B|BRAUN
SHARING EXPERTISE

Enteroport® plus

Instructions for use

en Software EPbb

CE 0123

Patient Safety

Attention: Consult accompanying documents! ⚠

Read instructions for use prior to use. Use the device only if regular instruction has been performed by specifically trained staff. For assistance in setting up, using, maintaining, to report unexpected operation or report events see contact informations on back page.

WARNING! Read instructions for use prior to use. Use the device only if regular instruction has been performed by specifically trained staff.

Operation

- Prior to use check audible and visual alarms during the self-test. Also check the device for possible damage.
- Connect the patient only after switching on the device. To prevent an incorrect dose from being delivered, the administration set must be disconnected when changing the patient tube system.
- Select administration set suitable for the pump and the intended medical application.
- Ensure the tubing is free of kinks to enable proper flow.
- Change disposables every 24h (observe national hygiene regulations).
- Compare displayed value with the entered value. Start pump only if values are consistent.
- Installation in rooms for medical purposes must be compliant with the appropriate regulations (e.g. VDE 0100, VDE 0107 or IEC publications). Observe national specifications and deviations.
- Operation of the device in explosive environments is not allowed.
- Air in line cannot be detected by the air detector if the air inlet occurs between the pump and patient connector (e.g. air inlet through the 3-way stopcocks, infusion ports and additional administration set components).
- Use only approved combinations of equipment, accessories, working parts and disposables.
- No modification of this equipment is allowed.
- It is recommended to use Enteroport® plus administration sets only.
- The use of unapproved or incompatible disposables may affect the technical data.
- In case of malfunction the selected flow rate and volume to be administered might present deviations.
- Additional drugs must only be administered via injection ports or directly via the feeding tube.
- Mains operation is permitted only with the mains adapter specified for this purpose.
- Only use the mains adapter included. The disconnection of the mains adapter from the device must be effortless and all pieces must be within reach of the patient for the seperation of the mains adapter from the device.
- Rollerclamp has to be closed in case of operation stop.
- To avoid strangulation hazards, cable and hoses should not wrapped around the body.
- **Any serious incident that has occurred in relation to this product should be reported to B. Braun and the competent authority of the country in which the product is operated.**
- In case of allergic reaction use an alternative device.

Safety Standards

- The Enteroport® plus satisfies all safety standards for medical electrical devices in terms of the IEC 60601-1 and IEC 60601-1-11.
- The EMC-limits (electro-magnetic compatibility) according to IEC 60601-1-2 are maintained. If the equipment is operated in the vicinity of other equipment which may cause high levels of interference (e.g. HF surgical equipment, nuclear spin tomography units, mobile telephones etc.) it may be disturbed (standstill with alarm may occur). Portable and mobile RF communications equipment can affect MEDICAL ELECTRICAL EQUIPMENT. For separation distances see chapter Technical Data (Electromagnetic Compatibility Guidance and Manufacturers Declaration Table 3).

Special Safety Instructions

Use of Enteroport® plus with sedated patients:

- For use with sedated patients, patients in a state of shock or in a state similar to shock, the following additional safety instructions have to be observed in addition to the general safety instructions:
- Fix substrate container at patient's level
- Feeding should take place via a percutaneous feeding tube, not via a nasogastric feeding tube
- Re-positioning system components during feeding leads to an increased risk of aspiration!
- Simultaneous therapy with drugs, influencing gastric emptying and peristalsis, also increases the risk of aspiration
- Disease-related gastric emptying disorders (e.g. gastroparesis with Diabetes Mellitus or pyloric stenosis)

The Enteroport® plus is not intended for use in neonatology.
The Enteroport® plus is not recommended to use in proximity to magnetic resonance imaging (MRI) equipment.

The essential performance is defined as follows:
The delivery of nutrition is performed either

- with the selected rate of 1 ... 400 ml/h ± 10%, or
- standstill with alarm (e.g. an error occurred).

Please add the sticker with short instructions for use in your language to the top of the pump housing (see chapter Overview).

Enteroport® plus

Content

The Enteroport® plus is an enteral nutrition pump, intended exclusively for enteral nutrition. The Enteroport® plus can be used in hospital care as well as in outpatient or home care.

The Enteroport® plus is easy to use and offers several modes of operation:

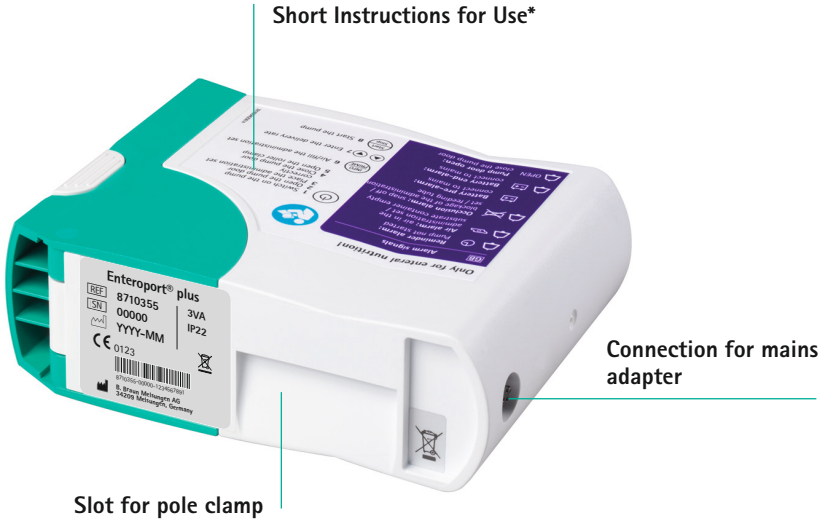
1. Continuous nutrition by selection of administration rate
2. Continuous nutrition by selection of volume / time
3. Intermittent Interval nutrition / bolus application

WARNING! The Enteroport® plus shall not be used
- for intravenous infusions
- if enteral nutrition is contraindicated
- in neonatology

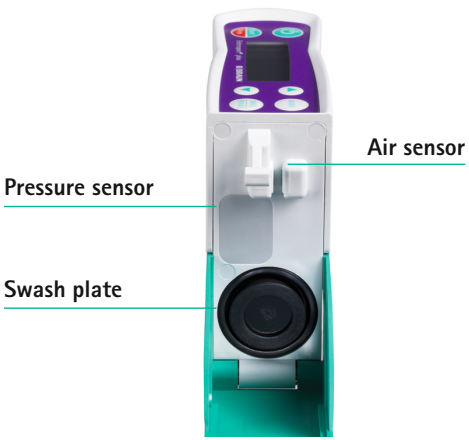
Even with pump-controlled nutrition, problems like diarrhea or a feeling of fullness may arise. The administration rate must be adapted to the individual patient needs. Frequent therapy monitoring is recommended.
The medical health care professional must decide if the administration of enteral nutrition via the Enteroport® plus pump is recommended for the specific patient.

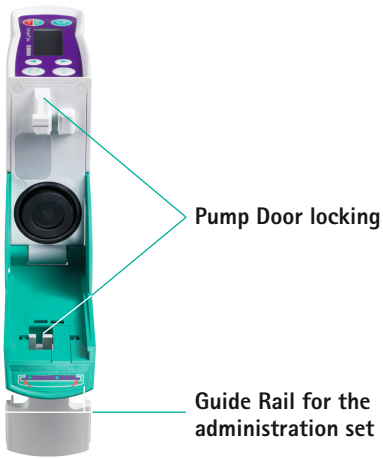
Further technical data and contraindications are described in these instruction for use.

Overview



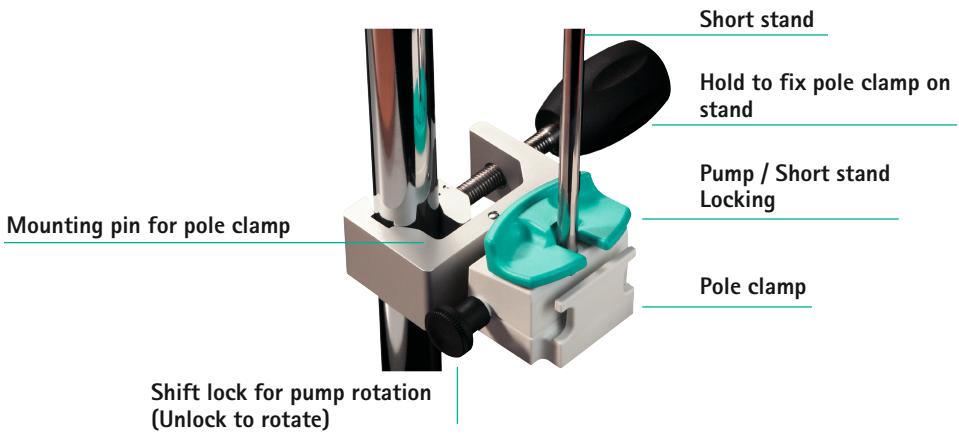
* Please add the sticker with short instructions for use in your language to the top of the pump housing.

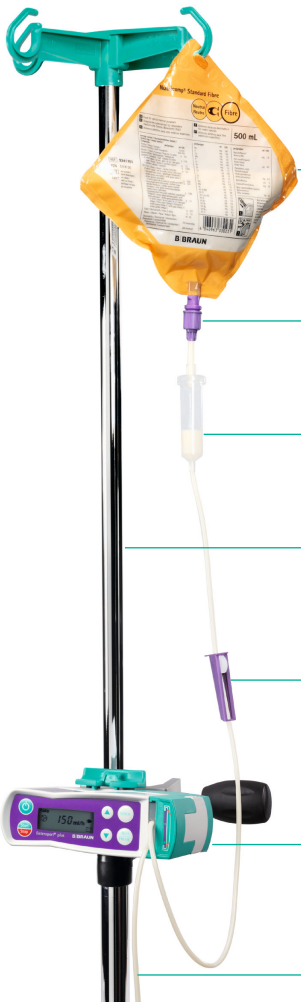




Pole clamp and short stand
The Enteroport® plus pole clamp can be installed vertically or horizontally on wall rail systems according to EN 12218 or vertical stands ø 16 mm – 40 mm (e.g. infusion stands).
The pole clamp can be rotated by 360° in steps of 90°. This will allow vertical and horizontal installation, e.g. on patients bed.

To fix the Enteroport® plus pump to the Pole Clamp, pull back the green short stand locking and slide the pump from above into the holder. The short stand locking will automatically snap in. Please verify that the pump is firmly fixed to the Pole Clamp.
If there is no appliance to hang the substrate up, a short stand can be used with the pole clamp.





Enteral Nutrition bag

Connection between Enteroport® plus administration Set and Enteral Nutrition bag

Enteroport® plus administration Set

Infusion Stand

Roller Clamp

Enteroport® plus Pump

Towards patient (applied part) – Enteroport® plus administration set has to be connected to enteral feeding tube

Operation

Button	Operation	Functions
 ON/OFF	ON: Press button	Pump is switched on; Wait for self-test and check display during self-test.
	OFF: Press button for 2 seconds	Pump is switched off.
	START: Press the START/STOP button briefly	Flow will be started
	STOP: Press the START/STOP button briefly	Flow will be stopped
	Press the MODE button to start the programming of the administration parameters.	For detailed information see chapter Operation: Volume/ Time mode" and „Operation: Bolus application mode"
	INFO: Press the INFO/PRIME button briefly to display administration parameters, battery charging status or remaining battery time.	INFO/PRIME If pump is switched off: Battery charge status is displayed. If pump is switched on and flow is started: Delivered volume is displayed; If button is pressed a second time: Delivery time is displayed; If button is pressed again: Remaining battery operation time is displayed. The display disappears automatically after 5 seconds.
	PRIME: Press button for about 5 seconds	Button INFO/PRIME can also be used to vent the administration set after pump is switched on and parameter set up has been completed. By pressing the INFO/PRIME button for approx. 5 sec. the administration set will be filled with substrate (max. 15 ml) at maximum administration rate. By releasing the INFO/PRIME button, the pump will stop. It is recommended to release the INFO/PRIME button when administration set is completely filled. - During priming, all operational alarms are switched off.
	By activating the ARROW UP and ARROW DOWN buttons, parameters can be adjusted to the desired values.	Can be used to increase administration parameters. Can be used to decrease administration parameters

Symbols

Display Symbol	Operation	Functions
	The Wheel symbol indicates whether the pump is delivering or not.	**Wheel rotates:** Pump is delivering fluid **Wheel stopped:** Pump has stopped
ml/h	Administration rate	Rate unit of the delivery protocol; Rate entry
ml	Volume	Volume unit of the delivery protocol; Volume entry
h	Time	Time unit of the delivery time and remaining battery operation time; Entry of the delivery time
BOL	Bolus	The symbol BOL indicates the interval feeding operational mode (bolus application)
ml/h BOL	Rate/Bolus	The symbol ml/ h followed by BOL indicates the bolus administration rate based on the interval feeding operational mode
ml BOL	Volume/Bolus	The symbol ml followed by BOL indicates the bolus volume to be delivered based on the interval feeding operational mode
h BOL	Cycle time/Bolus	The symbol h followed by BOL indicates the delivery time including the off time based on the interval feeding operational mode
	Bell	The bell symbol indicates an acoustic alarm
	Battery	The battery symbol indicates that the pump is working with battery and it is not connected to the mains power
	Connector	The connector symbol indicates mains operation

Product Symbol	Operation	Functions
	Classification	Defibrillation-proof Type CF Applied Part
	Protective Class	Class II Equipment
		See instructions for use
		Mandatory action: see instruction for use
		Temperature Limit
		Moisture Limit
		Limitation of the atmospheric pressure
		WARNING! Danger for people. Non-compliance could lead to death or serious injuries
LOT		Batch code
SN		Serial number
		Manufacturer
		Date of manufacture
		Labeling of electric and electronic devices according to directive 2002/96/EC (WEEE)
CE 0123		CE marking
		Keep dry
		Only for indoor use
		Direct Current (DC)
MD		Medical device

Loading Enteroport® plus administration set

All Enteroport® plus administration sets have an integrated support plate (cassette) on which the tubing system is already fixed in the loading position.

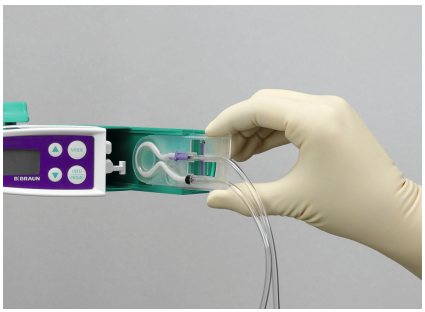
1. Switch on the Enteroport® plus with the ⏻-button and wait for self-test.

! Self-test:

Prior to the self-test, the software version (EPBB) will be displayed when the Enteroport® plus is switched on. While performing the self-test, all symbols will appear and the digital sequence 11:11, 22:22, 55: 55.
We recommend the user to check during the self-test if there is any defect on the display. All functions of the Enteroport® plus will be tested during the self-test.
The functionality of the audible alarm system will be confirmed by an acoustic signal while switching on the Enteroport® plus pump. After the self-test, the alarm level will be displayed (AL1 or AL2 .

2. Open pump door with usage of the white locking.

3. Slide the cassette of the administration set into the pump door track, check for correct fitting



4. Close the door, close pump door mechanism – it has to engage audibly. Do not force the door closed.

After loading the Enteroport® plus administration set and closing the pump door, the pump starts automatically activating all safety and control functions. This action is indicated on the display by the wheel sign rotating. After the process is completed, the pump can be started according to the (short) instructions for use.

WARNING! Operating alarms immediately stop the infusion. An audible tone sounds and the reason for the alarm is displayed. The recommended action is descriped in chapter „Alarm signals".

Venting the Enteroport® plus administration set

Before the actual flow starts, the administration set can be filled quickly, safely and under control by using the PRIME-function of the Enteroport® plus pump.

This is done by opening the roller clamp and pressing the (auto prime)-button for 5 seconds. The pump runs at maximum rate for the duration that the button is pressed, up to a maximum volume of 15 ml. The PRIME-function stops automatically after reaching the maximum volume. The PRIME-function is supported by an audible signal.

NOTE:
If the Enteroport® plus administration set is vented by gravity prior loading it into the pump, the administration set must be pre-filled up to 2-3 cm before the distal cone/Luer-Lock connector. This is necessary due to the automatic start of the pump and the related short-term delivery. The administration set must be changed every 24 h due to performance reasons.

Operation modes

The Enteroport® plus is delivered in "continuous" administration mode by selection of "rate" as pre-selected operation mode.
Other operation modes, which can be chosen by pressing the MODE button, are:

- Continuous administration mode by selection of Volume/Time
- Intermittent Interval Administration/Bolus application.
- Continuous administration mode by selection of rate

After the Enteroport® plus is switched on with the ON/OFF button and the self-test is successfully completed, the administration set has to be loaded and vented accordingly.

By using the (▲)- and (▼)-buttons, the intended rate can be selected in the range of 1-400 ml/h in variable increments of 1 ml/h. The flow rate can be increased/decreased by continuously pressing the (▲)- and (▼)-buttons.

After the rate has been entered, the administration can be started by pressing the (start stop)-button.

The administration can be stopped by pressing the (start stop)-button.

The pump is switched off by pressing the (⏻)-button for approx. 2 seconds.

Configuration mode

MODE ⏻	Configuration mode	To start the configuration mode the pump must be switched off! Simultaneously press MODE and ON/OFF buttons (in the sequence MODE, ON/OFF) for at least 2 seconds	The configuration mode enables the selection of alarm level, data lock and operation mode.
▲ ▼	Alarm level selection	Select alarm level by using the arrow up/arrow down buttons	AL1: All alarms are activated AL2: • Stand-by alarm inactive • Battery low alarm via staff call and display only, not audible • Volume-end alarm is inactive, instead of an audible alarm operation is continued with Keep Open Rate (KOR) (5ml/h). • Alarmvolume LO1..2 • Airvolume 2..25ml
▲ ▼ MODE	Activate/ Inactivate Data lock	Press the MODE button, then activate the desired data lock level by using the arrow up/arrow down buttons	OPEN: All operating parameters can be changed any time. SAFE: Operating Parameters can be changed only once, until the next start of the pump. Further changes can be made only after activating "OPEN" in configuration mode.
MODE	Data lock selection	After choosing the data lock level, press the MODE button twice to lock data selection	Provides safety against unintentional change of delivery parameters.

	Operation mode selection	Press MODE button to activate **Rate selection** - Rate selection ([RATE] flashes)	Select administration mode by using UP/DOWN buttons. The select operation mode will be descript with "ON" at the pump display The status of the operation mode can only be changed from OFF to ON, not the other way around. The activation of one operation mode results in the deactivation of all other operations modes.
	Operation mode selection	Press MODE button to activate **Volume/Timeselection** - Volume/Time selection ([RATE], [VOL], flash)	
	Operation mode selection	Press MODE button to activate **Bolus application** - Bolus application ([BOL] flashes)	
	Alarm level adjustment	Press the MODE button to activate alarm level adjustment, select alarm level by using UP/DOWN button	The loudness of the alarm level is adjustable in 2 steps: Level "L01" Level "L02"
	Air alarm volume	Press the MODE button to activate Air alarm volume adjustment, select level of air volume by using UP/ DOWN button	The air alarm volume is adjustable from 2-25 ml
	Exit configuration mode	Press ON/OFF button for at least 2 seconds	Pump is switched off

Operation: Volume/Time mode

Continuous nutrition by selection of Volume / Time

After the Enteroport® plus is switched on with the ⏻-button and the self-test is successfully completed, the administration set has to be loaded and vented accordingly.

The symbols RATE and 🕒 flash, VOL will be shown on the top of the display to request entry of the volume.

By using the ▲- and ▼-buttons, the flow volume required can be entered in the range of 1 – 5,000 ml in variable increments of 1 ml (in the range of 1- 49 ml) or 50 ml (in the range of 50 – 5,000 ml).

The time definition can be activated by using the MODE -button. The VOL symbol will then disappear, RATE symbol will flash and the 🕒 symbol will be shown continuously in the top line of the display to request entry of the flow time.

The time can be selected in the range of 15 min – 24 h by using the ▲- and ▼-buttons, variable in 15 min intervals.

The selection of volume and time can be adjusted by continuously pressing the ▲- and ▼-buttons.

By pressing the MODE-button again, the 🕒 symbol disappears and RATE symbol appears continuously. The calculated rate is displayed.

The pump can be started up by pressing the Start/Stop -button.

NOTE:
The programmed parameters will be validated by the pump. Therefore, it may happen that certain volume/time combinations are not possible i.e. not within the upper/lower limits. This is shown by a short audible signal. If larger or smaller volumes/times are desired, it is necessary to adjust the different parameters by scrolling through the list of parameters in the display and adjusting the values for the volume and time accordingly.

To start the pump, at least two parameters must be defined, i.e. the volume and one additional parameter (the third parameter is calculated automatically). The third parameter must be validated/viewed by pressing the MODE-button. If the entry is incomplete, a short audible signal will sound.

If the rate is changed after the volume and time have been entered, the flow time will be adjusted automatically. The 🕒-symbol will flash in the top display line. The volume is kept constant by the pump. The time parameter must be checked/validated again (MODE-button) to check for plausibility before the pump can be started up with the Start/Stop -button.

Within the operation mode Volume/Time selection, a "Keep Open Rate" (KOR) of 5 ml/h is integrated. The administration rate will be automatically adjusted to the KOR at the end of the volume to be infused until the pump is switched off. This enables feeding during the night without the necessity of flushing the administration set/feeding tube after application (this step can be done later during the following morning, so there is no need to wake up the patient).

Operation: Bolus application mode

Intermittent interval nutrition
(bolus application)

After the Enteroport® plus is switched on with the ⏻-button, the self-test is successfully completed and the administration set has been loaded and vented accordingly the symbols 🕒 and VOL will flash in the top line of the display. The RATE and BOL symbols appear continuously to request entry of the bolus rate.

By using the ▲- and ▼-buttons, the bolus rate can be selected in the range of 1 – 400 ml/h variable in increments of 1 ml/h. Selection of the bolus rate can be adjusted by contin-uously pressing the ▲- and ▼-buttons.

The bolus volume definition can be selected by pressing the MODE-button. The RATE symbol disappears, the 🕒 symbol flashes and the VOL and BOL symbols appear continuously to request the entry of the bolus volume.

By using the ▲- and ▼-buttons, the bolus volume required can be set up in the range of 1 – 1,000 ml in variable increments of 1 ml (in the range of 1 – 49 ml) or 50 ml (in the range of 50 – 1,000 ml).

The bolus time entry is called up by pressing the MODE-key once. The VOL symbol disappears, BOL and the 🕒 symbol appear continuously to request the entry of the bolus time. The pump software calculates the bolus time limits always with a 15 min minimum off time. If necessary, the bolus time will be adjusted automatically.

The cycle time can be selected in the range of 30 min – 24 h with the ▲- and ▼-buttons, variable in 15 min intervals. If necessary, the bolus time will be adjusted automatically.

The cycle time can be selected in the range of 30 min – 24 h with the ▲- and ▼-buttons variable in 15 min intervals.

Pressing the Start/Stop -button starts the pump.

NOTE:
To start the pump, all parameters must be selected. As long as a parameter is not selected or validated, the parameters symbol flashes. During the off time, a Keep Open Rate (KOR) of 5ml/h is activated to prevent possible blockage of the administration set or feeding tube. The individual bolus delivery setting operates continuously until either the substrate container is empty, or until the flow is ended by pressing the Start/Stop button.

EXAMPLE:
Bolus rate = 200 ml/h
Bolus volume = 400 ml

$$\text{ApplicationTime} = \frac{\text{BolusVolume}}{\text{BolusRate}} = 2\text{h}$$

A minimum cycle of 2 h and 15 min will be calculated by the pump, which is equivalent to an application time of 2 hours plus 15 min off time.

The default value for the "off time" can be adjusted by activating the ▲- and ▼-buttons.

If a cycle time of 5 h is set up in this example, the application time would be 2 h and the off time 3 h. This means that the pump would administer the solution for 2 h with an infusion rate of 200 ml/h, and after these 2 hours the infusion rate would be decreased to 5 ml/h (KOR mode).

Alarm signals

1. Supported optical signals

The alarm signals are visualized on the LCD display in the front of Enteroport® plus device.

Name	Symbol	Name	Symbol
Alarm symbol (Bell)		Air symbol	
Pressure symbol		Battery symbol	
Mains symbol		Value display	
Unit display	ml/h	Rotating wheel	
Bolus symbol	Bol	Clock symbol	
Volume symbol	Vol	Rate symbol	Rate

2. Alarm signal

All alarm conditions are technical, there are no physiological alarm conditions.

2.1. Device Alarms

When a device alarm occurs the infusion and battery charging is immediately stopped and display indicates the Bell-Symbol with a code number and a audible alarm (Periodic buzzer activation, 1sec on, 5sec off) is given. First, close the roller clamp for precaution reasons. Secondly, press the ON/OFF button to switch off the device. Then switch the device on again. In the case of a repeated device alarm the pump must be sent for service.

NOTE: The symbols will flash if nothing else is displayed. The intensity of the audible alarm signals will increase automatically after 25 sec. All alarms can be confirmed by pressing any button, except from the ⏻-button.

2.2. Operational Alarms

2.2.1. Pre-alarms

Pre-alarms occur a few minutes prior to operating alarms. During pre-alarms an audible tone sounds, a staff call is activated (optional) and the reason for the alarm is displayed. Pre-alarms do not stop the infusion.

Alarm Condition	Alarm reason/ recommended action	Alarm level	Optical alarm symbol	Audible alarm tone
Battery pre-alarm	The battery is almost discharged. Plug in power supply to recharge the battery.	AL1	Bell and Battery	Periodic buzzer activation (1sec on, 9sec off)
		AL2		No alarm

2.2.2. Operating alarms

Operating alarms immediately stop the infusion. An audible tone sounds, and the reason for the alarm is displayed. The alarm tone and message are turned off with any button. Recommended action depends on the reason of the alarm.

Alarm Condition	Alarm reason / recommended action	Alarm level	Optical alarm symbol	Audible alarm tone
Standby Alarm	Pump is switched on and not started. Start pump or switch off.	AL1	Bell and Clock	Periodic buzzer activation (1sec on, 5sec off)
		AL2	No alarm	
Battery empty alarm	The battery is discharged. The battery alarm will be on for 3 min. Then the pump will automatically turn off. Immediatly plug in power supply to recharge the battery.	AL1 AL2	Bell and Battery	Periodic buzzer activation (1sec on, 5sec off)
VTBD alarm	The programmed volume was infused. Start new infusion or switch of pump.	AL1	Bell and "VOL"	Periodic buzzer activation (1sec on, 5sec off)
		AL2	No alarm	
Open door alarm	The pump door is opened during delivery. Close roller clamp and check door.	AL1 AL2	Bell and "OPEN"	Periodic buzzer activation (1sec on, 5sec off)
Air alarm	The accumulated air volumes exeeds the limits. Check tubing and reservoir.	AL1 AL2	Bell and Air	Periodic buzzer activation (1sec on, 5sec off)
Pressure alarm	The pressure level was exceeded. Check administration set.	AL1 AL2	Bell and Pressure	Periodic buzzer activation (1sec on, 5sec off)

2.3. Information signals

When operating the device additional acoustic hint signals are given.

No.	Condition	Description	Optical symbol	Audible tone
1	Prime signal	Audible feedback that a prime is active	Rotating wheel	Periodic buzzer activation (0,5sec on, 2sec off)
2	Self-test signal	Self test of the audible alarm system.	Software version number	Buzzer activation (0,25sec on, 0,5sec off) for 3 times with lowest loudness level.
3	Action not allowed	Illegal attempt to adjust the parameters of a secured pump.	"SAFE"	Buzzer activation for 50ms
4	Action not allowed	Limit of the parameter adjustment reached.	---	
5	Button click signal	Audible feedback for pressed button	---	Short buzzer pulse

2.4. Alarm level

The alarm loudness is adjustable in 2 levels, LO1 45..60dB(A) or LO2 60..75dB(A). The real alarm loudness depends on the environmental conditions.

Power supply

Power supply

The Enteroport® plus nutrition pump can be operated from the mains supply as well as independently from the mains with the included battery. When operating for the first time, the Enteroport® plus should be connected to the mains supply to charge the battery. During mains operation, the battery is automatically charged within about 3.5 hours.

Mains operation

For in-patient application, it is advisable to connect the pump to the mains supply via the charger supplied with the Enteroport® plus. Do this by inserting the charger connector into the socket provided on the left-hand side of the pump, and then connect the mains adapter to the mains supply. During mains operation, the green indicator lamp on the mains adapter lights up. At the same time, the connector symbol on the pump display is lit. The battery charging process is signaled by the lighting of the yellow indicator lamp on the mains adapter and the -symbol on the pump display.

Battery operation

The Enteroport® plus pump is delivered with an integrated, rechargeable NiMH battery. The pump is automatically switched to battery operation when it is not operated with the mains supply. During battery operation, the -symbol is shown on the display.

With a fully charged battery, the Enteroport® plus will allow a mains independent operation for up to 35 hours at an average rate of 200ml/h (see table). During mains operation, the battery is automatically charged within about 3.5 hours.

After approx. 4 years, the battery may have a reduced capacity due to aging.

Infusion Rate (ml/h)	**Operating time** (h)
50	55
100	46
200	35
300	28
400	24

Table: Average battery operating time at different infusion rates

To get an information about the remaining battery operation time please do following steps: Switch pump on, press 3 times the INFO/PRIME button. Then the remaining battery operation time is displayed. The display disappears automatically after 5 seconds.

Technical Data

Type of unit	**Enteral nutrition pump**
Product class acc. to directive 93/42 EEC	IIa
Classification	defibrillation-proof, Type CF
Protective Class	II
Humidity Protection	IP 22 (Liquid ingress protection, dripping water tilted up to 15°)
Internal power supply	NiMH rechargeable battery, 2.4 V; 1900 mAh
Charging time	approximately 3.5 h
Power rating	3 VA (charging)
Current input	600 mA (charging)
Adminsitration Rate	1 – 400 ml/h, increments of 1 ml/h
Volume (Volume mode)	1 ml - 5,000 ml

Volume range	increments
1 ml - 49 ml	1 ml
50 ml - 5,000 ml	50 ml

Volume (Bolus mode) 1 ml - 1,000 ml

Volume range	increments
1 ml - 49 ml	1 ml
50 ml - 1,000 ml	50 ml

Flow time	15 min – 24 h, variable in 15 min intervals
Flow rate tolerance	± 10%
Occlusion detection pressure	max. 150 kPa (1.5 bar)
Air detection	Ultrasonic detector

Operating conditions	
• Temperature	+5°C ... + 40°C
• Atmospheric pressure	700 ... 1060 mbar
• Relative humidity	15 % ... 93 % (without condensation)
Storage conditions:	
• Temperature	- 20°C ... + 50°C
• Atmospheric pressure	500 ... 1060 mbar
• Relative humidity	10 % ... 93 % (without condensation)
Weight	approx. 450 g
Dimensions (W x h x D)	140 x 45 x 115 mm
EMC	IEC 60601-1-2
Flow principle	swash plate
Display	LCD, illuminated

Enteroport® plus Mains adapter

Product class acc. to regulation EU 2017/745	I
Rated Voltage	100 ... 240 V AC~ ; 50 ... 60 Hz
No load voltage	5,8 V DC ± 5 %
Charging current	600 mA ± 50 mA
Humidity protection	IP 67 (Liquid ingress protection, Immersion of water up to 1 meter depth)
Protective Class	⧈

Electromagnetic Compatibility Guidance and Manufacturers Declaration

WARNING!

Only original spare parts and components must be used to succeed the following compliance level.

In case of using the Enteroport® plus or any component in the environment of additional devices (i.e. HF-surgery device) the user should observe this arrangement to secure the function as specified.

Use of accessories and cables other than those specified, with the exception of parts sold by the manufacturer as replacement parts for internal components, may result in increased emissions or decreased immunity.

Do not use adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, observe and verify normal operation of the pump.

WARNING!

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

Table 1

Guidance and manufacturer's declaration – electromagnetic emission		
The Enteroport® plus is intended for use in the electromagnetic environment specified below. The customer or the user of the Enteroport® plus or any component should assure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment - guidance**
RF emissions CISPR 11	Group 1	The Enteroport® plus 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 Enteroport® plus 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 acc. to IEC 61000-3-2	complies	
Voltage fluctuations / flicker emissions acc. to IEC 61000-3-3	complies	

Table 2

Guidance and manufacturer's declaration – electromagnetic immunity			
The Enteroport® plus is intended for use in the electromagnetic environment specified below. The customer or the user of the Enteroport® plus or any component should assure that it is used in such an environment.			
Immunity test	**Test level IEC 60601-1-2 and IEC 60601-2-24**	**Compliance level**	**Electromagnetic environment – guidance**
Electrostatic discharge (ESD) according to IEC 61000-4-2	± 8 kV contact discharge ± 15 kV air discharge	± 8 kV contact discharge ± 15 kV air discharge	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrostatic transient / burst according to IEC 61000-4-4	± 2 kV for power supply lines	± 2 kV for power supply lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge according to IEC 61000-4-5	± 1 kV line to line	± 1 kV line to line	
Voltage dips, short interruptions and voltage variations on power supply input lines according to IEC 61000-4-11	0 % U_T [1] for ½ period 0 % U_T for 1 period 70 % U_T for 25 periods 0 % U_T for 250 periods	Complies by use of an internal energy source	
Power frequency (50/60 Hz) magnetic field according to IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Conducted RF interference according to IEC 61000-4-6	3 V_{rms} 150 kHz to 80 MHz outside ISM bands [2] 6 Vrms 150 kHz to 80 MHz in ISM and amateur radio bands [2]	3 V_{rms} 6 V_{rms} 150 kHz to 80 MHz in ISM and amateur radio bands [2]	Portable and mobile RF communications equipment should be used no closer to any part of the Enteroport® plus or its components, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance:** $d = 1{,}2\sqrt{P}$ $d = 2\sqrt{P}$

Radiated RF interference according to IEC 61000-4-3	10 V/m 80 MHz to 2.7 GHz	10 V/m	d = 1.2√P 80 MHz to 800 MHz [3] d = 2.3√P 800 MHz to 2.7 GHz [3] where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters [m]. [4] Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey [5] should be less than the compliance level in each frequency range. [6] Interference may occur in the vicinity of equipment marked with the following symbol. [7] 
Proximity fields from RF wireless Communications equipment according to IEC 61000-4-3	27 V/m (380 MHz to 390 MHz) 28 V/m (430 MHz to 470 MHz) 9 V/m (704 MHz to 787 MHz) 28 V/m (800 MHz to 960 MHz) 28 V/m (1700 MHz to 1990 MHz) 28 V/m (2400 MHz to 2570 MHz) 9 V/m (5100 MHz to 5800 MHz)	27 V/m (380 MHz to 390 MHz) 28 V/m (430 MHz to 470 MHz) 9 V/m (704 MHz to 787 MHz) 28 V/m (800 MHz to 960 MHz) 28 V/m (1700 MHz to 1990 MHz) 28 V/m (2400 MHz to 2570 MHz) 9 V/m (5100 MHz to 5800 MHz)	d ≥ 30 cm

Note 1: U_T is the a. c. mains voltage prior to application of the test level.

Note 2: The ISM (industrial, scientific and medical) bands between 150 kHz and 80 MHz are 6.765 MHz to 6.795 MHz; 13.553 MHz to 13.567 MHz; 26.957 MHz to 27.283 MHz und 40.66 MHz to 40.70 MHz. The amateur radio bands between 150 kHz and 80 MHz are 1.8 MHz to 2.0 MHz, 3.5 MHz to 4.0 MHz, 5.3 MHz to 5.4 MHz, 7 MHz to 7.3 MHz, 10.1 MHz to 10.15 MHz, 14 MHz to 14.2 MHz, 18.07 MHz to 18.17 MHz, 21.0 MHz to 21.4 MHz, 24.89 MHz to 24.99 MHz, 28.0 MHz to 29.7 MHz und 50.0 MHz to 54.0 MHz

Note 3: At 80 MHz and 800 MHz, the higher frequency range applies.

Note 4: The compliance levels in the ISM frequency bands between 150 kHz and 80 MHz and in the frequency range 80 MHz to 2.5 GHz are intended to decrease the likelihood that mobile/portable communications equipment could cause interference if it is inadvertently brought into patient areas. For this reason, an additional factor of 10/3 has been incorporated into the formulae used in calculating the recommended separation distance for transmitters in these frequency ranges.

Note 5: Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast, and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Enteroport® plus is used exceeds the applicable RF compliance level above, the Enteroport® plus should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the Enteroport® plus.

Note 6: Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 10 V/m.

Note 7: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

Table 3

Recommended separation distances between portable and mobile RF communications equipment and the Enteroport® plus			
The Enteroport® plus is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Enteroport® plus or component can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Enteroport® plus as recommended below, according to the maximum output power of the communications equipment			
Rated power of the ratio 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 2.7 MHz $d = 2.4\sqrt{P}$
<0.1	0.3	0.3	0.3
0.1	0.4	0.4	0.8
1	1.2	1.2	2.4
10	3.8	3.8	7.6
100	12	12	24
For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be determined 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 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.			

Warranty / Cleaning

Responsibility of the Manufacturer

The manufacturer, assembler, installer or importer considers himself responsible for the effects on safety, reliability and performance of the equipment only if:

- assembly operations, extensions, re-adjustments, modifications or repairs are carried out by persons authorized by him,
- the electrical installation of the relevant room complies with the appropriate requirements (e.g. VDE 0100, 0107, and/or the IED-publications resp. the national requirements),
- the equipment is used in accordance with the instructions for use and
- the technical safety checks are carried out regularly.

Warranty

B. Braun provides a 24 month warranty, as from the date of delivery. This covers repair or replacement of parts damaged as a result of design/manufacturing errors or material defects. Modifications or repairs to the unit undertaken by the owner or by third parties invalidate the warranty.


Symbol indicating separate collection for electrical and electronic equipment (2002/96/EC)

B. Braun offers, after the expected eight-years lifetime of the device, a disposal service for used devices.

Regular checks

Check for cleanliness, completeness and damage. Use only according to instructions for use. Check each time when switching on: self-test, audible alarm, completeness of display symbols, operation and alarm control indication.

Changing the battery

The battery can only be changed by the technical service agency responsible for the Enteroport® plus nutrition pump.

A battery change is recommended every 4 years.

Cleaning

Within every tubing change clean external surface of pump using mild soap suds. Do not use spray disinfectants at the mains power connection. Recommended: disinfectant for wiping available from B. Braun: Meliseptol® Foam pure, Melsitt 10% and Melsept SF 10%. After cleaning, allow the device to vent for at least 1 min prior to use. Do not spray into openings in the device. Be sure to observe the instructions provided concerning waste disposal and hygiene for batteries and disposables. Wipe magnifying- and displayglas on front of pump door only with a soft cloth. Do not use Hexaquart® or other alkylamine containing disinfectants.

Disposal

The pumps as well as battery packs can be returned to B. Braun for further disposal. When taking care of disposing of disposables as well as infusion solutions, please consider the applicable hygiene and disposal regulations.

Ordering Information

Inspection on Delivery

Despite careful packaging, the risk of transport damage cannot be entirely prevented. Upon delivery, please check that nothing is missing. Do not use a damaged device! Contact the service department.

Items included

Enteroport® Plus, Pole Clamp, Short Instructions for Use, Instructions for Use.

	Art. No.
Enteroport® plus, incl.	8710355

- Pole clamp
- Short instructions for Use
- Instructions for Use

Enteroport® plus mains adapter

Power Supply Enteroport plus Euro - Plug	8710360
Power Supply Enteroport plus UK - Plug	8710361
Power Supply Enteroport plus US - Plug	8710362
Power Supply Enteroport plus Brazil - Plug	8710363
Power Supply Enteroport plus AU - Plug	8710364
Short stand for pole clamp	8721670
Pole clamp	8721061

Enteroport® plus administration sets

Enteroport® plus Set bottle connection	8721688
Enteroport® plus Set with 500 ml empty nutrition bag	8721726
Enteroport® plus Set with 1000 ml empty nutrition bag	8721734
Enteroport® plus Set with 2500 ml empty nutrition bag	8721742
Enteroport® plus Set Multispike bottle connector	8721750

Enteroport® plus administration sets with safety, inverse Luer Lock Y-Port

Enteroport plus Set with 1000ml empty nutrition bag	8721735
Enteroport plus Set Multispike bottle connector	8721745

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