BeneFusion eSP

Syringe Pump

Data Sheet

Physical Specifications

Weight	≤ 1.6kg
Size	≤ 257x 150 x73mm
Screen	3.5 inch touchscreen TFT color LCD, 200x400 pixels
Brightness	1-8 levels, adjustable
Display	Infusion status (drug name, major infusion parameters, real-time pressure status) System status information (alarm information, infusion mode, battery status, relayed status, syringe brand or bed number)
Indicator on the door	Infusion status indicator

Parameters Specifications

Accuracy	≤ ±1.8%
Mode	Rate mode, Dose Mode, Dose Time Mode, Time mode, Sequential Mode, Intermittent Mode, Loading Dose Mode, Ramp Mode, Micro-infusion Mode Optional: TIVA Mode, PCA Mode, TCI Mode
Flow rate	0.01-2300ml/h
Increment	0.01ml/h (0.01-99.99ml/h), 0.1ml/h (100.0-999.9ml/h), 1ml/h (1000-2300ml/h)
Preset volume (VTBI)	0.01 ml - 9999.99 ml, increment: 0.01mL
Preset time	00:00:01-99:59:59
Accumulated volume	0.00 ml - 99999.99 ml
KVO	0.01 to 5.0ml/h, increment: 0.01ml/h
Purge rate	0.01-2300ml/h
Bolus rate	0.01-2300ml/h (automatic or manual)
Occlusion detection	50-1125mmHg (15 levels selectable, respectively are 50, 150, 225, 300, 375, 450, 525, 600, 675, 750, 825, 900, 975, 1050, 1125mmHg) default is 450mmHg, Pre-alarm: an alert will pop out when the pressure is continuously going up Auto-restart: On/Off, restart the infusion when the occlusion pressure is reduced. 4 units of pressure selectable: mmHg/kPa/bar/psi
Anti-bolus	Unexpected bolus reduced when the occlusion occurs
Dose rate units	ng/kg/min, ng/kg/h, ng/kg/24h, ug/kg/min, ug/kg/h, ug/kg/24h, mg/kg/min, mg/kg/h, mg/kg/24h, g/kg/min, g/kg/h, g/kg/24h, mU/kg/min, mU/kg/h, mU/kg/24h, U/kg/min, U/kg/h, U/kg/24h, kU/kg/min, kU/kg/h, kU/kg/24h, EU/kg/min, EU/kg/h, EU/kg/24h, mmol/kg/min, mmol/kg/h, mmol/kg/24h, mol/kg/min, mol/kg/h, mol/kg/24h, mcal/kg/min, mcal/kg/h, mcal/kg/24h, cal/kg/min, cal/kg/h, cal/kg/24h, kcal/kg/min, kcal/kg/h, kcal/kg/24h, mEq/kg/min, mEq/kg/h, mEq/kg/24h
Auto-lock time	1 - 5 minutes selectable, ON/OFF switchable
Drug library	Up to 5000 drugs, 30 categories, support color-coding drug name
History log	Up to 3500 events
Volume collection	Available in 4 methods: 24h total, current total, period, timing volume, supports history rate review
DERS (Dose Error Reduction System)	Available, definition of dose limits, automatic alarms when reaching dose limits

Syringes

Compatibility	1/2/3/5/6/10/12/20/30/35/50/60ml, automatic recognition of syringe size

Alarms

Type	Audible and visual alarm
2 Levels	High: Occlusion/ Syringe Empty/ Syringe Disengaged/ Plunger Grippers Error/ Battery Depleted/ VTBI Complete/ KVO Finish/ Relay Invalid/ System Error/ No Syringe Low: Extension Line Detached/ KVO Running/ Battery in Use/ Battery Error/ CMS/eGW Disconnected/ Standby Time Expired/ Dock Connection Interrupted/ System Time Error/ Relay Invalid Soon/ Time Near End/ Reminder/ Low Battery/ Syringe Near Empty
Sound volume	1-8 levels selectable, default is level 6
Reminder	1-5 minutes selectable, ON/OFF switchable

Connectivity

Communication	Wired/wireless
USB	Support drug library import, patient data import/export, history record export, calibration data import/export
Multifunctional connector	RS232, nurse call connector, DC adapter
Integration	Connect with BeneFusion nCS infusion central station Connect with BeneVision Central Monitoring System

Battery

Operating time	≥ 5 hours at 5ml/h (≥ 11 hours at 5ml/h for smart battery)
Charging time	≤ 5 hours to full capacity (≤ 6 hours for smart battery)

Power Supply

Voltage 100-240 V~, frequency 50/60Hz, current 0.5-0.21A

Work Environment

Temperature	5-40ºC for operating, -30-70 ºC for storage
Relative humidity	15-95% for operating, 10-95% for storage
Atmosphere pressure	57.0-107.4 kPa for operating, 16.0-107.4 kPa for storage
Classification	Type CF, Class I, IP33
Stackability	Supported with stack rack, maximum of 3 pumps can be stacked

Mindray Building, Keji 12th Road South,
High-tech Industrial Park, Nanshan, Shenzhen 518057, P.R. China
Tel: +86 755 8188 8998 Fax: +86 755 26582680
E-mail: intl-market@mindray.com www.mindray.com

P/N: ENG-BeneFusion eSP Datasheet-210285x2P-20201125

mindray

Declaration of Conformity CE 0123

Manufacturer: Shenzhen Mindray Scientific Co., Ltd.

6/F, Bldg 2, 1203 Nanhuan Avenue, Yutang Block, Guangming District,

518106 Shenzhen, PEOPLE'S REPUBLIC OF CHINA

EC-Representative: Shanghai International Holding Corp. GmbH (Europe)

Eiffestraße 80, 20537 Hamburg, Germany

Product:	*Infusion pump (Including Accessories)*	*Syringe pump (Including Accessories)*	*Infusion supervision system (Including Accessories)*
Model:	*BeneFusion nVP* *BeneFusion nVP ex* *BeneFusion nVP Neo* *BeneFusion eVP* *BeneFusion eVP ex* *BeneFusion eVP Neo*	*BeneFusion nSP* *BeneFusion nSP ex* *BeneFusion nSP Neo* *BeneFusion eSP* *BeneFusion eSP ex* *BeneFusion eSP Neo*	*BeneFusion nDS* *BeneFusion nDS ex* *BeneFusion eDS* *BeneFusion eDS ex*
GMDN Code:	*13215*	*13217*	*36179*
MD Code:	*MD 1101*	*MD 1101*	*MD 1111*

Classification: IIb（According to Rule 11 of MDD Annex IX）

Conformity Assessment Route: MDD Annex Ⅱ excluding (4)

We herewith declare under our sole responsibility that the above mentioned products meet the provisions of the Council Directive 93/42/EEC for Medical Device，as amended by 2007/47/EC. All supporting documentations are retained under the premises of the manufacturer.

Standards Applied:

List of (harmonized) standards for which documented evidence for compliance can be provided as attachment.

Notified Body: TÜV SÜD Product Service GmbH

	Ridlerstraße 65
	80339 München, Germany
Notified Body No. :	0123
Place, Date of Issue:	Shenzhen, 2023.3.14
Signature:	Bai Yanhong
Name of Authorized Signatory:	**Bai yanhong**
Position Held in Company:	Manager, Technical Regulation

Attachment of Declaration of Conformity: Applied Standards List-V2.0

Product:	Infusion pump
Model:	BeneFusion nVP, BeneFusion nVP ex, BeneFusion nVP Neo BeneFusion eVP, BeneFusion eVP ex, BeneFusion eVP Neo

Applied Standards:

EN 60601-2-24:2015	Medical electrical equipment -- Part 2-24: Particular requirements for the safety of infusion pumps and controllers
EN 60601-1:2006/A1:2013	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
IEC 60601-1-8:2006+A1:2012/ EN 60601-1-8:2007/A1:2013	Medical electrical equipment - Part 1-8: General requirements for basic safety and essential performance - Collateral Standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems
IEC 62366-1:2015	Medical devices - Application of usability engineering to medical devices
IEC 60601-1-6:2013	Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral Standard: Usability
EN ISO 14971:2019/A11:2021	Medical devices - Application of risk management to medical devices
EN 62304:2006/A1:2015	Medical device software - Software life-cycle processes
EN 60601-1-2:2015	Medical Electrical Equipment - Part 1-2 General Requirements for Safety - Collateral Standard: Electromagnetic compatibility-Requirements and tests
EN ISO 20417: 2021	Medical devices — Information to be supplied by the manufacturer
EN ISO 15223-1: 2021	Medical devices - Symbols to be used with information to be supplied by the manufacturer- Part 1: General requirements
EN 1789: 2020	Medical vehicles and their equipment - Road ambulances

Attachment of Declaration of Conformity: Applied Standards List-V2.0

Product:	Syringe pump
Model:	BeneFusion nSP, BeneFusion nSP ex, BeneFusion nSP Neo BeneFusion eSP, BeneFusion eSP ex, BeneFusion eSP Neo

Applied Standards:

EN 60601-2-24:2015	Medical electrical equipment -- Part 2-24: Particular requirements for the safety of infusion pumps and controllers
EN 60601-1:2006/A1:2013	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
IEC 60601-1-8:2006+A1:2012/ EN 60601-1-8:2007/A1:2013	Medical electrical equipment - Part 1-8: General requirements for basic safety and essential performance - Collateral Standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems
IEC 62366-1:2015	Medical devices - Application of usability engineering to medical devices
IEC 60601-1-6:2013	Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral Standard: Usability
EN ISO 14971:2019/A11:2021	Medical devices - Application of risk management to medical devices
EN 62304:2006/A1:2015	Medical device software - Software life-cycle processes
EN 60601-1-2:2015	Medical Electrical Equipment - Part 1-2 General Requirements for Safety - Collateral Standard: Electromagnetic compatibility-Requirements and tests
EN ISO 20417: 2021	Medical devices — Information to be supplied by the manufacturer
EN ISO 15223-1: 2021	Medical devices - Symbols to be used with information to be supplied by the manufacturer- Part 1: General requirements
EN 1789: 2020	Medical vehicles and their equipment - Road ambulances

Attachment of Declaration of Conformity: Applied Standards List-V2.0

Product:	Infusion supervision system
Model:	BeneFusion nDS, BeneFusion nDS ex BeneFusion eDS, BeneFusion eDS ex

Applied Standards:

EN 60601-1:2006/A1:2013	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
EN60601-1-8:2007/A11 :2017	Medical electrical equipment - Part 1-8: General requirements for basic safety and essential performance - Collateral Standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems
IEC 62366-1:2015	Medical devices - Application of usability engineering to medical devices
IEC 60601-1-6:2013	Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral Standard: Usability
EN ISO 14971:2019/A11:2021	Medical devices - Application of risk management to medical devices
EN 62304:2006/A1:2015	Medical device software - Software life-cycle processes
EN 60601-1-2:2015	Medical Electrical Equipment - Part 1-2 General Requirements for Safety - Collateral Standard: Electromagnetic compatibility-Requirements and tests
EN ISO 20417: 2021	Medical devices — Information to be supplied by the manufacturer
EN ISO 15223-1: 2021	Medical devices - Symbols to be used with information to be supplied by the manufacturer- Part 1: General requirements

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-244.10.08

Product Service

EC Certificate

Full Quality Assurance System
Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)
(Devices in Class IIa, IIb or III)

No. G1 002584 0006 Rev. 02

Manufacturer:

Shenzhen Mindray Scientific Co., Ltd.
6/F, Bldg 2, 1203 Nanhuan Avenue, Yutang Block
Guangming District
518106 Shenzhen
PEOPLE'S REPUBLIC OF CHINA

Product Category(ies):

Infusion pump,
Syringe pump,
Infusion supervision system

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex II. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class III devices an additional Annex II (4) certificate is mandatory. All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:G1 002584 0006 Rev. 02

Report No.: SH20115102

Valid from: 2020-11-04
Valid until: 2024-05-26

Date, 2020-11-04

Christoph Dicks
Head of Certification/Notified Body

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

TÜV®

Mindray PMLS Price List, Ex-works, Shenzhen, P.R.China

eSP Syringe Pump

Step1: Customized **Step2: Add to quotaion**

Quotation

	Ordering Category	Abbreviated Description	Full Description
	8521B-CTO-S01	eSP Syringe Pump	Sub Total
Step1:	**Select the national configuration**		
	Language	Roumanian	Roumanian
	Power cord	Power cord - EU	Power cord - EU
	Special country request	/	/
Step2:	**Select the functional configuration**		
Customized configurations, not recommended, for special requirement only. Some config. option may lead to an unc			
Fixed	Main Unit	eSP Main Unit	eSP Main Unit
Optional	WIFI Module	/	/
	Battery	Normal Battery	Normal Battery
	Pole Clamp	Standard Clamp	Standard Clamp
	Software	/	/

Traducere din limba engleză

NR. DE ÎNREGISTRARE. 04718Q10129R6L

CERTIFICAT
PRIVIND SISTEMUL DE MANAGEMENT AL CALITĂȚII

Prin prezentul documnt certificăm faptul că sistemul de management al calității

ShenZhenMindray Bio-Medical Electronics Co., Ltd.

Sediul social: Etajul 1~Etajul 4, Mindray Building, Keji 12th Road South, Hi-tech Industrial Park, Nanshan, Shenzhen, R.P. Chineză

Cod poștal: 518057

Adresa unității de producție: Mindray Building, Keji 12th Road South, Hi-tech Industrial Park, Nanshan, Shenzhen, R.P. Chineză; 1203 Nanhuan Avenue, Guangming District, Shenzhen, R.P. Chineză

A fost evaluat și conform cu următoarele standarde
GB/T 19001-2016 idt ISO 9001: 2015

Certificatul este valabil pentru următorul domeniu:

Proiectarea, dezvoltarea, producția și service-ul monitorului pentru pacient, Sistem centralizat de monitorizare, sistem de monitorizare prin telemetrie, monitor de telemetrie, monitor de semne vitale, oximetru de puls, monitoare de pacient, monitor de semne vitale & monitoare de pacient, senzor de unică folosință SpO2, senzor SpO2, cablu ECG, manșetă NIBP, Sondă de temperatură de unică folosință, Sondă de temperatură, Holter, Monitor portabil ECG, Sistem de analize, Defibrilator/Monitor, Electrocardiograf, Mașină de anestezie, ventilator, Sistem de diagnosticare cu ultrasunete, Sistem de diagnosticare cu ultrasunete, sistem de diagnosticare cu ultrasunete digital, Sistem de imagistică cu ultrasunete digital, sistem de administrare imagistică cu ultrasunete, sistem de radiografie digitală, sistem de radiografie mobilă, suport mobil, sistem de informații pentru imagistica radiografică, detector retropad și sistemul său de imagistică, analizator auto hematologie, analizator auto hematologie, analizator auto hematologie, analizator urină, automat Silde Maker & Statiner, citometru de flux, analizator de glicohemoglobină automat, analizator specific de proteine, sistem de prelucrare a probelor, analizator de chimie, analizator de chimie semi-auto, Cititor de microplăci. Spălător pentru microplăci. Sistem de prelucrare a probelor, analizator de imunoanaliză chimiluminiscentă, senzor CPR, monitor de semne vitale VS-900 Neo și reactiv de diagnostic vitro (a se vedea Anexa).

Data emiterii: 6 aprilie 2018
Data expirării: 5 aprilie 2021
Data modificării: 12 aprilie 2019

Director General
Semnătura indescifrabilă

BEIJING HUA GUANG CERTIFICATION OF MEDICAL DEVICES CO., LTD.

CNAS – SISTEM DE MANAGEMETN CNAS C047-M

Membru al Acordului de Recunoaștere Multilaterală
Notă: Acest certificat nu va fi valabil până când organizația nu va fi aprobată în baza auditului anual. Informațiile despre certificat sunt disponibile pe site-ul web al administrației de certificare și acreditare din Republica Populară Chineză (www.cnca.gov.cn) sau site-ul web al CMD (www.cmdc.com.cn). Adresa: 5th floor of Zhong Lian building , nr. Jia88,
An Ding Men Wai street Dungcheng District, beiging, 200022, R.P. Chineză, Telefon: 010-62351993

Subsemnatul ***CIUHU BOGDAN CONSTANTIN,***
traducător autorizat cu nr. 7319/2002 certific exactitatea traducerii cu textul documentului, redactat în limba ***engleză*** *şi vizat de mine.*