

Instructions for Use

Nutricia Flocare® Infinity™ III



| | | |
|--------|---|----|
| 1 | Introduction | 3 |
| 2 | Intended use | 3 |
| 3 | Safety information | 3 |
| 3.1 | General safety | 3 |
| 3.2 | Warnings, precautions and contra indications..... | 3 |
| 4 | Quick reference overview | 7 |
| 5 | User interface..... | 8 |
| 5.1 | Buttons..... | 8 |
| 5.1.1 | 🏠 Home button..... | 8 |
| 5.1.2 | ⌚ Snooze button..... | 8 |
| 5.1.3 | ℹ Information button | 8 |
| 5.1.4 | ▶ Start/pause button..... | 9 |
| 5.1.5 | ⌚ Fill set button..... | 9 |
| 5.1.6 | ⚙ Settings button | 9 |
| 5.1.7 | ☰ Therapy button..... | 9 |
| 5.1.8 | 🔌 On/Off button..... | 9 |
| 5.1.9 | Soft buttons | 9 |
| 5.2 | Pump status indicator | 9 |
| 5.3 | Display..... | 9 |
| 5.4 | Home screen..... | 10 |
| 5.4.1 | Status bar..... | 10 |
| 5.4.2 | Icons..... | 10 |
| 5.4.3 | Progress bar | 11 |
| 5.4.4 | Running indicator..... | 11 |
| 6 | Pump setup | 11 |
| 6.1 | Attaching to the pole clamp (optional) | 11 |
| 6.2 | Connect to the AC power plug | 11 |
| 6.3 | Switch the pump on | 11 |
| 6.4 | Set the language..... | 12 |
| 6.5 | Set the time and date..... | 12 |
| 6.6 | Switch the pump off..... | 12 |
| 7 | Operating Instructions..... | 12 |
| 7.1 | Load the Flocare Infinity giving set..... | 12 |
| 7.2 | Pause / running mode..... | 12 |
| 7.3 | Fill the Flocare Infinity giving set..... | 12 |
| 7.4 | Settings menu | 13 |
| 7.4.1 | Define therapy list..... | 13 |
| 7.4.2 | Personalised therapies..... | 13 |
| 7.4.3 | Therapy lock | 13 |
| 7.4.4 | Reset patient data..... | 13 |
| 7.4.5 | Sound | 13 |
| 7.4.6 | Display | 13 |
| 7.4.7 | Time and date..... | 14 |
| 7.4.8 | Language | 14 |
| 7.4.9 | Airplane mode | 14 |
| 7.4.10 | About this pump | 14 |
| 7.5 | Programming the pump | 14 |
| 7.5.1 | Program a VOLUME - RATE therapy | 14 |
| 7.5.2 | Program a RATE therapy (not recommended for volume sensitive patients)..... | 15 |
| 7.5.3 | Program an INTERMITTENT therapy..... | 15 |
| 7.5.4 | Change the parameters of an active therapy..... | 15 |
| 7.5.5 | Program a PERSONALISED THERAPY | 15 |
| 7.5.6 | Editing of a PERSONALISED THERAPY | 16 |
| 7.6 | Last feeding incomplete | 16 |

| | | |
|-----------|--|-----------|
| 7.7 | Information & memory functions | 16 |
| 7.7.1 | <i>Therapy information</i> | 16 |
| 7.7.2 | <i>Portions information</i> | 16 |
| 7.7.3 | <i>30-day history graph</i> | 16 |
| 7.7.4 | <i>Reset progress bar</i> | 16 |
| 7.8 | Keypad lock..... | 16 |
| 7.9 | Connect to a Nurse call or PDMS system..... | 17 |
| 7.10 | Battery | 17 |
| 8 | Advanced settings | 17 |
| 8.1 | Communications mode | 17 |
| 8.2 | Change PIN code | 17 |
| 8.3 | Factory reset..... | 18 |
| 9 | Alarms, warning messages and trouble shooting | 18 |
| 9.1 | Problem solver chart | 18 |
| 10 | Cleaning, inspection & servicing guidelines | 20 |
| 10.1 | Switching between patients..... | 20 |
| 10.2 | Cleaning & disinfection | 20 |
| 10.3 | Inspection | 21 |
| 10.3.1 | <i>Housing</i> | 21 |
| 10.3.2 | <i>Keypad</i> | 21 |
| 10.3.3 | <i>Rotor</i> | 21 |
| 10.3.4 | <i>AC power plug</i> | 21 |
| 10.3.5 | <i>Electrical</i> | 21 |
| 10.4 | Servicing..... | 22 |
| 10.5 | Repair..... | 22 |
| 10.6 | Spare parts..... | 22 |
| 10.7 | Accessories..... | 23 |
| 10.8 | Recycling & disposal | 23 |
| 11 | Specifications | 23 |
| 11.1 | Performance..... | 23 |
| 11.2 | Electrical / Mechanical..... | 23 |
| 11.3 | Operating | 24 |
| 11.4 | Storage | 24 |
| 11.5 | EMC | 24 |
| 11.6 | Volumetric accuracy | 24 |
| 11.7 | occlusion response times..... | 24 |
| 12 | Glossary of terms | 25 |
| 13 | Symbols | 25 |
| 14 | Warranty | 25 |

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.

The Flocare Infinity III pump provides better care while maintaining the accurate and safe performance you would expect. The Flocare Infinity III pump can provide individual tailored therapies for nutrition delivery.

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.

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.

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. It is recommended to follow the on-line training tool or get trained by an experienced and qualified trainer
- The Flocare Infinity III enteral feeding pump should only be used in combination with the appropriate Flocare® Infinity™ giving sets. The use of non-Flocare® Infinity™ giving sets will generate unforeseen hazards and will not provide the same 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 contains 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 Flocare Infinity III can be used for adult and paediatric patients, it is the responsibility of the healthcare giver to 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.

3.2 WARNINGS, PRECAUTIONS AND CONTRA INDICATIONS

General warnings / getting started

- Only use the Flocare Infinity III enteral feeding pump for delivery of enteral feeding solutions or hydration fluids. Do not use for intravenous administration.
- A leaking enteral feeding system might compromise the pumps 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, the Flocare Infinity giving set should be replaced.
- If the pump has been stored for any period of time, it should be plugged into the mains to recharge the battery before commencing enteral feeding. The battery will be completely charged after approximately 6 hours.
- 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.

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

- There are no cracks anywhere 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, perpendicularly in relation to the rotor and turn freely by hand.
- Verify the AC power socket pins are not bent or corroded.
- Verify that the AC power adapter incl. housing and cord is clean and not damaged.

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

Use of home brew tube feed / Powder based tube feed

- 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.
- Nutricia recommend using ready to feed tube nutrition as this is developed for the intended delivery specifications of the pump.
- 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.
- 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.

Technical & EMC

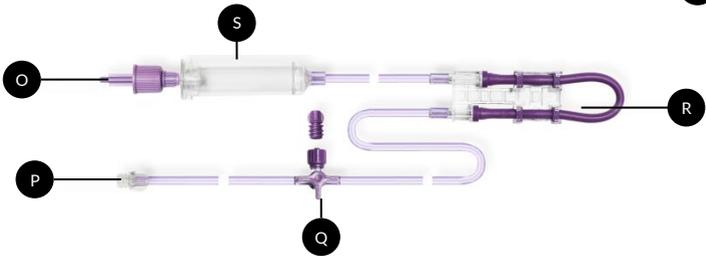
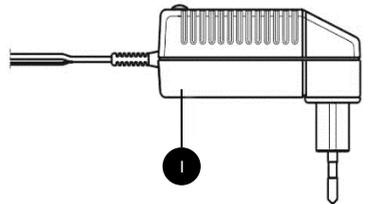
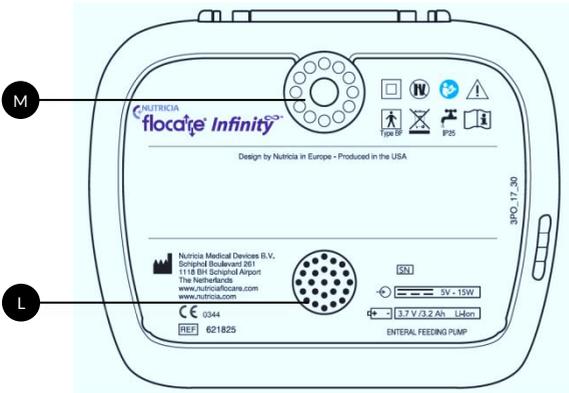
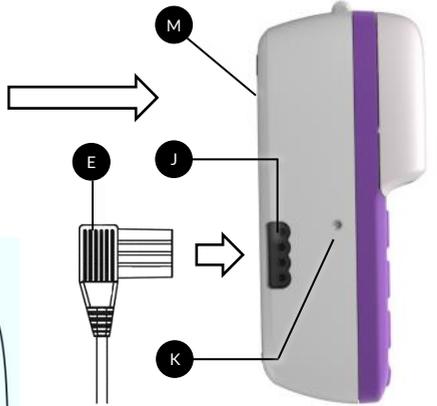
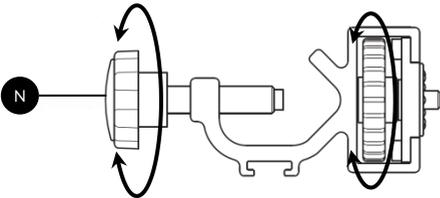
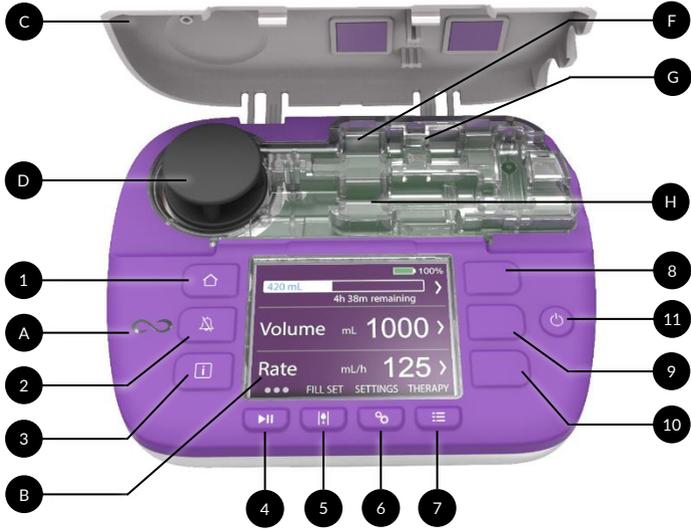
- The manufacturer recommends an inspection of the pump every 2 years by an authorised service centre or a trained and qualified technician.
- If a technical failure occurs or if the pump is dropped, the pump should be checked by an authorised service centre or a trained and qualified technician.
- Do 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.
- 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™ pump.
- 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.
- Portable and mobile RF communications equipment (cellular telephones) can affect medical electrical equipment.
- If the Flocare® Infinity™ pump is used adjacent to or stacked with other equipment, the pump should be observed to verify normal operation.

Alarm usage

- 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.

This page has been intentionally left blank

4 QUICK REFERENCE OVERVIEW



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

5 USER INTERFACE

5.1 BUTTONS

| | | | | | |
|----------|-----------------------|----------|-------------------|-----------|-----------------|
| 1 | 🏠 Home button | 5 | ⌘ Fill set button | 9 | SOFT button 2 |
| 2 | 🕒 Snooze button | 6 | ⚙ Settings button | 10 | SOFT button 3 |
| 3 | ℹ Information button | 7 | ☰ Therapy button | 11 | 🔌 ON/OFF button |
| 4 | ▶⏸ Start/pause button | 8 | SOFT button 1 | | |

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 Start/pause button

The START/PAUSE [] 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 SETTINGS [] 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 PERSONALISED 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 delivery 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

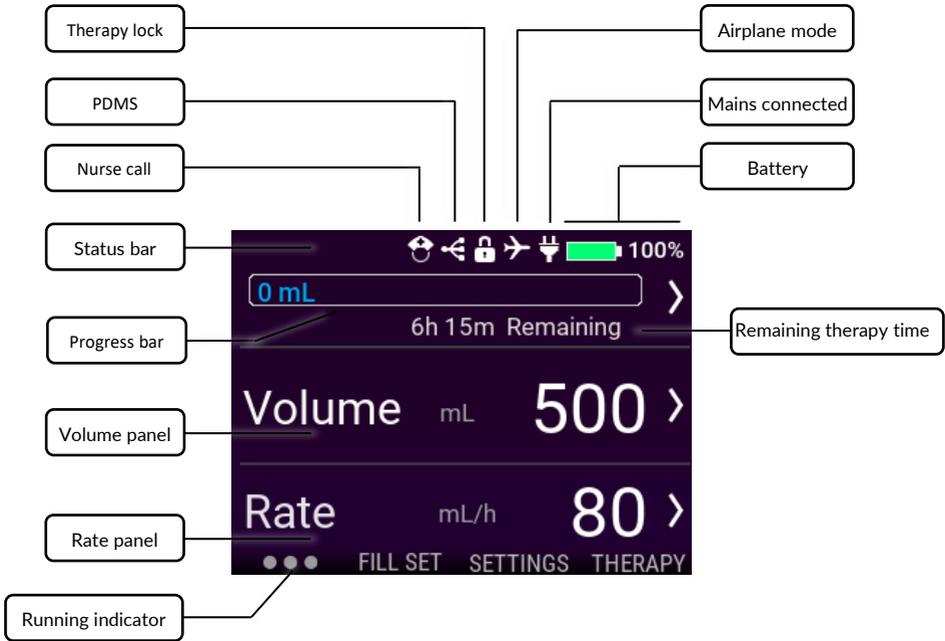
The Flocare Infinity III will perform a display test during each pump start. Carefully check for any sections or pixels that do not appear during the display test.

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 status bar location.

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 Airplane mode icon indicates that the pump has been set to flight mode and is safe to use in a commercial aircraft. (not available in first release)
- 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  138 mL

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  140 mL

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  125 0 0

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 [▶||] 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

Connect the AC power adapter 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 to be appeared 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 can be heard.

The pump will perform a self-test and inform the user when the device is ready to use, 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 7.6 'Last feeding incomplete' for more information.

6.4 SET THE LANGUAGE

Set the language by pressing the SETTINGS \odot 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 date and time by pressing the SETTINGS \odot button, navigate to TIME AND DATE and set these to your local time zone. The pump will not change to daylight 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 date and time setting.

6.6 SWITCH THE PUMP OFF

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

7 OPERATING INSTRUCTIONS

7.1 LOAD THE FLOCARE INFINITY GIVING SET

Follow the instructions for use on the packaging of the Flocare Infinity giving set, for setting up the enteral 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 seat the cassette into the pump
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 it is in running mode delivering a therapy to a patient. The pause or running modes are controlled by the START/PAUSE $\blacktriangleright||$ 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.

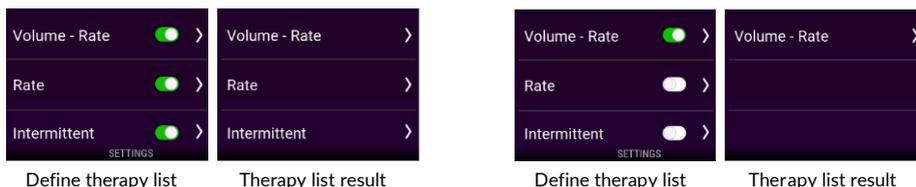
Note: when the FILL SET function is activated, all alarms are temporary deactivated helping avoid alarms being inadvertently triggered (e.g. air alarm).

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.

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



7.4.2 Personalised therapies

Personalise therapies provided 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 personalised therapy can be created, edited or erased.

Note: Personalised 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 will be automatically escalated to *High* in both settings '*Low*' and '*Medium*' after 3 min. This safety feature cannot be turned off.

The VOLUME DELIVERED ALARM is activated by default and the pump will generate an audio and visual warning. If it is not desired to be disturbed by the audio warning, the VOLUME DELIVERED ALARM can be switched OFF.

Caution: Disable the VOLUME DELIVERED alarm is not recommended so please consult your healthcare giver before doing so.

7.4.6 Display

The DISPLAY BRIGHTNESS can be set to a convenient level depending on the ambient conditions. Nutricia recommends 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 set to ON, the display will be dimmed after 2 min.

When AUTO DIMMING is set to 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 extend battery life.

7.4.7 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.

7.4.8 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 Infinity will guide you automatically through the language selection.

7.4.9 Airplane mode

Not in first release

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, last maintenance check date, PCB hardware revision, Software version, current Time and date settings and data communication mode.*

Note: a Nutricia help desk employee might ask for this information for support reasons.

7.5 PROGRAMMING THE PUMP

Caution: Before programming the pump, always be convinced 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 [▶||] 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 [▶||] 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 [▶||] 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 PERSONALISED THERAPY

The Flocare Infinity III provides the functionality to pre-program up to 3 personalised therapies and store them into the pump memory for later use. Programming a personalised therapy is considered as a pump setting rather

than a THERAPY itself. To program a personalised 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 PERSONALISED THERAPY

To EDIT or to DELETE a PERSONALISED 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 accessed 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 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 avoid 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 to support untrained users.

Note: the pump can still be turned OFF even when the keypad is locked.

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 (corporate code 35752) 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 (corporate code 35776) 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 first use, this will maximise the battery life time.

The battery microprocessor continuously monitors the battery state of health and the pump will warn the user when the battery is depleted for 70% or more and needs replacement.

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



Li-ion

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 can be accessed by following the below procedure:

- Make sure the pump is OFF.
- Press and hold SOFT BUTTON 1 and the ON/OFF button simultaneously until the advanced settings menu appears.

Caution: These settings are only intended to be set by qualified caregivers or qualified technicians.

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.

In Flight mode both PDMS and Nurse Call are disabled.

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.

9 ALARMS, WARNING MESSAGES AND TROUBLE SHOOTING

The Flocare Infinity III is equipped with several sensors and safety features linked to clear visual and audio alarms and warning messages on the display.

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 [ℹ️] can provide suggestions on the display to solve an alarm or warning condition.

Note: during an alarm or warning, all other buttons are disabled. The HOME [🏠] button is the only button that acknowledge and dismiss an alarm or warning message.

9.1 PROBLEM SOLVER CHART

In case any of the alarms listed on the problem solver chart 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.

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

| | | |
|----------------------|---|--|
| Occlusion out | The pump has detected an occlusion between the pump and the patient. The sensor area is dirty Recurring alarm | 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. 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. |
| Therapy completed | The pump has completed the delivery of the programmed therapy. | Press HOME [⏪] button if your therapy is completed. |
| Volume delivered | The therapy has reached its programmed target volume | Press the HOME [⏪] button to acknowledge the warning message. If your therapy is completed, turn the pump off. |
| 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. We recommend local cleanliness and hygiene policies are 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 dish washer.

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

Pump may be cleaned by rinsing with warm soapy water (standard washing up liquid) and a non-abrasive sponge, brush or soft cloth. Clean and remove any nutritional residue from the pump surface 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 where it meets the pump housing. Use a cotton swab to clean pathways of cassette insert and to remove any silicon residue from pump wheel roller pins. 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.

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 insert fully fixed in the rear housing surface 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 are not damaged, perpendicularly in relation to the rotor, free of dirt and turn 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 bare 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

Servicing activities are to be performed at an approved service centre or a Nutricia qualified Technician / BMET.

The pump does not require technical servicing under normal conditions of use in cases where proper cleaning and inspection protocols are adhered to, for a period of 2 years.

Servicing of the Flocare Infinity III includes replacement of: the door, rotor, battery, charger, back housing and label as well as cleaning/disinfection and an overall check on pump specifications and structural integrity.

In case there is a difference in performance characteristics, we recommend sending the pump back to an approved service centre or a qualified technician / BMET for inspection.

10.5 REPAIR

Repairs, re-calibration or component replacement(s) other than mentioned in chapter 10.4 'Servicing' shall be performed by authorised repair centres only.

Authorised repair centres:

Globally (outside of UK, Ireland, Greece and Italy)

Moog Medical Devices Group

UAB Viltechmeda

Mokslininku 6

LT-08412

Vilnius, Lithuania

Only for UK & Ireland

Hugo Technology Limited

4 Warwick Court

Saxon Business Park

Stroke Prior

Worcestershire

B60 4AD

United Kingdom

Only for Italy and Greece

Novaura Health Solutions S.r.l.

Via Ferri 6

20092

Cinisello Balsamo

Milan, Italy

10.6 SPARE PARTS

The following spare parts are available for the Flocare Infinity III. Please contact your local Nutricia sales representative for availability and ordering information of the respective parts.

- Door
- Back housing
- Battery
- Pump rotor
- Labelling: Back label sticker, Instruction for use (IFU), packaging
- AC power plug

Note: Use only Nutricia approved spare parts. Warranty and liability will void if other spare parts are used.

10.7 ACCESSORIES

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

- Carry bag
- Pump stand
- Nurse call & PDMS cable
- Pole clamp
- Various Flocare Infinity giving sets and feeding reservoirs

10.8 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 unit of the pumps 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 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 detection | > 1.5 mL of air in giving set after the pump set. |
| Upstream occlusion pressure | 84 kPa ± 21 kPa |
| Downstream occlusion pressure | -34 kPa ± 21 kPa |
| 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

| | |
|---------------------------------------|--|
| Pumping mechanism | Rotary peristaltic |
| Dimensions | TBD |
| Weight | TBD |
| Ingress protection (pump) | IP25 (washable under running tap water) |
| Ingress protection (AC power adapter) | IP21 (protection to condensation, wet cloth, only) |
| Battery | 3.7V, 3200 mAh, Lithium Ion |
| Charging | 100-240V, 50-60Hz |
| Air bubble detection | Ultrasonic |
| Upstream detection | Infrared |

Downstream detection
Display

Infrared
2.8" full colour, 640x480px, 175 degrees viewing angle

11.3 OPERATING

| | |
|----------------------|--------------------------|
| Atmospheric pressure | 70 – 106 kPa |
| Temperature | 5°- 40°C |
| Humidity | 15 – 90%, non-condensing |

11.4 STORAGE

| | |
|----------------------|--|
| Atmospheric pressure | 70 – 106 kPa |
| Temperature | 0°- 60°C |
| Humidity | 5 – 95%, non-condensing |
| Shelf life | None. A normal expect use life is 5 years. The battery life degrades over time and should be charged before any use. |

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.

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 (i.e. drills, saws, chain saws).

Check the pump regularly if operating near sources of electromagnetic emissions.

The Flocare Infinity III can safely be operated on commercial aircraft and is designed in accordance with EN 60601-1-2, EN 60601-1-4 and RT CA DO160D standards for electromagnetic emissions and immunity.

IEC60601 tables to be provided by MOOG.

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 [18°C to 25 °C] |
| 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 OCCLUSION RESPONSE TIMES

Occlusion response time at different flow rates table to be provided by MOOG.

12 GLOSSARY OF TERMS

BMET

Biomedical Equipment Technician

EMC

Electromagnetic compatibility

IFU

Instructions for Use

IP25

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 |  | Catalogue number |
|  | Serial number |  | Consult instructions for use |
|  | Caution |  | Consult accompanying documents |
|  | Type BF Shock protection |  | |
|  | Mechanical and fluid ingress |  | CE mark and Notified Body |
|  | Not for IV use |  | Waste Electrical and Electronic Equipment |
|  | Battery | | Direct current |
|  | Input voltage |  | Recyclable li-ion battery |
|  | Do not use if package is damaged |  | Fragile, handle with care |
|  | Keep away from sunlight |  | Keep dry |
|  | Humidity storage limit |  | Temperature storage limit |
|  | Atmospheric pressure storage limit | | |

14 WARRANTY

All service and repair activities should only be carried out by an approved service centre, authorised repair centre or a Nutricia qualified Technician / BMET. Any repairs conducted by a non-authorised centre will void the warranty.

The warranty is for a period of 24 months for customers from the date of delivery.

Warranty includes the Flocare Infinity III pump, pole clamp, and AC power plug

A Limited Warranty of 1 year is applied to the pump battery.

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 IFU.

Manufacturer information
Nutricia Medical Devices BV
Schiphol Boulevard 261
1118BH Schiphol Airport
The Netherlands
www.nutriciaflocare.com
www.nutricia.com

