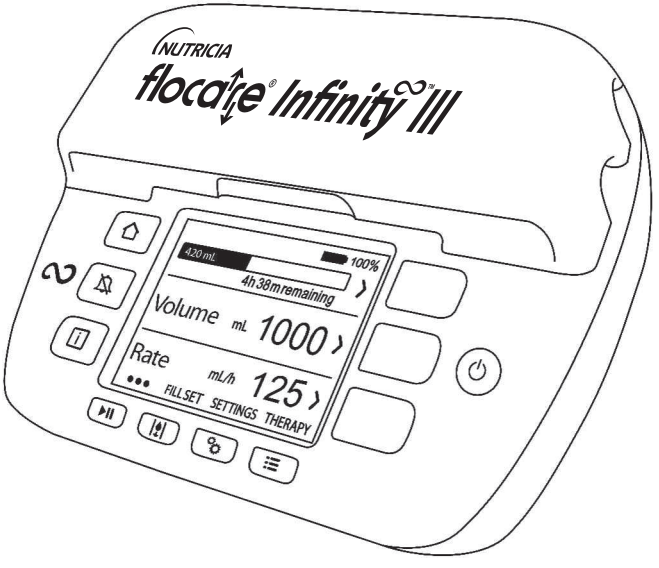
NUTRICIA
flocare®

EN

INSTRUCTIONS FOR USE

NUTRICIA
flocare® Infinity™ III



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1 INTRODUCTION

The Flocare® Infinity™ III pump is a rotary peristaltic enteral feeding pump. The pump provides a variety of options that allow for customisation for each patient and a flexible approach to enteral feeding therapy.

2 INTENDED USE

The Flocare Infinity III is intended to be used to administer enteral nutrition or hydration fluids in a safe, controlled and intuitive manner into the gastrointestinal tract of a patient who is unable to eat or drink normally.

The pump will operate in a clinical environment or home care setting and can be used by trained care givers and patients for bedside as well as for mobile use.

Medical indication

Pump assisted enteral feeding is indicated to patients at nutritional risk or malnourished who:

- cannot meet their nutrients requirements by normal dietary intake
- have a functioning gastrointestinal tract.

Intended target groups

The Flocare Infinity III pump system is intended for adult and/or paediatric patients.

Contra-indications

Do not use:

- if enteral feeding is contraindicated
- for Intravenous administration (Parenteral Nutrition)

Enteral feeding may not be appropriate for some patients depending on the Individual's diagnosis (e.g., intestinal obstruction). Consult your healthcare professional for advice on appropriateness of enteral feeding support.

3 SAFETY INFORMATION

3.1 GENERAL SAFETY

- Read the entire instructions for use before using the Flocare Infinity III enteral feeding pump.

- The user should be trained in the operation of the Flocare Infinity III and its accessories.
- The Flocare Infinity III enteral feeding pump shall only be used in combination with Flocare® Infinity™ giving sets. The use of non-Flocare Infinity giving sets will generate unforeseen hazards and will not provide the required functionality and safety. Consult your local Nutricia sales representative for information on available Flocare Infinity giving sets.
- Replace the Flocare Infinity giving set every 24 hours to maintain delivery accuracy, functionality, allow proper system performance and prevent potential retrograde growth of bacteria. Do not program volume and rate combinations which exceed a 24-hour feed regimen.
- Enteral pump fed patients should be regularly monitored and supervised. Specific patient groups require consistent and controlled administration of enteral nutrition as well as simultaneous application of medication (e.g. insulin administration). In these cases, regular and frequent checks, as determined by the attending healthcare professional, should be carried out to ensure correct administration of nutrition throughout the therapy period.
- Strangulation hazard: avoid leaving AC power plug cord and Flocare Infinity giving set tubing where infants or young children can become caught around the neck.
- Choking hazard: caution should be taken as the Flocare Infinity giving sets contain loose parts which may be dangerous for young children.
- Using the Flocare Infinity III pump's VOLUME function is recommended to program as good practice.
- The healthcare giver should verify that the patient can tolerate the programmed volume and flow rate.
- Do not use the pump in strong magnetic fields. e.g. MRI (Magnetic Resonance Imaging) environments.
- Notice: any serious incident that has occurred in relation to the device should be reported to Nutricia and the local competent authority.

3.2 WARNINGS AND PRECAUTIONS

General warnings

- Warning: Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.
- Medical electrical equipment needs special precautions regarding EMC and needs

to be installed and put into service according to the EMC information provided in the accompanying documents.

- 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 Flocare Infinity III, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.
- Warning: Use of this equipment adjacent to or stacked with other equipment 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.
- A leaking enteral feeding system might compromise the pump's ability to detect an occlusion. Ensure the enteral feeding system is installed and connected properly. During a feeding therapy, ensure there is no leakage observed within the system. In case of any leakage, tighten the connectors and closure caps and verify whether leakage stopped. In case the leakage still occurs, replace the Flocare Infinity giving set.
- In the event of malfunction of the pump or changes in its performance, please consult your local Sales Representative or care giver for a pump service inspection or replacement as required.
- Plug the pump charger into the mains to charge the battery before commencing enteral feeding.
- Use only approved cleaning agents, using non-approved cleaning agents might harm the pump.
- To avoid electrical shock, switch the pump off and remove the plug from the mains before cleaning the pump.
- Make sure the Infinity AC power adapter is completely dry before plugging into the mains.
- Do not cover the speaker at the back of the pump as to ensure any alarm is readily noticed.

Precautions

Before using or setting a feeding regimen, check the integrity of the pump for the items below:

- No cracks on the pump housing.
- The power pins of the AC adaptor socket of the pump are of equal length, not bent and not corroded.
- The keypad is not cut or damaged and the text is legible.

- Scratches on the display that affects display legibility.
- Inspect the rotor; verify that the rollers are not damaged, that it is perpendicular in relation to the rotor and turns freely by hand.
- Verify that the AC power adapter including housing, plug head and cord is clean and not damaged.

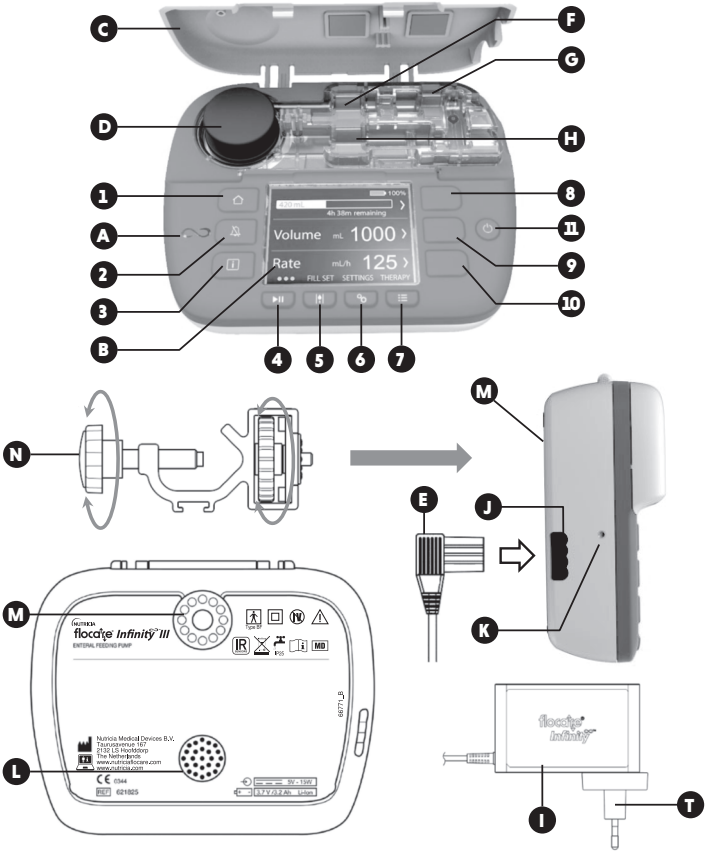
Caution: Do not use the pump if it is damaged.

- The health care professional is responsible to determine the therapy setting and clinical needs, as well as the appropriate surveillance scheme and its frequency. If the required surveillance scheme cannot be guaranteed by the care giver, then it is to be discussed with the healthcare professional, who can advise the patient an alternative therapy solution.
- For volume and nutrient sensitive patients (e.g. children with metabolic conditions using overnight and/or unmonitored therapy) where a constant nutrition delivery is vital and/or connected with consequential therapies (e.g. an insulin delivery pump):, additional surveillance is recommended to be put in place to verify good functioning of the enteral feeding system and programmed therapy.
- The sound level of the Infinity pumps audible alarm is to be set in 'HIGH' if the pump is operated in a noisy environment or the health carer is not nearby the pump, such as at night, to ensure the alarm is readily noticed when an alarm is activated. The intended operator position is in front of the pump.
- Nutricia recommends using ready to feed tube nutrition as this is developed for the intended delivery specifications of the pump.
- Any nutrition added into the enteral feeding line must be of a homogeneous nature and should remain homogeneous during the feeding regimen.
- Use only feeding solutions prescribed by the responsible clinician, registered dietician, registered nurse or other licensed practitioner.
- Before commencing any enteral feeding therapy, proper consideration is given to the feed appropriateness for tube feeding (thickness, homogeneity, selection of nasogastric tube Ch size, etc.), as to avoid occlusion or any other unexpected pump system behaviour. The condition and appropriateness of the nutrition can be addressed with the healthcare professional, who knows the clinical situation and needs of the patient and can best guide the patient in the selection of appropriate feed
- Non-liquid food ingredients and mixed or reconstituted foods may tend to occlude the flow within the feeding tube and Flocare Infinity giving set. Clinicians and caregivers should carefully monitor the pump during use with these types of feeds.
- Users must ensure that any substrate used for any mixed or reconstituted powdered

nutrition is indicated as suitable for enteral tube feeding delivery (refer to instructions for use on nutrition / substrate added).

- Mixed or reconstituted nutrition may have foam. If using this type of nutrition, allow it to sit for some time until the foam has been dissolved before pouring it into a feeding reservoir. This will reduce the chance of an 'AIR in giving set' alarm.
- If other forms than a standard, ready to feed formula (i.e. commercially available pre-packed or commercially prepared feeding solutions) are prescribed as enteral tube feed, it should be done with caution and aligned with the healthcare professional. Feeds supplied as tube feeds must be of a homogenous nature and should remain homogeneous during the feeding regimen as bigger particles or high viscous foods might result in blockages in the feeding line. It is noted that for instance 'home-made' – mixed tube feeds might give rise to issues when given as an enteral tube feed as the mixture will not stay in emulsion for a longer period.
- In using any mixed, reconstituted powdered nutrition or breast milk, we advise users to ensure the nutrition is prepared and dissolved properly as to avoid particles, foam accumulation or films in the Flocare Infinity giving set potentially hampering pump performance and a normal feeding regimen.
- If patients are advised by their healthcare professional to use a mixture of feeds, the feed must be given when there is direct supervision (e.g. parents) to ascertain the feeding therapy is running normally and to ensure proper actions are taken in case there is a pump failure or unexpected behaviours caused by the mix.
- Do not modify this equipment. Modification of this device or its accessories can result in physical hazards including delayed therapy, over delivery, under delivery, electrocution and fire. These hazards could result in patient injury or death.
- Do not use the Infinity alarm systems to trigger actions related to secondary (electrical) medical devices (e.g. a volumetric or syringe pump).
- Do not use pump functions for any other purpose than described in this manual. e.g. FILL SET function to overcome an occlusion or the AIR in giving set alarm to indicate end of therapy.

4 QUICK REFERENCE OVERVIEW



- **A** Pump status indicator
- **B** Colour display
- **C** Door
- **D** Pump rotor
- **E** Charger plug
- **F** Occlusion IN sensor
- **G** Air sensor
- **H** Occlusion OUT sensor
- **I** AC power plug
- **J** AC power socket
- **K** AC charging light
- **L** Speaker
- **M** Pole clamp interface
- **N** Pole clamp
- **O** ENPlus® connector
- **P** ENFit® connector
- **Q** Medication port
- **R** Cassette
- **S** Drip chamber
- **T** Detachable AC plug

5 USER INTERFACE

5.1 BUTTONS

- **1** Home button
- **2** Snooze button
- **3** Information button (i-button)
- **4** Start/pause button
- **5** Fill set button
- **6** Settings button
- **7** Therapy button
- **8** Soft button 1
- **9** Soft button 2
- **10** Soft button 3
- **11** On/Off button

5.1.1 Home button

The HOME button navigates back to the home screen or dashboard, in 1 touch from whichever screen you are in.

Additionally, the HOME button acknowledges an alarm or warning.

Note: the HOME button does not act as a back button to move one level up in a menu.

5.1.2 Snooze button

The alarm SNOOZE button silences the audio alarm signal for 2 minutes when the pump is in an alarm state.

This gives you the opportunity to investigate and addresses the indicated alarm without being distracted by the audio alarm signal.

Note: the alarm remains visible. The symbol on the display indicates that the alarm sound is snoozed.

5.1.3 [i] Information button

The INFORMATION [i] button (i-button) provides help and additional information about the actual pump state at any given time.

Examples:

- In a running mode, the information button provides information about the status of the therapy.
- In pause mode, the information button will give recommendations how to program a therapy depending on your selected therapy.
- In an alarm state, the information button provides recommendations on how to solve the indicated alarm by providing potential solutions.

5.1.4 ▶II Start/pause button

The START/PAUSE ▶II button starts or pauses a programmed therapy.

5.1.5 Fill set button

The FILL SET button primes the Flocare Infinity giving set to ensure that air within the system has been purged.

5.1.6 Settings button

The button provides access to the pump settings.

See chapter 7.4 'Settings menu' for full button functionality

5.1.7 ⁝≡ Therapy button

With the THERAPY ⁝≡ button, you can select your desired therapy.

See also chapter 7.5 'Programming the pump', 7.4.1 'Define therapy list' and 7.5.5 'Program a PERSONALISE THERAPY'.

5.1.8 ⏻ On/Off button

The ON/OFF button switches the pump ON and OFF.

Note: to avoid unintended button presses, the ON/OFF button needs to be pressed for 2 seconds for both switching the pump ON or OFF.

5.1.9 Soft buttons

The soft buttons relate to the function on the screen which has an action indicated by the "<, >, ▲,▼,◀,▶,+,-". symbol.

Note: the SOFT buttons are only active when accompanied with the above-mentioned symbols, if no symbol appears, the button is inactive.

5.2 PUMP STATUS INDICATOR

The pump status indicator provides a visual indication of the actual pump status.

- A green light indicates that the pump is in running mode and working normally.
- An orange light indicates that the pump is in pause mode and waits for user input.
- A red light indicates an alarm state; immediate action from the user is required.

5.3 DISPLAY

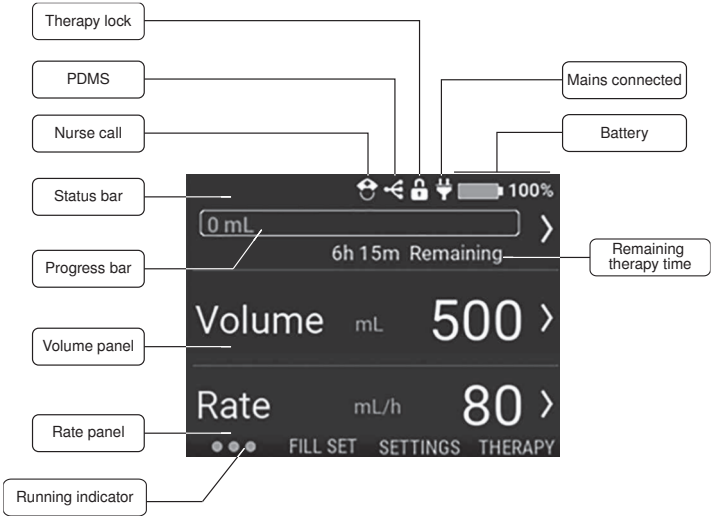
The Flocare Infinity III will perform a display test during each pump start. Carefully check for any sections or pixels that do not appear during the display test.

Caution: In case of any missing sections or pixels, the pump should not be used and to be send to an authorised service centre for inspection.

5.4 HOME SCREEN

The home screen lay-out corresponds with your selected therapy VOLUME / RATE, RATE or INTERMITTENT.

The grey lines separate the panels in PAUSE mode, and are a visual indicator that the navigation and selection buttons are active.



5.4.1 Status bar

The status bar shows the system status by presenting icons at the top of the screen.

Note: icons are shown in home screen view only and can change the status bar order.

5.4.2 Icons

- The Nurse call icon indicates that the pump is set to Nurse Call mode
- The PDMS icon indicates that the pump is set to PDMS mode
- The Therapy lock icon indicates that the current active therapy has been locked and cannot be modified unless unlocked.
- The Plug icon indicates whether the pump is connected to the mains.
- The Battery icon indicates the charged capacity in percentage.

5.4.3 Progress bar

The progress bar provides a quick overview about the amount of delivered tube feed since the last time the progress bar was cleared.

Note: refer to chapter 7.7.4 'Reset progress bar' for a manual reset of the progress bar.

VOLUME - RATE 

When a volume - rate therapy has been programmed, the progress bar is fully outlined and gives real-time information of the administered volume on the left side.

RATE

When a rate therapy has been programmed, the progress bar fades out at the end of the graph indicating that no volume has been programmed. The graph is static and shows only the administered volume since the last time it was cleared.

INTERMITTENT 

When an intermittent therapy has been programmed, the progress bar is separated into the number of programmed portions. The progress bar is capable to show up to 3 portions, if more portions are programmed, they will appear automatically after the previous administered portions has been delivered.

Progress of each individual portion is indicated by filling in real-time the programmed portion comparable to volume-rate.

5.4.4 Running indicator

The running indicator symbol becomes active after pressing the START/PAUSE ▶II button. The indicator shows 6 dots moving from the left to right and represents an active programmed therapy.

In PAUSE mode, only 3 static dots are visible

6 PUMP SETUP

6.1 ATTACHING TO THE POLE CLAMP (OPTIONAL)

1. Connect the Flocare Infinity III pole clamp (N) to a pole stand by rotating the black star shaped bolt clockwise.
2. Connect the Flocare Infinity III to the pole clamp interface (M) by rotating the grey wheel shaped disk clockwise until the pole clamp is fully connected to the pump without any clearance.

6.2 CONNECT TO THE AC POWER PLUG

Ensure the detachable AC plug is connected to the AC power plug.

Connect the AC power plug by gently pressing the charger plug (E) into the pump (J).

The charger plug is designed to fit in only one way. When the pump is connected to the mains, the blue AC charging light (K) should be on and the plug icon should appear in the pump screen next to the battery icon.

Note: The Flocare Infinity III is equipped with Lithium/Ion battery technology and needs to be fully charged for a period of 6 hours prior to first use.

6.3 SWITCH THE PUMP ON

Turn the pump ON by pressing and holding the ON/OFF button for approximately 2 seconds until the start-up sound.

The pump will perform a self-test and informs when the device is ready for use, as the home screen will be shown after the self-test.

Note: When a previous therapy has not been administered completely before the pump was turned OFF, the pump will show the warning message 'Last feeding incomplete'.

*Refer to chapter **7.5.4 'Change the parameters of an active therapy' for more information.***

6.4 SET THE LANGUAGE

Set the language by pressing the SETTINGS button, navigate to LANGUAGE and select your preferred language.

Note: at first pump start up or after a factory reset, the pump will guide you automatically through the language selection.

6.5 SET THE TIME AND DATE

Set the time and date by pressing the SETTINGS button, navigate to TIME AND DATE and set these to your local time zone. The pump will not change to daylights savings automatically nor will it change to other time zones during travelling.

Note: at first pump start up or after a factory reset, the pump will guide you automatically through the time and date setting.

6.6 SWITCH THE PUMP OFF

Switch the pump OFF by pressing and holding the ON/OFF button for approximately 2 seconds until the turn-off sound.

7 OPERATING INSTRUCTIONS

7.1 LOAD THE FLOCARE INFINITY GIVING SET

Follow the instructions for use of the Flocare Infinity giving set, for setting up the enteral feeding system.

1. Open the door
2. Position the purple looped section of the cassette (R) around the pump rotor (D)
3. Gently stretch (do not over stretch) and manually press the giving set into position by pressing the cassette downwards into the pump top housing. The cassette is designed to fit into the pump one way
4. Close the pump door
5. Pump is now ready to be programmed

7.2 PAUSE / RUNNING MODE

The Flocare Infinity III is either in pause mode waiting for user instructions or is in running mode delivering a therapy to a patient. The pause or running modes are controlled by the START/PAUSE ▶II button.

Note: when the pump has been untouched for 3 minutes or more in PAUSE mode, the pump will display the 'Pump needs attention' alarm message.

7.3 FILL THE FLOCARE INFINITY GIVING SET

The FILL SET function is used to prime a (new) Flocare Infinity giving set with nutrition or water and needs to be commenced before starting a feeding therapy. Ensure the Flocare Infinity giving set is disconnected from the patient feeding tube. Prime the set by press and hold the FILL SET button for 2 seconds to activate the FILL SET function and release the FILL SET button as soon as the pump generates a beep and automatically starts. The FILL SET can be manually stopped by pressing STOP in case the giving set is over filled.

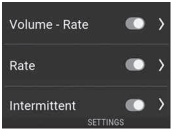
Note: when the FILL SET function is activated, all alarms are temporary deactivated helping avoid alarms being inadvertently triggered (e.g. air alarm).

7.4 SETTINGS MENU

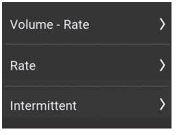
7.4.1 Define therapy list

DEFINE THERAPY LIST controls the list of available therapies that are visible when the THERAPY ☰ button is pressed. Therapies that are currently enabled are marked with a green switch symbol.

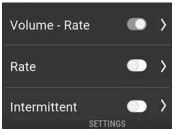
Personalise therapies are shown in the list of available Therapies once they have been enabled and programmed. 2 examples are shown below.



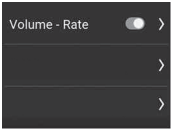
Define therapy list



Therapy list result



Define therapy list



Therapy list result

7.4.2 Personalise therapies

PERSONALISE THERAPIES provide the functionality to pre-program therapies that are often used. Once programmed, it automatically appears in the list when the THERAPY ☰ button is pressed. A personalise therapy can be created, edited or erased.

Note: Personalise therapies can be hidden using Define Therapy list.

7.4.3 Therapy lock

The THERAPY LOCK will lock an active therapy to avoid therapy tampering. It is not possible to select a new therapy or reprogram the active therapy when the THERAPY LOCK is activated, however it is possible to restart a locked therapy. Clearing the progress bar is still possible. A therapy lock can be activated in PAUSE mode only by pressing SETTINGS → THERAPY LOCK and a valid PIN code must be entered. When a therapy is locked, a lock symbol appears in the status bar. Unlocking a therapy is done via the same procedure.

Note: In case the therapy parameters need modification, consult your care giver.

7.4.4 Reset patient data

Reset patient data is designed to erase all collected patient data (non-personal).

The following data will reset: *Therapy parameters, Progress bar, Patient history data, Personalised therapies, Define therapy list, Sound settings and Display settings.*

Note: The internal LOG file will not be erased, data can be recovered upon request by Nutricia or an authorised repair centre.

7.4.5 Sound

The Flocare Infinity III supports 3 AUDIO VOLUMES, '*Low, Medium and High*' and can be set by the user. For safety reasons the alarm volume is automatically escalated to "*High"* in both settings '*Low*' and '*Medium*' after 3 min. This safety feature cannot be turned off.

7.4.6 Therapy completed

Notice: This menu option is only available from software version 1.07.0088 onwards.

The Flocare Infinity III can give a notification once the delivery of the programmed therapy is completed. This VOLUME DELIVERED alarm supports three different user configurable audio options.

'CONTINUOUS' is activated by default and the pump will generate a visual warning and a recurring audio alarm.

'ONLY ONCE' A single audio alarm once the delivery of the programmed therapy is completed.

'OFF' If no notification on programmed therapy is required, the VOLUME DELIVERED alarm can be switched off.

Caution: consult your care giver before disabling the VOLUME DELIVERED alarm.

7.4.7 Display

The DISPLAY BRIGHTNESS can be set to a convenient level depending on the ambient conditions. It is recommended to set the DISPLAY BRIGHTNESS to maximal when used in bright sunlight as to ensure full visibility. This display illumination can be set to AUTO DIMMING mode when connected to the mains. When AUTO DIMMING is ON, the display will be dimmed after 2 min. When AUTO DIMMING is OFF, the display will always be illuminated.

Note: When the pump is running on battery power only, the display will always be dimmed after 2 min. in order to preserve battery life.

7.4.8 Time and date

The Flocare Infinity III uses real time and dates in reporting the administered volumes in 30-day HISTORY as well as in the THERAPY DETAILS screens. To ensure accuracy of data, the actual time and date according to your local time zone must be set. Set the time and date by pressing the SETTINGS button, navigate to TIME AND DATE and set these to your local time zone.

Note: Daylight savings are not automatically performed.

7.4.9 Language

Set the language by pressing the SETTINGS button, navigate to LANGUAGE and select your preferred language.

Note: at first pump start up or after a factory reset, the Flocare Infinity III will guide you automatically through the language selection.

7.4.10 About this pump

Information concerning the pump is gathered in the ABOUT THIS PUMP screen where you can check: Serial number, Manufacturing date, PCBA hardware revision, Software version, current Date and time settings, communication mode, Battery state of health, Total operating hours and Total delivered volume.

Note: This information can be helpful for support reasons.

7.5 PROGRAMMING THE PUMP

Caution: Before programming the pump, always ensure that your selected therapy and its parameters are correct. In case of any doubts, consult your care giver.

Therapies are programmed via the THERAPY ☰ button.

The Flocare Infinity III supports the following therapies:

Volume – Rate	Administering of a programmed VOLUME (mL) with a programmed RATE (mL/h).
Rate	Administering with a programmed RATE (mL/h) but without a programmed VOLUME (mL)
Intermittent	Administering of a programmed VOLUME (mL) divided over different portions with a programmed RATE (mL/h) with programmed PAUSE (interval) times.

IMPORTANT:
Therapies RATE and INTERMITTENT are disabled by default, if a desired therapy does not appear when the THERAPY button is pressed, you can enable them by selecting: SETTINGS → DEFINE THERAPY LIST

See chapter 7.4.1 'Define therapy list' for more information.

7.5.1 Program a VOLUME - RATE therapy

- From the home screen press the THERAPY ☰ button
- Select VOLUME – RATE by pressing the associated soft button.
- Press the VOLUME soft button
- Change the Volume using the '+' and '-' buttons, and press the '>' button to accept the value.
- Press the RATE soft button
- Change the Rate using the '+' and '-' buttons, and press the '>' button to accept the value.

- Check your total therapy time underneath the VOLUME or RATE panel for additional safety.
- Press the START/PAUSE ▶II button to start your VOLUME-RATE therapy.

7.5.2 Program a RATE therapy (not recommended for volume sensitive patients)

- From the home screen press the THERAPY ☰ button
- Enter the RATE soft button
- Change the Rate using the '+' and '-' buttons, and press the '>' button to accept the value.
- Press the START/PAUSE ▶II button to start your RATE therapy.

7.5.3 Program an INTERMITTENT therapy

The INTERMITTENT therapy has a step- by step approach where all parameters need to be entered and validated prior to return to the home screen.

The Flocare Infinity III shows resulting parameters based on the user input for safety and convenience reasons.

Note: after each step, the Flocare Infinity III guides you to the next programming step.

- From the home screen press the THERAPY ☰ button
- Select INTERMITTENT by pressing the associated soft button.
- Press the TOTAL VOLUME soft button
- Change the Volume using the '+' and '-' buttons, and press the '>' button to accept the value.
- Press the PORTIONS soft button
- Change the required Portions using the '+' and '-' buttons, and press the '>' button to accept the value.
- Press the RATE soft button
- Change the Rate using the '+' and '-' buttons, and press the '>' button to accept the value.
- Press the PAUSE soft button
- Change the required Pause time using the '+' and '-' buttons, and press the '>' button to accept the value.
- Scroll up and down with soft button 1 and 3 through all programmed settings and verify the input
- Scroll to CONFIRM and validate the input by pressing soft button 2.
- Press the START/PAUSE ▶II button to start your INTERMITTENT therapy.

Note: When the pump is in the NEXT PORTION mode, the home screen will differ, indicating and counting down the time until the next portion. The running indicator will remain active during the count down.

7.5.4 Change the parameters of an active therapy

Changes to an active therapy are possible regardless whether a manual programmed or a personalised therapy is active. To change an active therapy, make sure the pump is in PAUSE mode.

Volume	Rate VOLUME and RATE parameters can be modified
Rate	RATE parameters can be modified.
Intermittent	RATE parameter can be modified. TOTAL VOLUME cannot be modified. PAUSE time can be modified only when the pump is in NEXT DELIVERY mode.

7.5.5 Program a PERSONALISE THERAPY

The Flocare Infinity III provides the functionality to pre-program up to 3 personalise therapies and store them into the pump memory for later use. Programming a personalise therapy is considered as a pump setting rather than a THERAPY itself. To program a personalise therapy, navigate from the HOME screen to SETTINGS → PERSONALISE THERAPIES.

- Select the therapy type by pressing the associated soft button 1, 2 or 3.
- Follow the step- by step instructions to program a PERSONALISED THERAPY.
- After programming, press YES with soft button 2 to confirm the PERSONALISED THERAPY and to return to the PERSONALISED THERAPY overview screen.

  Note: pressing NO will restart the procedure.
  Note: pressing YES will make the programmed PERSONALISED THERAPY available in the THERAPY menu.
- When finished programming a PERSONALISED THERAPY, press HOME ⌂ button to return to the home screen.

7.5.6 Editing of a PERSONALISE THERAPY

To EDIT or to DELETE a PERSONALISE THERAPY navigate from the HOME screen to SETTINGS → PERSONALISE THERAPIES and select the therapy that needs editing or deletion.

Note: deleting a therapy will erase all stored previous programmed therapy settings and make the personalised therapy available for re-programming a new personalised therapy.

7.6 LAST FEEDING INCOMPLETE

When a therapy has not been administered completely whilst the pump has been turned OFF, the pump will show the warning message: 'Last feeding incomplete'. You either have the option to RESTART the active therapy where the progress bar will be reset or you can

RESUME the delivery of the active therapy.

7.7 INFORMATION & MEMORY FUNCTIONS

7.7.1 Therapy information

When a 'VOLUME – RATE' or 'RATE' therapy has been programmed, the Flocare Infinity III provides useful information concerning your active therapy when the THERAPY INFORMATION button is pressed. This function can be accessed from the HOME SCREEN, SOFT BUTTON 1, THERAPY INFORMATION.

In general, the left side of the screen are past events, in the middle the actual events and on the right-hand side the estimated events for the future. The display will show [–] in case an event cannot be calculated.

Note: The Therapy information screen is also visible when the information button is pressed during running mode.

7.7.2 Portions information

When an INTERMITTENT therapy has been programmed, the Flocare Infinity III provides useful information concerning your individual portion when the PORTIONS INFORMATION button is pressed.

This function can be access from the HOME SCREEN → SOFT BUTTON 1 → PORTIONS INFORMATION.

7.7.3 30-day history graph

The Flocare Infinity III stores all administered therapies for a maximum period of 30 days.

The daily administered volume can be accessed by pressing SOFT BUTTON 1 from the home screen and pressing HISTORY. With the arrow buttons, you can navigate to earlier or later days. By pressing the + magnifying symbol you can zoom in on your selected day by showing a table of individual delivered therapies.

7.7.4 Reset progress bar

The Progress bar is automatically cleared after completion of each therapy where a VOLUME was programmed.

When there is a need to manually clear the Progress bar, navigate from the HOME screen to SOFT BUTTON 1 → RESET PROGRESS BAR.

7.8 KEYPAD LOCK

The keypad can be locked to prevent unintentional changes. The keypad lock can be activated by pressing the INFORMATION button and SOFT BUTTON 3 simultaneously when the pump is in running mode. Follow the same procedure to unlock the keypad. Icons will guide the user on how to unlock the keypad.

7.9 CONNECT TO A NURSE CALL OR PDMS SYSTEM

The power connector at the left-hand side of the pump offers the option of connecting the pump to an external alarm

system (Nurse call) or Patient Data Monitoring System (PDMS). For these functions, we offer the following accessories:

- The Flocare® Infinity™ Nurse Call enables connection to an external alarm system. Follow the instructions for use of the Flocare® Infinity™ Nurse Call to connect the pump.
- The Flocare® Infinity™ PDMS Cable enables connection to an external PDMS system. Follow the instructions for use of the Flocare® Infinity™ PDMS Cable to connect the pump to an external PDMS system

7.10 BATTERY

The Flocare Infinity III is equipped with Lithium/Ion battery technology and needs to be fully charged for a period of 6 hours prior to or during its first use, this will maximise the battery life time.

The battery microprocessor continuously monitors the battery state of health and the pump displays in the 'About this pump' screen when the battery is depleted for 70% or more and needs replacement.

Battery age	125 mL/h
≤1 years	24 hrs
≤2 years	24 hrs
≤3 years	20 hrs
≤4 years	16 hrs
≤5 years	12 hrs
70% depleted	7.2 hrs



Note: The battery capacity is an estimate. If you are unsure that enough battery capacity remains for your intended therapy, connect to the AC power adapter until recharged

8 ADVANCED SETTINGS

The Advanced settings menu is intended for qualified caregivers or qualified technicians /BMET only and can be accessed by following the below procedure:

- Make sure the pump is OFF.
- Press and hold the ON/OFF button immediately followed by SOFT BUTTON 1 and hold both buttons for approximately 2 seconds until the advanced settings menu appears.

8.1 COMMUNICATIONS MODE

- Off — No communication (standard mode)
- PDMS — To communicate with an external computer via the Flocare® Infinity™ PDMS Cable.
- Nurse call — To trigger an external nurse call system via the Flocare® Infinity™ Nurse Call Cable.

Note: See chapter 7.9 'Connect to a Nurse call or PDMS system' for more information.

8.2 CHANGE PIN CODE

Edit PIN Set and store a secret PIN code

Default PIN Change the PIN code to the default public PIN CODE 3584.

Note: See chapter 7.4.3 'Therapy lock' for more information.

8.3 FACTORY RESET

This will reset all user settings and brings the Flocare Infinity III to its original state.

Note: after a factory reset, the Flocare Infinity III shall ask to set the language and time and date.

8.4 LIVE SENSOR VALUES

The live sensor values are intended to be used for inspection and maintenance activities by qualified service centers and BMETs.

9 ALARMS, WARNING MESSAGES AND TROUBLE SHOOTING

The Flocare Infinity III is equipped with several sensors and safety features linked to audible and visible alarms and warning messages on the display. In case any of the alarms occur, the pump will generate an audible and visual alarm and stops administering. The back light of the display automatically switches on. Exception to this is the low battery alarm, in this situation the pump continues working. Infinity alarm conditions are classified as low priority indicating that operator awareness is required and future action is needed.

If an alarm or warning message appears on the display:

- The HOME ⌂ button acknowledges an alarm or warning state and dismisses the alarm or warning message.
- The SNOOZE 🔕 button snoozes the alarm or warning audio signal for 2 minutes

whilst the alarm or warning message remains on the display. A suppressed audio icon will appear on the display indicating that the audio signal has been snoozed.

- The INFORMATION button [i] can provide suggestions on the display to solve an alarm or warning condition.

Note: during an alarm or warning message, all other buttons are disabled.

The HOME ⌂ button is the only button that acknowledges an alarm or warning message.

9.1 PROBLEM SOLVER CHART

In case any of the alarms or warnings listed on the problem solver chart occur, the pump will generate an audible and visual alarm and pauses administering. The back light of the display automatically switches on. Exception to this is the low battery notification, in this situation the pump continues working.

In the event of any alarm or warning message: Acknowledge or SNOOZE the alarm and check the type of alarm and solution displayed. Feeding regimen can be restarted by pressing START/PAUSE ▶II button again once the cause of the alarm is solved.

PROBLEM SOLVER CHART		
Alarm description	**Cause**	**Solution**
Air in giving set	The pump has detected air in the giving set.	If your feeding reservoir is intended to be empty: Disconnect and discard feeding reservoir and Flocare Infinity giving set or replace as per training. If your feed reservoir is NOT intended to be empty: Disconnect from feeding tube and use FILL SET function to clear air. Reattach the feeding tube and recommence feed.
	The air sensor area is dirty	Make sure there is no excessive foam in the feeding reservoir. Make sure the air sensor is clean
Battery empty	The battery charge is critically low	Connect the pump to the AC power adapter and mains to recharge the battery immediately for 6 hours. During charging the pump can be used

PROBLEM SOLVER CHART		
Alarm description	**Cause**	**Solution**
Charging please wait	The battery is charging	Wait until the battery is charged
Door is open	The door is not properly closed	Close the door
Keypad is locked	The keypad is locked to prevent unintended button presses	Unlock the keypad by pressing i-Button [i] and SOFT BUTTON 3 simultaneously
Last feeding incomplete	The pump was turned off before the therapy was completed	Press START/PAUSE ▶II button to start the same therapy all over. Press RESUME to continue your active therapy
Low battery	The battery charge is low	Connect the pump to the AC power adapter and mains to recharge the battery immediately for 6 hours. During charging the pump can be used.
No plug symbol visible, while the pump is connected to the mains	The mains outlet does not work.	Connect the pump to another mains outlet.
	The AC power adapter is damaged	Contact your pump provider for replacement
Occlusion in	The pump has detected an occlusion between the pump and the feeding reservoir.	Check the Flocare Infinity giving set between the pump and the reservoir for kinks or other obstructions and correct if found. Restart the pump.
	The sensor area is dirty.	Clean the sensor area.
	Recurring alarm	If alarm persists, replace the Flocare Infinity giving set

PROBLEM SOLVER CHART		
Alarm description	**Cause**	**Solution**
Occlusion out	The pump has detected an occlusion between the pump and the patient.	Check the Flocare Infinity giving set between the pump and feeding tube for kinks or other obstructions and correct if found. Check your feeding tube for kinks or other obstructions according to your training and correct if found.
	The sensor area is dirty. Recurring alarm	Clean the sensor area. If alarm persists, replace the Flocare Infinity giving set
Pump needs attention	The pump has been untouched for 3 minutes or more	Press any button to acknowledge the warning message
Rate not set	No rate has been programmed when starting a therapy	Program a Rate (mL/h)
Re-insert giving set	Giving set not properly installed	Insert a Flocare Infinity giving set
Replace giving set	The giving set has been used for more than 24 hours	Replace the Flocare Infinity giving set with a new one
Service needed	Preventive maintenance service interval has elapsed	Return pump to pump provider for service.
Set > 24 hrs	Reminder that the giving set has been used for more than 24 hours and needs replacement	Replace the Flocare Infinity giving set with a new one.
System failure	The pump has encountered an internal system failure	Turn the pump OFF, make sure the pump door is closed and switch the pump back ON. If the error persists, contact pump provider for replacement.

PROBLEM SOLVER CHART		
Alarm/warning description	**Cause**	**Solution**
Therapy completed	The pump has completed the delivery of the programmed therapy	Pump has completed the delivery of the programmed therapy.
Volume not set	No volume has been programmed when starting a therapy	Program a Volume (mL)

10 CLEANING, INSPECTION & SERVICING GUIDELINES

10.1 SWITCHING BETWEEN PATIENTS

Enteral feeding pumps must be thoroughly cleaned and inspected before the pump is moved to another patient to ensure the pump is in pristine condition. Local cleaning and hygiene policies are to be followed up.

- Clean the pump as described in paragraph 10.2 'Cleaning & disinfection'.
- Perform inspection as described in paragraph 10.3 'Inspection'
- Clear the patient history (SETTINGS → RESET PATIENT DATA)

If all above actions were taken successfully, the pump can be used by a next user.

10.2 CLEANING & DISINFECTION

For optimum and safe pump operation, the pump should be kept clean and free from debris. It is recommended to clean the pump with a wet cloth after every completed feeding regimen.



Disconnect the pump from the mains before cleaning. To avoid electrical shock, never clean the pump with AC power adapter plugged into an outlet or when pump is on.

Do not immerse the pump in water.

Do not use aggressive cleaners or disinfectants such as acetone, benzene or iodine.

Note: the pump is not intended to be cleaned using a dishwasher.

Do not sterilize the pump, e.g. by irradiation, EtO, steam or in an autoclave. It is recommended

to clean the pump regularly under (running) warm tap water with standard washing up liquid, a non-abrasive sponge, brush or soft cloth. Clean and remove any nutritional residue from the pump paying particular attention to the sensor area on the top housing, the rotor including its rollers and in the corners of the keypad and screen. Then dry the pump with a clean cloth. After cleaning, the pump can be disinfected using a mild, diluted disinfectant or cleaning solution and damp cloth. Follow local policies for cleaning and disinfection of medical equipment. Alcohol based disinfectants can be used as long as the contact period is short (less than 5 minutes). Only use 70% Isopropyl alcohol or alcohol based disinfectants. Use of Metrex Cavacide® (ammonium chloride), MetriCide®, Bleach/ Chlorine solution (5% chlorine or equivalent and 95% water) and Antisept N® (povidone iodine) or equivalent is advised.

Ensure any cleaning solution, detergent and disinfectant wipes are compatible with the device. During and after the application of any detergent, look for signs of damage and physical changes like cracking, colour changes, etc. to the medical device. In case any effects are observed in using the agent or in case of any doubt in approved cleaning agent usage, potential negative effect of cleaning agent used or concerns/ complaints, stop using the agent, consult the products instructions for use or contact your local Sales Representative for further information and verification.

Caution: ensure the pump is properly cleaned after every use, free from defects, scratches and any obstruction, such as dried enteral feed that may hinder the optimal performance of the pump. ***Note:*** *Failure to properly maintain the pump could affect the warranty.*

10.3 INSPECTION

10.3.1 Housing

- Check the housing and cassette insert area for any dirt, cracks, cuts, and damage.
- Bronze coloured threaded insert of the pole clamp interface (M) fully fixed in the rear housing and that it is flush with the housing.
- With the door open, verify that the door closure clips and hinges are not broken or cracked.

10.3.2 Keypad

- Not cut or worn out, text and symbols on the buttons are legible.

10.3.3 Rotor

- Verify that the rotor is free of damage, perpendicularly in relation to the pump and free of dirt.
- Verify that the rollers of the rotor are not damaged, perpendicularly in relation to the rotor, free of dirt and can be turned freely by hand.

10.3.4 AC power plug

- Check for any signs of cuts or damage on the AC power plug, pins and power cord.
- The pins are not bent or corroded.
- The power cord is clean, there are no cuts or exposed wires visible.

10.3.5 Electrical

- Turn the pump on, if the pump does not turn on or gives battery alarm after it is started up, connect the AC power plug and charge for at least 20 minutes and then restart this section.
- Plug the charger plug into the pump and verify that the blue charging light located next to charging port is lit when connected. Verify that the plug symbol appears next to the battery symbol.

Caution: If the pump failed on any of the above described inspections, the pump should not be used and send back to an authorised service centre for inspection.

10.4 SERVICING

There are no user-serviceable parts, servicing activities are to be performed at an approved service centre or a Nutricia qualified Technician / BMET. An inspection of the pump by an authorised service centre or a trained and qualified technician / BMET is recommended in the following cases:

- Switching between patients
- In case of any change in performance characteristics or pump alarm messages/ warnings
- In case the pump has been dropped.

The pump does not require preventive maintenance, routine servicing, or calibration under normal conditions of use in cases where proper cleaning and inspection protocols are adhered to, for a period of 5 years

10.5 ACCESSORIES

The following ancillaries and accessories are available for the Flocare Infinity III pump, please contact your local Nutricia sales representative for availability and ordering information of the respective parts.

- Carry bags
- Flocare Infinity Stands and Frames
- Various Flocare Infinity giving sets and feeding reservoirs
- Flocare Infinity Nurse Call - cable length: 5m
- Flocare Infinity Data cable - cable length: 3m
- AC Power adapter module - cable length: 3m

10.6 RECYCLING & DISPOSAL

The pump and its electrical accessories (AC power plug, PDMS cable, Nurse Call cable), should be disposed according to local standards and regulations governing the disposal of electronic waste (e-waste). Other accessories can be disposed of or recycled as standard non-hazardous waste.

Note: In case of pump scrapping, always notify your Nutricia sales representative of the pump serial number

11 SPECIFICATIONS

MEDICAL EQUIPMENT

Nutricia Flocare Infinity III Enteral Feeding pump

11.1 PERFORMANCE

Volumetric accuracy (1)	±5%
Flow rate	1 – 600 mL/h in 1 mL/h increments
Priming rate	700 mL/h
Administering volume	1 – 3500 mL in 1 mL increments
Battery life (2)	24h @ 125mL/h, 12h @ 250mL/h
Air bubble alarm	> 1.5 mL of air in giving set after the pump set.
Upstream occlusion pressure	-34 kPa ± 21 kPa for 5 seconds;
Downstream occlusion pressure	84 kPa ± 21 kPa for 30 seconds 103 kPa ± 21kPa for 5 seconds
Therapies	Volume/Rate ; Flow rate ; Intermittent
Number of intermittent boluses	2 – 12
Time interval intermittent boluses	5 min. - 24h, 5 min. increments
Number of user programmable therapies	3

(1) See chapter 11.6 'Volumetric accuracy' for additional information
(2) For batteries not older than 2 years

11.2 ELECTRICAL / MECHANICAL

Flocare Infinity III pump

Pumping mechanism	Rotary peristaltic
Dimensions	~154mm x 120mm x 49mm (L, W, H)
Weight	~432g
Ingress protection (pump)	IP25 (washable under running tap water)
Battery	3.7V; 3200 mAh; Lithium Ion
Air bubble detection	Infrared
Upstream detection	Infrared
Downstream detection	Infrared
Display	2.8" full colour; 640x480px; 175 degrees viewing angle

AC power adapter

Brand	Delta Electronics, Inc.
Type	MDS-030AAC05
Input voltage	100-240V AC; 50-60Hz
Output	5V DC; 3A
Ingress protection class	IP22

11.3 OPERATING

Atmospheric pressure	65 -106 kPa
Temperature	5 – 40°C
Humidity	15 – 95%, non-condensing

11.4 TRANSPORT & STORAGE

Atmospheric pressure	50 – 106 kPa
Temperature	-20 – 60°C
Humidity	10 – 95%, non-condensing

Shelf life	None. A normal expected pump (technical) use life is 5 years. The battery life degrades over time and might be subjected to earlier replacement. The expected service life of the battery is 2 to 5 years, depending on usage and number of charging cycles.

Note: Environmental conditions listed apply before and after the pump has been removed from the packaging.
Note: Time to recover from maximum and minimum storage temperature to operating temperature is ~30 min.

11.5 EMC

Electromagnetic emissions may affect the operation of any electronic medical device, including enteral feeding pumps.
The Flocare Infinity III will not be affected by electromagnetic emissions in most environments. However, some electromagnetic fields produced by personal communication equipment, household appliances, or occupational tools may cause electromagnetic interference (EMI) which can affect the pump's essential performance.
Possible sources of electromagnetic interference with electronic medical devices include, but are not limited to: cellular phones, cordless telephones, microwave ovens, anti-theft/security systems, blenders, and high-powered tools.
Check the pump regularly if operating near sources of electromagnetic emissions.
The Flocare Infinity III is designed in accordance with EN 60601-1-2, EN 60601-1-4 for electromagnetic emissions and immunity. (Refer to APPENDIX A: GUIDANCE AND MANUFACTURER'S DECLARATION–ELECTROMAGNETIC COMPATIBILITY in the eIFU). The use of other accessories, adaptors and cables than listed within this manual may result in increased emissions or decreased immunity of the equipment of the Flocare Infinity III pump.

11.6 VOLUMETRIC ACCURACY

Test Condition for measuring volumetric accuracy:

Fluid	Tap Water
Fluid level (head height)	152 mm ± 76mm, with respect to the centre of the pump rotor
Back Pressure	None
Temperature	Room Temperature [18ºC to 25 ºC]
Disposable set	Flocare Infinity giving set
Rate	100 mL/hr
Volume	100 mL

Reservoir	Open reservoir
Pump position	Installed on pole clamp
Feeding Tube	None
Head height impact	<1.5% per 152 mm
Back pressure impact	<0.5% per 6.9 kPa

11.7 ALARM RESPONSE TIMES

Maximum time to alarm (mm:ss)

Occlusion alarm						
Flow rate	1 mL/h	5 mL/h	50 mL/h	100 mL/h	300 mL/h	600 mL/h
Upstream	8:00	2:30	1:20	1:00	0:30	0:30
Downstream	55:00	11:00	2:00	1:00	0:30	0:30

Air alarm				
Flow rate	1 mL/h	20 mL/h	100 mL/h	600 mL/h
Air	120:00	6:00	1:20	0:30

12 GLOSSARY OF TERMS

BMET

Biomedical Equipment Technician

EMC

Electromagnetic compatibility

IFU

Instructions for Use

IP25 (example)

IP Code, International Protection Marking. IP rating determines how resistant something is to environmental elements. For a medical device, as per the IEC 60529 standard.

Occlusion

A blockage of the system preventing a flow causing a downstream pressure to increase or an upstream pressure to decrease, activating the pump occlusion out or occlusion in alarm.

PDMS

Patient Data Monitoring System

RF

Radio Frequency

Rotor

Black circular wheel, located on the pump. The Flocare Infinity giving set is attached around the rotor which then rotates to push fluid or nutrition along the Flocare Infinity giving set.

13 SYMBOLS


Manufacturer


Serial number


Caution


Type BF Shock protection



Mechanical and fluid ingress


Not for IV use


Battery


Input voltage


Do not use if package is damaged


Keep away from sunlight


Humidity storage / operating limit


Medical device


Manufacturing date


Catalogue number


Consult instructions for use


Consult accompanying documents


Class II equipment



CE mark and Notified Body identification number


Waste Electrical and Electronic Equipment

Direct current


Atmospheric pressure storage / operating limit


Fragile, handle with care


Keep dry


Temperature storage / operating limit


Unique Device Identification


Infrared sensor

14 WARRANTY

All service and repair activities should only be carried out by an approved service centre, authorised repair centre or a qualified Technician / BMET. The warranty is for a period of 36 months for customers from the date of delivery. Warranty includes the Flocare Infinity III pump, pole clamp, and AC power adapter. Warranty covers replacement, within the period for normal wear and tear and not from misuse.

Limitations on warranty

Warranty will be void if the product has been misused, tampered with or the performance specifications have been altered. Warranty will be void if the product is used outside of the recommendations contained with this instruction. Any repairs conducted by a non-authorised centre will void the warranty.

APPENDIX A GUIDANCE AND MANUFACTURER'S DECLARATION – ELECTROMAGNETIC COMPATIBILITY

Test	Limit	Electromagnetic environment - guidance
Conducted emission	CISPR 11, Group 1, Class B	Device uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment
Radiated emission	CISPR 11, Group 1, Class B	Device uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment
Harmonic current emissions (IEC 61000-3-2)	Class A	Device is suitable for direct connection to the public low-voltage power supply network
Test	**Compliance level**	**Electromagnetic environment - guidance**
Electrostatic Discharge (IEC 61000-4-2)	Contact Discharge: ±8 kV Air Discharge ±2 kV, ±4 kV, ±8 kV, ±15 kV	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 filed (IEC 61000-4-3)	80-2700 MHz; 1kHz AM 80 %; 10 V/m	Portable and mobile RF communications equipment should be used no closer to any part of the device, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = 1.2\sqrt{P}$ for 80 MHz to 800 MHz $d = 2.3\sqrt{P}$ for 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)

Proximity fields form RF wireless communications equipment (IEC 61000-4-3)	385 MHz; Pulse Modulation : 18 Hz; 27 V/m 450 MHz, FM + 5 Hz deviation: 1 kHz sine; 28 V/m 710, 745, 780 MHz; Pulse Modulation: 217 Hz; 9 V/m 810, 870, 930 MHz; Pulse Modulation: 18 Hz; 28 V/m 1720, 1845, 1970 MHz; Pulse ModulationPulse Modulation: 217 Hz; 28 V/m 2450 MHz; Pulse Modulation: 217 Hz; 28 V/m; 5240, 5500, 5785 MHz; Pulse Modulation: 217 Hz; 9 V/m	Portable and mobile RF communications equipment should be used no closer to any part of the device, including cables, than the recommended separation distance 30 cm
Electrical fast transients / bursts (IEC 61000-4-4)	Power lines: 2 kV; 100 kHz repetition frequency Signal lines: 1 kV; 100 kHz repetition frequency	Mains power quality should be that of a typical environment
Surges (IEC 61000-4-5)	L-N: 1kV at 0°,90°,180°,270°	Mains power quality should be that of a typical environment

Conducted disturbances inducted by RF fields (IEC 61000-4-6)	0.15-80 MHz; 1kHz AM 80 %; 3 Vrms, 6 Vrms in ISM and amateur radio band	Portable and mobile RF communications equipment should be used no closer to any part of the device, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter Recommended separation distance $d = 1.2\sqrt{P}$ for 150 kHz to 80MHz 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)
Rated power frequency magnetic fields (IEC 61000-4-8)	30 A/m, 50 Hz	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment
Voltage dips / Voltage interruptions (IEC 61000-4-11)	0 % UT for 0.5 cycle at 0°,45°,90°,135°, 180°,225°,270°,315° 0 % UT for 1 cycle at 0° 70 % UT for 25/30 cycles at 0° 0 % UT for 250/300 cycles 0°	Mains power quality should be that of a typical environment. If the user of the device requires continued operation during power mains interruptions, it is recommended that the device is powered from an uninterruptible power supply or battery.
Proximity magnetic fields (IEC 61000-4-39)	30 kHz; 8 A/m; CW 134 kHz; 65 A/m; PM:2,1 kHz 13,56 MHz; 7,5 A/m; PM: 50 kHz	RFID, WPT and similar equipment should be used no closer to any part of the device, including cables, than the recommended separation distance 15 cm