



To whom it may concern,

In France, Nutricia Limited has received a very small number of reports where patients who are using the Flocare® Infinity™ II pump have experienced an unexpected, unnoticed disruption during the delivery of their enteral nutrition. Your dietitian would like to reassure you there have been no such reports in the UK or Ireland, but we would like to share some useful information to be read in conjunction with the 28036_F, Instruction manual Flocare® UK Export, August 2019 & 28036_G, Instruction manual Flocare® Infinity™ UK Export, May 2021.

If you have any queries, please contact your managing Healthcare Professional.

Yours faithfully,

Nutricia Limited.

THE FOLLOWING INSTRUCTIONS SHOULD BE READ IN CONJUNCTION WITH 28036_F, Instruction manual Flocare® UK Export, August 2019 & 28036_G, Instruction manual Flocare® Infinity™ UK Export, May 2021
IN THE EVENT OF ANY CONFLICT BETWEEN THE 28036_F, Instruction manual Flocare UK Export, August 2019 & 28036_G, Instruction manual Flocare® Infinity™ UK Export, May 2021, THE INSTRUCTIONS IN THIS MANUAL SHOULD BE FOLLOWED.

1. Alarm Volume Level

If you are using your pump in a noisy environment or if a carer is not close to the pump, we would recommend you keep the volume level of the pump alarm on HIGH. Below are the details about how to set the alarm volume:



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".

Now switch the pump off and back on by pressing the on/off button and continue as usual.

2. Regular Monitoring

Everyone who receives an enteral tube feed using the Flocare® Infinity™ II pump should be regularly checked on and supervised (the managing dietitian can recommend how frequently checks should be made).

3. Mixed Feeding Regimens

If you are using a mixed or reconstituted enteral nutrition (i.e. not pre-prepared), the enteral feed must be given under supervision.

Please follow the advice below:

- Check the enteral feed is running normally and act on it if that is not the case
- Check the volume of feed in the container at regular intervals
- Always use the DOSE function – please see the picture guide enclosed
- Always be guided by your dietitian and contact them if you have any concerns.

It is important to keep the pump clean by following the instructions:

- To make sure the pump works properly, it must be kept clean and free of any debris like dried nutritional feed which may stop enteral nutrition flowing through the pump and giving set properly. The pump should be cleaned with a wet cloth after every enteral feeding session and especially between patient uses (if applicable)
- Always make sure the rollers on the rotor are clean so they can spin easily
- Carefully mix any enteral nutrition, making sure the powder has completely dissolved. This can result in foam and air bubbles forming; therefore, nutritional mixes should be allowed to sit for 10-15 minutes before use. This will help to reduce the chance of air in the giving set.

PRE-PROGRAMMING SET-UP (FOR PACK OR OPTRI BOTTLE)



1 Wash hands thoroughly, check feed and expiry date



2 Attach Flocare Infinity Pack giving set to prescribed feed (or water)



3 Screw tightly



4 Open door and insert giving set



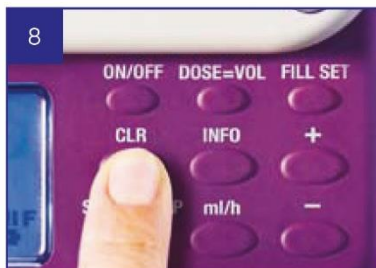
5 Close door (click)



6 Press and hold ON/OFF until beeps



7 Wait for VOLUME screen to be displayed (after calibration symbols)



8 Press CLR (short press)



9 Rate screen will be displayed, use +/- keys to programme rate

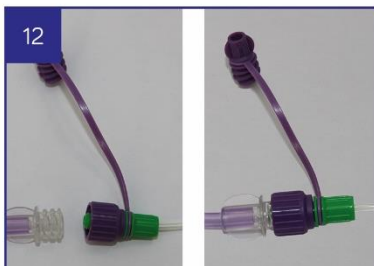
10 Programming a dose



Press DOSE=VOL, use +/- keys to programme dose



Press and hold FILL SET until beeps;
to stop fill cycle press FILL SET again.
DO NOT OVERFILL



Connect giving set
to feeding tube



Press START/STOP
(3 beeps)



The RUN symbol will rotate to
indicate that the pump is working

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 expected service life of the battery is 2 to 5 years, depending on usage and number of charging cycles. 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).

Limitations of warranty

Solely for the benefit of the original buyer/user, Nutricia Medical Devices B.V. warrants all new Flocare® Infinity™ pumps, of its manufacture to be free from defects in material and workmanship, excluding normal wear and tear, and will replace or repair, at its service facility or other location designated by Nutricia Medical Devices B.V., any Flocare® Infinity™ pump returned to it within thirty-six (36) months of original purchase by the buyer/user. Such repair or replacement shall be free of charge.

Nutricia Medical Devices B.V. warrants to the original buyer/user, all repaired or replaced pumps to be free from defects in material and workmanship and will replace or repair such products, at its service facility or other location designated by Nutricia Medical Devices B.V. Such repair or replacement shall carry a warranty of ninety (90) days from the date of repair or replacement or the balance of the new pumps warranty as described above, whichever is greater.

THIS WARRANTY APPLIES ONLY TO FLOCARE® INFINITY™ PUMPS MANUFACTURED BY NUTRICIA MEDICAL DEVICES B.V. AND IS THE ONLY WARRANTY GIVEN WITH RESPECT TO THE PUMPS. NO WARRANTIES IMPLIED IN LAW, INCLUDING, BUT NOT LIMITED TO THE IMPLIED WARRANTIES OF MERCHANTABILITY AND FITNESS FOR PARTICULAR PURPOSE, SHALL APPLY. NUTRICIA MEDICAL DEVICES B.V. WILL BE LIABLE, IN ANY EVENT, ONLY FOR THE PURCHASE PRICE OF THE DEFECTIVE PRODUCT, BUT NOT FOR ANY CONSEQUENTIAL DAMAGES.

This Warranty may not be modified, amended or otherwise changed, except by a written document properly executed by a corporate officer of Nutricia Medical Devices B.V.

THE WARRANTY IS VOID IF THE FLOCARE® INFINITY™ PUMP IS SUBJECT TO ABUSE, ACCIDENT, ALTERATION, MODIFICATION, TAMPERING, MISUSE OR THE UNAUTHORIZED REPAIR OR SERVICE IN ANY WAY WITHOUT PRIOR AUTHORIZATION FROM NUTRICIA MEDICAL DEVICES B.V. IN ANY EVENT, NUTRICIA MEDICAL DEVICES B.V.'S LIABILITY SHALL NEVER EXCEED THE ORIGINAL PURCHASE PRICE OF THE PUMP AND SHALL NOT EXTEND TO ANY CONSEQUENTIAL LOSS OR DAMAGE.

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.