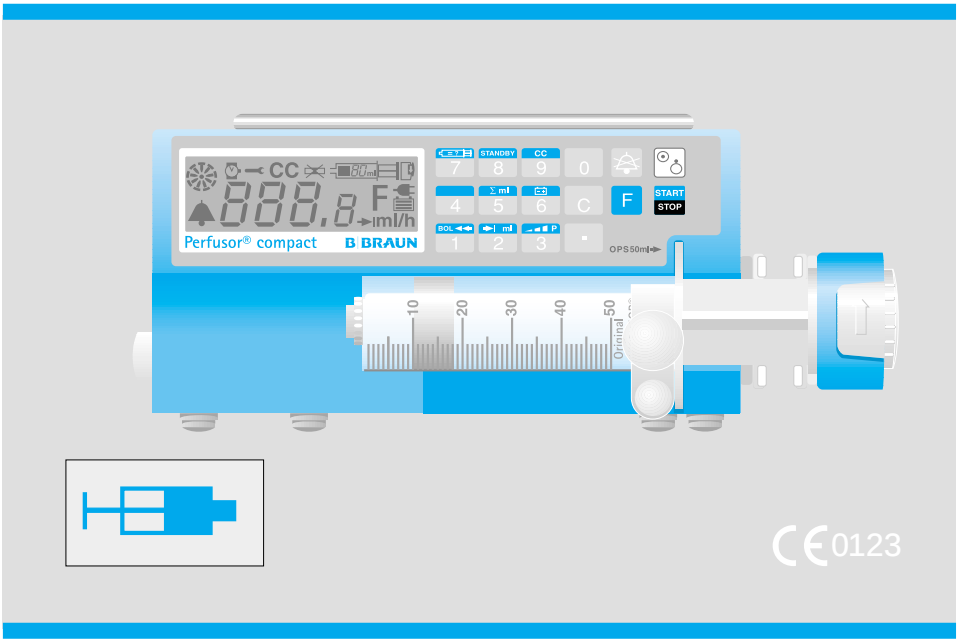
Perfusor® compact

Instructions for use



Software AA

B BRAUN

Patient Safety

Attention: take note of accompanying documents! ⚠

▶ First read the Instructions for Use.
Use of the equipment presupposes regular checking by specially-trained staff.

Operation

▶ Make sure that the unit has been positioned safely and is stable and secure.

▶ Prior to use: always ensure the functioning of the audible and visual alarms during the automatic check (see page 6). Also check the staff call and syringe setting features for possible damage.

▶ Connection to patient is only permissible when the device is switched on. Interrupt the connection to change syringes. There is otherwise a danger of incorrect dosage.

▶ Select syringe/catheter suitable for use with the connection system and medical application.

▶ Make the connection ensuring that the infusion line is free of kinks so that a flow is possible.

▶ Replace disposable articles after 24 hours.

▶ It is presupposed that installation in rooms used for medical purposes will comply with the appropriate regulations (e.g. VDE 0100, VDE 0107 or IEC publications). Care must also be taken to observe regional specifications and national variations.

▶ Do not use in an area endangered by risk of explosion.

▶ Compare displayed and input values. Use only when these match.

Other Components

▶ Work in the area of the pressure shut-down facility, or variations in pressure (e.g. as caused by change in level), can affect the accuracy of the device.

▶ Where several infusion lines are connected, the possibility of their exerting a mutual influence on each other cannot be excluded. Cases of possible incompatibility can be found in the directions on use of the medicament or appliances in question.

See also VDE 0753, Part 5, "Application Rules for Parallel Infusion - Possible Application Methods", or the BBM application directives for parallel infusion (38910004).

▶ Only combinations of equipment, accessories, working parts and disposable parts that have been shown to be compatible shall be used.

▶ The use of disposable parts that have not been tested or approved might well exert an influence on the technical data.

▶ Connected analogue and digital components must verifiably satisfy the EN specifications (e.g. EN60950 on data processing devices and EN60601 on medical electrical devices). Anyone who additionally connects devices to the signal input or output part is a system configurator and is thereby responsible for compliance with the systems standard EN60601-1-1.

Safety Standards

Perfusor compact satisfies all safety standards for medical electrical devices in terms of the IEC 601-1 and IEC 601-2 (-24) publications.
Note: IEC 601-1 corresponds to the European Standard EN60601.

Perfusor compact

Contents

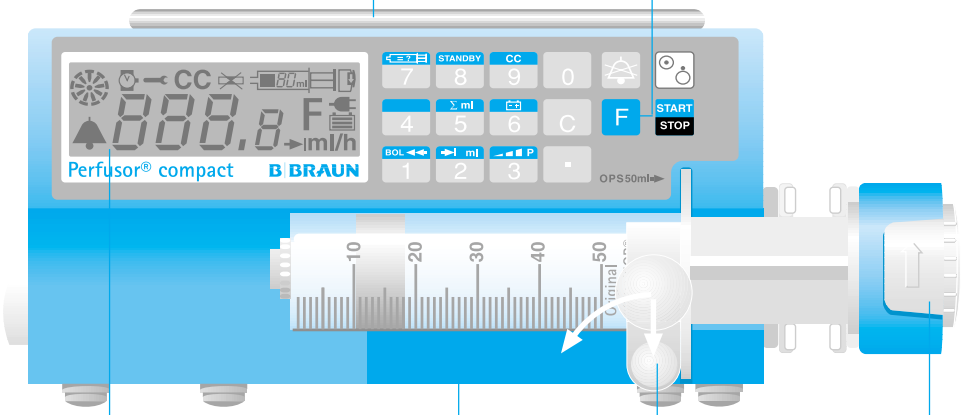
The Perfusor compact is a transportable infusion syringe pump in accordance with EN60601-2-24 (draft), Points 2.2.18 and 2.2.23 that is suitable for dispensing liquids in nutritional and infusion therapy. The medical specialist must decide on suitability for application on the basis of the warranted properties and the technical data.

For further details please refer to these Instructions for Use.

Overview

Handle
Always use the handle when carrying

Operation
For special functions first press the **F** button.

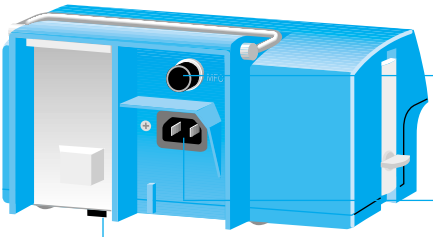


Display
Shows all important features at a glance: rate, type of syringe, mains or rechargeable battery, carriage control and alarm symbol (see "Alarms" on page 9).

Syringe holder
Locks in the syringe. To remove, pull and swing to the left.

The drive unit can be moved by hand after the locking lever has been opened.

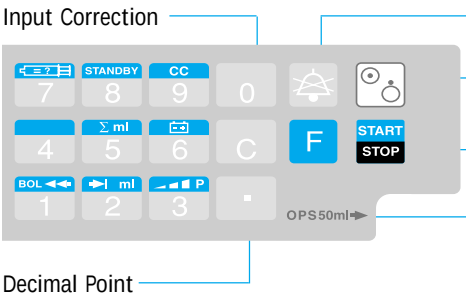
Short instructions for use and Syringe Table
See the underside of the device.

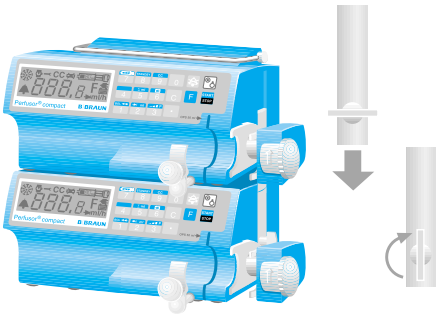


Multi-Function Connector (MFC)
Connection for staff call; ambulance cars (12V) and interface.

Mains Connection
Connection for the mains supply. In the event of power failure, automatic switch-over to battery.

Battery
Press here to change the battery. Interrupt the connection to the patient during changing of the battery. Switch off the device and pull the cover downwards. Always renew all batteries, taking care to observe waste disposal regulations.

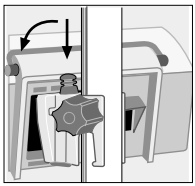




Transport/Carriage
A maximum of three devices can be connected together. Special care is required here if a patient is already connected. Avoid external mechanical influence!

Locking Devices Together
Place one device on top of the other. Push down the connecting part until clicks into place. Lock by turning the vane until it is vertical.

To disconnect, turn until horizontal and then push upwards.



Stand Clamp/Attachment on Stand
Attach the Perfusor compact from above, clicking it into place. To release, press the black button. For safety purposes attach each device separately to the stand.

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

Packaging: Reusable, therefore environmentally acceptable (returns will be accepted).

Extent of Delivery: Perfusor compact, power lead, pole clamp, instructions for use, 4 batteries.

Operation

1. Insert Syringe

▶ Raise syringe and prime infusion line.

Tip: an alternative is to evacuate the air using the bolus button (non-delayed start of infusion).

▶ Switch on using ⏻. – Note the automatic check:

- After switching on, all display elements must appear for approx. 2 sec and the audible alarm must be heard (see Display, page 4).
- Then comes the rate display:
  111.1 222.2 555.5
- Then the software version: AA
  In addition the 🔧, **CC**, ➔ml and decimal point blink.

▶ Open the syringe holder, release and pull out the drive unit.

Insert the syringe such that the grip and the pressure plate reach the guide. Lock syringe holder again. If the syringe has been "correctly" placed the release catch will snap back on its own.

(The type-of-syringe number displayed must match that of the syringe inserted - see table.)

▶ Confirm the type of syringe by pressing **F** .

▶ Connect the patient.

2. Setting the Rate

▶ Value between 0.1 and 99.9 ml/h. Check display. To correct:

Press **C** and enter the rate anew.

3. Start Infusion

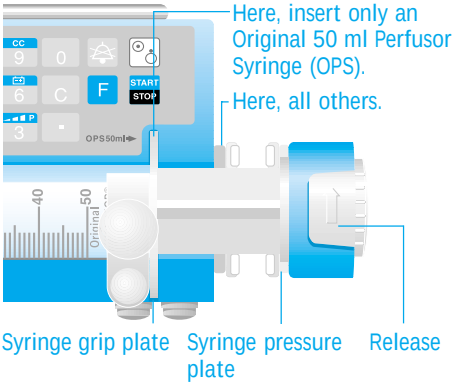
▶ Press **START**. Running control is displayed.

4. Stop the Infusion

▶ Press **STOP** or ⏻ for 2 sec. Disconnect the patient.

▶ Open the syringe holder. Remove the syringe.

▶ To switch off, press ⏻ for 2 sec .



Change of Syringes

▶ Press **STOP**.

Disconnect the patient!

▶ Remove the syringe. Fit a new air-extracted syringe with infusion line.

▶ Confirm the type of syringe using button **F**. (Only necessary when using another syringe type than before.)

▶ Connect the patient and press **START**.

To Alter the Rate

▶ Press **STOP**.

▶ Press **C** and enter the new rate.

▶ Press **START**.

To Alter the Rate Without Interrupting the Infusion

While the infusion is taking place: simply press **C** and enter the new rate, then confirm this with **F**. The new rate will now apply.

(If **F** is not pressed the display reverts to the old rate after 10 sec).

Special Functions F

- Activate the special functions using the **F** button (**F** is shown in the display).
- During infusion only the status can be shown; when stopped, changes in value can also be shown.
- Use the **F** button to confirm input values or to interrupt the function.

Syringe Selection

Open the syringe holder, press the symbol for syringe selection; the syringe code blinks. Press **C**, enter a new number and confirm this using **F**. After adjustment check the new syringe number once while infusion is taking place by pressing **F** and .

BOL Bolus

(The bolus rate can be altered by the service unit.)

Checking the bolus rate: Press **F**, then press **BOL**, each individually.

Initiating the bolus:
First press **F**, then - while holding this - press **BOL** and keep both pressed. An audible signal will be given for each ml.

Take care not to overdose!
Given a bolus rate of 800 ml/h, e.g. 0.1 ml will be reached in just 0.45 sec.

STANDBY Standby

A pause in the infusion without a reminder alarm signal being sounded. Set values are retained. The display shows and **F**.

∑ ml Infused Volume

Shows the volume already infused. If this exceeds 999.9 ml ---,- will be shown on the display.
Return the volume to 0,0 ml by pressing **C** or by switching the device off.

ml Volume Preselection

Infusion stops automatically when the set volume is reached. Display of the preselected volume:

Press first **F**, then Volume Preselection (ml).

To alter:
Press **C** and then enter the desired volume.

For 0 ml the volume limitation is switched off. Below 1 ml the volume precision can be reduced. During active volume selection the symbol displayed blinks. Volume preselection is erased when the device is switched off.

CC CC Operation

Shows the actual Dianet address for control by PC. To change the address:

Press **C** and enter the new address. To start CC operation: press **START**.

Battery Capacity

Shows the remaining capacity of the (rechargeable) battery:
low medium high

P Occlusion Pressure

The device switches off in the event of line failure. The switch-off pressure can be set at from P1 (low) to P3 (high). To alter:

Press **F** and then select 1, 2 or 3.

At the sounding of the pressure alarm the bolus volume built up by the device (approx. 1 ml at the highest compression phase) is automatically reduced.

Mains/Battery Operation

General Information
Check that the mains voltage corresponds to that on the main label! In the event of power failure the device switches automatically to battery operation. Alternatively, a rechargeable battery pack from B. Braun can optionally be used.

To ensure safe and reliable operation certain rules of application must be noted.

▶ The capacity display is a trend display (low, medium, high).

▶ The actual capacity available can vary from this due to
- different battery manufacturers
- temperature
- varying load (e.g. frequent bolus input).

▶ Batteries can explode or leak causing damage if they
- are opened or burned,
- are wrongly poled,
- are used such that new and old batteries are placed together,
- used together with a different make of batteries.

▶ Batteries should be removed from the device during longer period of non-use (storage > 3 months).

▶ The batteries should be renewed when
- a signal such as "battery empty" or "battery pre-alarm" is given
- breakdown or interruption occurs in connection with frequent bolus requirements.
- After a period of use of > 2 years, even if the capacity display indicator shows "full".

▶ The switch-on test checks whether the internal energy supply is capable of sounding a power-failure alarm. If the energy source is exhausted an alarm acknowledgement is produced. In this case the operator may only use the device under constant supervision, since a power failure would remain undetected by the device.

▶ Only alkali-manganese batteries may be placed in the battery compartment.
- The alkali-manganese batteries recommended are free of mercury and cadmium.
- Conventional carbon-cell batteries are give an incorrect reading on the capacity display and cannot therefore guarantee reliable operation.
- NiCd rechargeable batteries must not be connected to the battery contact points as their various physical properties disturb the alarm.

▶ NiCd rechargeable batteries are available as an accumulator pack (accessories).
- The accumulator pack is charged by the Perfusor during mains connection.

Alarms

Causes of Alarm

▶ Audible alarm: the alarm signal blinks in cases of alarm.

Battery empty, battery pre-alarm beginning 30 min. before the battery is empty.

Pressure alarm because of an occlusion; automatic bolus reduction.

Pre-alarm 3 min. before syringe is empty (only black field is blinking) resp. infusion end.

Reminder alarm if the awaited input has not been received and pre-alarms

Syringe frame pressure plate has not been correctly positioned.

+ Pressure alarm, automatic bolus reduction has been interrupted. Bolus has to be reduced manually.

Syringe catch at the drive head has not clicked into place.

Volume alarm, quantity reached.

▶ Eliminate the cause of alarm and then press the start button. If the alarm sounds again, contact the service unit.

Interrupts the alarm for a period of 2 min.

Displays

F Special function is active

Mains operation

Vol. preselection active

+ Service mode of operation; blinks when the service interval has elapsed.

Operation / Running control

CC Operation

Interface Operations
Descriptions of interfaces are available from B. Braun.

Connection to the input interface (MFC). Two possibilities are envisaged:

Documentation
All operational data can be called up and recorded via an external PC.

CC Operation
All functions can be specified using an external computer. This must satisfy the IEC 601-1 safety standards and must comply with the conditions of the IEC 513 single-fault safety requirement.

Check Regularly

Check for cleanliness, completeness and damage. Operate in accordance with the Instructions for Use. On switching on, check: the self-check, alarm signal, operating and alarm-control displays. Check battery contacts once a year for corrosion and clean them using a soft rubber.

Hygiene / Waste Disposal

Clean using mild soap suds. Do not use spray disinfectant at the mains connection. Recommended: disinfectant for wiping available from B. Braun (e.g. Meliseptol). Before operating the device allow to air for at least 1 min.
Do not spray into openings in the device. Be sure to observe the instructions provided on waste disposal and hygiene.

Technical Data

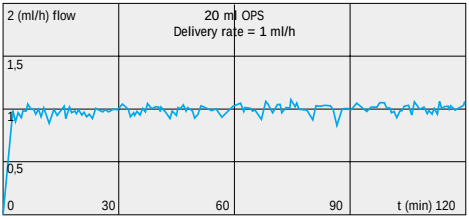
Type of unit	Infusion Syringe Pump
Classification	defibrillation proof; CF type Protection class II
Moisture protection	IP 22; drip protected for horizontal usage
Rated voltage	230/240 V, 50/60 Hz ~ or 110/120 V, 50/60 Hz ~
Power input	12 VA / 24 VA
External extra-low voltage	12 V ⎓ d.c. (e.g. ambulance cars)
Staff call	Max. 24 V / 1 A / 24 VA Arbitrary connection polarity (VDE 0834)
RFI EN55011 EMC	EN60601-1-2
Time of operation	100 % (continous operation)
Operating conditions	
- Relative humidity	30 % ... 90 % (without condensation)
- Temperature	+ 5 °C ... + 40 °C
- Atmospheric pressure	500 mbar ... 1060 mbar
Storage conditions	
- Relative humidity	30 % ... 90 %
- Temperature	- 20 °C ... + 55 °C
- Atmospheric pressure	500 mbar ... 1060 mbar
Type of battery pack	NiCd (rechargeable)
Operating time of rech. battery	> 10 h at ≤ 10 ml/h
Recharging time	> 16 h
Battery	4 x 1.5 V alkali manganese (DuracelI recommended)
Operating life of battery	> 80 h at ≤ 10 ml/h
Weight/Dimensions (WxHxD)	Approx. 1.5 kg; 190 x 100 x 120 mm

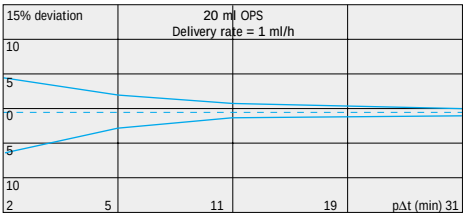
Selectable B. Braun syringes	20 ml Original Perfusor Syringe 50 ml Original Perfusor Syringe 50 ml Omnifix LL 50 ml Proinjekt
Delivery rate	0.1 - 99.9 ml/h (in 0.1 ml/h increments)
Bolus rate	800 ml/h
Delivery preselection	0.1 - 999.9 ml in 0.1 ml increments
Accuracy of set delivery rate	typ. ± 2,5 %, (measuring time > 1 h and infusion volume > 2 ml)
Occlusion alarm pressure	3 settings (low, medium, high; max. 1.2 bar)
Alarm in the event of incorrect dosage	a) Malfunctions of the device For incorrect dosages of > 0.015 ml due to malfunctions of the device the pump automatically switches off. b) At shutdown typ. 1 ml bolus volume at highest compression phase with 50 ml OPS ⚠ max. alarm delay time at 5 ml/h = 6:50 min.

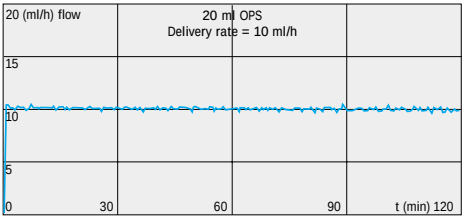
Syringe table showing minimum lifting volume required to activate the 3-min prior alarm

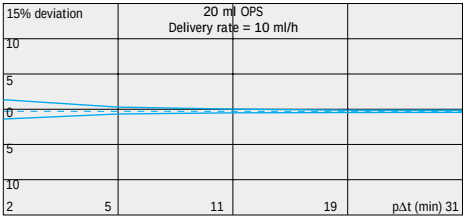
Type	Code No.	Min. Vol.
OPS 50 ml	50	5,6 ml
Proinjekt 50 ml	51	9,8 ml
Omnifix 50 ml	52	9,2 ml
Euroject 50 ml	61	9,3 ml
B-D Plpak 50/60 ml	61	9,3 ml
Terumo 50/60 ml	54	7,0 ml
Terumo (USA) 60 ml	60	7,3 ml
Monoject (USA) 50/60 ml	62	5,4 ml
Monoject (EU) 50/60 ml	55	9,6 ml
OPS 20 ml	20	5,3 ml
Omnifix 20 ml	22	6,3 ml
Terumo 20 ml	23	4,5 ml
B-D Plpak 20 ml	24	5,3 ml
Monoject (USA) 20 ml	26	6,5 ml
Monoject (EU) 20 ml	29	4,4 ml

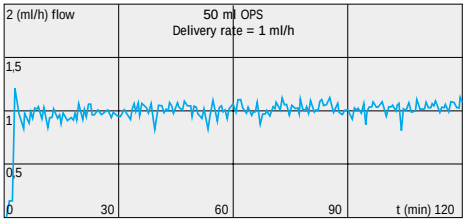
Start-up and Trumpet Curves

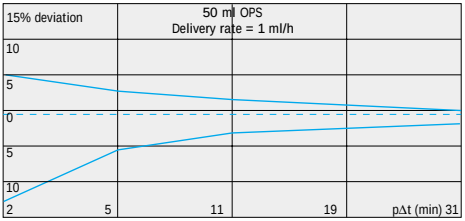


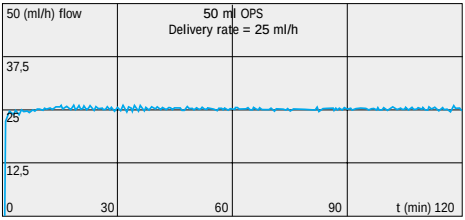


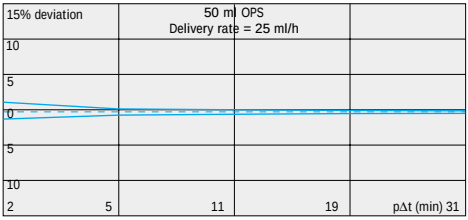












The graphs show the accuracy/uniformity of flow in relation to time. Allow for the following:

The delivery behaviour or delivery precision is essentially influenced by the types of (disposable) syringe used. Significant deviations may be encountered if use is made of (disposable) syringes other than those stated in the order data.

Trumpet Curves
Measured values for second and last hour in each case.
Measurement interval Δt = 5 min
Observation interval p · Δt (min)

Start-up Curves

Measurement interval	Δt = 5 min
Measurement duration	T = 120 min
Flow Q_i	(ml/h)

Warranty

Responsibility of the Manufacturer

Manufacturer, assembly and installation personnel or instructors can only be held responsible for any effects on device safety, reliability and performance if

- Installation, expansion work, readjustments, modifications or repairs are carried out by personnel authorised by the above and
- The electrical wiring in the room concerned satisfies the requirements of VDE 0100, 0107 and/or the IEC publications and
- The device is operated in line with the instructions for use.
- The regular technical inspections are carried out.

The CE mark confirms that this medical product complies with the "Council Directive on Medical Devices 93/42/EEC" dated 14th June 1993.

B. Braun Melsungen AG

Warranty

B. Braun provides 24 months warranty, as from the date of delivery, for every Perfusor compact. 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.

The warranty does not cover the following: Elimination of faults attributable to incorrect/ inexpert handling, or to normal wear and tear incl. normal batteries and rechargeable batteries.

Service

A technical inspection must be carried out on the Perfusor compact every 2 years, with an entry being made in the medical product book in accordance with the checklist.

Service work must be carried out exclusively by personnel instructed by B. Braun.

Ordering

▶ Copy and send by post or by fax to:

B. Braun Melsungen AG
Sparte Medical
Postfach 1120
34209 Melsungen

Fax +49-(0) 5661 - 71 - 37 98

▶ Telephone orders:
Tel.: +49-(0) 5661 - 71 - 0

Delivery address:

	Qty/Art.no.
Original Perfusor Syringes	
Original Perfusor Syringe 50 ml with draw-off cannula	____0872 8810
Original Perfusor Syringe 50 ml without draw-off cannula	____0872 8844
Original Perfusor Syringe 50 ml with draw-off cannula and particle filter, with light protection	____0872 8828
Original Perfusor Syringe 50 ml with draw-off cannula and particle filter	____0872 8852
Original Perfusor Syringe 20 ml with draw-off cannula	____0872 8623
Original Perfusor Syringe 20 ml without draw-off cannula	____0872 8615
Original Perfusor Syringe 20 ml with draw-off cannula and particle filter	____0872 8631
Original Perfusor Tubing	
Original Perfusor tubing N, made of PVC, with Luer lock connectors, 150 cm	____0872 2960
Original Perfusor tubing L, made of PVC, with Luer lock connectors, 200 cm	____0872 2862
Original Perfusor tubing MR, made of PVC, with Luer lock connectors, 75 cm	____0872 2870
Original Perfusor tubing M, made of PVC, with loose lock nut on patient end, 150 cm	____0872 2994
Original Perfusor tubing PE, made of PE, with Luer lock connectors, 150 cm	____0872 2935
Original Perfusor tubing S, made of PVC, light-protected, with Luer lock connectors, 150 cm	____0872 2919
Original Perfusor tubing PES, made of PE, light-protected, with Luer lock connectors, pressure-resistant, 150 cm	____0872 3010
Original Perfusor tubing MK, made of PVC, with cannula, with Luer lock connectors, 75 cm	____0872 2889
Original Perfusor tubing, made of PVC, with sterile filter 0.22 µ, with Luer lock connectors, 200 cm (not for use together with 20 ml syringes)	____0872 3001

Perfusor compact (230 / 240 V)	____0871 4827
Perfusor compact (110 / 120 V)	____0871 4835

Recommended accessories for the Perfusor compact

Connecting lead for staff call	____0871 1682
Connecting lead for ambulance car (12 V)	____0871 1674
Interface lead with electrical isolation	____0871 1661
Rechargeable battery pack	____0871 4991
Y-lead for central mains power supply for 2 Perfusors	____0870 0109

Ordered by (name):

Date / Signature:

Sparte Medical
B. Braun Melsungen AG
Postfach 1120
D-34209 Melsungen

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Fax +49-(0) 5661- 71- 20 44

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