

The Smart Charger Instructions for Use

To be used with Sequana Medical's **alfapump**® System and **alfapump**® Programmer IV

The Smart Charger Instructions for Use



Part of the **alfapump**® System. Do not combine with other systems. Only to be used with other components of the **alfapump**® System such as Sequana Medical's **alfapump**® and **alfapump**® Programmer IV.



The Smart Charger Instructions for Use

An instructional guide on how to use the Smart Charger to charge your **alfapump**[®]. Instructions for use of the Smart Charger during the **alfapump** implant procedure are contained in the **alfapump**[®] **System Instructions for Use**.

Instructions for use of the Smart Charger to program **alfapump**[®] settings are contained in the **alfapump**[®] **Programmer IV Instructions for Use**.

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1. Charging Accessories - The Smart Charger

1.1 Overview

The Automated Low-Flow Ascites Pump (**alfapump**®) System is a new form of treatment for refractory ascites. The system is designed to transport ascites from the abdomen (peritoneal cavity) to the bladder, allowing it to be eliminated from the body through normal urination. The **alfapump**® moves the ascites according to a schedule determined by your physician. Two fully implanted catheters are connected to the **alfapump**®: one which collects ascites from the peritoneal cavity and moves it to the **alfapump**®, and one which transports the ascites from the **alfapump**® into the bladder.

For the **alfapump**® to operate correctly the internal battery requires regular charging. This is done by holding the Smart Charger directly over the **alfapump**®. The **alfapump**® is charged wirelessly through the skin. It is important that you charge the **alfapump**® regularly as part of your daily routine. The Smart Charger should always be returned to its Docking Station so that it remains charged as well. The Docking Station needs to be connected to the power outlet and should be placed on a stable surface, just like a normal house phone.

Each time you charge your **alfapump**®, its data is automatically transferred to the Smart Charger. During your follow-up visits, your physician will be able to connect your Smart Charger to a computer and transfer the **alfapump**® data, and also change the settings if needed. For this reason, it is important that you always take your Smart Charger with you whenever you visit your doctor or attend hospital.

1.2 Intended Use

The **alfapump**® System is intended for single patient use only in adult patients with refractory or recurrent ascites due to liver cirrhosis. It is indicated for the removal of excess peritoneal fluid from the peritoneal cavity into the bladder, where it can be eliminated through normal urination.

The intended use of the Smart Charger is to charge your **alfapump**®. The intended user must be able to read the **Smart Charger Instructions for Use** and must be trained by a clinician on how the Smart Charger is used to charge the **alfapump**®.

The Smart Charger is intended for single-patient use only. Each Smart Charger is programmed to work with only one **alfapump**®, so you may not change Smart Chargers unless the new Smart Charger has been specifically programmed to match your implanted **alfapump**®.

In addition, the Smart Charger is used during follow-up visits to transfer the pumping history to a computer and if necessary, to change **alfapump**® settings. Separate instructions on using the Smart Charger for this purpose are provided to your physician.

The Smart Charger is intended to be used in a home healthcare environment.

Note: You must bring your Smart Charger to each follow-up visit so that your physician can transfer the pumping history to the **alfapump**® Programmer IV and change the settings if needed.

1.3 Components



Smart Charger

This hand-held charger allows you to charge your **alfapump**® through the skin. When being used to charge the **alfapump**®, pump data is transferred to the charger's internal memory. During follow-up visits, your physician will transfer this data to a special Sequana computer.



Docking Station

This base station holds the Smart Charger and keeps it charged. It must always be plugged into the wall socket in order to charge the Smart Charger.

Note: The Smart Charger depends on its Docking Station for charging; the Docking Station depends on a power outlet to work.

1.4 Scope of Delivery

The Smart Charger is intended to be used with the following accessories available from Sequana Medical.

Accessories	Comment	Part No.
alfapump®	Cannot be purchased individually	01473
Smart Charger	Hand-held paddle	01475
Docking Station	Stand for Smart Charger	01476
Power supply cord type A (US)	2.00 m	01289
Smart Charger Instructions for Use	This document	01463
Carrying case	Carrying case is intended for transportation only. Neither the Smart Charger or the Docking Station are intended to be operated in the carrying case.	00343

2. Warnings and Precautions

These warnings and precautions apply to the overall use of the Smart Charger. Failure to observe these warnings and precautions might lead to hazardous situations which, if not avoided, could result in serious injury.

If there is any concern that your Smart Charger has been damaged, please contact your physician.

2.1 General Warnings

- Do not disassemble or attempt to repair the Smart Charger.
- Do not attempt to charge other wearable devices or implanted devices such as hip implants, cardiac pacemakers, implantable neuro-stimulators, implantable infusion pumps, implantable infusion pumps circulatory support devices, tachyarrhythmia / implantable defibrillators and cochlear implant systems with the Smart Charger. Do not place the Smart Charger over any other implanted or wearable device than the alfapump.
- Only use the provided Docking Station to charge the Smart Charger. Only use the provided power cable to connect the Docking Station to the power outlet.
- Do not use a multiple socket or extension cord.
- The Docking Station must be plugged into a power outlet while charging the Smart Charger. Docking Station complies with FCC radiation exposure limits set forth for an uncontrolled environment. This equipment (Docking Station) should be installed and operated with a minimum distance of 20 cm between the radiator and the body.
- Do not use the Smart Charger where it may be exposed to flammable gas.
- Keep the charger away from children and pets.
- Strangulation hazard: Place Docking Station power cord inaccessible to small children and pets or make sure that the cord is secured to the wall and not hanging freely.
- The Smart Charger was not tested for the home environment electrostatic discharge.
 - Potential risk: In case of electrostatic discharge, loss of USB communication might be possible.
 - What can be done to mitigate risks if electromagnetic interference affects are encountered: perform a Smart Charger Reset. If not successful, please contact your physician.
- Do not operate the Smart Charger and the Docking Station within the carrying case because of the potential risk of heating up and fire.
- Do not replace the battery of the Smart Charger.

- The Smart Charger housing may get warmed up to 110°F (43°C). The recommended charging session time of 15 minutes shall be considered.
- Do not use the Smart Charger directly on unhealed wounds.
- The implantation of the alfapump may result in infection that could delay liver transplant or impact transplant listing status.

2.2 Storage and Handling

To ensure the Smart Charger functions in accordance with its design specifications, store and handle the Smart Charger and Docking Station with care to avoid damage from environmental factors that may impair their function including, but not limited to, the following:

- Operate the Smart Charger and Docking Station only as intended. Do not use them for any other purpose.
- Always place the Docking Station in such a way that you can easily access the power cord.
- Do not operate the Smart Charger or Docking Station at an altitude of more than 2000 m.
- The Smart Charger and Docking Station are not waterproof. Do not spill water or other liquids on them. If medication or another liquid is spilt on them, wipe it off immediately with a damp cloth.
- Do not use the Smart Charger and Docking Station if wet, or connect it to a power outlet with wet hands.
- Store the Smart Charger and Docking Station in a dry place away from direct sunlight.
- Do not use or store in humid locations, such as a bathroom or sauna.
- The Smart Charger and Docking Station should not be dropped or handled in a manner that could cause damage.
- Keep the Smart Charger and Docking Station out of the reach of unsupervised infants and children.
- Do not cover the Smart Charger with a blanket or towel etc., while charging as it may overheat.
- Keep the Smart Charger away from credit cards while charging. It is also recommended not to place the Smart Charger on top of electronic devices such as mobile phones and watches. The Smart Charger might erase its content or damage electrical components.

- If the Smart Charger feels too warm for your comfort during charging, you may stop charging and wait for an hour before restarting it. It is possible that the Smart Charger might reach 118.4 °F if it is badly placed (3 cm or further from the implanted **alfapump**®), or if the room temperature is 86 °F or higher. If possible, try to place the Smart Charger closer to the **alfapump**® and/or find a cooler room. You may also charge over a thin T-shirt or cloth.

USB connector (for physician use only)

The USB connector is for your physician's use only and it is used to connect the Smart Charger to Sequana Medical's **alfapump**® Programmer IV. Do not connect any other device to the USB connector (USB-A or USB-C).

Disposal

The Smart Charger contains a rechargeable lithium-polymer battery and should not be thrown away with other household waste. To avoid possible harm to the environment or human health due to uncontrolled waste disposal, please return the Smart Charger to your physician when you no longer need it.

Note: *If you are concerned that your Smart Charger may have been damaged, please contact your physician.*

2.3 Medical Therapy Hazards

Magnetic Resonance (MR) Safety Information

The **alfapump**® is MR unsafe.

This diagnostic procedure is contraindicated due to possible movement of the **alfapump**®, damage to the pump circuitry, tissue damage in the vicinity of the **alfapump**® and/or catheter dislocation.

Wireless and Data Safety

Wireless communication and data safety between **alfapump**® and Smart Charger are ensured through a factory pairing mechanism that prevents unauthorized access.

Data transferred between the devices is absent from patient demographic and hospital information and is checked for integrity upon every transfer. To avoid data loss backup mechanisms are implemented, this data can be accessed through proprietary software which is available to Sequana Medical only.

Hyperbaric oxygen therapy

Hyperbaric oxygen therapy is contraindicated because the environmental conditions entailed in this therapy are out of the defined range of use for the **alfapump**® System.

Supersonic therapy and high-frequency heat therapy

Supersonic and high-frequency heat therapies should not be used on patients with the **alfapump**® System due to possible heating effects of the implanted **alfapump**®. If the therapy must be performed, it should not be applied in the immediate vicinity of the **alfapump**® System or the surrounding areas. The **alfapump**® System should be continuously monitored during the treatment and system function must be checked after the therapy.

Transcutaneous Electrical Nerve Stimulation (TENS)

TENS therapy should not be used on patients with the **alfapump**® System. If the therapy must be used, the TENS electrodes should be placed as close as possible to each other to reduce the spread of electricity, and as far away as possible from the **alfapump**. After stimulation, **alfapump**® System function must be checked.

Lithotripsy

Lithotripsy should not be used on patients with the **alfapump**® System because electrical and/or mechanical interferences with the **alfapump**® are possible. If this therapy must be used, the selected site for electrical and mechanical stress should be as far as possible from the **alfapump**®. After the procedure, **alfapump**® System function must be checked.

Defibrillation

The circuitry of the **alfapump**® is protected against the energies normally induced by defibrillation. Nevertheless, complete protection is not possible. The implanted **alfapump**® can be damaged by defibrillation. Circumstances permitting the energy setting should not be higher than necessary for defibrillation and the distance between the paddles and the **alfapump**® should be at least 10 cm. After defibrillation, the **alfapump**® System function must be checked.

Radiation therapy

The electronic circuit elements of the **alfapump**® can be damaged by radiation therapy. The **alfapump**® should be shielded during the therapy. Following the radiation treatment, the **alfapump**® System function must be checked.

Electrocautery

Electrocautery should not be performed within 15 cm of an implanted **alfapump**® because it could damage the pump circuitry. For trans-urethral electro-resection of the prostate, it is recommended to place the neutral electrode on the buttocks or upper thigh, but not in the thoracic area. The **alfapump**® System function must be checked and monitored after the procedure.

Note: *Pacemakers, implantable defibrillators and other active implants are not contraindicated but must be verified for proper functioning using manufacturer's labelling after implantation of the **alfapump**® System.*

2.4 Environmental Hazards

Care has been exercised in the design and manufacture of the **alfapump**® System to minimize damage under normal use. However, electronic devices are susceptible to many environmental stresses including, but not limited to, the following examples:

2.4.1 Clinical areas Electromagnetic Interference (EMI)

EMI can sometimes cause complications. If complications occur, they will typically be minor and not affect the long-term performance of the **alfapump**®.

2.4.2 Residential areas Household appliances

Electric household appliances (e.g. stoves, microwave ovens, radios, televisions, VCRs, electric shavers and toothbrushes) will not generally affect **alfapump**® operation if the appliances are in good condition and properly grounded and insulated.

Mobile phones

Use of mobile phones near the **alfapump**® during charging and programming has the potential to cause operational complications. Do not carry mobile phones in pants pockets or on belt clips within 15 cm of the **alfapump**®.

Some mobile phones emit signals even when they are not turned on and are only on standby. Possible mobile phone interference while charging or programming is only temporary and the **alfapump**® will function properly again once the mobile phone is out of immediate vicinity of the **alfapump**®.

Interference due to strong electromagnetic fields

Operational complications can be caused by interferences from strong electromagnetic fields, such as those stemming from electric arc welders, electric melting furnaces, radio, radar and television transmitters, exposed ignition systems (e.g., internal combustion engines), electrical tools, high-voltage power lines and defective electrical equipment that is not properly grounded or sufficiently insulated. Please ask your physician before exposing your implanted **alfapump**® to strong electromagnetic fields.

Note: “Harmful interference” is defined in 47 CFR §2.1 by the FCC as follows: *Interference which endangers the functioning of a radionavigation service or of the other safety services or seriously degrades, obstructs, or repeatedly interrupts a radio communication service operating in accordance with the [ITU] Radio Regulations.*

This device complies with Part 15 of the FCC Rules. 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.

2.5 Cybersecurity information

When using the Smart Charger and the Docking Station, the following needs to be considered to minimize the potential risk of security attacks during use:

- The Smart Charger and the Docking Station shall be used in home environment only. Their use in public places shall be avoided.
- Do not leave the Smart Charger or the Docking Station unattended.
- Do not use third party devices with Sequana Medical Smart Charger, Docking Station or any other alfapump System components.

In case of cybersecurity incidents, firmware updates may be performed as part of field safety corrective actions:

- The user is request to comply at its earliest convenience with field safety corrective actions.
- All device corrective actions will be addressed by Sequana Medical personnel.
- Users are not responsible for managing firmware updates themselves.
- In the event of device and cybersecurity concerns, the user should contact Sequana Medical Customer Service (see Customer Service contacts, Chapter 7).

3. Device Features

The **alfapump**® charging system consists of the Smart Charger and the Docking Station.

3.1 Smart Charger

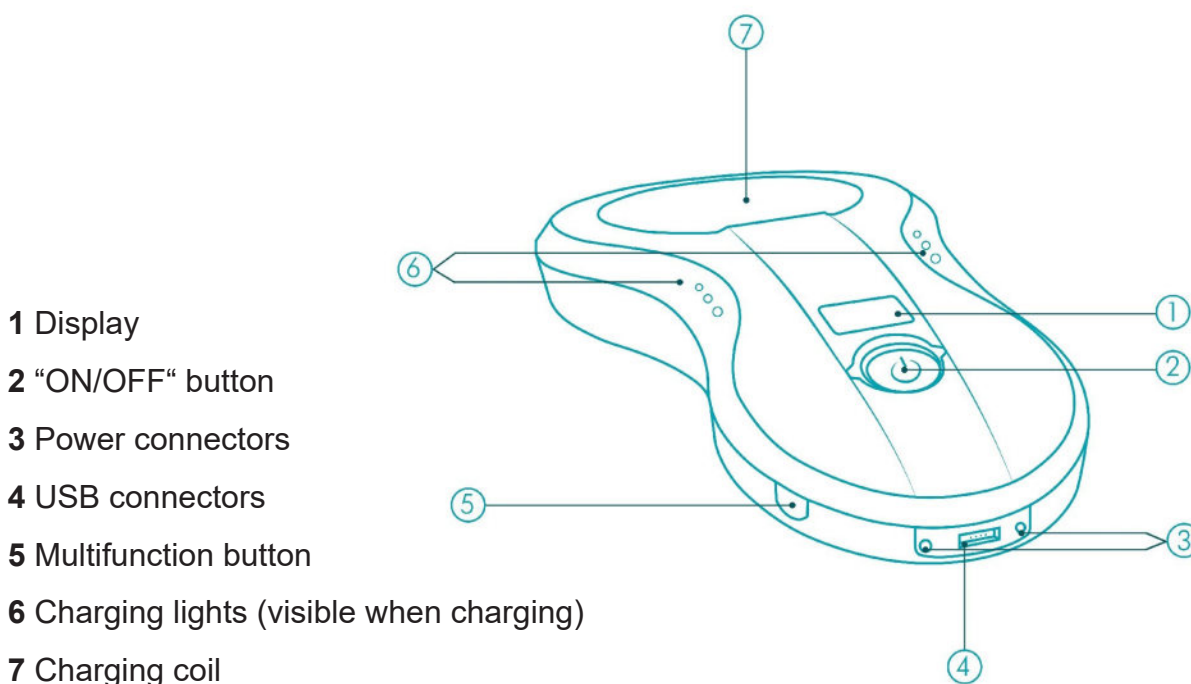


Figure 3-1: Smart Charger features

"ON"/"OFF" button

To start charging your implanted **alfapump**®, press the "ON"/"OFF" button on the Smart Charger once the charger has been correctly positioned. To stop charging the **alfapump**® at any time, once again press the "ON"/"OFF" button.

Charging coil

The charging coil sends out the power to charge the **alfapump**®. The charging coil should always be placed as close as possible to the implanted **alfapump**®.

Charging indicators

When lit, the charging indicators are visible from both sides of your Smart Charger and shine green, yellow or red.

Display

The display provides you with information on the battery and the charging status.

When the Smart Charger is not charging the **alfapump®**, this display will show the battery status of the Smart Charger. While charging the **alfapump®**, this display will show either the battery status of the implanted **alfapump®** or an indication of charger and pump contact to help you maximize your charging. If an error occurs, the charger will inform you of this by displaying an error icon (see **section “5. Warning and Error Messages”** for explanations on error icons).

Multifunction button

The multifunction button allows you to toggle (switch over) between the different messages on the display.

Power connector

At the side of the Smart Charger there are two power connectors which connect to the two pins on the Docking Station.

USB connector (only to be used by the physician)

At the side of the Smart Charger there is a socket where a special USB cable can be inserted. This may only be used by the physician, who has a special USB cable which allows downloading of pump data.

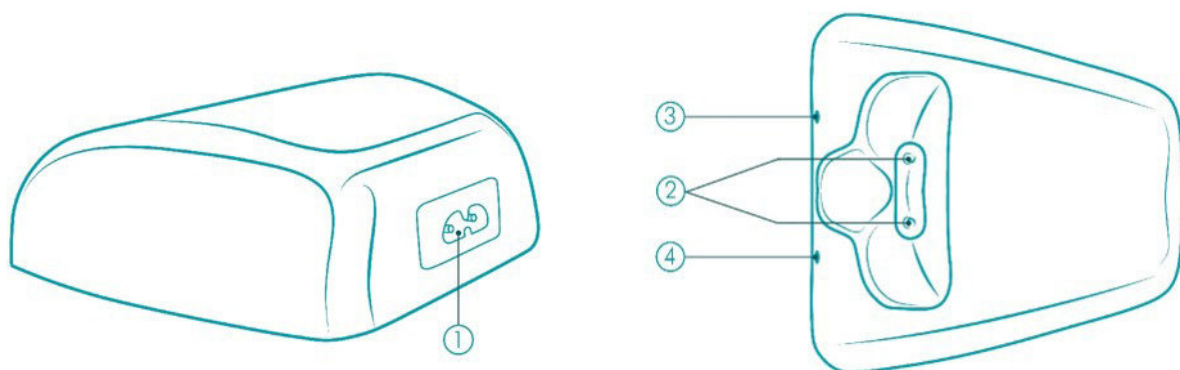
Caution: *Do not put the Smart Charger on metal surfaces or near any other electronic equipment or credit cards when charging.*

Note: *While the implanted **alfapump®** is being charged, the pumping history is transferred automatically to the Smart Charger. This means that when you have a follow-up appointment and your physician connects your Smart Charger to the **alfapump®** Programmer IV, it will have access to the pumping history, right up until the last time you charged the **alfapump®**.*

Note: *The Smart Charger will switch off on its own when not charging the **alfapump®** and no other functions are active.*

Note: *Make sure your Smart Charger is charged before each follow-up visit.*

3.2 Docking Station



- 1 Connector for the power cord
- 2 Power pins for connecting the Smart Charger
- 3 Green charging indicator, lights when Smart Charger is being charged
- 4 Blue power indicator, lights when Docking Station is connected to a wall socket

Figure 3-2: Docking Station features

Connector for power cord and blue power indicator

Use the enclosed power cord to connect your Docking Station to a wall socket. The Docking Station can handle voltages from AC 110 V to 230 V. The blue power indicator will light up when the Docking Station is connected to a suitable power supply. To disconnect it, remove the plug from the wall socket and remove the other end from the Docking Station.

Power pins for connecting the Smart Charger and green charging indicator

Place the Smart Charger in the recess on the front of the Docking Station, with the display facing outwards (away from the connector) and make sure that the Smart Charger slides all the way down until a beep sounds and the green charging indicator lights up. The green charging indicator will stay lit until the charger is fully charged. In addition the display of the Smart Charger shows the battery charging level (see **table 4-1**).

Note: *The Docking Station has no power button to switch off. To power down the Docking Station disconnect the power cable.*

3.3 Smart Charger Display

As described above, the display is located on the upper side of your Smart Charger and always only shows one message at a time.

The Smart Charger display switches between several different messages (screens), depending on your actions. For example, when placing the Smart Charger into the Docking Station, a battery symbol with the topmost bar flashing (see “**Table 4-1: Display images when the Smart Charger is on but is not being used to charge the alfapump®**”) will be displayed. The display will continue to show the battery level until it is fully charged. Once the battery is fully charged the topmost bar will stop flashing, and after five seconds the display will go off.

When the Smart Charger is removed from the Docking Station, a beep sounds and its display shows the battery charge level. Once the Smart Charger is placed over the alfapump®, you may press the “ON”/“OFF” button and the display will show the quality of charging until communication with the alfapump® is established. From this moment on, the battery status of the alfapump® is shown. If charging is interrupted because the Smart Charger is moved away from the alfapump®, the quality of charging icon is shown again until charging is re-established or stopped. When charging is stopped, the last known status of the battery of the alfapump® is shown for 5 seconds.

There are a few potential errors which might occur when charging. If an error occurs, the display will show a message to inform you. These error icons are explained in **section “5. Warning and Error Messages”**.

3.4 Smart Charger Sound

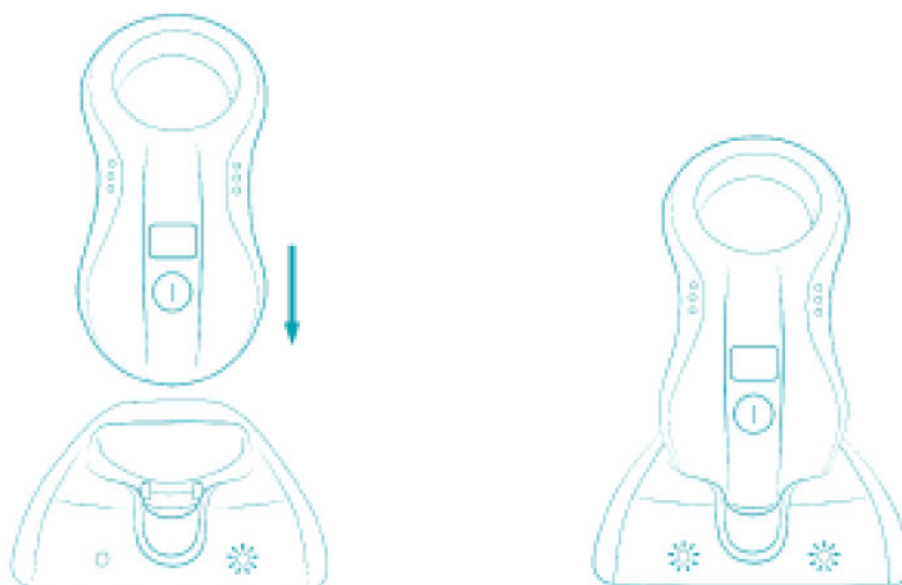
Every time you press a button or you place or remove the Smart Charger from the Docking Station a short beep sounds in confirmation.

3.5 Smart Charger Reset

In certain situations, it may be necessary to reset the Smart Charger. These potential scenarios are explained in **section “6. Troubleshooting”**.

4. Charging

4.1 Using the Docking Station to Charge your Smart Charger



1. Make sure the Docking Station is plugged into a power outlet by its power cord and the blue power indicator is on. The Docking Station cannot charge the Smart Charger unless it is plugged into a power outlet.
2. Place the Smart Charger into the Docking Station. Here there are two pins to guide the Smart Charger into place; make sure the Smart Charger slides all the way down.

Note: Please push the Smart Charger firmly down into the Docking Station until a beep sounds and the green charging indicator appears.

Note: It is recommended that the battery should be at least 50 % charged before removing the Smart Charger from its Docking Station.

When the Smart Charger is switched **ON** but is not charging the **alfapump®**, the display will show the following images:

Display Icon	When you will see it	What it means
	When you remove the Smart Charger from the Docking Station. When you press the multi-function button.	Battery level of the Smart Charger The number of battery bars shows the charge level of the Smart Charger.
 the topmost bar is flashing	When the Smart Charger is being charged in the Docking Station.	The Smart Charger is charging The topmost bar of the battery icon is flashing on and off, which indicates the level of charging that will be reached next.
	When the battery of the Smart Charger is empty. (If you see this symbol, you must place the Smart Charger on its Docking Station immediately in order to start charging it).	The Smart Charger battery is empty and it has gone into sleep mode An empty battery symbol will appear and flash on and off for 5 seconds. Any further interaction will lead to the same empty battery symbol re-appearing and flashing for 5 seconds until the Smart Charger is returned to the Docking Station.

*Table 4-1: Display images when the Smart Charger is on but is not being used to charge the **alfapump®***

4.2 Using the Smart Charger to Charge your alfapump®

1. Place the charging coil of your Smart Charger directly over the implanted **alfapump®**.
2. Switch on the Smart Charger by pressing the “ON”/“OFF” button on the Smart Charger. The Smart Charger will beep and all three charging indicators (visible from both sides on the front of your Smart Charger) will light up (green, yellow and red).
3. On the Smart Charger display, the quality of charging icon will appear showing how well the **alfapump®** is charging. Slowly move the Smart Charger around to maximize the charging quality displayed by the length of the bar.
 - Solid yellow charging indicators mean the Smart Charger is not yet able to charge the **alfapump®**.
 - Green charging indicators will start flashing on and off as soon as charging of the **alfapump®** has begun.
 - Once communication with the **alfapump®** is established, the battery level of the **alfapump®** appears on the display.

Note: It is possible that the green lights might start flashing while the yellow lights are still on. This indicates that charging is possible but the position is not optimal. The yellow lights will go off after some time once the best charging position has been found.

Note: It may take up to 60 seconds for the yellow lights to turn off after the best charge location has been found, even if the green lights have already started to flash.

- Flashing yellow charging indicators indicate a timeout. The Smart Charger has stopped charging and a warning icon will be shown on the display; please refer to “**Table 4-3: Charging indicator meanings**” below for explanations.
- Flashing red charging indicators mean that the **alfapump** is not charging due to an error. An error icon will be shown on the display; please refer to “**Table 4-3: Charging indicator meanings**” below for explanations.

Note: If the red indicators continue to flash, contact your physician.

Note: The Smart Charger is considered as a transit-operable device while the Docking Station is considered as a Non-TRANSIT-OPERABLE Equipment.

Note: The medical staff is intended to provide training to support the patient in the safe use of the device. The patient or their caregivers are trained while hospitalized by the site staff. The training success is determined by patient successfully charging the Smart Charger with the accompanying documentation.

When charging the **alfapump®**, the Smart Charger's display will show the following images:

Display Icon	When you will see it	What it means
	When you press the "ON"/"OFF" button to initiate charging. The display changes after one second.	The Smart Charger has been turned on
	When you press the "ON"/"OFF" button to initiate charging (after the initial screen, shown above). When you press the multi-function button during charging. If charging is interrupted because of bad placement (in order to assist positioning of the charger).	The quality of charging the alfapump® This image helps you to find the best placement position to charge the alfapump® . The number of bars in the icon represents the quality of charging.
 One bar flashing	When you charge the alfapump .	The alfapump® is charging The topmost bar of the battery icon is flashing on and off, which indicates the level of charging that will be reached next.
	After you charge the alfapump , the display shows for 30 seconds if you stopped charging yourself or 5 minutes if charging stopped because the battery is full.	Battery level of the alfapump® The number of battery bars shows the charge level of the alfapump® Full bar (all segments green) = full battery Empty bar = empty battery
	When you press the multi-function button twice while charging.	Battery level of the Smart Charger While charging the alfapump® , you may press the multifunction button to view the battery level of the Smart Charger
	When you stop charging but the charger is still downloading some log files. After one minute the charger stops downloading log files automatically.	It indicates the quality of radio transmission between Charger and alfapump® while downloading log files. Please keep the charger close to the pump during this time.

*Table 4-2: Display images when the Smart Charger is on and is being used to charge the **alfapump®***

When you have finished charging the **alfapump®**:

1. The green charging indicators will stop flashing and stay on permanently. The display will show that the **alfapump®** is fully charged and you will hear a long beep.
2. Turn the Smart Charger off by pressing the “ON”/“OFF” button. You will hear a long beep and all charging indicators will switch off.

What the charging indicators mean:

Color	Status	Beeping sound	What it means
All lights	Single flash	1 short beep	Smart Charger has been turned on
All lights	Off	1 long beep	Smart Charger has been turned off
Green	Flashing	None	Charging the alfapump®
Green	On	1 long beep; repeated every minute for 5 minutes	The alfapump® is fully charged
Green and yellow	Green flashing; yellow on	None	Charging the alfapump® but with poor placement
Yellow	On	2 short beeps; repeated once every minute	The Smart Charger is not able to charge the alfapump®
Yellow	Flashing	1 short beep; repeated once every minute	A timeout occurred and the Smart Charger stopped because normal charging was no longer possible. Wait ten minutes before pressing the “ON”/“OFF” button again (see “ Table 5-1: Warning messages ”).
Red	Flashing	1 short beep; repeated once every minute	An error occurred and the Smart Charger stopped automatically. Wait ten minutes before pressing the “ON”/“OFF” button again (see “ Table 5-2: Error Messages ”).

Table 4-3: Charging indicator meanings

Note: You can always cancel charging your pump by pressing the “ON”/“OFF” button. There is no button to switch off the Smart Charger as such. Instead the Smart Charger will switch off on its own if no longer needed.

4.3 Battery Charging Times

Charging the alfapump®

These are typical times but can vary on how deep your pump is implanted:

- To charge the **alfapump®** when fully empty: 2.5 hours minimum.
- To charge the **alfapump®** for a daily volume of 700 ml: approximately
- 30 minutes per day, depending on charger-to-pump placement. Charging two times 15 minutes will result in a more efficient charging than charging one time for 30 minutes.
- A full battery charge of the **alfapump®** allows the **alfapump®** to move up to 4 litres of ascites from the peritoneal cavity to the bladder.

Note: Charge 15 minutes at a time. Charging several times for 15 minutes will reduce the overall daily charging time.

Charging the Smart Charger

To charge the Smart Charger when the battery is completely empty: 5 hours.

Note: Leave the Smart Charger on the Docking Station when it is not being used to charge the **alfapump®**.

Note: The nominal battery capacity of the Smart Charger allows at least 2 charging sessions of the alfapump of 15 minutes each. Therefore, one fully-charged Smart Charger can recharge the alfapump for 30 minutes in total (= 2 charging sessions x 15 minutes charging time).

5. Warning and Error Messages

The Smart Charger is designed to support patient safety. If there is any warning or error, the Smart Charger will stop charging the **alfapump**®, and activate two short beeps and show one of the following messages:

Table 5-1: Warning messages

Message	What it means	What to do
No screen displayed. Smart Charger does switch ON.	An ESD event might have occurred. The Smart Charger became temporarily non-functional.	Press the MF-button uninterruptedly for 10 s until the Smart Charger becomes functional again.
	A timeout has occurred. The Smart Charger has been using its maximum allowed power.	Turn off the Smart Charger and wait 10 minutes before charging again. If situation persists, ensure the alfapump ® System is at least 5 m away from any other device with radio (wireless) capabilities.
	A timeout has occurred. The Smart Charger has not been communicating with the alfapump .	Turn off the Smart Charger and wait 10 minutes before charging again.
	A timeout has occurred. The Smart Charger has not been charging the alfapump .	Turn off the Smart Charger and wait 10 minutes before charging again.
	The alfapump has become too hot and the Smart Charger has stopped charging.	Turn off the Smart Charger and wait 10 minutes before charging again.
	A timeout has occurred, self-priming was active for more than its allowed time.	Turn off the Smart Charger.
	The Smart Charger is defective, but limited charging is still possible.	Contact your physician to arrange a replacement.

	The alfapump manual pump mode has not been turned off.	Contact your physician.
	The calibration of the Smart Charger is not valid	Contact Sequana Medical to arrange for a replacement
	The Smart Charger has been reset.	Press the “ON”/“OFF” button to continue

Table 5-2: Error Messages

Message	What it means	What to do
	The Smart Charger is using too much power.	Turn off the Smart Charger and move it away from any metal surfaces; wait 10 minutes before charging again.
	The temperature of the Smart Charger is too high.	Turn off the Smart Charger and wait 10 minutes before turning on and charging again.
	The Smart Charger is receiving conflicting information from the alfapump ®.	Turn off the Smart Charger; be sure no other patient is in the same room. Turn on the Smart Charger and start charging again.
	The Smart Charger may have malfunctioned.	Exchange the Smart Charger and contact Sequana Medical to pair it to the alfapump ®.
	The Smart Charger is not fully functional.	Contact Sequana Medical and have the displayed code ready.

Note: It might be helpful to reset a Smart Charger if an error appears constantly. You can reset a Smart Charger by pressing the multifunction button firmly for more than 10 seconds.

6. Troubleshooting

6.1 Device Related

This section addresses any potential device related issues. If any problems remain unresolved after following the troubleshooting steps, please contact your physician.

What if the alfapump® doesn't seem to charge?

Pay close attention to the display and charging indicators shown on the Smart Charger. Make sure the charging coil of your Smart Charger is placed as close as possible to the alfapump®'s implantation site. Make sure the green charging indicators are flashing; when the alfapump® is fully charged, the green indicators will stop flashing and remain on. If something is wrong, the display and charging indicators will inform you. See **table 4-1**, **table 4-2**, **table 4-3** and **table 5-2** for explanations of the display images and charging indicators, and what you should do in each circumstance.

What if the Smart Charger's yellow charging indicators are on while the green charging indicators are still flashing?

The Smart Charger is not positioned properly. To find a better position, move the Smart Charger around slowly to increase the length of the bar on the quality of charging display image. The yellow indicators should go off and the green lights should remain.

Note: Once the best location has been found, it could take up to 60 seconds for the yellow indicators to turn off. Solid green lights mean that your alfapump® is fully charged.

What if the Smart Charger's yellow charging indicators are flashing?

The alfapump is no longer charging. A timeout has occurred. Make sure no metal/magnetic parts are within 5 cm (e.g., mobile phones, belt buckle or money clips). Turn off the Smart Charger, wait 10 minutes and turn it on again.

What if the Smart Charger's red charging indicators are flashing?

The alfapump® has stopped charging. A hardware malfunction has occurred. Make sure no metal/magnetic parts are within 5 cm (e.g., mobile phones, belt buckle or money clips). Turn off the Smart Charger, wait 10 minutes and turn on again. If the red lights persist, contact your physician.

What if the Smart Charger heats up during charging?

There may be a slight temperature increase of the Smart Charger which does not affect its performance. If you find the heating uncomfortable, stop charging. You can avoid this by charging more frequently but for shorter periods of time.

What if there is an unexpected sound?

Minor sounds can result from the pumping function of the **alfapump®** System. If any sound lasts for longer than 10 seconds or causes you concern, please contact your physician. Beeping sounds are programmed to come from the Smart Charger to report messages, in association with the display and charging indicators. Explanations on what these beeping sounds sound like and what they mean are provided in “**Table 5-2: Error Messages**”.

What if the charging indicators stay on even when the Smart Charger is switched off?

The Smart Charger was not turned off. Press the “ON”/“OFF” button again or return the Smart Charger to its Docking Station.

What if the Smart Charger will not switch on?

The battery of the Smart Charger was disconnected because too much current was used. To restart the Smart Charger place it firmly into the Docking Station and wait for 10 minutes.

What if the Smart Charger will not switch off?

You may need to reset the Smart Charger by pressing the multifunction button (located on the lower right side of the charger) firmly for more than 10 seconds.

What if an error on the display screen appears constantly?

You may need to reset the Smart Charger by pressing the multifunction button (located on the lower right side of the charger) firmly for more than 10 seconds.

6.2 Frequently Asked Questions

This section answers frequently asked questions. If you have additional questions that aren't answered here, please ask your physician.

How long should I charge the alfapump®?

It takes approximately 2.5 hours to charge the alfapump® when fully discharged (empty). The charging time depends on the amount of ascites being moved per day; if 700 ml of ascites is the programmed daily volume, approximately 30 minutes per day (two times 15 minutes for best results) is usually sufficient but depends on Smart Charger to alfapump® contact. If you missed charging for one day, the charging time the next day will be approximately twice as long. If you miss charging for more than 2 days or 3 days, the alfapump® might stop working and will need to be charged before it's able to move ascites again.

How can I make sure the alfapump® is charging properly?

The green charging indicators on the Smart Charger will flash when the alfapump® is charging.

How do I know when the alfapump® is fully charged?

The green charging indicators will stop flashing and become solid, and a long beep alert on the Smart Charger confirms that the alfapump® is fully charged. The display will show a full battery.

How long should I charge the Smart Charger?

The charging time depends on the battery status. We recommend always returning your Smart Charger to the Docking Station when not using it to charge the alfapump®.

How do I see when the Smart Charger has finished charging?

While the Smart Charger is charging in the Docking Station, its display shows its current battery status. When the Smart Charger has finished charging, this display will turn off.

Can I charge the alfapump® through clothing?

Charging directly over the skin is preferable, but you can charge through clothes that are up to 7 mm thick. Be sure there are no metal pieces in your clothing beneath the Smart Charger.

Can I use any other charging systems?

No, only your Smart Charger can be used to charge the alfapump®, and only Sequana Medical's Docking Station can be used to charge the Smart Charger.

Do mobile phones or other electromagnetic fields have any influence on the Smart Charger?

Yes, keep the Smart Charger away from strong magnetic and electrical fields as well as from metal parts (e.g., mobile phones, belt buckle or money clips).

Can I fly and pass the X-Ray at the airport?

Yes you can, but always carry the patient implant card with you.

Can I leave the Smart Charger in the car?

Yes, but protect the Smart Charger from cold temperatures and direct sunlight. Extreme temperatures can damage the Smart Charger.

Are the Smart Charger and Docking Station waterproof or water resistant?

Neither the Smart Charger nor the Docking Station are waterproof, so please protect them from contact with water. Both devices may be cleaned with a damp cloth.

How can I clean the Smart Charger and Docking Station?

The Smart Charger and Docking Station may be cleaned with a damp cloth. Mild soap or cleaner is also okay, but do not use any strong solvent.

Is the implanted alfapump® compatible with my pacemaker?

The **alfapump** is not known to cause any other implanted device to fail. As a measure of precaution, we strongly recommend that you not place your Smart Charger over any other implanted device while charging.

Can other medical treatments (e.g. intraperitoneal chemotherapy) still be performed?

The **alfapump** can be temporarily turned off if other medical treatments (e.g. intraperitoneal chemotherapy) are performed.

What can I do if I am still experiencing a build-up of ascites?

Make sure the **alfapump**® is fully charged and repeat charging every day. The charging procedure might take up to 2.5 hours per day depending on the amount of ascites to be moved per day. If the **alfapump**® is fully charged and you are still experiencing a build-up of ascites, please call your physician to schedule a follow-up appointment.

Do I have to bring my Smart Charger and Docking Station to my follow-up visits?

Yes, you need to bring your Smart Charger, Docking Station and Power supply cord with you to every follow-up visit. Please make sure your Smart Charger is fully charged prior to each visit.

7. Support and Service

Swiss Technical Office

Sequana Medical NV

Technoparkstrasse 1

8005 Zurich

Switzerland

Phone: +41 44 403 55 00

For general inquiries or to request additional training, we can also be reached via email at info@sequanamedical.com.

Customer Service:

Sequana Medical US Inc.

265 Franklin Street , Suite 1702

Boston, MA 02110

USA

Phone: +1 617-963-5280

In the event of device and cybersecurity concerns, reach us via email at vigilance@sequanamedical.com.

8. Technical Data

8.1 Smart Charger

Only to be charged with the included Docking Station (reference number 01476).

Classification:	Internally powered Medical Equipment, Applied Part, Type BF
Degree of protection against ingress of liquids:	IP22
Operation:	Continuous operation
Size (L x W x H):	200 mm x 100 mm x 30 mm
Weight:	< 290 g
Battery:	Lithium Polymer, rechargeable: 4.2 V / 4000 mAh
Input:	DC 5 V to 12 V; 1 A to 0.4 A
Charging time:	< 5 hours when battery is completely depleted
Radio transmission:	915 MHz (US/CA), 1 mW
Charging Frequency:	296 kHz, 10 W max.

8.2 Docking Station

For use only with the Smart Charger (reference number 01475)

Classification:	Isolation class II
Degree of protection against ingress of liquids:	IP21
Operation:	Continuous operation
Size (L x W x H):	145 mm x 145 mm x 50 mm
Weight:	< 330 g
Input:	AC 100 V to 240 V; 0.2 A - 0.1 A; 50/60 Hz
Output:	DC 5 V; 2 A

8.3 Environmental conditions for use (Smart Charger and Docking Station)

Operating temperature for the Smart Charger: 41 °F to 86 °F (5 °C to 30 °C)

Operating temperature for the Docking Station: 41 °F to 86 °F (5 °C to 30 °C)

Operating humidity: 15% to 90%

Atmospheric pressure: 800 mbar to 1060 mbar

8.4 Environmental conditions for transport and storage (Smart Charger and Docking Station)

Temperature: 41 °F to 104 °F (5 °C to 40 °C)

Relative humidity: 15% to 90%

Atmospheric pressure: 700 mbar to 1060 mbar

Note: Do not store in direct sunlight.

Note: The patient shall always use the carrying case provided by Sequana Medical for transporting the Smart Charger, the Docking Station and the Power supply cord to the follow-up visits.

8.5 Wireless Characteristics

Radio Transmission (Smart Charger to **alfapump**®):

Frequency	Transmission Power	Transfer Rate	Modulation	Duty Cycle
915 MHz (US/CA)	-7 dBm	76.8 kbit/s	GFSK	100 %

9. Maintenance and Cleaning

The Smart Charger and Docking Station must be handled with care. If either are dropped or stored in temperatures outside of the allowed range, their functioning can be impaired. Please refer to “**2. Warnings and Precautions**” for information on storage and handling.

No further maintenance or service is required; there are no parts in the Smart Charger or Docking Station which can be individually serviced or replaced. If you think either device is not working correctly, please inform your physician. Do not replace the battery of the Smart Charger.

Changes or modifications not expressly approved by the party responsible for compliance could void the user’s authority to operate the equipment.

The Smart Charger and Docking Station may be cleaned with a damp cloth. Mild soap or cleaner is also acceptable, but do not use any strong solvent. The Smart Charger and Docking Station may be cleaned in this way as often as you like.

No special maintenance action is required to maintain the basic safety of the device with regard to electromagnetic disturbances throughout its expected service life (24 months).

The typical service life of the internal power electrical source of the device and the expected service life of the accessories are designed to fulfil the expected service life of the device (24 months).

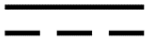
10. Appendices

10.1 Appendix A: Explanations of Symbols used in the alfapump® System

Refer to the labels to see which symbols apply to which part of the **alfapump®** System.

Symbol	Standard Reference	Symbol Title	Explanatory Text
	ISO 15223-1, Clause 5.1.1 ISO 7000 (Symbol No. 3082)	Manufacturer	Identifies the medical device manufacturer.
	ISO 15223-1, Clause 5.1.3 ISO 7000 (Symbol No. 2497)	Date of Manufacture	Indicates the date on which the medical device was manufactured.
	ISO 15223-1, Clause 5.7.7	Medical device	Indicates that the item is a medical device.
	ISO 15223-1, Clause 5.1.4 ISO 7000 (Symbol No. 2607)	Use By Date	Indicates the date after which the medical device is not to be used.
	ISO 15223-1, Clause 5.1.6 ISO 7000 (Symbol No. 2493)	Catalogue or Model Number	Indicates the manufacturer's catalogue number so the medical device can be identified.
	ISO 15223-1, Clause 5.1.7 ISO 7000 (Symbol No. 2498)	Serial Number	Indicates the manufacturer's serial number so a specific medical device can be identified.
	ISO 15223-1, Clause 5.1.5 ISO 7000 (Symbol No. 2492)	Batch Code	Indicates the manufacturer's batch or lot code.
	ISO 15223-1, Clause 5.2.3 ISO 7000 (Symbol No. 2501)	Sterilized using Ethylene Oxide	Indicates the medical device has been sterilized using ethylene oxide.
	ISO 15223-1 Clause 5.2.13 ISO 7000 (Symbol No. 3708)	Single sterile barrier system with protective packaging inside	Indicates there is a single sterile barrier system with protective packaging inside.
	ISO 15223-1 Clause 5.3.2 ISO 7000 (Symbol No. 0624)	Keep away from sunlight	Indicates the medical device needs protection from light sources.
	ISO 15223-1, Clause 5.3.7 ISO 7000 (Symbol No. 0632)	Temperature Limit	Indicates the temperature limits to which the medical device can be safely exposed.
	ISO 15223-1, Clause 5.3.8 ISO 7000 (Symbol No. 2620)	Humidity Limitation	Indicates the range of humidity to which the medical device can be safely exposed.

	ISO 15223-1, Clause 5.3.9 ISO 7000 (Symbol No. 2621)	Atmospheric pressure limitation	Indicates the range of atmospheric pressure to which the medical device can be safely exposed.
	ISO 15223-1, Clause 5.3.4 ISO 7000 (Symbol No. 0626)	Keep dry	Indicates the medical device needs to be protected from moisture.
	ISO 15223-1, Clause 5.3.1 ISO 7000 (Symbol No. 0621)	Fragile, Handle with Care	Indicates the medical device can be broken or damaged if not handled with care.
	ISO 15223-1, Clause 5.4.2 ISO 7000 (Symbol No. 1051)	Do not re-use	Indicates the medical device is intended for one use, or for use on a single patient during a single procedure.
	ISO 15223-1, Clause 5.2.6 ISO 7000 (Symbol No. 2608)	Do not re-sterilize	Indicates the medical device should not be re-sterilized.
	ISO 15223-1, Clause 5.7.3	Patient identification	Indicates the identification data of the patient.
	ISO 15223-1, Clause 5.7.4 ISO 7000 (Symbol No. 3705)	Patient information website	Indicates a website where a patient can obtain additional information on the medical product.
	ISO 15223-1, Clause 5.7.5	Health care centre or doctor	Indicates the address of the health care centre or doctor where medical information about patient may be found.
	ISO 15223-1, Clause 5.7.6	Date	Indicates the date that information was entered or a medical procedure took place.
	ISO 15223-1, Clause 5.2.8 ISO 7000 (Symbol No. 2606)	Do not use if package is damaged and consult instructions for use	Indicates the medical device should not be used if the package is damaged or opened and the user should consult the instructions for use.
	ISO 15223-1, Clause 5.4.3 ISO 7000 (Symbol No. 1641)	Consult Instructions for Use	Indicates the need for the user to consult the instructions for use.
	IEC 60601-1 ISO 7010 (Symbol No. M002)	Refer to instruction manual/ booklet	Indicates the user must consult the instructions for use.

	ISO 15223-1 Clause 5.7.10	Unique device identifier	Indicates a carrier that contains unique identifier information.
	ASTM F2503	Magnetic Resonance (MR) Unsafe	Indicates the medical device is MR Unsafe and should be kept away from magnetic resonance (MR) imaging equipment.
	IEC 60601-1, Table D.1 (Symbol No. 20) IEC 60417 (Symbol No. 5333)	Type BF Applied Part	Identifies a type BF applied part complying with IEC 60601-1.
	IEC 60601-1, Table D.1 (Symbol No. 1) IEC 60417 (Symbol No. 5032)	Alternating current	Indicates that the equipment is suitable for alternating current only; to identify relevant terminals.
	IEC 60601-1, Table D.1 (Symbol No. 4) IEC 60417 (Symbol No. 5031)	Direct current	Indicates that the equipment is suitable for direct current only; to identify relevant terminals.
IP_{N₁}N₂	IEC 60601-1, Table D.3 (Symbol No. 2) IEC 60529	Degree of protection	Manufacturer-determined degree of particle and water ingress protection, where: N1= degree of protection from particulates (scale of 0-6); and N2 = degree of protection from water (scale of 0-8) NOTE When a characteristic numeral is not required to be specified, it is replaced by the letter "X".
	IEC 60601-1, Table D.1 (Symbol No. 9) IEC 60417 (Symbol No. 5172)	Class II equipment	Identifies equipment meeting the safety requirements specified for Class II equipment according to IEC 61140.
	IEC 60417 (Symbol No. 5134) ISO 7000 (Symbol No. 5134)	Electrostatic sensitive devices	Indicates electrostatic sensitive devices on packages containing them or on the device itself.

	IEC 60417 (Symbol No. 5140) ISO 7000 (Symbol No. 5140)	Non-ionizing electromagnetic radiation.	Indicates generally elevated, potentially hazardous, levels of non-ionizing radiation, or to indicate equipment or systems e.g. in the medical electrical area that include RF transmitters or that intentionally apply RF electromagnetic energy for diagnosis or treatment.
	IEC 60417 (Symbol No. 5957)	For indoor use only	Identifies electrical equipment designed primarily for indoor use.
	21 CFR 801.15(c)(1)(i)F 21 CFR 801.109	Prescription Use Only	Caution: Federal law (USA) restricts this device to sale by or on the order of physician. (CFR 21 801.109)
	IEC 60601-1, Annex D (Symbol No. 14)	"ON"/"OFF" button	Smart Charger's "ON"/"OFF" button.
	/	Sequana Medical's symbol for the alfapump ® System	Indicates that the device is part of the alfapump ® System.

10.2 Appendix B: Manufacturer's Declaration for the Smart Charger with Docking Station

Electromagnetic compatibility (EMC)

WARNING: The Smart Charger with Docking Station needs to be installed and put into service according to the EMC information provided in the next tables. Precautions to be taken to prevent adverse events due to electromagnetic disturbances include ensuring that power input voltage and line frequency are within the defined range according to the intended use of the device. For precautions related to the EMC environment, please refer to the "Electromagnetic Environment Guidance" column of the tables below.

WARNING: Portable and mobile RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the Smart Charger and its accessories. Otherwise, degradation of performance may result.

WARNING: The use of cables, power supplies, accessories other than those specified by the manufacturer may result in increased electromagnetic emissions and/or decreased electromagnetic immunity and it may result in improper operation.

WARNING: The Smart Charger with Docking Station should not be used adjacent to or stacked with other equipment and that if adjacent or stacked use is necessary, the Smart Charger with Docking Station should be observed to verify normal operation in the configuration in which it will be used.

WARNING: The use of cables, power supplies, accessories other than those specified by the manufacturer may result in increased emission and/or decreased immunity.

Accessories	Comment	Part no.
Power supply cord type A (US)	2.00 m	01289
Smart Charger USB-C Cable (for physicians only)	2.0 m (to be used with alfapump ® Programmer IV)	02399
Smart Charger Instructions for Use	This document	01463

No Essential Performance has been defined for the Smart Charger and its accessories. Therefore, no loss of or degradation of Essential Performance of the Smart Charger and its accessories are to be expected due to electromagnetic disturbances.

Guidance and Manufacturer's Declaration / electromagnetic Emission - Table 201 Medical Device according to group 1/class B, tested according to CISPR 11

The Smart Charger with Docking Station is suitable for use in the specified electromagnetic environment. The customer and/or user of the Smart Charger with Docking Station should ensure that it is used in an electromagnetic environment as described below.

Emission test (IEC 60601-1-2 4.1 edition)	Compliance	Electromagnetic Environment Guidance
RF emission <i>CISPR 11</i>	Group 1	The Smart Charger with Docking Station uses RF energy only for internal function. Therefore, RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emission <i>CISPR 11</i>	Class B	The Smart Charger with Docking Station is suitable for use in all establishments, including domestic establishments and those directly connected to the public low voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions <i>EN 61000-3-2</i>	Class A	
Flicker emissions <i>EN 61000-3-3</i>	Complies	

Note: *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:*

- *Reorient or relocate the receiving antenna.*
- *Increase the separation between the equipment and receiver.*
- *Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.*
- *Consult the dealer or an experienced radio/TV technician for help.*

Guidance and Manufacturer's Declaration / electromagnetic Immunity - Table 202 See sub-clauses 6.8.201 a) 3.)

The Smart Charger with Docking Station is suitable for use in the specified electromagnetic environment. The customer and/or user of the Smart Charger with Docking Station should ensure that it is used in an electromagnetic environment as described below.

Immunity Test Standard (IEC 60601-1-2 4.1 edition)	IEC 60601-1-2 Test-Level	Compliance-Level	Electromagnetic Environment Guidance
Electrostatic discharge (ESD) <i>EN 61000-4-2</i>	± 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 materials, the relative humidity should be at least 30 %.
Electrical fast transient <i>EN 61000-4-4</i>	± 2 kV for power supply lines ± 1 kV for USB lines	± 2 kV for power supply lines ± 1 kV for USB lines	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Smart Charger with Docking Station requires correct display functions, it is recommended to filter the power supply line.
Surge <i>EN 61000-4-5</i>	L-N: ± 1 kV	L-N: ± 1 kV	
Power frequency magnetic field (50 Hz/60 Hz) <i>EN 61000-4-8</i>	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

Voltage dips, short interruptions on power supply input lines <i>EN 61000-4-11</i>	Voltage dips $0^\circ U_T$ (0.5 cycles) at 0° , 45° , 90° , 135° , 180° , 225° , 270° , 315° $0^\circ U_T$ (1 cycle) and $70\% U_T$ (25/30 cycles) at 0° Voltage interruptions $0^\circ U_T$ (250/300 cycles)	Voltage dips $0^\circ U_T$ (0.5 cycles) at 0° , 45° , 90° , 135° , 180° , 225° , 270° , 315° $0^\circ U_T$ (1 cycle) and $70\% U_T$ (25/30 cycles) at 0° Voltage interruptions $0^\circ U_T$ (250/300 cycles)	Main power quality should be that of a typical commercial or hospital environment if the user of the Smart Charger with Docking Station requires continued operation during power mains interruption, it is recommended to power the device from a battery or USV.
Radiated fields in close proximity <i>EN 61000-4-39</i>	8 A/m at 30 kHz 65 A/m at 134.2 kHz 7.5 A/m at 13.56 kHz	8 A/m at 30 kHz 65 A/m at 134.2 kHz 7.5 A/m at 13.56 kHz	
Note: U_T is the a.c. mains voltage prior to application of the test level			

Guidance and Manufacturer's Declaration / electromagnetic Immunity

The Smart Charger with Docking Station is intended for use in the electromagnetic environment specified below. The customer and/or user of Smart Charger with Docking Station should assure that it is used in such an environment.

Portable and mobile RF communications equipment should be used no closer to any part of Smart Charger with Docking Station, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.

Immunity Test Standard (IEC 60601-1-2 4.1 edition)	IEC 60601-1-2 Test-Level	Compliance-Level	Recommended Separation Distance
<i>Conducted RF IEC 61000-4-6</i>	3 V 150 kHz to 80 MHz 6 V (Amateur and ISM radio bands between 150 kHz and 80 MHz)	3 V 150 kHz to 80 MHz 6 V (Amateur and ISM radio bands between 150 kHz and 80 MHz)	$d = 0.35 \sqrt{P}$ 150 kHz to 80 MHz
<i>Radiated RF IEC 61000-4-3 Additional test frequencies according to Table 9 of IEC 60601-1-2</i>	10 V/m 80 MHz to 800 MHz	10 V/m 80 MHz to 800 MHz	$d = 0.35 \sqrt{P}$ 80 MHz to 800 MHz
	10 V/m 80 MHz to 2,7 GHz	10 V/m 80 MHz to 2,7 GHz	$d = 0.7 \sqrt{P}$ 800 MHz to 2,7 GHz

Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m).

Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, a should be less than the compliance level in each frequency range. b Interference may occur in the vicinity of equipment marked with the following symbol:



Note: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

^a Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Smart Charger with Docking Station is used exceeds the applicable RF compliance level above, the Smart Charger with Docking Station should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the Smart Charger with Docking Station.

Wireless functions and wireless technology

The Smart Charger P5 and **alfapump** can wirelessly communicate. Communication takes place through the Smart Charger P5, which serve as the primary interface for communication and charging of the alfapump. The Smart Charger P5 transmits power transcutaneously to and communicates via RF with the alfapump. Each time the patient charges the **alfapump**, its pump performance data is automatically transferred to the Smart Charger P5.

The wireless radio communication between the Smart Charger P5 and the **alfapump** is based on a single channel communication at a frequency of 907 ± 1 MHz with a maximum transmission power of 5mW. This is a usable frequency within the 915 MHz radio band according to local regulations in US and Canada. The SRD RF link incorporated in the **alfapump** System is technically implemented via one RF chip in the implant and another in the Smart Charger P5.

Summary of wireless functionalities

RF communication between **alfapump** and Smart Charger P5 allows:

1. Download performance data from the implantable device to the Smart Charger P5
2. Set new treatment parameters (including target session volume, maximum daily volume, time segments for **alfapump** to be active, power on/off the treatment)

The Smart Charger P5 transmits power transcutaneously to the alfapump to recharge the pump internal rechargeable battery across the patient's skin at 296 kHz.

Radio communication specifications and operating characteristics

Smart Charger P5:

Description	Frequency/ Frequency band (MHz)	RX bandwidth	Modulation	Effective radiated power
Radio communication	915	230 kHz	GFSK	0.224 mW

alfapump®:

Description	Frequency/ Frequency band (MHz)	RX bandwidth	Modulation	Effective radiated power
Radio communication	915	230 kHz	GFSK	0.019 mW

Quality of Service

The wireless coexistence of the **alfapump** System was tested with acceptable results according to ANSI C63.27. These key performance indicators were monitored during the wireless coexistence tests and define the Quality-of-Service of the **alfapump** System for a safe and effective operation:

Name	Description
RSSI	Received signal strength indicator
PER	Packet Error Rate: number of incorrectly received data packets
Time to complete requests	Elapsed time that occurs from sending a request and receive the response for the same request

Wireless coexistence acceptance criteria are reported in table below:

Required Bit rate	RSSI	PER	Time to complete requests
> 4.6 kbit/s	Min -80dBm	Max 50% of total packets	Max 10 minutes

Security of the **alfapump** System is addressed through:

- Unique ID and pairing mechanism
- Cyclic redundancy check for data integrity
- Absence of patient demographic and hospital info from any transferred data
- Hardware and software design implementation with redundancies for data storage and transfer.

Recommended separation distances between portable and mobile RF-communications equipment and the Smart Charger with Docking Station for equipment that is not life supporting.

The Smart Charger with Docking Station is intended for use in the electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Smart Charger with Docking Station can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Smart Charger with Docking Station as recommended below, according to the maximum output power of the communication equipment.

Output power rating of the transmitter (P _{Trans.}) [W]	Separation distance (depending on transmitter frequency)		
	50 kHz to 80 MHz $d=0.35*\sqrt{P_{Trans}}$ [m]	80 MHz to 800 MHz $d=0.35*\sqrt{P_{Trans}}$ [m]	800 MHz to 2.5 GHz $d=0.37*\sqrt{P_{Trans}}$ [m]
0.01	0.035	0.035	0.0703
0.1	0.11	0.11	0.22
1	0.35	0.35	0.70
2	0.49	0.49	0.99
10	1.1	1.1	2.2
100	3.5	3.5	7.0
For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer. Note 1: At 80MHz and 800MHz, the separation distance for the higher frequency range applies. Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			

Field strength from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range.

Interference may occur in the vicinity of equipment marked with the following symbol:



WARNING: Smart Charger with Docking Station may be interfered with other equipment, even if that other equipment complies with CISPR emission requirements.

WARNING: RF sources in the vicinity of the device (e.g., electromagnetic security systems, cellular telephones, RFID or other in-band transmitters) might interfere with the alfapump System, causing operational complications.

WARNING: Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the Smart Charger, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

WARNING: In case of wireless issue, it is recommended to move away from other potential portable and mobile RF communications equipment. Restart the Smart Charger and check device symbols and indicators. In case problem persists, please contact Sequana Medical Customer Service (see Customer Service contacts, Chapter 5.1).

Manufacturer's Declaration of Conformity - 47 CFR § 2.1077 Compliance Information

Unique Identifier: Smart Charger, Part No.: 01475

FCC ID: 2BDJN01475

Responsible Party – U.S. Contact Information:

Americas Compliance consulting, LLC dba iCertifi

FCC FRN: 0033399411

2445 NE Division Street, Suite 202

Bend, Oregon (OR)

97703, United States

Tel: 866-885-4575

Email: fccagent@icertifi.com

FCC Compliance 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.

10.3 Appendix C: Imprint

**Legal Manufacturer:**

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For general inquiries, we can also be reached via email at info@sequanamedical.com.

Caution: Federal law restricts this device to sale by or on the order of a physician.
Rx only.

Sequana Medical's alfapump® system, and methods of use thereof, is covered by one or more of the patents referenced at www.sequanamedical.com/patents. This webpage serves as notice under 35 U.S.C. § 287(a) of patent marking.

Other patents pending.

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QCBD 01463_CR21001 Rev. 01.60

