NUTRICIA
flocare® Infinity™

INSTRUCTIONS FOR USE
For enteral use only
Read this manual before using the pump

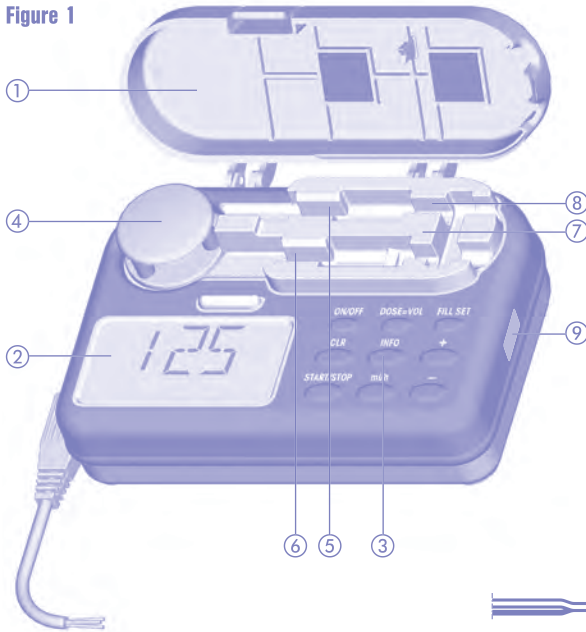**Figure 1**

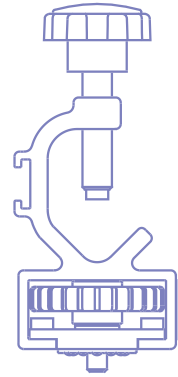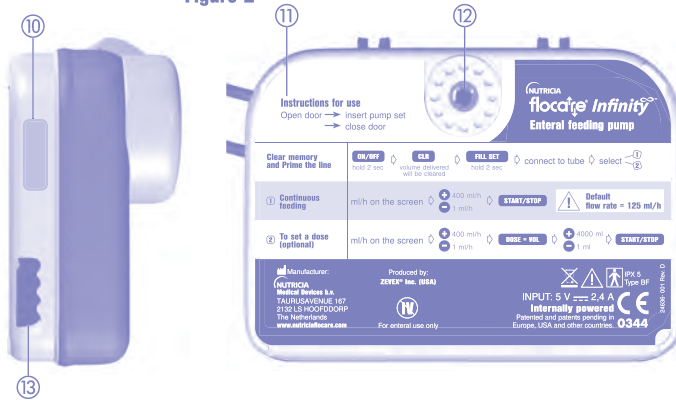ON/OFF   DOSE=VOL   FILL SET

CLR   INFO   +

START/STOP   ml/h   −

Figure 3

Figure 4

Figure 2

Instructions for use
Open door → insert pump set
→ close door

nutricia
flocare Infinity
Enteral feeding pump

Clear memory and Prime the line	ON/OFF hold 2 sec.	CLR volume delivered will be cleared	FILL SET hold 2 sec.	connect to tube	select ① ②
① Continuous feeding	ml/h on the screen	✚ 400 ml/h − 1 ml/h	START/STOP		Default flow rate = 125 ml/h
② To set a dose (optional)	ml/h on the screen	✚ 400 ml/h − 1 ml/h	DOSE = VOL	✚ 4000 ml − 1 ml	START/STOP

Manufacturer:
NUTRICIA
Medical Devices b.v.
TAURUSAVENUE 167
2132 LS HOOFDDORP
The Netherlands
www.nutriciaflocare.com

Produced by:
ZEVEX® Inc. (USA)

For enteral use only

INPUT: 5 V ⎓ 2,4 A
Internally powered
Patented and patents pending in
Europe, USA and other countries.

IPX 5
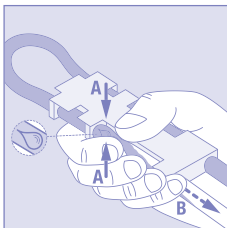Type BF

CE 0344
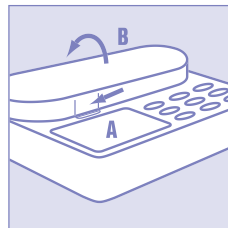
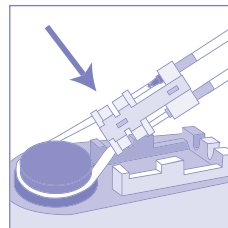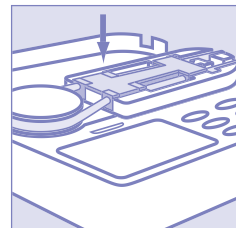**Figure 5a**

A
A
B

Figure 5b

B
A

Figure 5c

Figure 5d

INTRODUCTION

- The Flocare® Infinity™ is a small, lightweight, rotary peristaltic enteral feeding pump designed to deliver programmed doses of enteral nutrition solutions at selectable rates. The pump is intended for enteral use only for both portable and bedside use.

PREPARATION

- Check the integrity of the pump. Do not use the pump if it is damaged. If a technical failure occurs or if the pump is dropped, the pump should be checked by a qualified technician.
- Do not use the pump in areas where there is a risk of explosions e.g. in the presence of flammable anaesthetics.
- 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. The battery capacity is an approximation. If you are unsure that enough capacity remains for your intended use, recharge it.
- The Flocare® Infinity® pump should only be used in combination with the appropriate Flocare® Infinity® pump set to ensure proper fluid delivery ! (consult your local Nutricia sales representative for information on availbale pump sets).
- This pump operates in any orientation, making it ideal for ambulatory as well as bedside use.
- Check the position of the feeding tube, as advised by your healthcare professional, before commencing tube feeding.
- 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. Using the Infinity® pump's DOSE function is recommended in these cases (see section "To set a Dose").
- For bedside use, the multi-position pole clamp (figure 3) can be attached to the pump with the screw provided. The pump can be fixed in any position (rotatable in 360°).
- Where possible, we recommend using ready to feed tube nutrition as this is developed for the intended delivery specifications of the pump.
- If using any mixed or reconstituted powdered nutrition, we advise users to ensure the nutrition is prepared and dissolved properly to avoid particles or accumulation in the feeding set potentially hampering pump performance and a normal feeding regimen. Any nutrition added into the enteral feeding line must be of a homogeneous nature and should remain homogeneous during the feeding regimen.
- Also, 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 solution, allow it to sit for 10 to 15 minutes before pouring it into a feeding reservoir. This will reduce the chance of an alarm due to air in the tubing.

SERVICE AND WARRANTY

Service Life - Under normal conditions of use, including proper cleaning and inspection, if servicing recommendations and protocols are adhered to, the pump has an expected lifespan of minimum 5 years.
The manufacturer recommends an inspection of the pump at an authorised service centre every 2 years as indicated on the pump (indicator 9). Only authorised personnel should perform service work on Infinity® pumps. Please contact your local Sales Organisation / Nutricia Subsidiary for all service and repair of pumps (see address at the back of the booklet).

OPERATING INSTRUCTIONS

INSERTION OF THE FLOCARE® INFINITY™ PUMP SET

- Connect the set to the feed container as instructed on the packaging of the Flocare® Infinity™ pump set.
  Remove the dust cap from end of pump set.
- The Flocare® Infinity™ pump sets are equipped with an "automatic free-flow protection", as a consequence the set has no roller clamp.
  Fill the pump set completely with feed by gently pinching on the side of the cassette that is marked with a drop (point A on figure 5a) or fill the pump set with help of the pump (see paragraph: filling the pump set).
- Open the pump door by pressing up on the lower wall and rotating the door upwards at the same time (see figure 5b).
- Position the looped section of the silicone tubing around the rotor.
  Stretching lightly, (see figure 5c) seat the cassette into the pump (see figure 5d).
- Close the pump door.

SWITCHING "ON"

ON/OFF

For proper pump operation, make sure the pump door is closed prior to switching the pump on by holding the "ON/OFF" key for 2 seconds otherwise the pump will generate an error.

The pump beeps and carries out a short self test, showing the pump serial number in 8 digits. Verify that all display segments and symbols are active as shown in figure 6 (see next page).

The pump displays the total volume delivered since the memory was cleared and switches in the hold mode ready for programming.

SWITCHING "OFF"

ON/OFF

Press the "ON/OFF" key and keep it pressed for 2 seconds. A continuous alarm will be heard and the pump switches off.

The feeding program (installed parameters) and total volume administered since the last clearance will be retained in the pump's memory.

If the pump shuts down due to low battery voltage, the memory will be retained for 24 hours.

"HOLD" MODE

START/STOP

To temporarily pause the pump, or switch into "hold" mode whilst operating, press the "START/STOP" key once. Three beeps are heard and the run symbol disappears.

The programmed flow rate (ml/h), volume (DOSE=VOL) and the administered volume (ml) are retained.

The "hold" mode is used to temporarily stop the flow of feed:
• to change the feeding program (installed parameters),
• to change the feed container,
• to administer medication without switching the pump off,
• to silence an alarm and correct problems.

After 3 minutes a two tone audible alarm sounds and the message "PUSH STRT" appears in the display.

Press "START/STOP" to stop the alarm and to extend the hold mode by a further 3 minutes or press "START/STOP" twice (3 beeps will be heard) to resume programmed settings.

FILLING THE PUMP SET

ON/OFF
▽
FILL SET

The FILL SET function offered by the Infinity pump is used to fill a (new) feeding set with nutrition (or water as the case may be). When the FILL SET function runs all alarms are deactivated helping avoid alarms being inadvertently triggered (e.g. air alarm).

The FILL SET function should only be used to fill an empty (air-filled) feeding set. Use of the FILL SET function at any other time may cause the pump to incorrectly calibrate.

Ensure the feeding set is not connected to the patients feeding tube when the pump is in the hold mode:

Press and hold the "FILL SET" key for 2 seconds to activate the "FILL SET" maneuver. Release the button as soon as the pump generates a beep and starts pumping at a flow rate of approx. 700ml/h. During this maneuver the message "FILL SET" appears in the display. The pump will automatically stop when the Flocare® Pack Infinity™ pump set is completely filled with feed. However this "FILL SET" maneuver can at anytime be stopped by pushing the "FILL SET" key a second time. The pump will return to the hold mode when the "FILL SET" maneuver is complete or stopped.

DISPLAY

The pump has a liquid crystal display (L.C.D.) with large alphanumeric characters, smaller symbols, words and a back light. The following information can be found in the display:

• Flow rate (ml/h), volume (ml), is displayed through the large characters.
Words below describe what the number relates to (rate, dose or volume).
The pump also displays messages, for example "end of dose" will appear when the pump has finished delivering a single feed dose.

• The arcs around the run symbol rotate when the pump is running.

run

ml / hr

RATE DOSE VOLUME
FEED INTERVAL

E IIII F

Figure 6

• The remaining battery capacity (see paragraph: battery operation).
• The wall plug symbol indicates that the charger is plugged in.

The back light of the display turns off 10 seconds after the last key is pressed.
The back light will switch on for 10 seconds when the charger is connected to the mains.

PROGRAMMING THE PUMP

• The Flocare® Infinity™ pump can be used for continuous or dose feeding.
• Insert the pump set in the pump, switch the pump on and fill the pump set when necessary (see paragraph: filling the pump set).
• The display shows the total volume delivered since the pump was last cleared.
• If necessary clear the volume delivered by pressing the "CLR" key.
• The last installed flow rate (ml/h) is now displayed.
• The pump is now in the "hold" mode and is ready for programming.
• **We strongly recommend that for those patients where interruptions or delay in therapy could affect their health status, the DOSE setting of the Infinity pump must be used and programmed.**

CONTINUOUS FEEDING

ON/OFF ⇨ ml/h ⇨ ⊕ 400 ml/h ⊖ 1 ml/h ⇨ START/STOP

• Adjust the flow rate (ml/h) if required by using the "+" or "-" key. Hold either key down to change rapidly.
• If another parameter is indicated in the LCD, it will be necessary to first press the "ml/h" key followed by the "+" or "-" key to set the flow rate.
• The flow rate ranges from 1 - 400 ml/h in 1ml increments.
• The flow rate slows down and stops shortly at 50 - 125 - 250 ml/h.

- Press the "DOSE=VOL" key and make sure the value is put at 0 ml indicated by the word "CONT". This means the pump will run in a continuous mode.
- Start the pump by pressing "START/STOP".
- The arcs around the word "run" start rotating.
- The flow rate (ml/h) is displayed whilst functioning.

TO SET A DOSE

Ensure that the volume of nutrition in the container is greater than is actually needed, i.e. more than the set DOSE to be administered, so as to avoid excessive air bubbles getting in the feeding line.

ON/OFF ⇨ **ml/h** ⇨ ➕ *400 ml/h* ➖ *1 ml/h* ⇨ **DOSE=VOL** ⇨ ➕ *4000 ml* ➖ *1 ml* ⇨ **START/STOP**

the hold mode, with the last flow rate (ml/h) displayed in the LCD:
- Set the flow rate by pressing the "+" or "-" key.

If another parameter is displayed:
- Press first the "ml/h" key followed by "+" or "-" key to adjust the flow rate. The flow rate can be set between 1 and 400 ml/h, with increments of 1ml.
- Press the "DOSE=VOL" key and install the volume to be administered with the "+" and "-" key. The range goes from 1 - 4000 ml, with steps from 1ml.
- Start the pump by pressing "START/STOP".

During functioning the following parameters can be found in the display:
- By pressing the "ml/h" key the "flow rate" is displayed.

INFO • By pressing the "INFO" key the total volume since the memory was cleared will be visualized.

When the required volume or dose has been delivered, "END OF DOSE" will appear and the pump will beep (or mute, depending upon the pumps' configuration (see paragraph: set up mode).

TO CHANGE THE FEEDING PROGRAM DURING FUNCTIONING

- Press the "START/STOP" key to pause the pump.
- Change the program by pressing the required key (ml/h or DOSE=VOL) and adjust using the "+" or "-" keys.
- Restart the pump by pressing the "START/STOP" key again.

CLEARING THE MEMORY

All parameters and values can be cleared one after the other in the following way:
- Press "START/STOP" to pause the pump.
- Select the parameter that needs to be cleared.
- Press the "CLR" key to clear the memory. The parameter or value returns to its default value:
  ml/h = 0 ml/h
  VOL = cont = No dose set. Pump will feed continuously until feed container is empty or pump is stopped
  INFO = 0 ml = Volume delivered is cleared

In order to keep a clear overview of the daily amount of feed delivered, clear the total volume delivered as each daily feeding schedule is started, as follows:

START/STOP

⇩

CLR

- Switch the pump "ON"
- Immediately after the self-test the pump displays total volume delivered.
- Press the "CLR" key. The total volume delivered returns to "0 ml".
- The pump displays the previous programmed flow rate (ml/h).
- The pump is in the "HOLD" mode ready for programming.

- When another feeding program needs to be started, or the pump will be used for another patient, all settings (rate and dose) can be returned to default and the volume delivered can be set at zero by simply pressing the "CLR" key and keeping it pressed for 2 seconds.

BATTERY OPERATION

- The Flocare® Infinity™ pump is equipped with a Lithium-ion battery.
- The battery symbol in the display is automatically replaced by the plug symbol when the adapter is plugged in. The "fuel gauge" then indicates that the battery is charging by displaying the segments in an ascending low to high pattern starting with the leftmost segment.
  This pattern continuously repeats while the pump is charging.

- To check the status of the battery, disconnect the charger from the pump and turn the pump on. The bars between E and F (E=Empty, F=Full) represent the "fuel gauge" of the battery. Each bar is approximately 1/4 of a full battery charge. If 2 bars appear the battery is half full and remaining operating time is approximately 12 hours at a flow rate of 125 ml/h.

- In case of power failure the pump automatically switches to battery powered operation.
- When during functioning the last block is gone, the battery symbol will blink to indicate that there is approximately 1 hour of charge left. The display will flash "BATT" every 3 seconds, alternating with the active display and the pump will beep every 2 seconds to remind the user of the low battery charge condition. Plug in the charger to continue to run and recharge the battery.
- As the battery level decreases the pump may not be able to deliver tube feeds at rates greater than 300 ml/h, even though some battery capacity remains. The pump will alarm and indicate "BATT". If this happens, either recharge the battery or select a lower rate to complete the feed cycle.
- In case of battery failure, caused by, for example, an excessive temperature condition (which may resolve itself with time) or by a complete battery failure, the E, F and battery symbol will flash. Turn the pump "off" and contact your healthcare provider or refer the pump to service.

CONNECTION TO AN EXTERNAL ALARM SYSTEM

The power connector at the side of the pump offers the option of connecting the pump to an external alarm system or Patient Data Monitoring System (PDMS).
- The Flocare® Infinity™ Nurse Call (corporate code 35752) enables connection to an external alarm system. This external alarm system may be with open or closed contact. 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.

MAINTENANCE AND CLEANING

- For good pump operation, the pump should be kept clean and free of debris like (dried) tube nutrition. It is recommended to clean the pump with a wet cloth after every finished feeding regimen and specifically in between patient uses (if applicable).
- Detergent and disinfectant cleaning agents and wipes can damage plastic surfaces of medical devices when they are not compatible with the surface material. Damaged surfaces may compromise the ability to decontaminate medical devices adequately and / or may interfere with device function and affect their integrity and performance. Ensure cleaning solutions, detergents and

disinfectant wipes are compatible with the device. Look for signs of damage, cracking, colour changes, etc. to the medical device during and after the application. In case of doubt, contact your local (Nutricia) sales representative.

- Avoid harsh or agressive cleaners/ disinfectants such as acetone, benzene or iodine.
- Do not sterilize the pump by irradiation, EtO, steam or in an autoclave.
- Always unplug the pump prior to cleaning to avoid electric shock hazard.
- On a regular basis thoroughly clean all surfaces of the pump (including the sensors and rotor) with warm soapy water, a 5% bleach solution in water, a multipurpose disinfectant cleaner or a soft cloth.
- The Flocare® Infinity™ pump may be rinsed by holding under a stream of warm, clean water. Do not submerge the pump!
- Always maintain the rollers on the rotor in a clean state to ensure they spin freely.
- The adaptor normally does not require cleaning. When desired, a dry or slightly damp cloth may be used to clean the outside surface of the adaptor. Make sure the adaptor is disconnected from the wall outlet.
- Pump disposal: At the end of their service lifetime , the pump and its electrical accessories (AC Adapter Charger and Data Download Accessory Cable), should be disposed of 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.

WARNINGS AND CAUTIONS

- Strangulation hazard: avoid leaving power adapter cord, feeding set tubing or other choking hazards where infants or young children can become caught. If these objects get wrapped about one's neck, strangulation can occur.
- The manufacturer recommends an inspection of the pump at an authorised service centre every 2 years.
- If any fault occurs during use, or if the pump is dropped, it should be checked by authorised technical personnel prior to use.
- Replace the Flocare® Infinity™ pump set every 24 hours to maintain delivery accuracy and prevent the growth of harmful bacteria. Dispose of Flocare® Infinity™ disposable sets properly, as required by local law.
- 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 (e.g. the fill set function) for any other purpose than described in this manual, as this may cause the pump to incorrectly calibrate.
- No modification of this equipment is allowed.
- The AIR alarm should not be used to indicate an end of dose. NOTE: do not mute the audio alarm for end of dose alarm in these instances ('end of dose' will appear in the pump screen).
- Non-liquid food ingredients and mixed or reconstituted foods may have a tendency to occlude flow within the feeding tube and feeding set. They may also have the tendency to adhere to the tubing wall and obstruct the enteral feeding pump optical air-in-line sensor. Clinicians and caregivers should carefully monitor the pump during use with these type of feedings.
- The Flocare® Infinity™ pump delivers the dose within +/-5% volumetric accuracy under the following conditions:
    - utilizing Flocare Infinity disposable giving sets
    - fluid head height at +152 mm ± 76 mm with respect to center of rotor.

ALARM FUNCTIONS AND SAFETY FEATURES

In case any of the problems listed on the problem solver chart occur, the pump delivers an audible and visual alarm and stops working. The back light of the LCD automatically switches on.

Exception to this is the low battery alarm "BATT", in this situation the pump continues working.

Action in the event of an alarm:

Check the type of alarm displayed by the large display characters.

- Press the "START/STOP" key to stop the audible and visual alarm.
- Correct the cause of the alarm as described in the table.
- Start the pump again by pressing "START/STOP".

The problem solver chart gives a clear explanation of the alarms.

PROBLEM SOLVER CHART
Always follow the instructions below in case a problem occurs.
Using methods other than those described may cause the pump to function incorrectly.

Condition	Cause	Correction
NO SET	• The set is not fitted or wrongly fitted in the pump.	• Stop the alarm by pressing "START/STOP" • Insert the Flocare- Infinity- feeding set into the pump as indicated on the blister packaging (or refer to Fig 5a - 5d) and close the door. • Restart the pump.
	• The pressure sensor area is dirty (Fig 1, position 5 & 6)	• Clean the sensors, reinsert the feeding set in the pump and restart the pump.
PUSH STRT	• The pump has been untouched in hold mode for 3 minutes or more.	• Stop the alarm and prolong the hold mode with another 3 minutes by pressing "START/STOP" key. • Program the pump and start it by pressing the "START/STOP".
END OF DOSE	• The pump administered the installed dose = volume.	• The programmed dose/volume has been administered • Press start/stop to switch off the alarm • Press INFO and then CLR to reset the administered volume (to reset the flow rate and dose as well, press the CLR button for 3 seconds)
PROG	• No flow rate is installed. Flow rate = 0 ml/h	• Make sure the correct flow rate is programmed.
DOOR	• The door is not correctly closed.	• Make sure the door is properly closed prior to starting a feeding program.
AIR	• The pump detected air in the pump set.	• Make sure there is no excessive foam in the reservoir and ensure there is enough feed in the reservoir for the set therapy. • If the feeding reservoir is empty, replace the reservoir and continue feeding. If necessary, prime the set (FILL SET).
	• The air sensor area is dirty(Fig 1, position 8).	• Make sure the air sensor is clean.
	• The feeding set is not inserted correctly.	• Make sure the feeding set is properly inserted in the pump. (Fig 5a - 5d)
BATT **the pump** **remains working**	• The battery capacity is too low. The pump is not able to deliver highly viscous fluids at high flow rates with the present charge level of the battery.	• Connect the adaptor to the pump and mains and charge the pump for approx. 6 hours. During charging the pump can be used.
Battery, "E" and "F" **flashing**	• Battery failure.	• Turn the pump "off", contact your healthcare provider or refer the pump to service.
FILL SET	• The pump is priming the set.	• Press the "FILL SET" key another time to stop the pump and bring it back in the hold mode.
OCC IN	• The pump detected an upstream occlusion between the pump and the feeding bag.	• Stop the alarm by pressing the "START/STOP" key. • Remove the feeding set out of the pump and check the permeability by flushing the line. • Re-insert the feeding set in the pump and restart.
	• The pressure sensor area is dirty (Fig 1, position 5 & 6).	• Clean the sensors, reinsert the feeding set in the pump and restart the pump.
OCC OUT	• The pump detected a downstream occlusion between the pump and the patient.	• Stop the alarm by pressing the "START/STOP" key. • Remove the feeding set out of the pump and check the permeability by flushing the line. • Check the permeability of the feeding tube. • Re-insert the feeding set in the pump and restart.
	• The pressure sensor area is dirty (Fig 1, position 5 & 6).	• Clean the sensors, reinsert the feeding set in the pump and restart the pump.

Condition	Cause	Correction
OCC OUT (repeated)	• Calibration not yet completed on the current feeding set	• Stop the alarm by pressing the "START/STOP" key. • Start the pump by pressing the "START/STOP" key and let it run only briefly. • Stop the pump by pressing the "START/STOP" key insuring that there has been no occlusion out alarm. • Remove the feeding set from the pump and reinsert the feeding set in the pump. • Restart the pump by pressing the "START/STOP" key.
LOCK	• Only the current feeding schedule is allowed for this patient. Another feeding program is not allowed by your healthcare professional.	• The programming feature is blocked in the set up mode of the pump. Ask your healthcare professional to modify this setting.
ER01 - ER99	• The self test detected an electronic error	• Turn the pump "off", make sure the pump door is closed and switch the pump back "on". If the error persists, contact your healthcare provider or refer the pump to service.
ER40	• Keypad pressed or stuck during pump start up.	• Restart pump by ensuring keypad is not pressed.
No plug symbol visible, while the pump is connected to the mains.	• The wall outlet doesn't work. • The adaptor is damaged.	• Connect the pump to another wall outlet. • Contact your healthcare professional or Nutricia subsidiary to replace the adaptor.

SET UP MODE

The set up mode is used
- to set the alarm level,
- to lock the keypad,
- to switch the audible alarm off when a dose is administered,
- to switch the light of the LCD permanently on when connected to the mains,
- to enable connection with a Nurse call or Patient Data Monitoring System (PDMS).

This set up mode may only be entered by healthcare professionals and authorised personnel trained to use this application of the pump.

The patient or his/her relatives without permission of the physician, dietician, nurse or other licensed practitioner, may not change the settings of the set up mode.

TO SET THE ALARM LEVEL

ON/OFF 2 sec **&** **+** 2 sec ⇨ **+** Beep high **–** Beep low

Hold the '+' key down and press "ON/OFF" for 2 seconds. The pump enters the set up mode.

First the alarm level can be set:

"BEEP HIGH" (+) or "BEEP LOW" (-)

Use the "+" or "-" key to change the setting from "high" to "low" or from "low" to "high".

TO LOCK THE KEYPAD

FILL SET ➡ ⊕ Lock
⊖ Unlk

Hold the '+' key down and press "ON/OFF" for 2 seconds. The pump enters the set up mode. Press the "FILL SET" key to switch to the next setting:

"UNLK" the keypad (-) or "LOCK" the keypad (+). In the "LOCK" mode the feeding program of the pump can no longer be changed.

Use the "+" or "-" key to change the setting from "lock" to "unlk" or vice versa.

TO MUTE WHEN DOSE DONE

FILL SET ➡ ⊕ Beep when done
⊖ Mute when done

Hold the '+' key down and press "ON/OFF" for 2 seconds. The pump enters the set up mode. Press the "FILL SET" key to switch to the next setting:

"BEEP WHEN DONE" (+): the pump will give an alarm when the dose is administered or "MUTE WHEN DONE" (-): the pump will not give an alarm after administering the dose. Use the "+" or "-" key to change the setting from "beep when done" to "mute when done" or vice versa.

TO SWITCH LIGHT ON
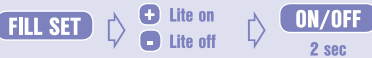
FILL SET ➡ ⊕ Lite on ➡ **ON/OFF**
⊖ Lite off 2 sec

Hold the '+' key down and press "ON/OFF" for 2 seconds. The pump enters the set up mode. Press the "FILL SET" key to switch to the next setting:

"LITE ON" (+) the light of the LCD remains on when the pump is connected to the mains. "LITE OFF" (-) the light of the LCD switches off after a few seconds even if connected to the mains. Use the "+" or "-" key to change the setting from "lite on" to "lite off" or vice versa.

TO CONNECT WITH NURSE CALL OR PDMS

FILL SET ➡ ⊕ OUTP PDMS ➡ **ON/OFF**
⊖ OUTP NRSE 2 sec

Hold the '+' key down and press "ON/OFF" for 2 seconds. The pump enters the set up mode. Press the "FILL SET" key to switch to the next setting:

"OUTP PDMS" (+) to connect with a Patient Data Monitoring System. "OUTP NRSE" to connect with a NURSE CALL system. Use the "+" or "-" key to change to setting from "OUTP PDMS", to "OUTP NRSE" or "OUTP OFF" and vice versa.

Press the "ON/OFF" key and hold it down for 2 seconds to exit the SET UP mode. The settings are automatically saved.

TECHNICAL SPECIFICATIONS

- This Flocare® Infinity® pump in combination with the adapter and the Flocare® Infinity® Nurse Call are designed to EN 60601-1-2, EN 61000-3-2, EN 61000-3-3, RTCA DO-160D standards for electromagnetic emissions and immunity and are in compliance with Directive 93/42/EEC.

    CE 0344

- IEC 601: Class II ☐ Medical Device Directive: Class IIa
- Microprocessor controlled
- Type BF Shock Protection (EN60601-1) degree of protection against electrical shock. No electrical connection to the patient. Drop from any height of 90cm shall not damage pump operation.
- Charger: ⊐ input 100-240V AC / 50-60 Hz / 0.4A Max.
    output 5 V DC 3 A
- Battery: internal rechargeable Lithium ion battery, 3.7 V DC 2500 mAh
- Battery capacity: 24 hours at 125 ml/h
- IPX 5: EN60529 degree of protection against water entering the enclosure. Water jets from any direction shall have no effect on the pump.
- Dimensions: 140 x 95 x 35 mm
- Weight: approx. 392 g
- Accuracy flow rate: ±5,0% with appropriate Flocare® Infinity® pump set

• Humidity:	Operation mode:	30% to 75% noncondensing
	Storage:	10% to 95 % noncondensing
• Temperature:	Operation mode:	+5°C to +40°C
	Storage and transportation:	-20°C to +65°C
• Atmospheric pressure:	Operation mode:	70-106 kPa
	Storage and transportation:	50-106 kPa
• Occlusion detection pressure:	Upstream occlusion:	-34 kPa (tolerance 21 kPa)
	Downstream occlusion:	83 kPa (tolerane 21 kPa)

- Air bubble detection: The amount of air, that must pass the air sensor before the air alarm is activated, varies from 0.5 to 1,5 ml which relates to an air bubble with an approximate length in the tubing of 9 - 26 cm.
- The Flocare® Infinity® can safely be operated on commercial aircraft.
- 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.
- In case of pump scrapping, always notify your Nutricia sales unit of the pumps serial number.
- At the end of their service lifetime, the pump and its electrical accessories (AC Adapter Charger and Data Download Accessory Cable), should be disposed of 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.

APPENDIX A: GUIDANCE AND MANUFACTURER'S DECLARATION - ELECTROMAGNETIC COMPATIBILITY

Electromagnetic emissions may affect the operation of any electronic medical de-vice, including enteral feeding pumps.

The Flocare® Infinity® Pump 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 telep-hones, microwave ovens, anti-theft/security systems, blenders, and high-powered tools (i e drills, saws, chain saws). If electromagnetic emitting devices are operated within one yard/meter of the Flocare® Infinity® Pump, the pump may automatically shut off and settings may return to their default values. Check the pump regularly if operating near sources of electromagnetic emissions.

The Flocare® Infinity® Pump 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.

Guidance and manufacturer's Declaration – Electromagnetic emissions		
The Flocare® Infinity® enteral feeding pump is intended for use in the electromagnetic environment specified below. The customer or the user of the Flocare® Infinity™ enteral feeding pump should assure that it is used in such an environment.		
Emissions test	Compliance	Electromagnetic environment – guidance
RF Emissions CISPR 11	Group 1	The Flocare® Infinity® 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.
RF Emissions CISPR 11	Class B	The Flocare® Infinity® is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ Flicker emissions IEC 61000-3-3	Complies	

Guidance and manufacturer's Declaration – Electromagnetic immunity			
The Flocare® Infinity® enteral feeding pump is intended for use in the electromagnetic environment specified below. The customer or the user of the Flocare® Infinity® enteral feeding pump should assure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
Electrostatic discharge (ESD) IEC 61000-4-2	± 8 kV contact ± 15 kV air	± 8 kV contact ± 15 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electric fast transient/burst IEC 61000-4-4	+/-2 kV @ PRR 100kHz for power supply lines ± 1 kV @ PRR 100kHz for input/ output lines	+/-2 kV @ PRR 100kHz for power supply lines ± 1 kV @ PRR 100kHz for input/ output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV line to line	± 1 kV line to line	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply lines. IEC 61000-4-11	70 % UT; 25/30 cycles single phase: at 0° 0 % UT; 1 cycle at 0° 0 % UT; 0,5 cycle at 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0 % UT; 250/300 cycle (5s)	70 % UT; 25/30 cycles single phase: at 0° 0 % UT; 1 cycle at 0° 0 % UT; 0,5 cycle at 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0 % UT; 250/300 cycle (5s)	Mains power quality should be that of a typical commercial or hospital environment. The Flocare® Infinity™ allows continued operation during power mains interruptions via the internal battery.

Guidance and manufacturer's Declaration – Electromagnetic immunity

The Flocare® Infinity® enteral feeding pump is intended for use in the electromagnetic environment specified below. The customer or the user of the Flocare® Infinity® enteral feeding pump should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in the typical commercial or hospital environment.

NOTE U_T is the a.c. mains voltage prior to application of the test level.

Recommended separation distances between portable and mobile RF communications equipment and the Flocare® Infinity™ enteral feeding pump

The Flocare® Infinity® enteral feeding pump is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Flocare® Infinity® can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Flocare® Infinity® as recommended below, according to the maximum output power of the communications equipment.

Rated Maximum output power of transmitter (W)	Separation distance according to frequency of transmitter (m)		
	150 KHz to 80 MHz $d = 1.2\sqrt{P}$	80 MHz to 800 MHz $d = 1.2\sqrt{P}$	800 MHz to 6 GHz $d = 2.3\sqrt{P}$
0,01	0.12	0.12	0.23
0,1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in Watts (W) according to the transmitter manufacturer.

NOTE 1   At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2   These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Guidance and manufacturer's Declaration – Electromagnetic immunity			
The Flocare® Infinity™ enteral feeding pump is intended for use in the electromagnetic environment specified below. The customer or the user of the Flocare® Infinity™ enteral feeding pump should assure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
			Portable and mobile RF communications equipment should be used no closer to any part of the Flocare® Infinity™, including cables, than the recommended separation distance calculated from the equation applicable toe the frequency of the transmitter: **Recommended separation distance**
Conducted RF IEC 61000-4-6	3 Vrms 150 KHz TO 80 MHz outside ISM and amateur radio bands 80% AM at 1 kHz	3 Vrms	$d = 1.2\sqrt{P}$ $d = 1.2\sqrt{P}$ 80 MHz to 800 MHz $d = 2.3\sqrt{P}$ 800 MHz to 6 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 metres (m).
Radiated RF IEC 61000-4-3	6 Vrms 150 kHz to 80 MHz in ISM and amateur radio bands 80% AM at 1 kHz	6 Vrms	Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[a] should be less than the compliance level in each frequency range.[b] Interference may occur in the vicinity of equipment marked with the following symbol:
Proximity fields from RF wireless communications equipment IEC 61000-4-3	10 V/m 80 MHz to 2.7 GHz 80% AM at 1 kHz 9 V/m to 28 V/m 15 specific frequencies up to 5,785 GHz	10 V/m 9 V/m to 28 V/m	
Radiated RF RTCA/DO-160E Section 20	75 V/m 100 MHz to 8 GHz	No Equipment Category specified (75 V/m)	
NOTE 1 At 80 Mhz and 800 MHz, the higher frequency range applies.			
NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			
a. Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measurement field strength in the location in which the Flocare® Infinity™ is used exceeds the applicable RF compliance level above, the Flocare® Infinity™ should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the Flocare® Infinity™.			
b. Over the frequency range 150 KHz to 80 MHz, field strengths should be less than 3 V/m.			