[Product name]
Disposable Pressure Transducer

[Type & specification]
Single channel, double channel, triple channel

[Structure and composition]
This product is composed of an infusion set, a stopcock, and a blood pressure transmission tube.

[Intended use]
It is intended for arterial or venous blood pressure monitoring.

[Indications]
No specific disease or medical condition. This product is only intended for the diseases or conditions requiring arterial or venous blood pressure monitoring, including but not limited to the following:
1. Arterial (Eg. radial artery, dorsalis pedis artery, brachial artery, femoral artery) blood pressure monitoring;
2. Venous (Eg. central venous) blood pressure monitoring

[Contraindications]
1. Infections at the puncture site;
2. Coagulation disorders and severe bleeding disorders;
3. Radial artery puncture manometry is contraindicated in patients whose surgical operation involves the same site and who have a positive ALLEN test;
4. Patients with vascular diseases, such as vasculitis.

[Complications]
1. Infection
2. Air embolism
3. Catheter embolism and blood regurgitation
4. Bleeding and hematoma

[Patient target group]
Patients who need and are eligible for invasive pressure monitoring.

[Intended users]
This product can be used by professional doctors, who have been properly trained for this operation.

[Instructions for use]
1. Confirm whether the product cable connector matches the invasive voltage cable of the monitor, and turn on the monitor;
2. Prepare sodium heparin saline in the infusion bag according to the physician's instructions;
3.Open the package under aseptic operation, confirm whether the product is in good condition, and confirm that all connecting parts of the product are firmly connected, and ensure that all stopcocks are in safe or desired positions;

⚠ **Before use, make sure that the connectors are tightened to avoid leakage or blood return of the system**

4. Insert the closure-piercing into the infusion bag, turn on the flow regulator, gently squeeze the infusion bag, and squeeze the sensor flush valve simultaneously until all the air is out of the tube;
5. Turn off the flow regulator and put the infusion bag in the pressurization bag and hang it on the hanging rod approximately 60 cm away from the patient;

⚠ **Do not pressurize the infusion bag at this time**

6. Carefully check all parts filled with liquid in the system to ensure that all air bubbles have been discharged; confirm that there are no clearly observable air bubbles in the tube;
7. Pressurize the infusion bag to 300 mmHg, gently squeeze the flush valve, and remove the residual small air bubbles in the tube until no air bubbles flow out from the tube;
8. Connect the cable connector of the product with the cable on the monitor;
9. Connect the transmission tube to the corresponding catheter of the patient, squeeze the flush valve to remove the blood in the tube, and complete the establishment of the pressure monitoring channel;
10. Clamp the product on the fixing device to ensure that the position of the dome is flush with the patient's heart;
11. Close the stopcock connected to the dome to the patient side, so that the chip is zeroed in the state of atmospheric communication;

⚠ **The stopcock must be rotated 90° to fully close, preventing blood regurgitation or preventing contamination**

⚠ **There must be no air bubbles left in the tube**

12. Zero the monitor according to the IFU, and, after the zero setting, rotate the stopcock to close the channel related to zero setting and start pressure monitoring.

⚠ **Keep the dome of the product at the same level as the heart at all times during monitoring**

13. Abnormal conditions and handling measures:
(1) If zero setting is not possible, check whether the cable connectors between the product and the monitor are well matched, and replace the product with a new one if the match is abnormal.
(2) Abnormal blood pressure readings should be accompanied by corresponding clinical signs; if they

are inconsistent, verify whether the sensor is functioning normally by using a known or calibrated blood pressure measurement method.
(3) If the waveform and value are found to be weak, it may be due to the following reasons:
Wrong stopcock position;
There is air in the tube;
There is a blood embolism in the tube;
The catheter or puncture needle tip is positioned in contact with the vessel wall;
Testing and debugging should be performed for the above reasons. This product may not cause malfunctions that are harmful to the operators or users during proper use.
14. Each set of product can be used by patients for no more than 7 days.
15. After using the product, make sure that the cable connector of the product is disconnected from the monitor, and the transmission tube is disconnected from the catheter at the patient end; please do not discard it at will, and it should be recycled and destroyed by the medical institution.

[Performance parameters]

Excitation Voltage	2-10V (rms)
Pressure Ranges	-50-300 mmHg
Excitation Impedance	1200-3300 Ω
Signal Impedance	275-315 Ω
Sensitivity	5μV/V/mmHg ± 1%
Zero Pressure Offset	≤ ±1 mmHg
Offset Drift	≤ ± 1 mmHg/8 hrs

[Precautions, warnings and reminders]
1. This product can be used by professional doctors, who have been properly trained for this operation. Please read the instruction for use carefully before use.
2. This product is sterilized by ethylene oxide and supplied sterile. The shelf life is 5 years, please use it within the shelf life.
3. Please check whether the package is in good condition before use, and do not use if damaged.
4. After opening the package, please check whether the product is in good condition, and do not use if damaged.
5. Confirm whether the stopcock can operate normally before use, regularly check the tubes to ensure that no bubble remains, and ensure the well connection of the tubes and the stopcock.
6. Please stop using the device if connector fracture, leakage, or inaccurate measurement occurs in the use process.
7. Zero setting is needed for every position change of patients; timely zero setting is needed for any disagreement over the measurement data or waveform.
8. If fail to zero the device, please first make sure that the monitor is on the zero setting interface, and then check the connecting part between the monitor cable and the pressure transducer; if still fail, please replace the monitor or pressure transducer.
9. Approximately 1 minute is needed before the sealability of the flush valve is visually checked via small liquid drops; a regular check should be carried out 30 minutes after the installment to ensure the normal pressure in the infusion bag and the normal flow rate, and ensure no leakage because a small leakage may cause wrong readings on the monitor.
10. The puncture needle should be properly fixed to ensure the sealability, so that the heparin saline can be dripped into the human body normally, thus ensuring the safety and effectiveness of the product and reducing related problems during clinical use.
11. In the use process, please do not change its structure without permission.
12. Devices such as I.V. Cannulas and central venous catheters used in conjunction with this product should have a standard Luer lock connector. Ensure the close cooperation of the connection and prevent blockage, leakage or other factors affecting the flow rate. If the above conditions occur during combined use, please immediately turn off the stopcock and discontinue the use.
13. According to the electromagnetic compatibility report of this product, it should be used in a specified electromagnetic environment, to avoid the impact of possible electromagnetic interference on the accuracy of the measurement.
14. Portable and mobile radio frequency communications equipment may interfere with the normal operation of this product.
15. In practical use, only 0.9% normal saline spiked with a certain volume of heparin sodium should be filled in the tubes, and this product should not be used for drug infusion.
16. This product should not be used for the storage or infusion of fat-soluble liquid or drug such as lipid emulsion.
17. Use of accessories and cables other than those

CE 2862

specified, in addition to the configuration and cables provided by the manufacturer, may result in increased radiated emissions or reduced immunity.

18. This product should not be used in close to or stacked on with other equipment, and if it must be used in close to or stacked, it should be observed to verify that it can operate normally under the configuration used.

19. This product has no anti-defibrillation function, and can be only connected to the monitor marked with anti-defibrillation function at the patient end; and the pressure transducer is connected to the monitor to measure blood pressure normally.

20. This product is for single use, do not reuse, otherwise it may cause infection.

21. Please destroy the product after use, and the destruction procedure should be carried out by a qualified or authorized organization in accordance with the relevant local regulations for harmless disposal.

22. If any incident occurs in relation to the device, please notify the manufacturer and, if applicable, report to the competent authorities of the Member State in which it occurred.

[Operating environment and storage]

1. This product must be used in a sterile environment;
2. This product should be kept in a dry, cool and ventilated environment, keep away from sunlight and provided with moisture proof measures;
3. The product should be kept away from fire, heat and corrosive gases.
4. Handle carefully during transportation and avoid violent collisions.
5. Operating, transportation and storage conditions:

Item	Operating Environment	Transportation and Storage Environment
Temperature	15-40℃	-25-70 ℃
Humidity	20-90%	20-90%
Atmospheric Pressure	70-106 kPa	70-106 kPa

[Production batch No.] see the primary package

[Production date] see the primary package

[Expiration date] see the primary package

[Explanation of symbols]

	Manufacturer		Date of manufacture

	Use-by date	LOT	Batch code
	Do not re-use		Caution
	Single sterile barrier system	STERILE EO	Sterilized using ethylene oxide
MD	Medical device	UDI	Unique device identifier
CE 2862	CE Marking	REF	Catalogue number
	Keep away from sunlight		Keep dry
	Fragile, handle with care		Temperature limit
	Humidity limitation		Type CF applied part
EC REP	Authorized representative in the European Community/ European Union		Do not use if package is damaged and consult instructions for use
	Consult instructions for use or consult electronic instructions for use		Do not resterilize. Indicates a medical device that is not to be resterilized

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