BeneFusion eSP

Syringe Pump

Data Sheet

Digitally signed by Gorgan Vasile-Dan
Date: 2023.05.15 18:30:08 EEST
Reason: MoldSign Signature
Location: Moldova

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

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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
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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

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