仿單標籤粘貼表

產品名稱	"必勃朗" 精密注射器	申請廠商	台灣柏朗股份有限公司
衛生署給證號碼	衛署醫器輸	字第　006023	號

市售醫療器材得僅放置經審查核定之中文仿單。但如市售醫療器材同時放置中、外文仿單者，外文仿單內容須與核定本之中文仿單內容相符。

Perfusor® compact

1

REF 8714835

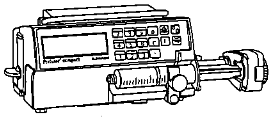
SN serialno.

LOT 000batch000

VERS. XXSWXX

CN 注射器泵
生产地址: Carl-Braun-Str. 1
34212 Melsungen
Germany
产品标准: YZB/GEM 3280-2005
注册号: 国食药监械（进）
字2006第2540627号
售后服务单位:贝朗医疗（上海）
国际贸易有限公司

Made in Germany



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CE 0123

GS1-128 AI-order: (01)-(10)-(21)

B|BRAUN B. Braun Melsungen AG
Carl-Braun-Straβe 1
D-34212 Melsungen, Germany

行政院衛生署 騎縫章 (器輸) 食品藥物管理局

100. 8. 22

行政院 騎縫 (器輸) 食品藥物

100. 8. 22

"必勃朗"精密注射器

B. Braun Perfusor Precision Syringe Pump
衛署醫器輸字第　006023　號
製造批號如包裝所示
製造廠名稱：B. Braun Melsungen AG
製造廠地址：Carl-Braun-Straβe 1, 34212 Melsungen, Germany
藥商名稱：台灣柏朗股份有限公司
藥商地址：台北市松山區健康路 152 號 9 樓

行政院衛生署 騎縫章 (器輸) 食品藥物管理局

100. 8. 22

"必勃朗"精密注射器

"B. Braun" Perfusor Precision Syringe Pump

衛署醫器輸字第 006023 號

※使用前請務必詳閱原廠之使用說明書並遵照指示使用。

主要設備:

~~8714835 Perfusor Compact~~
註銷規格 102. 12. 11

用途

輸液注射幫浦

產品敘述

本產品是一台攜帶型輸液注射幫浦，可用來進行輸液、營養治療及家庭護理。本產品是以軟體控制且利用旋轉軸承驅動機制（swievel-drive mechanism）運轉。
本產品為一般醫院使用，亦可用在內科或外科各類需要輸液的病患。
醫療專業人員可根據設備性能和技術資料並依實際情況來決定如何使用本設備。

病人安全

■ 前先詳閱原廠之使用說明書且設備需由專業技術人員做常規性檢查。

操作

■ 確認機器安全穩固地安置妥當。
■ 使用前：永遠確保警報器的聲音和視覺功能正常，並檢查醫護人員呼叫功能和注射筒設定是否有損壞。
■ 只有在機器開機後才允許和病患做連接，更換注射筒時須易中斷與病患間的連接，否則會導致劑量不正確的危險。
■ 選擇適合系統連結和使用藥品的注射筒/導管。
■ 連接後需確保輸液管路沒有糾結以保持管路暢通。
■ 耗材使用 24 小時後需更換。
■ 器材需安裝再以醫療使用為目的的房間且符合適當的規定（如 VDE 0100、VDE 0107 或 IEC 規範），亦需注意當地規格和國際規範的不同。
■ 不可使用在有爆炸風險的危險區域。
■ 比對機器顯示和輸入的數值，只有在兩者符合時才能使用。

其他附件

■ 在壓力關閉或壓力變動的區域作業會影響儀器的準確度。
■ 在多條輸液管路連結的地方，不可排除其運用會相互影響的可能性，此種不相容的案例可以在藥物使用說明中被發現。
■ 併用時只可使用相容的設備、配件、零件和耗材。
■ 使用未經測試或核可的耗材可能會影響產品性能。
■ 連接類比或數位配件需滿足 EN 規格驗證。任何連結儀器到訊號輸入或輸出端的人即為系統配置者，需要對系統符合 EN60601-1-1 負責。

安全標準

本產品符合醫電類醫療設備安全標準，如 IEC601-1 和 IEC601-2(-24)。
註：IEC601-1 與歐洲標準 EN60601 實質對等。

產品規格

Perfusor Compact

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 - Temperature - Atmospheric pressure	 30 % ... 90 % (without condensation) + 5 °C ... + 40 °C 500 mbar ... 1060 mbar
Storage conditions - Relative humidity - Temperature - Atmospheric pressure	 30 % ... 90 % - 20 °C ... + 55 °C 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 (Duracell 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	(see table below)

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

配件

名稱	描述	產品代碼
Y-cable	中央電源線，可連接兩台 Perfusor 幫浦	8700109
Universal clamp MICU	通用型支架夾，救護車用	8700150
Universal clamp fm	通用型支架夾，fm 輸液管理系統用	8718474
Universal clamp rotatable	通用型支架夾，可旋轉	8718482
MFC-RS 232 interface lead	連接線，用來連接RS322介面	8711661
MFC 12 V connecting lead	連接線，用來連接救護車 12V port	8711674
MFC connecting lead	連接線，用來連接醫護人員呼叫系統	8711682
Rechargeable battery pack	可充電式電池	34501690
Rechargeable battery pack	可充電式電池	8714991

製造廠名稱：B. Braun Melsungen AG
製造廠地址：Carl-Braun-Straβe 1, 34212 Melsungen, Germany
藥商名稱：台灣柏朗股份有限公司
藥商地址：台北市松山區健康路 152 號 9 樓

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1.1.4. Intended use, indications for use and contraindications

Infusion syringe pump

1.1.5. General description of the device

The Perfusor® compact is a transportable infusion syringe pump for administrating fluids in nutritional therapy and infusion technique as well as for home care applications. The pump is software controlled and operates using a swivel-drive mechanism.

It is intended for general hospital use and may be used to deliver fluids to patients affected by a wide variety of medical and surgical conditions.
The medical specialist must decide on suitability for application on the basis of the warranted properties and the technical data.

1.1.6. Drawings, photographs

Perfusor® compact
Photo documentation
No.: M650_000001
(Art.-No. 8714827)
Version: 02
Date of issue: 2006-03-21

see ANNEX

10

1.1.7. Classification according to the international regulations

Classification according to the Medical Devices Directive 93/42/EEC

Class II b
Conformity Assessment Procedure II.3

1.1.8. Universal Medical Device Nomenclature System (UMDNS), or Global Medical Device Nomenclature (GMDN) medical device product classification code and designation

UMDNS classification code: 13-217
Designation: Infusion Pumps, Syringe

GMDN classification code: 13217
Designation: Infusion pump, syringe

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1. Device description, material and process specifications

1.1. Device description

1.1.1. Name of the device (brand name)

Perfusor® compact

1.1.2. Device variants

Art. No.	Designation	Description	Classification acc. to MDD 93/42/EEC
8714835	Perfusor® compact	Perfusor® compact 110 / 120 V, inclusive universal clamp fm	IIb

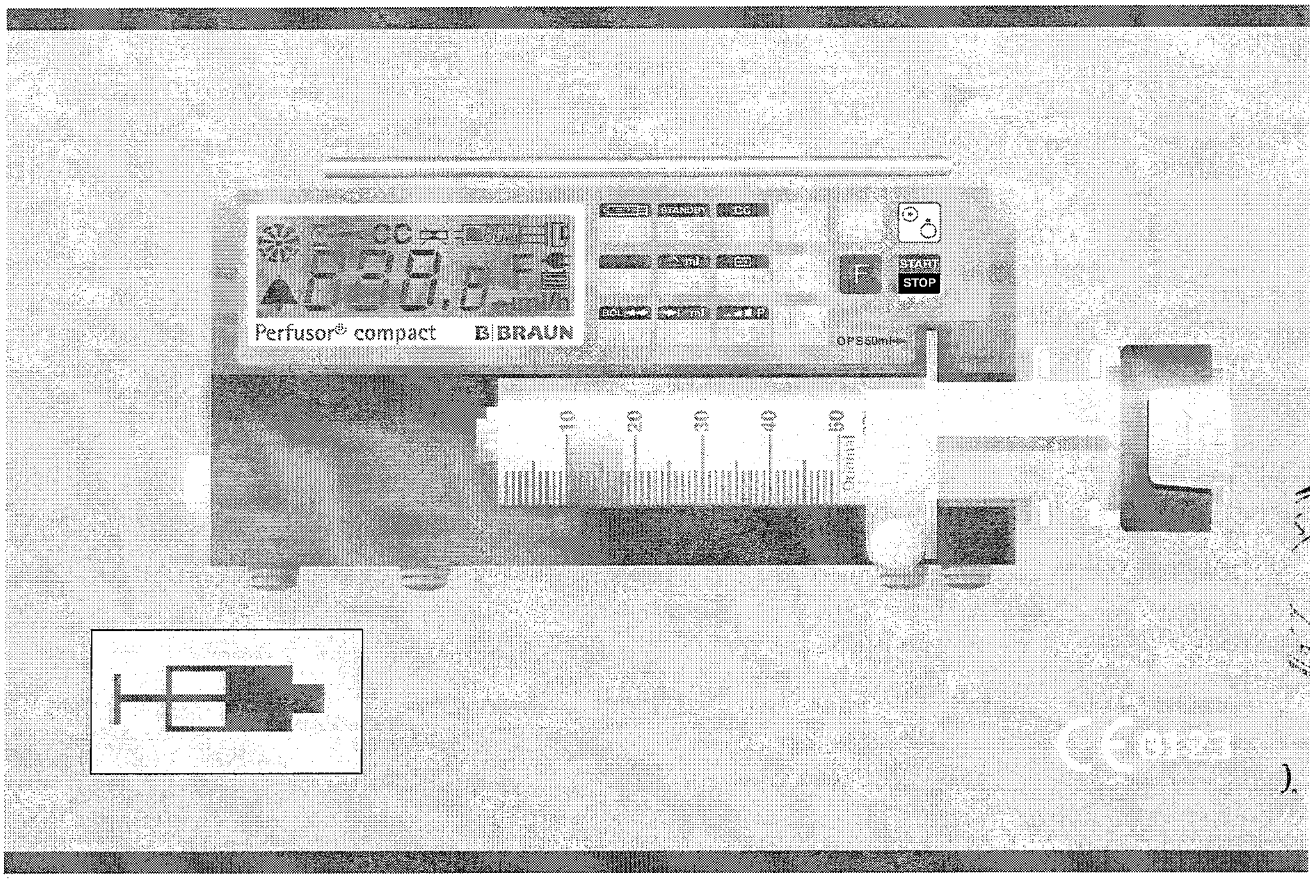
1.1.3. Accessories and other devices intended to be used in combination with the device

Art. No.	Designation	Description	Classification acc. to MDD 93/42/EEC
8700109	Y-cable	For central power supply for 2 Perfusor pumps	accessory
8700150	Univeral clamp MICU	Universal clamp for a Mobile Intensive Care Unit (Ambulance Car)	accessory
8711661	MFC-RS 232 Interface lead	MFC-RS 232 interface cable with electrical isolation	accessory
8711674	MFC 12V-Connection lead	MFC connecting lead for ambulance car (12V)	accessory
8711682	MFC Connection lead	MFC connecting lead for staff call	accessory
8714991	Battery Pack Perfusor® compact	Rechargeable Battery Pack	accessory
8718474	Universal clamp fm	-/-	accessory
8718482	Universal clamp rotateable	-/-	accessory
34501690	Battery Pack Perfusor® compact	Rechargeable Battery Pack	accessory

100

Perfusor® compact

Instructions for use



Software AA

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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.

Technical Data

Type of unit	Infusion Syringe Pump
Classification	defibrillation proof; CF type Protection class II
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Rated voltage	230/240 V, 50/60 Hz ~ or 110/120 V, 50/60 Hz ~
Power input	12 VA / 24 VA
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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 (Duracell recommended)
Operating life of battery	> 80 h at ≤ 10 ml/h
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