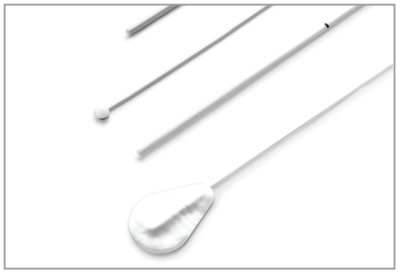
Temperature Accessories

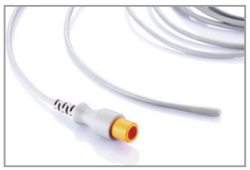
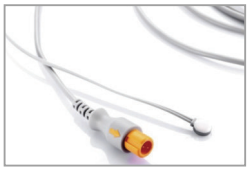


Reusable Temperature Probes

- Available in Rectal/Esophageal and Skin Surface Styles
- Flexible and durable cables
- Outstanding cable material, enduring repeated cleaning and disinfection
- Latex free
- Good biocompatibility, avoiding allergic reactions to patient

For BeneVision, ePM, uMEC, series monitors, BeneHeart defibrillator

38.5.

Picture	Model	Part No.	No. Description	Purchasing Unit
	MR401B	0011-30-37392	Reusable Temp Probe, Adu, Esophageal/Rectal, 2 Pin, 3 m	Each
	MR402B	0011-30-37394	Reusable Temp Probe, Ped/Neo, Esophageal/Rectal, 2 Pin, 3 m	Each
	MR403B	0011-30-37393	Reusable Temp Probe, Adu, Skin, 2 Pin, 3.6 m	Each
	MR404B	0011-30-37395	Reusable Temp Probe, Ped/Neo, Skin, 2 Pin, 3.6 m	Each

Invasive Blood Pressure (IBP) Accessories

Invasive Blood Pressure Cables

- Compatible solution with major monitor IBP module interface and disposable pressure transducer brands in the market
- Flexible and durable cables
- Outstanding cable material, enduring repeated cleaning and disinfection
- Latex free

For BeneVision, ePM, uMEC series monitors, BeneHeart defibrillator

Picture	Model	Part No.	No. Description	Purchasing Unit
	IM2201	001C-30-70759	12 Pin IBP Cable (for ICU Medical), 4 m	Each
	IM2202	001C-30-70757	12 Pin IBP Cable (for BD), 4 m	Each
	IM2207	0010-21-43082	12 Pin IBP Cable (for Memscap, SP844 82031 transducer), 4 m	Each

38.6.

Picture	Model	Part No.	No. Description	Purchasing Unit
	IM2211	0010-21-12179	12 Pin IBP Cable (for Edwards), 4 m	Each
	IM2206	115-017849-00	12 Pin IBP cable (for Utah), 4 m	Each

Y-type IBP cable: For BeneView, iPM series patient monitor, BeneHeart DX

Picture	Model	Part No.	No. Description	Purchasing Unit
	IM2204	040-001029-00	Y-type IBP cable (switch one connector to two connectors)	Each

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To Whom It May Concern,

CONFIRMATION LETTER

We, Mindray Medical Poland Sp. z o.o., with the address at ul. Cybernetyki 9, 02-677 Warsaw, Poland, subsidiary of Shenzhen Mindray Bio-Medical Electronics Co., Ltd., ("Mindray") the manufacturer of Mindray A9 anesthesia machine hereby confirm the following:

- Mindray A9 ACA (automatic controlled anesthesia) is suitable for pediatric and adult patients.

18.
- Vacuum Liquid collection bottle/flask, with or without overflow protection is reusable.
- On A9 anesthesia systems in the event of the power supply from the mains or internal batteries failure the operation of machine can be continued by applying manual ventilation and supplying oxygen by activating Back-up Fresh Gas Flow Control before battery is empty and setting the flow of O2 and AIR (possibility to mix gasses manually).

26.
- Predefined ventilation parameters and alarms – according to patient demographic data (IBW based on height, weight, age). Patient age group (adult, pediatric) also defines preset ventilation parameters and alarm limits.

21.2.
- Multi-step maneuver: Multi-step pressure increasing and decreasing according to user set levels with option to set optimal positive pressure level at the end of expiratory (PEEP).

This confirmation letter is (integral) part of the anesthesia machine Mindray A9 datasheet. If there are parameters with different values in the datasheet and confirmation letter, the information in the confirmation letter should be used.

Signature/stamp

enlei Gao - General Manager
Członek Zarządu/Member of the Board

Mindray Medical Poland Sp. z o.o.
ul. Cybernetyki 9, 02-677 Warszawa
tel. +48 22 463 80 80
NIP 1080017640, REGON 147173040

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Warszawa, dn. 06.06.2025 r.

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- On A9 anesthesia systems in the event of the power supply from the mains or internal batteries failure the operation of machine can be continued by applying manual ventilation and supplying oxygen by activating Back-up Fresh Gas Flow Control before battery is empty and setting the flow of O2 and AIR (possibility to mix gasses manually).
- Predefined ventilation parameters and alarms – according to patient demographic data (IBW based on height, weight, age). Patient age group (adult, pediatric) also defines preset ventilation parameters and alarm limits.
- Multi-step maneuver: Multi-step pressure increasing and decreasing according to user set levels with option to set optimal positive pressure level at the end of expiratory (PEEP).

This confirmation letter is (integral) part of the anesthesia machine Mindray A9 datasheet. If there are parameters with different values in the datasheet and confirmation letter, the information in the confirmation letter should be used.

Signature/stamp

enlei Gao - General Manager

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Mindray Medical Poland Sp. z o.o.
ul. Cybernetyki 9, 02-677 Warszawa
tel. +48 22 463 80 80
NIP 1080017640, REGON 147173040

BeneVision N Series

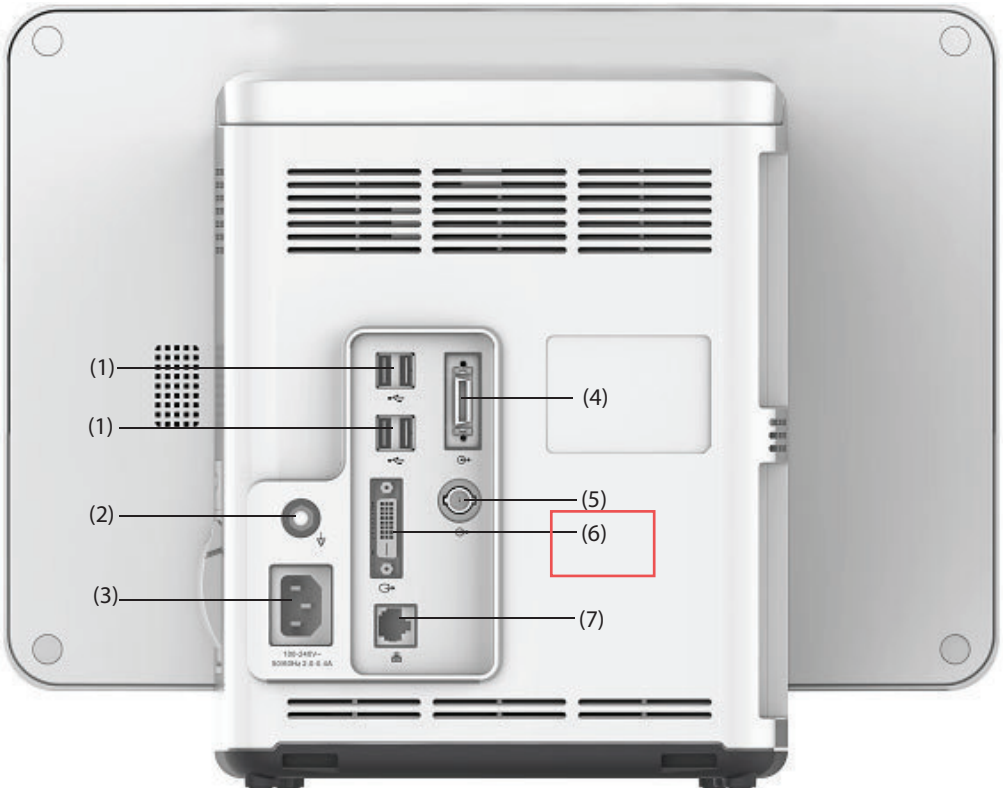
Patient Monitor

Operator's Manual

Volume I

(BeneVision N22/BeneVision N19/BeneVision N17/
BeneVision N15/BeneVision N12/BeneVision N12C)

2.3.3.4 N15, N12, N12C Rear View



(1) USB connectors

Connect USB devices, for example the keyboard, mouse, and barcode reader.

(2) Equipotential Grounding Terminal

When using the monitor together with other devices, connect their equipotential grounding terminals together to eliminate the potential difference between them.

(3) AC Power input

(4) Satellite module rack connector

For N15, connects the SMR and N1 or T1 Dock.

For N12/N12C, connect N1 or T1 Dock.

(5) Nurse call connector

It is a BNC connector. It connects the monitor to the hospital's nurse call system through the nurse call cable (PN: 8000-21-10361). Alarms from the monitor are sent to the nurse station through the nurse call system, if configured to do so.

(6) Digital video connector: connects external display. 36.7.3.

(7) Network Connector

It is a standard RJ45 connector which connects the monitor to the central monitoring system (CMS) or other network devices.

BeneVision N1

Patient Monitor

Operator's Manual

1. Enter the **Graphic Trends** review page.
2. Select ••• → select **Group Setup** → select the desired tab.

NOTE

- **You cannot edit the trend groups labeled All or Standard.**
- **ECG parameter and waveform are always displayed in the first row on the trend page. It cannot be deleted or moved.**

18.2.6.4 Changing the Resolution of Trend Data

To change the length of trend data displayed on the current screen, follow this procedure:

1. Enter the **Graphic Trends** review page.
2. Select **Zoom**.
   - **8 min:** the screen displays eight minutes of trend data. You can view the recent one hour data.
   - **30 min, 1 hr, 2 hrs, 4 hrs**: the screen displays 30 minutes, one hour, two hours, or four hours of trend data. You can view the recent four hour data.
   - **8 hrs, 12 hrs, 24 hrs, 48 hrs**: the screen displays eight hours, 12 hours, 24 hours, or 48 hours of trend data. You can view the recent 120 hours of data.

18.2.6.5 Changing the Number of Waveforms

To change the number of waveforms displayed on the trend review page, follow this procedure:

1. Enter the **Graphic Trends** review page.
2. Select ••• and set **Trends**.

18.2.6.6 Printing a Graphic Trends Report

Before print a graphic trends report, set the **Graphic Trends** report as described in *21.6.3 Setting Tabular Trends Reports*.

To print a **Graphic Trends** report, follow this procedure:

1. Enter the **Graphic Trends** review page.
2. Select  at the upper left corner to enter the **Print Setup** menu.
3. Select **Print**.

18.2.7 Reviewing Events

The monitor stores events in real time, including technical alarm events, physiological alarm events, manual events, and operational events. When an event occurs, all the measurement numerics and three event-related waveforms 16 seconds before and after the event are stored.

NOTE

- **A total loss of power has no impact on the events stored.**
- **Alarms are saved as events and will be maintained if the equipment is powered down. The time of equipment power down is not recorded as an event and cannot be reviewed.**
- **Earlier events will be overwritten by later ones if the capacity is reached.**

37.3.3.

18.2.7.1 Entering the Events Review Page

To enter the events review page, select the **Main Menu** quick key → from the **Review** column select **Events**.

The **Events** page displays event list. Events are displayed in descending chronological order. The most recent event is displayed at the top.The number of asterisk symbols before an event indicate alarm priorities.

Different color blocks are displayed on the left of each event to indicate different event types.

1. Enter the **Graphic Trends** review page.
2. Select ••• → select **Group Setup** → select the desired tab.

NOTE

- **You cannot edit the trend groups labeled All or Standard.**
- **ECG parameter and waveform are always displayed in the first row on the trend page. It cannot be deleted or moved.**

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   - **30 min, 1 hr, 2 hrs, 4 hrs**: the screen displays 30 minutes, one hour, two hours, or four hours of trend data. You can view the recent four hour data.
   - **8 hrs, 12 hrs, 24 hrs, 48 hrs**: the screen displays eight hours, 12 hours, 24 hours, or 48 hours of trend data. You can view the recent 120 hours of data.

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Different color blocks are displayed on the left of each event to indicate different event types.

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Anesthesia accessory

CATALOGUE 2022.06

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P/N:ENG-Anesthesia accessory catalogue-210210X64P-20220606

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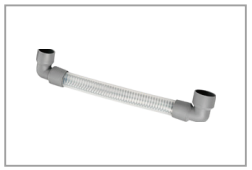
Picture	Part No.	Description	Apply to
	115-006557-00	Waste gas transfer hose, from main unit to AGSS assembly (801-0631-00074-00)	A7/A5/ WATO EX-65 Pro/ EX-55 Pro EX-65/EX-55 EX-35/EX-30 EX-20
34. 	115-009097-00	AGSS high flow receiving hose, from AGSS assembly to hospital's waste gas disposal system	All
	115-009073-00	AGSS low flow receiving hose, from AGSS assembly to hospital's waste gas disposal system	
	082-001372-00	AGSS receiving hosing, (35G-WAGD-DS/FG2-3), from AGSS assembly to vacum system	

Active AGSS kit

Part No.	Description	Apply to
115-030332-00	**AGSS kit, low flow, high vacuum, including:** - AGSS Assembly, low-flow - Waste gas transfer hose, from main unit to AGSS assembly - AGSS low flow receiving hose, from AGSS assembly to hospital's waste gas disposal system - AGSS Three-way connector, from ACGO to AGSS	A7/A5/ WATO EX-65 Pro/ EX-55 Pro EX-65/EX-55 EX-35/
115-030333-00	**AGSS kit, high flow, low vacuum, including:** - AGSS Assembly, high-flow - Waste gas transfer hose, from main unit to AGSS assembly - AGSS high flow receiving hose, from AGSS assembly to hospital's waste gas disposal system - AGSS Three-way connector, from ACGO to AGSS	A7/A5/ WATO EX-65 Pro/ EX-55 Pro EX-65/EX-55 EX-35/
115-011860-00	**AGSS kit, low flow, high vacuum, including:** - AGSS Assembly, low-flow - Waste gas transfer hose, from main unit to AGSS assembly - AGSS low flow receiving hose, from AGSS assembly to hospital's waste gas disposal system - AGSS mounting kit	WATO EX-30/ EX-20
115-011859-00	**AGSS kit, high flow, low vacuum, including:** - AGSS Assembly, high-flow - Waste gas transfer hose, from main unit to AGSS assembly - AGSS high flow receiving hose, from AGSS assembly to hospital's waste gas disposal system - AGSS mounting kit	WATO EX-30/ EX-20

BeneVision N1

Patient Monitor

Operator's Manual

11 Monitoring Respiration (Resp)

11.1 Resp Introduction

37.4.2.

Impedance respiration is measured across the thorax. When the patient is breathing or ventilated, the volume of air changes in the lungs, resulting in impedance changes between the electrodes. Respiration rate (RR) is calculated from these impedance changes, and a respiration waveform appears on the patient monitor screen.

Respiration monitoring is intended for adult, pediatric and neonatal patients.

11.2 Resp Safety Information

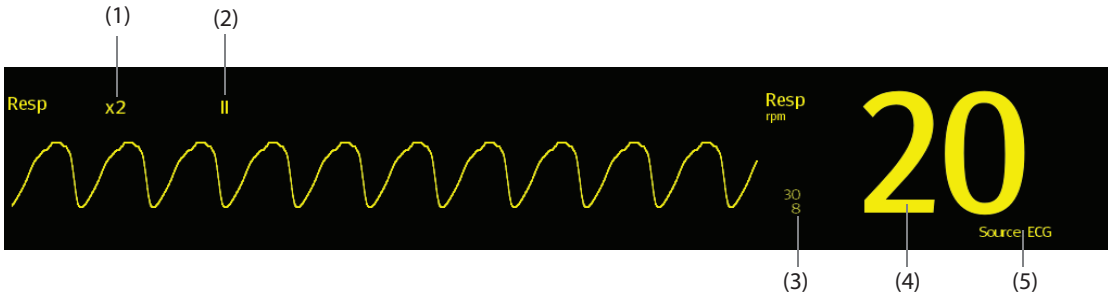
WARNING

- **When monitoring the patient's respiration, do not use ESU-proof ECG cables.**
- **The respiration measurement does not recognize the cause of apneas. It only indicates an alarm if no breath is detected when a pre-adjusted time has elapsed since the last detected breath. Therefore, it cannot be used for diagnostic purpose.**
- **When using the electrosurgery unit, ensure proper contact of the ESU return electrode to the patient to avoid burns at monitor measurement sites. Also ensure that the ESU return electrode is near the operating area.**

CAUTION

- **Only use parts and accessories specified in this manual.**
- **The impedance respiration measurement may cause rate changes in Minute Ventilation Rate Responsive Pacemakers. Set the pacemaker rate responsive mode off or disable the impedance respiration measurement on the monitor.**
- **Respiration monitoring is not for use on the patients who are very active, as this will cause false alarms.**

11.3 Resp Display



(1) Resp waveform gain (2) Resp lead label (3) Alarm limits

(4) Respiration rate (RR) (5) RR source

NOTE

- **If ESU-proof ECG cables are used, the Resp waveform area will display the message "Check Leads". Replace the ECG cable if necessary.**

11.4 Preparing for Resp Monitoring

11.4.1 Preparing the Patient

Follow this procedure to prepare the patient:

1. Shave hair from skin at chosen sites.
2. Gently rub skin surface at sites to remove dead skin cells.
3. Thoroughly cleanse the site with a mild soap and water solution.
4. Dry the skin completely before applying the electrodes.

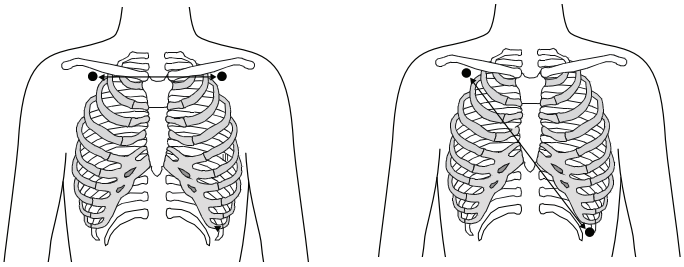
CAUTION

- **Proper skin preparation is necessary for good signal quality at the electrode site, as the skin is a poor conductor of electricity.**

11.4.2 Placing the Electrodes

37.4.2. As the Respiration measurement adopts the standard ECG electrode placement, you can use different ECG cables. Since the respiration signal is measured between two ECG electrodes, if a standard ECG electrode placement is applied, the two electrodes should be RA and LA of ECG Lead I, or RA and LL of ECG Lead II.

For more information, see *9.4.4 ECG Electrode Placement*.



(1) (2)

(1) Lead I (2) Lead II

CAUTION

- **To reduce cardiovascular artifact, apply the respiration electrodes so that the liver area and the ventricles of the heart are not in the line between the respiratory electrodes. This is especially important for neonatal patients.**
- **To optimize the respiration waveform, place the RA and LA electrodes horizontally when monitoring respiration with ECG Lead I; place the RA and LL electrodes diagonally when monitoring respiration with ECG Lead II.**
- **To optimize respiratory waveforms for patients breathing mainly abdominally, apply the LL electrode on the left abdomen at the point of maximum abdominal expansion.**
- **For patients expand chests laterally (normally neonatal patients), to avoid negative intrathoracic pressure and optimize respiratory waveforms, respectively apply the electrodes in the right midaxillary and the left lateral chest areas at the maximum point of the breathing movement.**
- **Periodically inspect the electrode application site to ensure skin quality. If the skin quality changes, replace the electrodes or change the application site.**

NOTE

- **Store the electrodes at room temperature. Open the electrode package immediately prior to use.**
- **Check that the electrode packages are intact and not expired. Make sure the electrode gel is moist.**

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Warszawa, dn. 09.06.2025 r.

To Whom It May Concern,

CONFIRMATION LETTER

We, Mindray Medical Poland Sp. z o.o., with the address at ul. Cybernetyki 9, 02-677 Warsaw, Poland, subsidiary of Shenzhen Mindray Bio-Medical Electronics Co., Ltd., ("Mindray") the manufacturer of Mindray BeneVision N12/N15/N17/N19/N22 monitors hereby confirm the following:

36.6. • Monitor cooling: ensures silent and long-lasting operation while preventing environmental dust accumulation - passive (without cooling fan).

This confirmation letter is (integral) part of the BeneVision N12/N15/N17/N19/N22 datasheet. If there are parameters with different values in the datasheet and confirmation letter, the information in the confirmation letter should be used.

Signature/stamp

[redacted] eral Manager

[redacted] mber of the Board

Mindray Medical Poland Sp. z o.o.
ul. Cybernetyki 9, 02-677 Warszawa
tel. +48 22 463 80 80
NIP 1080017640, REGON 147173040

A9

Anesthesia System

Operator's Manual

Alarm Item	Setting Range	Step
BIS High Limit	2 to 100	1
BIS Low Limit	0 to 98	

TABLE 12-37 Alarms

12.11.8 NMT Module

Stimulation output:	Pulse width	100, 200, or 300 μs; monophasic rectangle pulse Accuracy: ± 10 %
	Stimulation current peak	Output range: 0 to 60 mA Step: 5 mA Accuracy: ± 5 % or ± 2 mA, whichever is greater
	Maximum skin resistance	3 kΩ @ 60 mA, 5 kΩ @ 40 mA
Block Recovery:	OFF, 1,2, 3, 4, 5%, 10%, 20%, 30%, 40%. 50%, 60%, 70%, 80%, 90%, 100%	
TOF (Train Of Four) mode:	TOF-Ratio (response percentage)	5% to 160%
	TOF-Count (number of responses)	0 to 4
	TOF-T1% (response to the first stimulus as percentage of the reference value)	0% to 200%
ST (Single Twitch) mode:	ST-Ratio (response percentage)	0% to 200%
DBS (Double-Burst Stimulation) 3.2/ 3.3 mode:	DBS-Ratio (response percentage)	5% to 160%
	DBS-Count (number of responses)	0 to 2
PTC (Post-Tetanic Count) mode:	PTC-Count (number of responses)	0 to 20

TABLE 12-38 NMT Module

12.12 Ventilator Specifications

General Ventilator Specifications	
Drive Pressure:	280 to 600 kPa
Maximum Inspiratory Flow:	180 L/min
Low Flow Anesthesia:	The accuracy of Tidal Volume shall be within the specification at 0.2L/min to 1L/min total fresh gas flow.

22.5.

TABLE 12-39 General Ventilator Specifications

Ventilator Setting Parameter	Range
Apnea Tinsp:	0.2 to 10 s, Step: 0.1 s

TABLE 12-40 Ventilator Setting Parameter and Range

4.8.1.1.3 Display Interval

In the List Trends menu, you can set the display interval to [**1 Min**], [**5 Min**], [**10 Min**], [**15 Min**], [**30 Min**], [**1 Hour**] and [**2 Hour**].

4.8.1.1.4 Display Group

In the List Trends menu, you can set the display group to [**NMT**], [**BIS**], [**Gas**], [**Gas Flow**], [**Ventilator**], [**eMAC**] and [**All**].

4.8.1.2 Graphic Trends

29.

Graphic trends display allows the user to observe the trend of the physiological parameters. The trend is reflected through a curve. Every point on the curve corresponds to the parameter value at a specific time point. Graphic trends can also record standby and parameter alarm events Graphic trend data automatically displays in one minute intervals unless the zoom is selected.

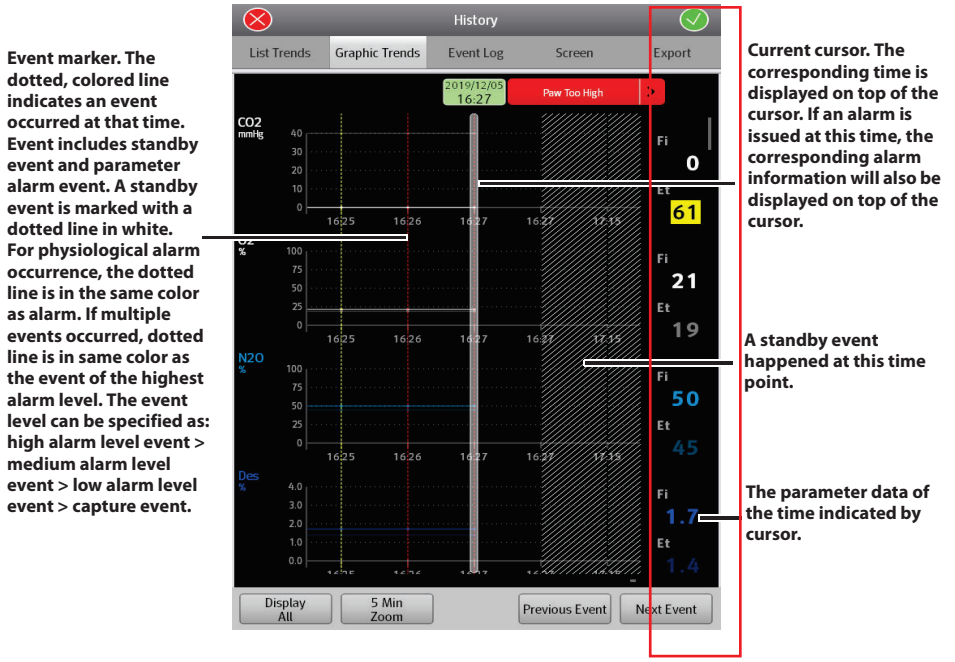

Figure 4-32 Graphic Trends

4.8.1.2.1 About Graphic Trends

- Graphic Trends store the data with the interval in 1 minute.
- Graphic Trends displays the trend records in descending order beginning with the most recent.
- Graphic Trends are not stored when the system is in standby.
- The display period of data is a rolling 48 hours of continuous data.
- Graphic Trends highlights the parameter data in the corresponding alarm color if an alarm condition existed for the parameter at the time of trend record storage.

4.8.1.2.2 Graphic Trend Events Buttons

Drag the horizontal or vertical progress bar to view the updated trend data.

BUTTON	FUNCTION
Previous Event	The cursor moves from the current event to the previous event.

4.8.1 History

Select the [**History**] soft key on the Main Screen to open the [**History**] menu. The menu contains the List Trends, the Graphic Trends, the Event Log, Screen and Export tabs. The List Trends, Graphic Trends and Event Log tabs on the History screen are associated. When you switch among the tabs, the cursor is automatically positioned to the record that is related to the previous page.

4.8.1.1 List Trends

On the [**List Trends**] screen, you can view the parameter data and events of a patient. If no display interval is set, the trends will be displayed based on the data with an interval of one minute by default.

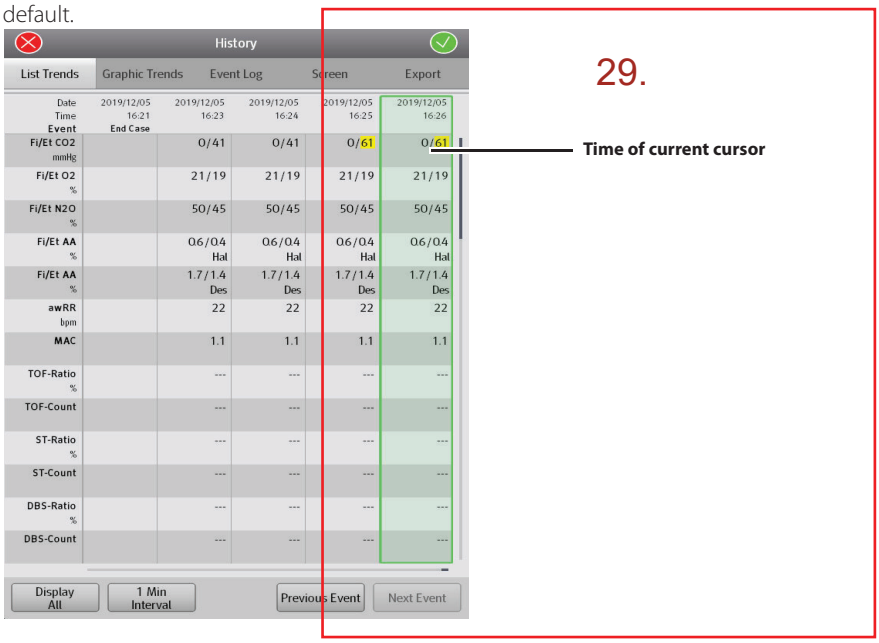

Figure 4-31 List Trends

4.8.1.1.1 About List Trends

- The horizontal coordinates of a list trend show the time and date.
- List Trends displays the parameter name on the vertical axis and it is always visible.
- List Trends displays the trend records in descending order beginning with the most recent on the right side of the grid.
- Graphic Trends are not stored when the system is in standby.
- List Trends can display the trend data of 48 consecutive hours.
- List Trends highlights the parameter data in the corresponding alarm color if an alarm condition existed for the parameter at the time of trend record storage.

4.8.1.1.2 List Trend Events Buttons

Drag the horizontal or vertical progress bar to view the updated trend data.

BUTTON	FUNCTION
Previous Event	The cursor moves from the current event to the previous event.
Next Event	The cursor moves from the current event to the next event.

Table 4-4 List Trend Events Buttons

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Accessories and Consumables

CATALOGUE 2024.07

www.mindray.com

P/N:ENG-Accessories and Consumables Catalogue-210210X160P-20240717

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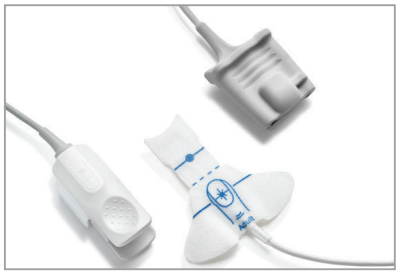
SpO_2 Accessories

Mindray SpO_2 Accessories



Integrated SpO_2 Cable

For BeneVision, ePM, uMEC, VS series monitors, BeneHeart defibrillator

Picture	Model	Part No.	No. Description	Purchasing Unit
	512FLH	115-012807-00	Integrative reusable SpO_2 sensor, Adult, Finger, >30 kg, 3 m	Each
	518BLH	115-020887-00	Integrative reusable SpO_2 sensor, Neo, Foot (adult/pediatric, finger), <5 kg, 3 m	Each

Mindray SpO_2 Cable

For BeneVision, ePM, uMEC, VS series monitors, BeneHeart defibrillator

- Ergonomic design, precise engineering and clinical testing guaranteeing reliable measurement
- Well anti-electromagnetic interference, suitable for complex electrical environment
- Flexible and durable cables
- Outstanding cable jacket, enduring repeated cleaning and disinfection
- Easy to change sensor, meeting clinical requirements for patient use
- Latex free

Picture	Model	Part No.	No. Description	Purchasing Unit
	562A	0010-20-42710 (009-004600-00)	Mindray SpO_2 extension cable, 7 Pin, 2.5 m	Each
	562B	040-001443-00	Mindray SpO_2 extension cable, 7 Pin, 1.2 m	Each

38.2.

For Telemetry

Picture	Model	Part No.	No. Description	Purchasing Unit
	SAT 10	115-029488-00	Mindray SpO_2 module for BeneVision TM80, 6 Pin, 0.5 m	Each
		125-000058-00	Masimo SpO_2 module for BeneVision TM80 and TMS 40	Each

Declaration of Conformity-V1.0

CE 0123

Declaration of Conformity

Manufacturer: Shenzhen Mindray Bio-Medical Electronics Co., Ltd.
Mindray Building, Keji 12th Road South, Hi-tech Industrial Park, Nanshan, Shenzhen, 518057, P. R. China

EC-Representative: Shanghai International Holding Corp. GmbH (Europe)
Eiffestraße 80
20537 Hamburg, Germany

Product: Anesthesia System (Including Accessories)

Model: **A8/A9**

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 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

Start of CE-Marking: 2019.12.20

Place, Date of Issue: Shenzhen, 2019.12.20

Signature: [redacted]

Name of Authorized Signatory: Mr. Wang Xinbing

Position Held in Company: Manager, Technical Regulation

Applied Standards List

Product: Anesthesia System

Model: A8/A9

Applied Standards:

EN ISO 14971:2012	Medical devices – Application of risk management to medical devices
EN 62304:2006/A1:2015	Medical device software - Software life cycle processes.
EN 60601-1: 2006/A1:2013	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
EN 60601-1-2:2015	Medical electrical equipment -- Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests
EN 60601-1-6:2010/A1:2015	Medical electrical equipment - Part 1-6: General requirements for safety - Collateral standard: Usability
EN 60601-1-8:2007/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 - Part 1: Application of usability engineering to medical devices
EN ISO 10993-1:2009/AC:2010	Biological evaluation of medical devices - Part 1: Evaluation and testing
EN1041:2008	Information supplied by the manufacturer with medical devices

ISO 15223-1:2016	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements
ISO 80601-2-13:2011/A1:2015/A2:2018	Medical electrical equipment Part2.requirements for the safety of anesthetic workstations
EN ISO 80601-2-55:2011	Medical electrical equipment. Particular requirements for the basic safety and essential performance of respiratory gas monitors
EN ISO 5359:2014/A1:2017	Anaesthetic and respiratory equipment - Low-pressure hose assemblies for use with medical gases
EN ISO 5356-1:2015	Anaesthetic and respiratory equipment - Conical connectors - Part 1: Cones and sockets
ISO 5360:2016	Anaesthetic vaporizers - Agent-specific filling systems
EN ISO 10079-3:2014	Medical suction equipment - Part 3: Suction equipment powered from a vacuum or positive pressure gas source
EN 60601-2-26:2015	Medical electrical equipment - Part 2-26: Particular requirements for the basic safety and essential performance of electroencephalographs
IEC 60601-2-10:2016	Medical electrical equipment - Part 2-10: Particular requirements for the basic safety and essential performance of nerve and muscle stimulators
EN ISO 18082:2014/A1:2017	Anaesthetic and respiratory equipment - Dimensions of non-interchangeable screw-threaded (NIST) low-pressure connectors for medical gases

ISO 17664:2017

Processing of health care products - Information to be provided by the medical device manufacturer for the processing of medical devices

Declaration of Conformity-V3.0

Declaration of Conformity

CE 0123

Manufacturer:	Shenzhen Mindray Bio-Medical Electronics Co., Ltd. Mindray Building, Keji 12th Road South, Hi-tech Industrial Park, Nanshan, Shenzhen, 518057, P. R. China
EC-Representative:	Shanghai International Holding Corp. GmbH (Europe) Eiffestraße 80 20537 Hamburg, Germany
Product:	Patient Monitor (Including Accessories)
Model:	BeneVision N17/BeneVision N15/ BeneVision N12/BeneVision N12C
Classification:	Ⅱb （According to Rule 10 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
Start of CE-Marking:	**2016-12-17**
Place, Date of Issue:	Shenzhen, 2018.12.29
Signature:	[redacted]
Name of Authorized Signatory:	Mr. Wang Xinbing
Position Held in Company:	Manager, Technical Regulation

Product:	**Patient Monitor**
Model:	**BeneVision N17/BeneVision N15/BeneVision N12/ BeneVision N12C**

Applied Standards:

EN ISO 14971:2012	Medical devices – Application of risk management to medical devices
EN 1041:2008	Information supplied by the manufacturer with medical devices
EN ISO 15223-1-2016	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements
EN ISO 10993-1:2009/AC:2010	Biological evaluation of medical devices - Part 1: Evaluation and testing
EN ISO 10993-5:2009	Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity
ISO 10993-10:2010	Biological evaluation of medical devices - Part 10: Tests for irritation and and skin sensitization
EN 60601-1: 2006 /A1:2013	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
EN 60601-1-2: 2015	Medical electrical equipment -- Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests
IEC 60601-1-6:2013	Medical electrical equipment -- Part 1-6: General requirements for basic safety and essential performance - Collateral Standard: Usability
IEC 60601-1-8:2012	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 60601-2-10:2012	Medical electrical equipment - Part 2-10: Particular requirements for the basic safety and essential performance of nerve and muscle stimulators
IEC 60601-2-25:2011	Medical electrical equipment - Part 2-25: Particular requirements for the basic safety and essential performance of electrocardiographs
IEC 60601-2-26:2012	Medical electrical equipment - Part 2-26: Particular requirements for the basic safety and essential performance of electroencephalographs
IEC 60601-2-27:2011	Medical electrical equipment - Part 2-27: Particular requirements for the basic safety and essential performance of electrocardiographic monitoring equipment
EN IEC 80601-2-30:2013	Medical electrical equipment -- Part 2-30: Particular requirements for the basic safety and essential performance of automated non-invasive sphygmomanometers
IEC 60601-2-34:2011	Medical electrical equipment - Part 2-34: particular requirements for the basic safety, including essential performance, of invasive blood pressure monitoring equipment
IEC 60601-2-49:2011	Medical electrical equipment - Part 2-49: Particular requirements for the basic safety and essential performance of multifunction patient monitoring equipment
ISO 80601-2-55:2011	Medical electrical equipment -- Part 2-55: Particular requirements for the basic safety and essential performance of respiratory gas monitors
ISO 80601-2-56:2009	Medical electrical equipment Part 2-56: Particular requirements for basic safety and essential performance of clinical thermometers for body temperature measurement
ISO 80601-2-61:2011	Medical electrical equipment Part 2-61: Particular requirements for basic safety and essential performance of pulse oximeter equipment
ISO 81060-2:2013	Non-invasive sphygmomanometers - Part 2: Clinical validation of automated measurement type

IEC 62366-1:2015	Medical devices Part 1: Application of usability engineering to medical devices
IEC 62304:2015	Medical device software - Software life cycle processes

Declaration of Conformity V1.0

CE 0123

Declaration of Conformity

Manufacturer:	Shenzhen Mindray Bio-Medical Electronics Co., Ltd. Mindray Building, Keji 12th Road South, High-tech Industrial Park, Nanshan, Shenzhen, 518057, P. R. China
Manufacturer SRN:	CN-MF-000014156
EC-Representative:	Shanghai International Holding Corp. GmbH (Europe) Eiffestraße 80, 20537 Hamburg, Germany
EC-Representative SRN:	DE-AR-000000001
Product:	Patient monitor
Model:	BeneVision N1 / BeneVision M1
Basic UDI-DI:	69449040AB0100002034
Classification:	IIb （According to Rule 10 of MDR Annex VIII）
Conformity Assessment Route:	Annex IX excluding CHAPTER II
GMDN code:	33586
CND code:	Z120302
Intended Purpose:	The patient monitor is intended for monitoring, displaying, reviewing, storing, alarming and transferring of multiple physiological parameters.

We declare that the above mentioned products meet the provisions of the REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT. All supporting documentations are retained under the premises of the manufacturer. This declaration of conformity is issued under the sole responsibility of the manufacturer.

References to CS:	/
Notified Body:	TÜV SÜD Product Service GmbH Ridlerstraße 65 80339 München, Germany.
Notified Body No. :	0123
Identification of the Certificate:	G10 044751 0176
Start of CE-Marking:	2017-10-25

I hereby am appointed as the authorized person to deal with all the registration and quality management affairs in my capacity as Deputy Director of Technical Regulation Department of Shenzhen Mindray Bio-Medical Electronics Co., Ltd, Effective immediately.

Place, Date of Issue: Shenzhen, [redacted] 2023.7.11

Signature: .....

Name of Authorized Signatory: Mr. Wang Xinbing

Position Held in Company: Deputy Director, Technical Regulation

Attachment of Declaration of Conformity: Applied Standards List-V1.0

Applied Standards List

Product: **Patient Monitor**

Model: BeneVision N1 / BeneVision M1

Standards Applied:

EN ISO 14971:2019 A11:2021	Medical devices - Application of risk management to medical devices
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 medical device labels, labelling and information to be supplied — Part 1: General requirements
EN ISO 10993-1:2020	Biological evaluation of medical devices - Part 1: Evaluation and testing
EN ISO 10993-5:2009	Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity
EN ISO 10993-10:2013	Biological evaluation of medical devices Part 10: Tests for irritation and skin sensitization Third Edition
EN 60601-1:2006+A1:2013+A2:2021	Medical electrical equipment -- Part 1: General requirements for basic safety and essential performance
EN 60601-1-2:2015/A1:2021	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests
EN 60601-1-6:2010/A1:2015/A2:2021	Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
EN 60601-1-8:2007/A1:2013/A2:2021	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
EN 60601-2-25:2015	Medical electrical equipment - Part 2-25: Particular requirements for the basic safety and essential performance of electrocardiographs
EN 60601-2-27:2014	Medical electrical equipment - Part 2-27: Particular requirements for the basic safety and essential performance of electrocardiographic monitoring equipment
EN IEC 80601-2-30:2019	Medical electrical equipment - Part 2-30: Particular requirements for the basic safety and essential performance of automated non-invasive sphygmomanometers
EN 60601-2-34:2014	Medical electrical equipment Part 2-34: Particular requirements for the basic safety and essential performance of invasive blood pressure monitoring equipment
EN IEC 80601-2-49:2019	Medical electrical equipment - Part 2-49: Particular requirements for the basic safety and essential performance of multifunction patient monitoring equipment
EN ISO 80601-2-55:2018	Medical electrical equipment -- Part 2-55: Particular requirements for the basic safety and essential performance of respiratory gas monitors
EN ISO 80601-2-56:2017/A1:2020	Medical electrical equipment Part 2-56: Particular requirements for basic safety and essential performance of clinical thermometers for body temperature measurement
EN ISO 80601-2-61:2019	Medical electrical equipment-Part 2-61: Particular requirements for basic safety and essential performance of pulse oximeter equipment

ISO 81060-2: 2013	Non-invasive sphygmomanometers -- Part 2: Clinical investigation of automated measurement type
EN 62304: 2015	Medical device software - Software lifecycle processes
EN 62366-1:2015+A1:2020	Medical devices – Application of usability engineering to medical devices

LETTER OF AUTHORIZATION

To whom it may concern,

We, **MR Global (HK) Limited**, with business office at Rm 1115-1116, 11/F, Tower 1, Grand Century Place, 193 Prince Edward Road West, Mongkok, Kowloon, Hong Kong P.R. China **("Mindray")** hereby certify that we authorize **UAB MedUS Medical**, with business office at Veiverių g. 153,KAUNAS,46147,Lithuania **("You")** as the exclusive distributor for sales of below **Product(s)** and in below authorized **Territory and Customer Segment.**

1. Products, Territory and Customer Segment under exclusivity:

No.	Product Line	Model	Territory	Customer Segment	Additional Remarks if any
1	PMLS	A1,A3,A5,A7,A8,A9,WATO EX-35,WATO EX-65,WATO EX-65 Pro	Lithuania,Latvia,Estonia	Private,Public	
2	PMLS	BeneVision,BeneVision N1,BeneVision N12,BeneVision N15,BeneVision N17,BeneVision N19,BeneVision N22,eGateway,EP30,High Level Module,High-end accessories,Monitors of the high-end accessories,TM80	Lithuania,Latvia,Estonia	Private,Public	
3	PMLS	ePM 10,ePM 10M,ePM 12,ePM 12M,ePM 15,ePM 15M,HYPERVISOR X,uMEC 100,uMEC 120,uMEC 150,uMEC10,uMEC12,uMEC15	Lithuania,Latvia,Estonia	Private,Public	
4	PMLS	C3,SV300,SV600,SV70,SV800,TV50,TV80	Lithuania,Latvia,Estonia	Private,Public	
5	PMLS	PM-60,VS 8,VS 9,VS Accessories	Lithuania,Latvia,Estonia	Private,Public	
6	PMLS	BeneHeart D3,BeneHeart D30,BeneHeart D6,BeneHeart D60,BeneHeart DX	Lithuania,Latvia,Estonia	Private,Public	
7	PMLS	BeneHeart R12,BeneHeart R3	Lithuania,Latvia,Estonia	Private,Public	
8	Infusion Pump	BeneFusion eDS,BeneFusion eSP,BeneFusion eVP,BeneFusion MRI Station,BeneFusion nDS,BeneFusion nSP,BeneFusion nVP,Infusion Accessories and Disposables,Infusion Pump General Accessory,Pump Accessories	Lithuania,Latvia,Estonia	Private,Public	
9	Surgical	Double Pendant,HyBase 3000,HyBase 6100,HyBase 8300,HyBase 8500,HyBase V8,HyBase V8 Classic,HyBase V9,HyLED 200,HyLED 200M,HyLED 600,HyLED 600/600,HyLED 600M,HyLED C5,HyLED C5/C5,HyLED C5/C5/C5,HyLED C5M,HyLED C7,HyLED C7/C5,HyLED C7/C5/C5,HyLED C7/C7,HyLED C7/C7/C5,HyLED C7/C7/C7,HyLED C7M,HyLED C8,HyLED C8/C5,HyLED C8/C5/C5,HyLED C8/C7,HyLED C8/C7/C7,HyLED C8/C8,HyLED C8/C8/C5,HyLED C8/C8/C7,HyLED C8/C8/C8,HyLED C8M,HyLED X5,HyLED X5/X5,HyLED X9,HyLED X9/X5,HyLED X9/X5/X5,HyLED X9/X9,HyLED X9/X9/X5,HyLE	Lithuania,Latvia,Estonia	Private,Public	

mindray 迈瑞

		D X9/X9/X9,HyLED X9M,HyLED(Video),HyLink,HyPort 3000,HyPort 3000/HyPort 3000,HyPort 3000/HyPort 6000,HyPort 3000/HyPort 9000,HyPort 6000,HyPort 6000/HyPort 6000,HyPort 6000/HyPort 9000,HyPort 9000,HyPort 9000/HyPort 9000,HyPort P20,HyPort P30,HyPort P60,HyPort P90,HyPort R80,HyPort R80-I,HyPort R80-II,Lights and Pendant			

2. You further understand and agree as follows supplementary to the abovementioned Customer Segment within the Territory; In case of any inconsistency between the above table and this clause 2 hereof, this clause 2 shall prevail.

Except Estonia Pre-hospital market.

This letter of authorization is valid and effective from the Issuance Date hereof until **31st December 2024** (**"Expiry Date"**). On the Expiry Date this letter of authorization shall cease to be effective without notice. Furthermore, Mindray reserves the right to revoke unilaterally this letter of authorization by giving fifteen (15) days written notice without any compensation, indemnity, damages being due to You.

For avoidance of doubt, the underlying Exclusive Distribution and Supply Agreement (Agreement No. EDA2024003760-V01) will continue to be valid and effective in accordance with its terms, unless explicitly amended by this letter of authorization.

Best regards,

MR
By [redacted]

Signature Name: Lu Xiaozhen
Signature Title: Authorized Representative
Issuance Date:

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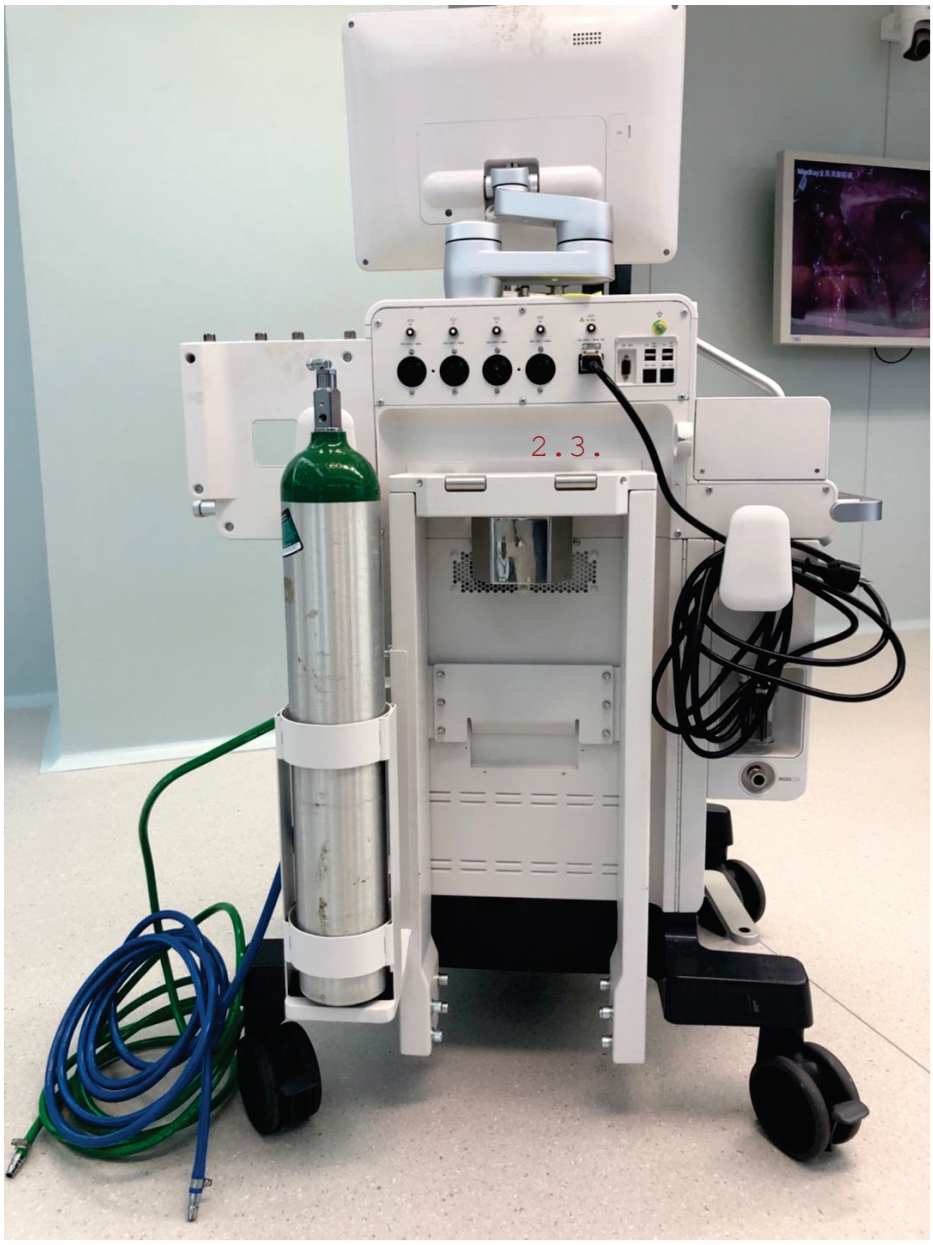
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