bluepoint M E D I C A L

ST-BL

Disposable neonatal flow sensor

de	Gebrauchsanweisung	**en**	Instructions for use
fr	Mode d'emploi	**es**	Instrucctiones de uso
it	Istruzioni per l'uso	nl	Gebruiksaanwijzing
pl	Instrukcja użycia	**ru**	Инструкция по применению
zn	使用說明	**ja**	使用説明書

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Intended use and medical purpose of ST-BLR

Intended use:

ST-BL is a disposable neonatal hot wire anemometric flow sensor, for measuring gas flow in Dräger's neonatal ventilators. ST-BL flow sensor is compatible to:

- Dräger neonatal flow sensor ISO 15, REF 8411130

Intended medical indications:

Disposable neonatal flow sensor for measuring respiratory gas flow in neonatal ventilators.

Intended user profile:

Healthcare professional, trained for the application

Intended patient groups:

premature and newborn babies and infants

Clinical environment:

Professional healthcare facility

Contraindications:

Not intended to be used with flammable anaesthetic mixtures.

Not intended to be reused, autoclaved or sterilized.

General warnings and safety notices

Safety symbols used in this document:

⚠	Indicates potential harmful conditions that may lead to serious injury.
ⓘ	Important information on a topic or procedure, or conditions that may lead to damage or malfunctions of the device.

General warnings:

⚠	Do not use this medical product if it appears or is suspected to be damaged. Damage to the product may result in degraded performance.
⚠	Do not use this product if its packaging has been open before. Risk of infection, cross contamination!
⚠	No modification of this medical product is allowed.
⚠	ST-BL neonatal flow sensor is for single patient use only. Reusing the flow sensor may affect patient safety due to the possible contamination of the sensor.
⚠	ST-BL flow sensor **cannot** be autoclaved of sterilized.
⚠	Strictly follow the instructions for use. Handling of the device requires full understanding and strict observation of the operating instructions of basic device (ventilator) and these instructions for use.
⚠	The flow sensor must be calibrated within basic device (ventilator) and system check must be performed prior to patient use.

⚠	Due to fire risk - do not introduce any medicaments or other substances based on combustible solvents, such as alcohol, into the patient system.
	Do not use explosive anaesthetic agents (e.g. ether or cyclopropane).

General safety notices:

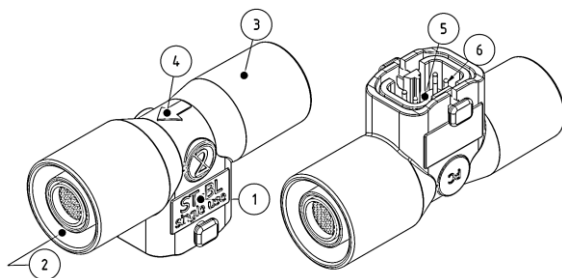| 𝒾	The medical device is intended only for the application described herein.
𝒾	Serious incident that has occurred in relation to this medical device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.
	To report patient safety related events, send an email to the following manufacturer's address:
	prrc@bluepoint-medical.com with at least following information:
	- order number and product name
	- batch number of the product
	- date of the serious incident
	- description of the serious incident affecting the patient or any injuries
	- your contact data (institution, address, contact person/representation, title and telephone number)

ST-BL Sensor overview

1. Product name
2. 15F sensor connector (to the patient)
3. 15M sensor connector (to the Y-piece/ventilator)
4. Sensor installing position (inspiratory flow direction)
5. Sensor plug
6. Sensor pins

The sensor insert by ST-BL neonatal flow sensor **cannot** be removed or replaced.

Installing, calibrating and operating of the flow sensor

⚠	This medical product must be connected/installed to the basic device (ventilator) according to the instructions for use of basic device. Risk for faulty operation!
⚠	Ensure correct positioning and secure connection of this product to the basic device (electrically, mechanically, flow direction). Risk for leakages and faulty operation!
⚠	The flow sensor and Y-piece must be angled approximately 45° downwards to prevent collecting of condensing water into flow sensor. Risk for faulty operation!
⚠	The flow sensor cable plug of the basic device has to be securely connected to the flow sensor plug. The sensor cable must be positioned along the breathing hoses laid free and not causing any mechanically stress to flow sensor plug during operation. Risk for leakages and faulty operation!
⚠	The flow sensor must be calibrated within basic device (ventilator) prior to patient use.
⚠	The flow sensor calibration must be performed in accordance with instructions for use of basic device (ventilator).
⚠	A preoperational device system check must be performed according to the instructions for use of basic device (ventilator) prior to patient use. If a malfunction is detected, do not operate the device! Patient hazard!
⚠	Due to fire risk – do not use this product with medicaments or other substances based on combustible solvents. Before medication nebulization, disconnect the flow sensor completely from the basic device. Follow the instructions for use of basic device for operating with deactivated flow monitoring and use an independent monitoring. The patient may otherwise be jeopardized.

Disposal

The flow sensor must be disposed of as infectious waste.

Technical information

Measuring principle:	Hot wire anemometry
Measuring range:	0 to 30 L/min, depending on ventilator(evaluation electronics)
Accuracy:	DIN EN ISO 80601-2-12,
	Typically ±10% of measured value under calibration conditions depending on ventilator(evaluation electronics)
Sensor connectors:	15F/15M acc. DIN EN ISO 5356-1
Recommended operating conditions:	
Temperature:	10°C to 40°C
Relative humidity:	5% to 95%, non-condensing
Atmospheric pressure:	700hPa to 1060hPa
Recommended storage and transport conditions:	
Temperature:	-20°C to 50°C
Relative humidity:	5% to 95%, non-condensing
Atmospheric pressure:	700hPa to 1060hPa

Ordering information

Product name	UDI number	Order number
ST-BL disposable neonatal flow sensor, (5pcs per Box)	24251679601726	9030132002

ST-BL Marking and symbols explanation

REF	de: Katalognummer en: Catalogue number
LOT	de: Chargennummer en: Batch code
UDI	de: einmalige Produktkennung en: Unique Device Identification
MD	de: Medizinprodukt en: Medical device
⎙	de: Stückzahl en: Number of units
⚒	de: Herstellungsdatum en: Date of manufacture
⧖	de: Ablaufdatum en: Expiry date
▰	de: Hersteller en: Manufacturer
CE 0482	de: CE-Kennzeichnung. Kennnummer der benannten Stelle en: CE-European Conformity authorization mark.
🕮	de: Gebrauchsanweisung beachten en: Consult instructions for use
⚠	de: Die Warnhinweise in der Gebrauchsanweisung beachten! en: Observe the warnings in the instructions for use

⊘ (symbol)	de: Nur für den einmaligen Gebrauch en: Do not reuse
NON STERILE	de: nicht steril en: non-sterile
(symbol)	de: Bei geöffneter oder beschädigter Verpackung nicht mehr verwenden en: Do not use if package is damaged and consult instructions for use.
PHT	de: Bei der Herstellung wurde kein DEHP verwendet en: Does not contain Phthalates
LATEX	de: Bei der Herstellung wurde kein Naturkautschuklatex verwendet. en: Does not contain Latex
(symbol)	de: Von Hitze und Sonnenlicht fernhalten en: keep away from heat and sunlight
(symbol)	de: Lagertemperaturbegrenzung en: Storage temperature limitation
(symbol)	de: Feuchtigkeitsgrenzwerte en: Humidity limitation
(symbol)	de: Grenzwerte des atmosphärischen Drucks en: Atmospheric pressure limitation
(symbol)	de: Nicht mit dem Hausmüll entsorgen en: Do not dispose of with domestic waste

ST-BL – Instructions for use

Multilingual version: en, de

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