- Classification according to IEC 60601-2-24:
    - Type 1 Ambulatory pump

1.4.3 FCC and IC Information for EMC and Radio Frequency

FCC ID: 2AR6L-SORRELWIP

IC: 24632-SORRELWIP

CAN ICES-3 (B) /NMB-3 (B) HVIN 04 FVIN 1.2.0

Sorrel Medical Ltd. has not approved any changes or modifications to this device by the user. Any changes or modifications not expressly approved by Sorrel Medical Ltd. could void the user's authority to operate the equipment.

Sorrel Medical Ltd. n'approuve aucune modification apportée à l'appareil par l'utilisateur, quelle qu'en soit la nature. Tout changement ou modification peuvent annuler le droit d'utilisation de l'appareil par l'utilisateur.

Class B digital device warnings

The FCC Wants You to Know

This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to Part 15 of the FCC rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

a) Reorient or relocate the receiving antenna.

b) Increase the separation between the equipment and receiver.

c) Connect the equipment to an outlet on a circuit different from that to which the receiver is connected.

d) Consult the dealer or an experienced radio/TV technician.

CAN ICES-3 (B) / NMB-3 (B)

This Class B digital apparatus complies with Canadian ICES-003.

Cet appareil numérique de classe B est conforme à la norme canadienne ICES-003.

Interference statement

This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation. Changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

This device contains licence-exempt transmitter(s)/receiver(s) that comply with Innovation,Science and Economic Development Canada's licence-exempt RSS(s). Operation is subject to the following two conditions:(1) This device may not cause interference.(2) This device must accept any interference, including interference that may cause undesired operation of the device.

Wireless notice

This device complies with FCC/ISED radiation exposure limits set forth for an uncontrolled environment and meets the FCC radio frequency (RF) Exposure Guidelines and RSS-102 of the ISED radio frequency (RF) Exposure rules. This transmitter must not be co-located or operating in conjunction with any other antenna or transmitter.

Cet appareil contient des émetteurs / récepteurs exemptés de licence conformes aux RSS (RSS) d'Innovation, Sciences et Développement économique Canada. Le fonctionnement est soumis aux deux conditions suivantes :

(1) Cet appareil ne doit pas causer d'interférences.

(2) Cet appareil doit accepter toutes les interférences, y compris celles susceptibles de provoquer un fonctionnement indésirable de l'appareil.

1.4.4 Biocompatibility

All materials in the pump casing and in the fluid path have been tested for biocompatibility, and are in compliance with applicable international standard ISO 10993-1 for biocompatibility.

1.4.5 Degree of Protection against Ingress of Water and Dust

The Sorrel Wearable Infusion Pump meets the IP65 splash/dust requirements according to IEC 60529.

1.5. Warnings and Safety Precautions

All warnings and safety precautions should be read carefully before operating the Wearable Infusion Pump.

 WARNING: No modification of this equipment is allowed.

 Safety information specific to particular pump functions appear in the relevant sections of this manual.

1.5.1 General Warnings Precautions

To ensure safety and proper operation, read the User Manual before operating this device. In addition, adhere to the following safety guidelines:

- It is important that you do not try to give yourself the injection unless you have received training from your healthcare provider.
- Do not shake the Wearable Infusion Pump.
- Do not use the Wearable Infusion Pump and pre-filled cartridge if either has been dropped onto a hard surface. Part of the Wearable Infusion Pump and pre-filled cartridge may be broken even if you cannot see the break. Use a new Wearable Infusion Pump and pre-filled cartridge.
- Do not reuse the Wearable Infusion Pump and pre-filled cartridge. The Wearable Infusion Pump and pre-filled cartridge are for single use only.
- The Wearable Infusion Pump is only to be used with a 3 mL pre-filled cartridge.
- Do not use the Wearable Infusion Pump if its single pack unit is damaged.
- Do not use the Wearable Infusion Pump after the expiration date that appears on the single pack.
- To avoid damage to the pump, keep the Wearable Infusion Pump away from unattended children and pets.

1.5.1.1 Waste Disposal

Waste Disposal Safety Precautions

- Keep used pumps and packaging and tubing out of the reach of children.
- Pumps should be disposed of in a proper manner, considering the nature of residual fluid that may be contained within, in accordance with disposal practices.
- Do not dispose of the pump in or near fire.
- The Wearable Infusion Pump contains a needle.
- When disposing of the device, use a FDA-cleared sharps disposal container.
- If you do not have a FDA-cleared sharps disposal container, you may use a household container that is:
    - made of a heavy-duty plastic,
    - can be closed with a tight-fitting, puncture-resistant lid, without sharps being able to come out,
    - upright and stable during use,
    - leak-resistant, and
    - properly labeled to warn of hazardous waste inside the container.
- When your sharps disposal container is almost full, you will need to follow your community guidelines for the right way to dispose of your sharps disposal container. There may be state or local laws about how you should throw away used needles and syringes. For more information about safe

sharps disposal, and for specific information about sharps disposal in the state that you live in, go to the FDA's website at: http://www.fda.gov/safesharpsdisposal .

- Do not dispose of your used sharps disposal container in your household trash unless your community guidelines permit this. Do not recycle your used sharps disposal container.
- Do not recycle the Wearable Infusion Pump without specific guidance from the device manufacturer
- Important: Always keep the sharps disposal container out of the reach of children.

1.5.1.2 Explosion Hazard

The equipment is not suitable for use in the presence of flammable anesthetic mixture with air or with oxygen or nitrous oxide.

1.5.1.3 Electromagnetic Compatibility

The Wearable Infusion Pump is designed to conform to the electromagnetic compatibility (EMC) standard IEC 60601-1-2 and to operate accurately in conjunction with other medical equipment which also meets the requirements of this standard. To avoid electromagnetic interference that may affect the operation of the pump, do not use the pump near sources of strong electric and magnetic interference (EMI), such as MRI, CT, diathermy, electromagnetic security systems (e.g., metal detectors), and large electric motors.

Portable and mobile RF communication equipment, such as RF emitters, cellular telephones, 2-way radios, Bluetooth™ devices, and microwave ovens in close proximity to this device may affect wireless communications with the Infusion pump and/or the operation of the Infusion pump.

This device has been tested for compliance with FCC RF exposure limits in a portable configuration. This device must not be used with any other antenna or transmitter that has not been approved to operate in conjunction with this device.

Special precautions need to be exercised regarding EMC. These include:

- Maintaining a minimum separation distance of 2 1⁄2 ft. (3⁄4 m) between the Infusion pump system and portable/mobile RF communications equipment.
- Managing the electromagnetic environment to permit the device to perform as intended without disturbing other equipment.
- Separating the device from all other electronic equipment. If the device must be used near other electrical equipment, monitor the equipment to ensure there is no electromagnetic interference.
- Devices should not be used adjacent to or stacked with other equipment. If the device must be used adjacent to or stacked with other equipment, monitor the device to verify normal operation.

- Some of these EMI sources (mostly RF emitters) may not be visible and the device can potentially be exposed to fields from these EMI sources without the user's awareness.
- If you identify or suspect that external RF sources or other equipment are influencing device operation (from known or unknown sources), try to (as applicable) increase the pump's distance from the EMI source, re-orient the device, or relocate the device,

The EMC limits for the Medical Device Directive 93/42/EEC (EN301489-1/-17 IEC/EN 60601-1-2:2014) are designed to provide reasonable protection against harmful interference in a typical home use installation. The equipment generates, and can radiate, radio frequency energy, and if not used in accordance with the instructions, may cause harmful interference to other devices in the vicinity. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference with other devices, the user is encouraged to try to correct the interference by one or more of the following measures:

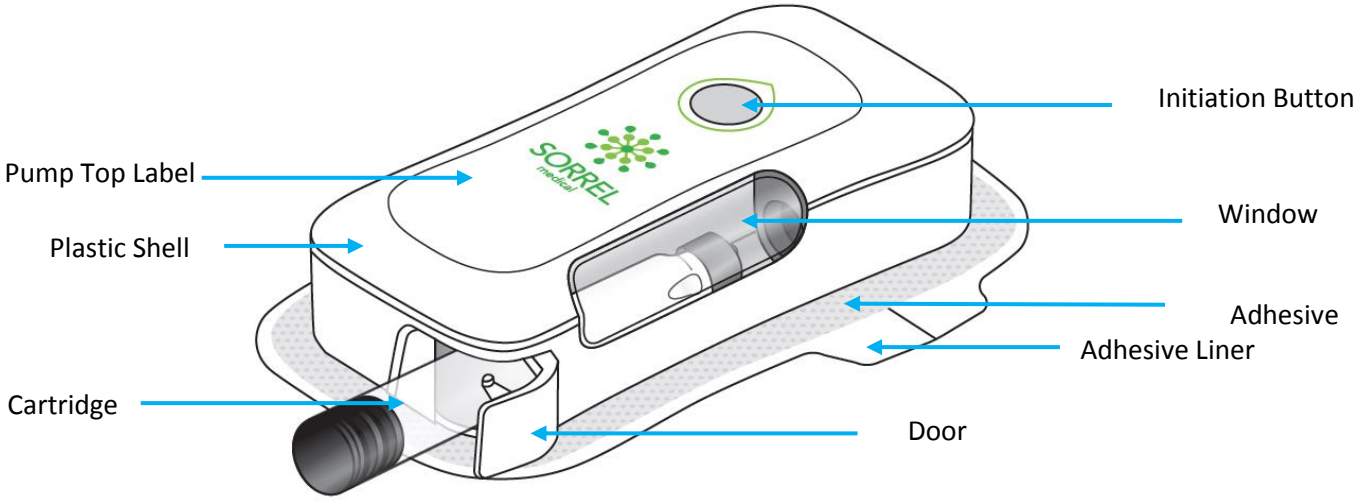
- Reorient or relocate the receiving device
- Increase the distance separating between the equipment parts
- Consult the manufacturer or field service technician for help

 Electromagnetic Safety Precautions

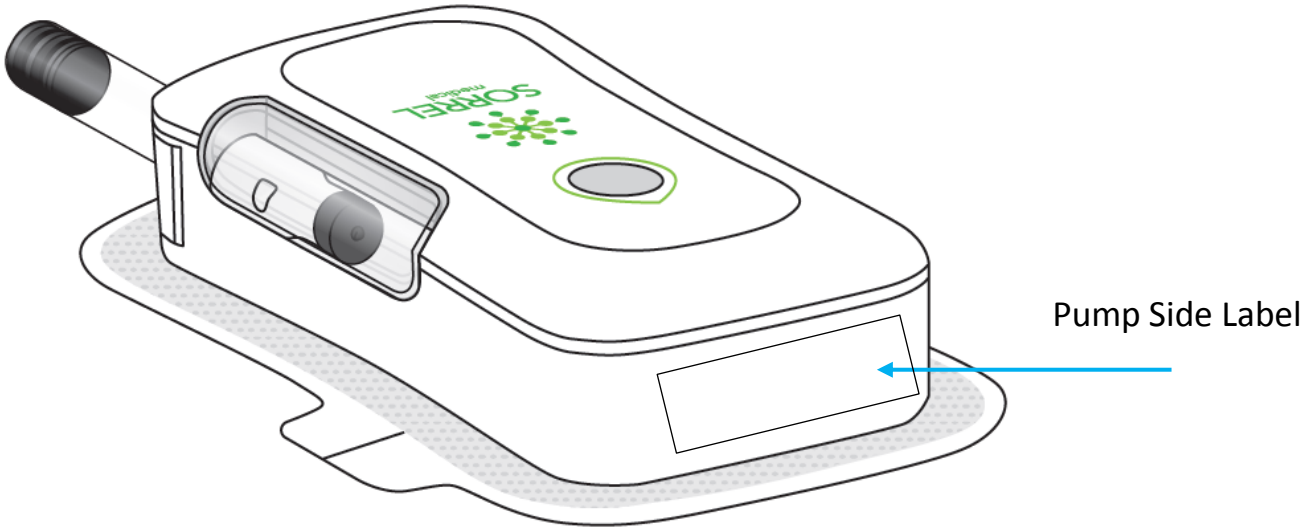
- Do not expose the pump to therapeutic levels of ionizing radiation, as permanent damage to the pump electronic circuitry may occur. Remove the pump from the patient during therapeutic radiation sessions.
- Do not expose the pump to magnetic resonance imaging (MRI) equipment and do not use the pump in the vicinity of it, as magnetic fields may adversely affect the operation of the pump. Remove the pump from the patient during MRI procedures, and keep it at a safe distance from magnetic energy.

2. WEARABLE INFUSION PUMP OVERVIEW

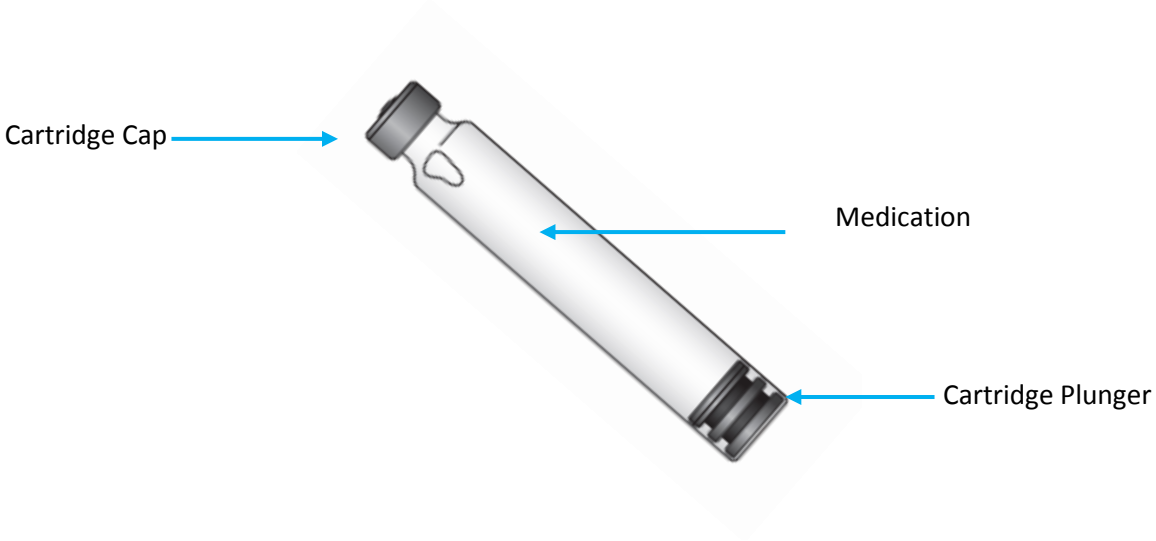
2.1. Top View



2.2. Side View



2.3. Pre-filled Medication Cartridge



2.4. Single Unit Pack

3. INSTRUCTIONS FOR USE

The patient is an intended operator of the Wearable Infusion Pump.

3.1. Step 1 - Prepare

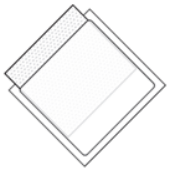
3.1.1 Gather all materials in a clean, well-lit area:

- Wearable Infusion Pump single unit kit

- Pre-filled medication cartridge

- Adhesive bandage

- Alcohol wipe



- Cotton ball or gauze pad

- Sharps disposal container*

*In case you do not have a sharps disposal container – please refer to section 1.5.1.1

Handle the medication according to your healthcare provider's instructions, including but not limited to: refrigeration of the pre-filled cartridge.

Review the information written on the paper cover of the single unit pack including the expiration date and the medication information.

3.1.2 Visually inspect the cartridge to verify cartridge integrity.

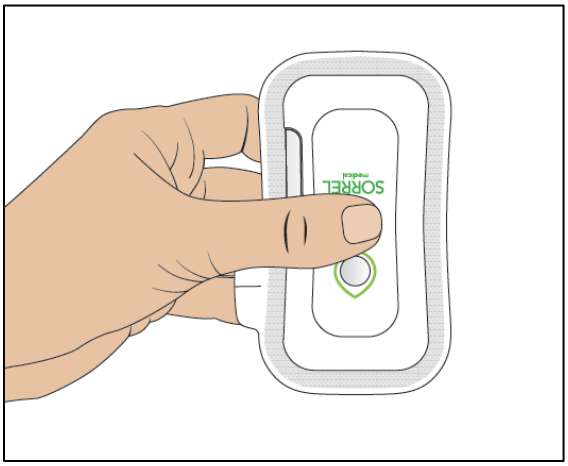
If there are any cracks or leaks coming from the cartridge- do not use the cartridge, and proceed to consult with your healthcare provider.

3.1.3 Peel the paper cover from the single unit pack and proceed to remove the plastic cover.

3.1.4 Now that the Wearable Infusion Pump is visible, remove the pump from the single unit pack.

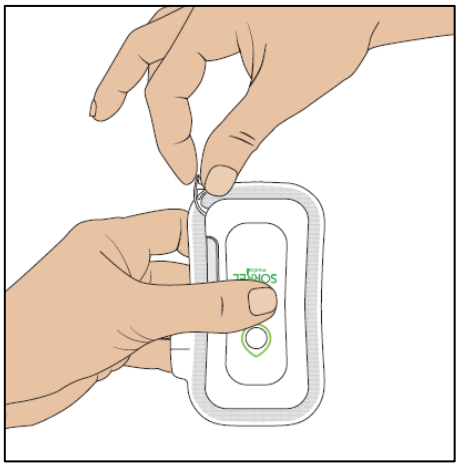
It is recommended to keep the single unit pack for later; it can be used for easy disposal of the pump.

3.1.5 Visually inspect the pump to verify integrity prior to use.

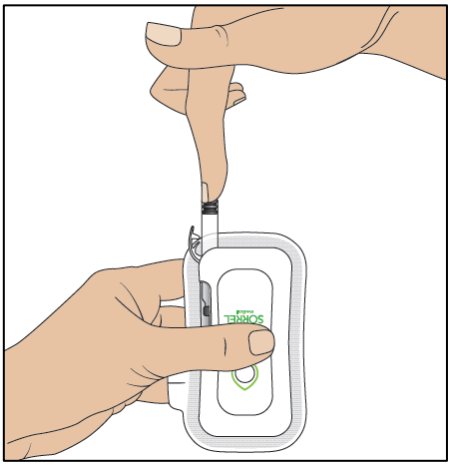


If there are any cracks in the plastic shell of the pump, indication that the pump is damaged or impaired, or if the needle is visible - do not use the pump, and proceed to consult with your healthcare provider.

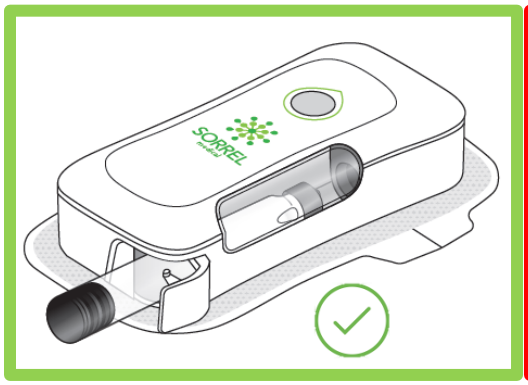
3.1.6 Open the pump door.



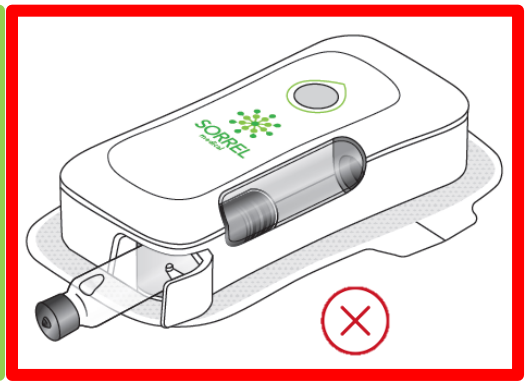
3.1.7 Load the cartridge into the pump, with the cartridge cap head first, and push inside until secure in place.



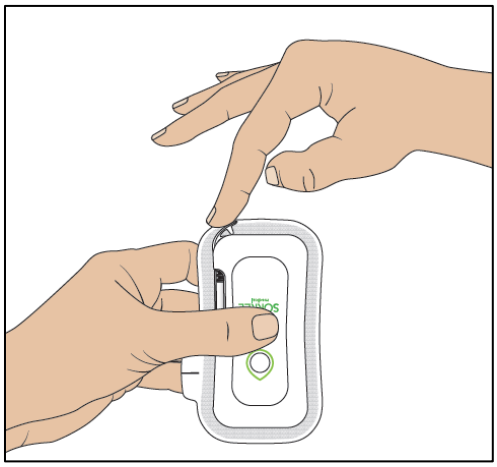
Correct insertion:



Incorrect insertion:



3.1.8 Close the pump door; you should hear a click when the door closes successfully.



3.1.9 Choose an injection site that is appropriate for subcutaneous injections; a relatively smooth skin surface, without hair, open wounds or scars:

- Abdomen: at or under the level of the belly button, about two inches away from the navel
- Arm: back or side of the upper arm
- Thigh: front of the thigh
- Lower back
- Buttocks

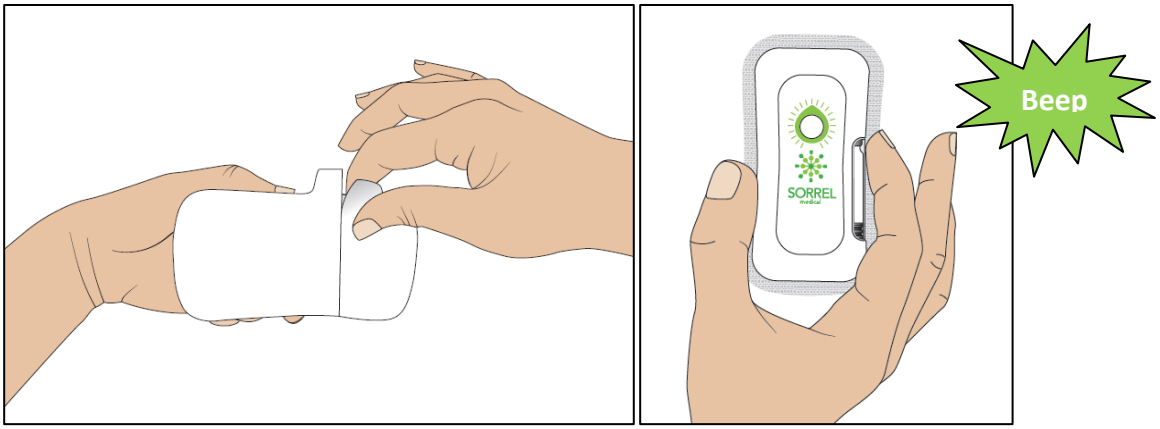
3.1.9.1 Prepare the injection site by swabbing it with an alcohol wipe.

Swabbing of the skin and application of the pump to the skin should be done consecutively, within a reasonable timeframe.

3.2. Step 2 - Inject

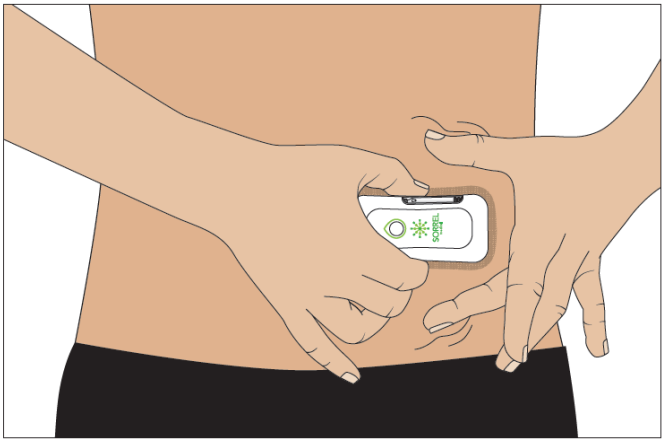
3.2.1 Remove the adhesive liner from the Wearable Infusion Pump by pulling at the adhesive liner tab. Peel one side of the adhesive liner, and then the other. The adhesive liner, once separated from the Wearable Infusion Pump, can be discarded.

- Once the adhesive liner has been removed, a beep will sound and the initiation button will light up momentarily

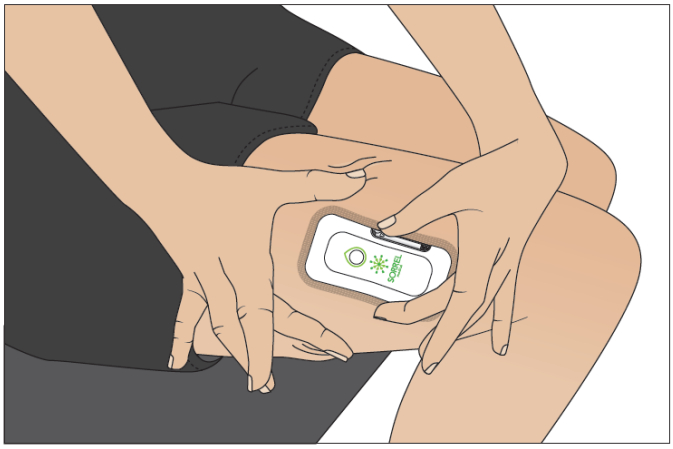


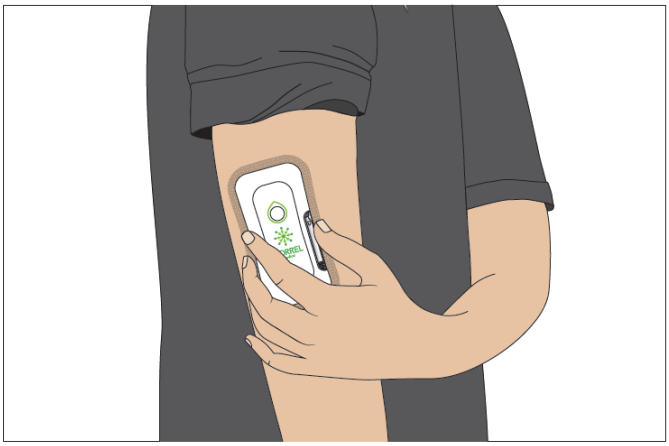
3.2.2 Prepare your injection area for application of the pump; ensure there are no folds of the skin, and place the pump on your skin firmly.

Abdomen placement:

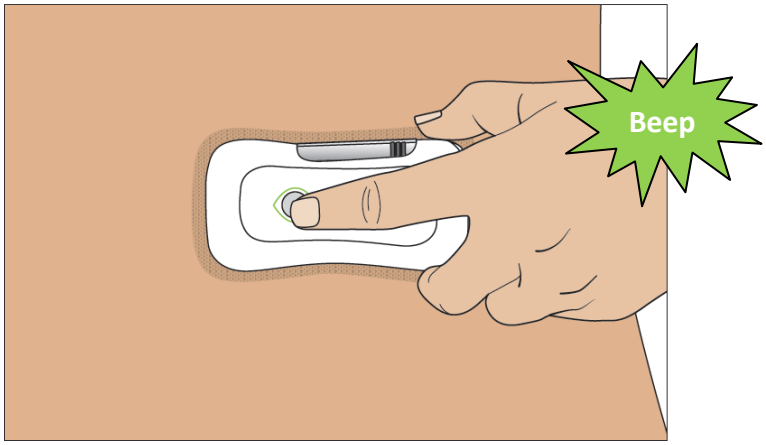


Thigh placement:



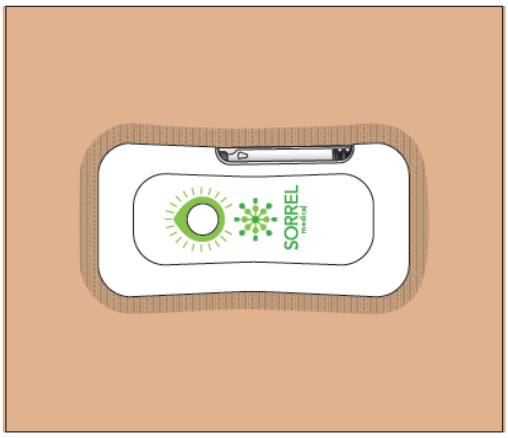
Arm placement: 

3.2.3 Press the initiation button to begin delivery of the medication



- The pump shall beep with initiation of delivery and the green light shall begin blinking, and will continue blinking throughout the delivery.

	If at this point you do not see a green blinking light illuminating the initiation button, try pressing the initiation button once more. Make sure the cartridge has been inserted into the pump, and that the pump is adhered to the skin. If still there is no green light, an error has occurred. Do not continue using the pump. Remove the pump from your skin and contact your healthcare provider for further assistance.



3.2.4 During delivery:

- Do not open the pump door during delivery
- Take notice if alarms sound during delivery (refer to section 4)
- Take notice if there is leakage from the pump during delivery

A slight stinging sensation in the injection site is expected.

If there is leakage from the pump during delivery, an error has occurred. Do not continue using the pump. Remove the pump from your skin and contact your healthcare provider for further assistance.

3.3. Step 3 - Finish

When the injection is finished you should hear a beeping sequence and the green light will stop blinking. At this point no light illuminating the initiation button should be seen.

3.3.1 Remove the pump from the skin by pulling at the adhesive.

There should not be a needle visible when the pump is removed from the body.
If this is not the case - take extra care when handling and disposing of the pump.

3.3.2 Look through the pump window to verify that the medication was delivered, by viewing that the cartridge is empty.

3.3.3 Optional: Return the used pump into its original single unit pack for easy handling and disposal of the used pump.

3.3.4 Optional: For downloading the treatment summary from your Wearable Infusion Pump prior to disposal, open the Sorrel Wearable Infusion Pump smartphone application and follow the instructions.

The Sorrel Wearable Infusion Pump smartphone application allows you to download the treatment summary from our Wearable Infusion Pump and provides a summary of your treatment; date, time, flow rate, volume infused, pump serial number, and alarm information if relevant. This information can then be shared from your smartphone.

3.3.5 Dispose of the pump into a designated sharps disposal container.

This device is for single use only. Do not try to reuse it.

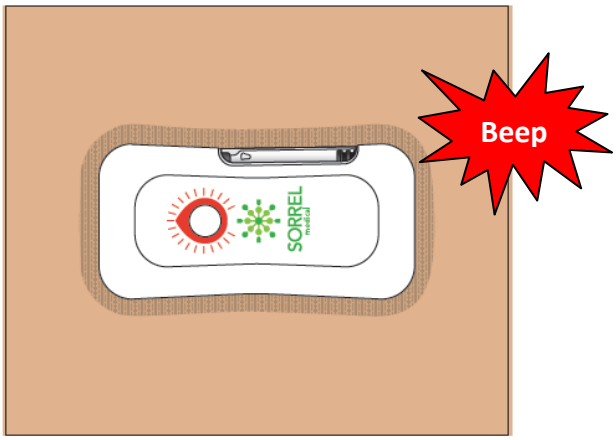
3.3.6 Check your injection site.

- If there is blood, press a cotton ball or gauze pad on your injection site. Do not rub the injection site. Apply an adhesive bandage if needed.
- Some irritation or redness of the skin may be present briefly after the injection has ended. This should disappear shortly. If it continues, contact your healthcare provider for further assistance.

4 ALARMS

4.1 Alarm Information

The Wearable Infusion Pump has only one type of alarm (high-priority), which may occur due to several reasons. In case of alarm, there will be consecutive beeping in two cycles, and then a 5 minute break before the next cycle. In addition, the initiation button will turn from green to red. Removing the device from the body will stop the alarm beeping sounds.
Alarm information can be seen in the treatment summary, via the smartphone application.



4.1.1 If an alarm occurs, the use of the Wearable Infusion Pump has ended, and the device must be removed from the body. Once removed, consult with your healthcare provider.

4.1.2 Alarm volume is always Max. Maximum alarm volume is 55 dBA

5 MAINTENANCE AND STORAGE

This device is for single use only! Do not try to reuse, clean or disinfect it.

5.1 Battery Classification

The UL 1642 Standard for Lithium batteries classifies the Lithium-Manganese battery used in the Wearable Infusion Pump as primary battery (non-rechargeable).

5.2 Transport and Storage

The pump should always be transported in its single pack. During handling and transport, protect the pump and the single pack from water, excessive humidity, and heat sources.

To safeguard the pump against prolonged exposure to dust and moisture, the pump must be stored in a clean and dry environment.

Specific recommendations for transport and long term storage conditions are listed in the following table.

Condition	Parameters	
	Transport (transient – up to 24 hours)	Long term storage
Temperature	-40ºC (-40ºF) to +70ºC (+158ºF)	2ºC (36ºF) to 27ºC (81ºF)
Relative humidity	20% RH to 85% RH	20% RH to 85% RH
Atmospheric pressure	69.6 kPa to 106 kPa (696 hPa to 1060 hPa)	69.6 kPa to 106 kPa (696 hPa to 1060 hPa)

6 TECHNICAL SPECIFICATIONS

6.1 Pump Accuracy

The dose accuracy of the Wearable Infusion per ISO 11608-1 under normal conditions is ±10% for dose of 0.1mL and ±5% for doses of up to 3mL.

The rated accuracy of the Wearable Infusion per IEC 60601-2-24 under normal conditions is ±5%.

Testing was performed under normal conditions at room temperature (25^{o}C, 72 ^{o}F).

Normal conditions to ensure optimal accuracy

- Barometric pressure of sea level altitude (101kPa)
- Subcutaneous medication with water like fluid characteristics

In the Wearable Infusion Pump, as in all infusion systems, external factors may cause fluctuations in rate accuracy. Conditions that can cause flow fluctuations include:

- Fluid characteristics that deviate from water-like characteristics, such as density, viscosity and homogeneity
- Barometric pressure below 101kPa

6.1.1 Start-up and Trumpet Graphs

The following graphs and curves were derived from the pump accuracy testing procedures described in the IEC60601-2-24 standard.

The start-up graphs represent startup flow versus operating time for the first half of the 3 mL cartridge (filled with 3 mL water) from the start of the infusion ("Stabilization period"), while the trumpet curve represents the percent flow rate deviation from the programmed rate over time of the second half of the cartridge ("Analysis period"). The horizontal axis represents the observation time intervals, which were adapted to represent the time of the delivery.

Over long observation windows, short-term fluctuation has little effect on accuracy, as represented by the flat part of the curve. As the observation window is reduced, short-term fluctuations have a greater effect, as represented by the "mouth" of the trumpet.

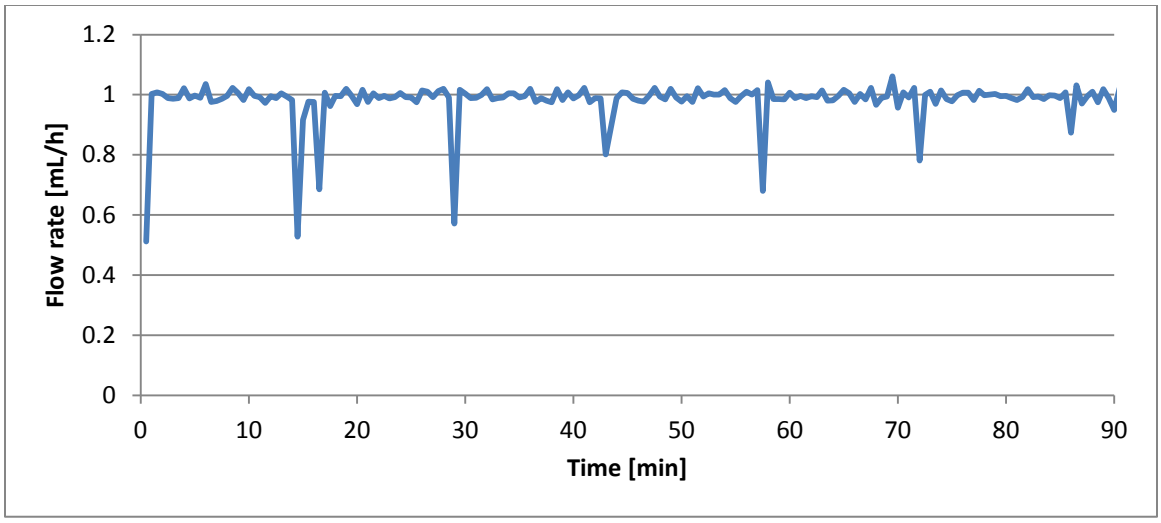


Figure 6.1. Delivery Startup Graph ("Stabilization period"), first 1.5 hours of Test Period, 1 mL/h

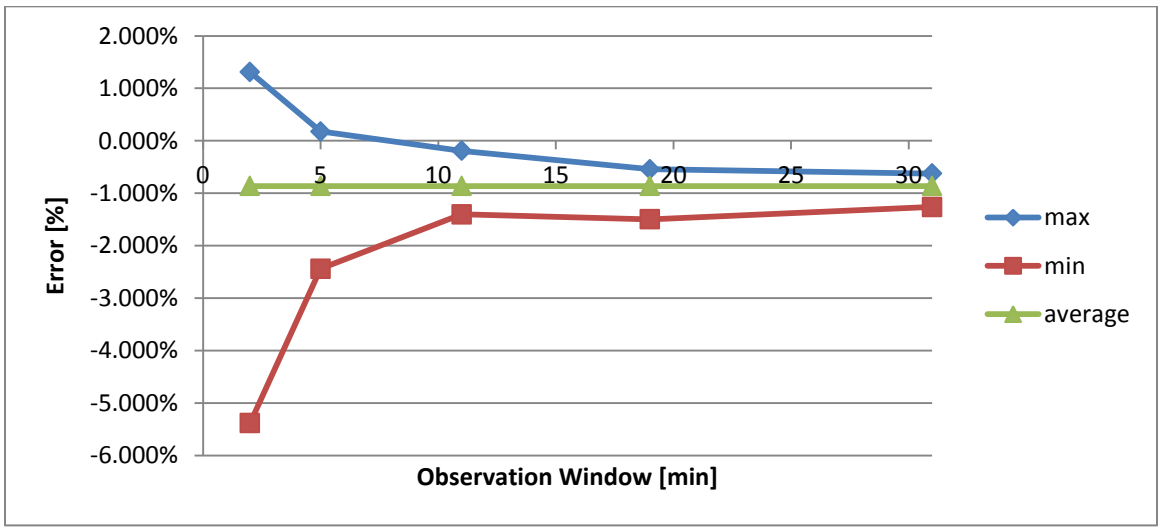


Figure 6.2. Trumpet Graph ("Analysis period"), second (and last) 1.5 hours of Test Period, 1 mL/h

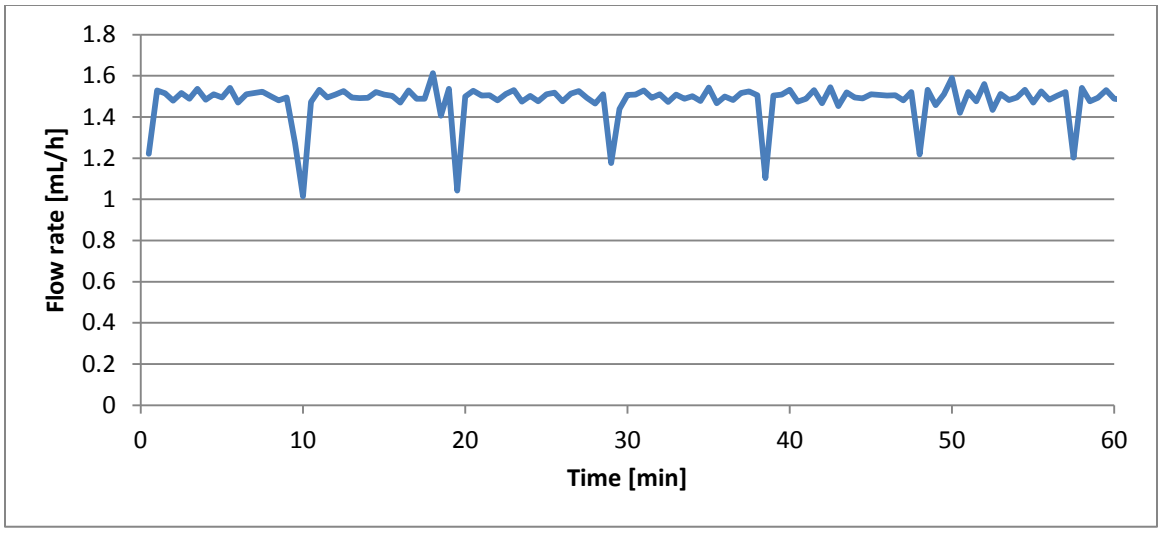


Figure 6.3. Delivery Startup Graph ("Stabilization period"), first hour of Test Period, 1.5 mL/h

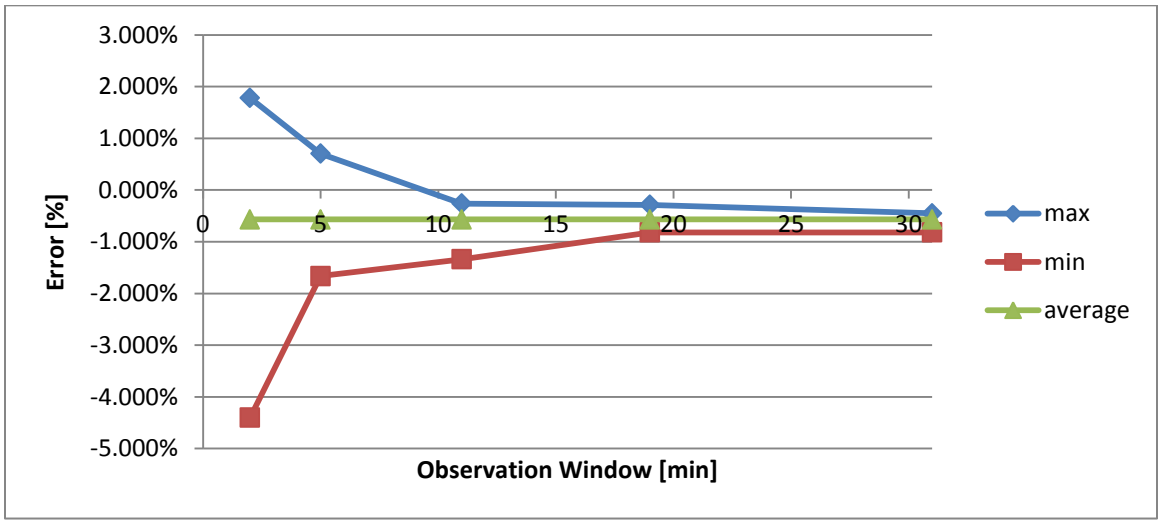


Figure 6.4. Trumpet Graph ("Analysis period"), second (and last) hour of Test Period, 1.5 mL/h

6.2 Pump Specifications

The following table lists and describes pump specifications.

Parameter	Description
GENERAL	
Type of Pump	Container, type 1 ambulatory
Operating Principle	Piston

Patient population	Adult and pediatric
Delivery Mode	Continuous
Delivery route	Subcutaneous
System delivery accuracy (Nominal)	±5%
Sensors	Air sensor, cartridge sensor, temperature sensor
Occlusion alarm threshold	4 bar
Maximum time for activation of the occlusion alarm	1 mL/h: 02:27 [min:sec], 1.5 mL/h: 02:05 [min:sec]
History log	Yes
ELECTRICAL SAFETY	
Electrical Safety	Compliant with IEC 60601-1 - Edition 3.1
Electromagnetic compatibility	Compliant with IEC 60601-1-2 – Edition 4.0
Recovery time for defibrillation-proof applied parts	< 1 sec
MECHANICAL AND POWER SPECIFICATIONS	
Pump Size	23 x 95 x 46 mm HxWxD (0.91 x 3.74 x 1.81 inches)
Pump Weight	70 grams
Ingress Protection	IP65
Power Source	Non-rechargeable Li- Manganese battery 3.0 V/1000 mA
Battery consumption	6 hours of work at 0.5 mL/h
OPERATING ENVIRONMENT	
Temperature	+5°C to 40°C (41°F to 104°F)
Relative Humidity	15% to 95%
Atmospheric pressure	50 kPa to 106 kPa (500 hPa to 1060 hPa)
TRANSPORT ENVIRONMENT	
Temperature	-40°C to + 70°C (-40°F to 158°F)
Relative Humidity	20% to 85%
Atmospheric pressure	69.6 kPa to 106 kPa (696 hPa to 1060 hPa)
STORAGE ENVIRONMENT	
Temperature	2°C to 27°C (36°F to 81°F)
Relative Humidity	20% to 85%
Atmospheric pressure	69.6 kPa to 106 kPa (696 hPa to 1060 hPa)

The following list provides guidelines about environmental conditions and situations to be avoided when working with or storing the Wearable Infusion Pump:

- Avoid locations where there is inadequate ventilation.
- Avoid locations where sudden impact or vibration may occur.
- Avoid damp locations or locations where moisture level may increase considerably.
- Avoid locations with large temperature fluctuations.
- Avoid locations near an electrical heating apparatus.
- Avoid locations exposed to chemicals or explosive gases.

6.3 Pump Ranges

Parameter	Range	Increments
Volume To Be Infused (mL)	0.1-3	0.1
Rate (mL/h)	0.01-60	0.01
Time	00:01-05:59	1 min / 1 hour

6.4 Electromagnetic Compatibility Statement

The following sections provide information about testing of and recommendations for electromagnetic compatibility statement.

6.4.1 Electromagnetic Emission

The Wearable Infusion Pump is intended for use in the electromagnetic environment specified below. The customer or the user of the pump should ensure that it is used in such an environment.

Emission Test	Compliance	Electromagnetic Environment Guidance
RF emission	CISPR 11 class B	The pump is suitable for use in home healthcare environment.

6.4.2 Electromagnetic Immunity

The Wearable Infusion Pump is intended for use in the electromagnetic environment specified below.

The customer or the user of the pump should ensure that it is used in the following environment.

Use of this equipment adjacent to or stacked with other equipment (see below table) should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.

Test Method	Test Level	Compliance Level	Electromagnetic Environment Guidance
Electrostatic discharge (ESD) per IEC 61000-4-2	± 8 kV contact; ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV air*,**	±8 kV contact; ±15 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Radiated RF EM field immunity per IEC 61000-4-3	10 V/m, 80 MHz – 2.7 GHz, 80 % AM at 1 kHz*	10 V/m, 80 MHz – 2.7 GHz, 80 % AM at 1 kHz	NA
	10 V/m, 26 MHz – 2.5 GHz**	10 V/m, 26 MHz – 2.5 GHz	NA
Power frequency (50/60 Hz) magnetic field immunity per IEC 61000-4-8	30 A/m*	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
RF wireless communications equipment fields Immunity per IEC 61000-4-3	Frequencies and levels as specified at IEC 60601-1-2, Table 9*	Max. 28 V/m	NA

* The pump was tested according to the EMC requirements of IEC 60601-1-2 (fourth edition)

** The pump was tested according to the EMC requirements of ISO 11608-1 (third edition)

7 COMPLIANCE INFORMATION STATEMENTS

7.1 FCC Declaration of Conformity

We Sorrel Medical Ltd. declare:

Type of equipment: Infusion Pump

Brand name or trademark: Wearable Infusion Pump

Product Identification number: SORREL V04 | FCC ID: 2AR6L-SORRELWIP

Applicable Compliance Statements: (e.g. for part 15 devices see §15.19(a)(3))

Country of origin: Israel

Manufacturer: Sorrel Medical Ltd.

Responsible Party name (IN USA): Z & B Enterprises, Inc.

Address: 12154 Darnestown Road, #236, Gaithersburg, MD 20878, USA

Telephone: 301-251-9570

Internet E-Mail: rhonashanker07@verizon.net

Standards applied:

- FCC Part 15B - For Unintentional radiators; (test report number: XXX)
- FCC Part 15C - For Intentional radiators; (test report number: XXX)

Test reports/ certificates issued by: TBD

Telecom Certification Body by: TBD

As manufacturer/ manufacturer's authorized representative within the USA, we declare under our sole of responsibility that the equipment follows the provisions of FCC Equipment Authorization Procedures under CERTIFICATION (47 CFR Section 2.907) and / or SUPPLIER'S DECLARATION OF CONFORMITY (47 CFR Section 2.906) as stated above.

Thus,  is placed on the product

Date of issue: December 28, 2018

Place of issue: Israel

(Signature & Name of authorized person) (Company Stamp)

7.2 EU Declaration of Conformity

We Sorrel Medical Ltd. declare under our sole responsibility:

Type of equipment: Infusion Pump

Brand name or trademark: Wearable Infusion Pump

Product Identification number: V04

Traceability Identification: 15126-000-0001

Country of origin: Israel

Manufacturer: Sorrel Medical Ltd.

The authorized representative located within the Community is: Mrs. Dr. Stephanie Vorwerk

Company: MedNet GmbH

Address: Borkstrasse 10, Munster 48163, Germany

Essential requirements according to directives:

- 2014/30/EU EMCD
- 2014/35/EU LVD
- 1999/5/EC R&TTE or 2014/53 RED
- 2011/65/EU RoHS

Standards applied:

- EN 301489-17, EN 301489-3
- EN 300 328 V2.1.1 , EN 300 330 V2.1.1
- EN 62479

Other normative references: CEPT Radio Resolution 4561

Radio Equipment Class: Class 2

Test reports/ certificates issued by: Global United Technology Services Co., Ltd. (GTS) China.

As manufacturer/ manufacturer's authorized representative within the EEA, we declare under our sole of responsibility that the equipment follows the provisions of the Directive(s) as stated above.

Thus, CE is placed on the product

Date of issue: December 28, 2018

Place of issue: Israel

(Signature & Name of authorized person) (Company Stamp)

SORREL medical

EC REP

MEDNET GmbH
Borkstrasse 10
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CE 0123

eng

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