Product Manual

Disposable Blood Pressure Transducer

Suzhou RainMed Medical Technology Co., Ltd.

CE 2797

IFU-F-02/0.1

The product manual illustrates how to operate this product properly, so please read the manual carefully before using it. After reading, please keep this manual carefully so as to refer to it when in need.

【Product Name】

Product Name: Disposable Blood Pressure Transducer (Hereinafter referred to as Blood Pressure Transducer)

【specification model】

Model Number	Specification
CPT-1200	Pressure Tube Length: 1200±50mm
CPT-1500	Pressure Tube Length: 1500±50mm
CPT-2000	Pressure Tube Length: 2000±50mm

【Product Structure】

This product is made up of blue internal thread plug, one-way Stopcock, cable (8-core insulated cable, 8-core conductor, cable sheath, crystal connector), pressure sensing component (including pressure sensor chip; identification chip; top and bottom cover; thread terminal), pressure Tube component (including pressure Tube and the Tapers at both ends), extension Tube component (including extension Tube and the Tapers at both ends), Three-way Stopcock, internal thread plug and external thread plug. Among them, the adhesive for sealed and fixed thread terminals and Tube materials is medical grade UV glue, and the welding adhesive for chip and cable is lead-free solder wire. The structure diagram of the Blood Pressure Transducer is shown in Fig. 1.

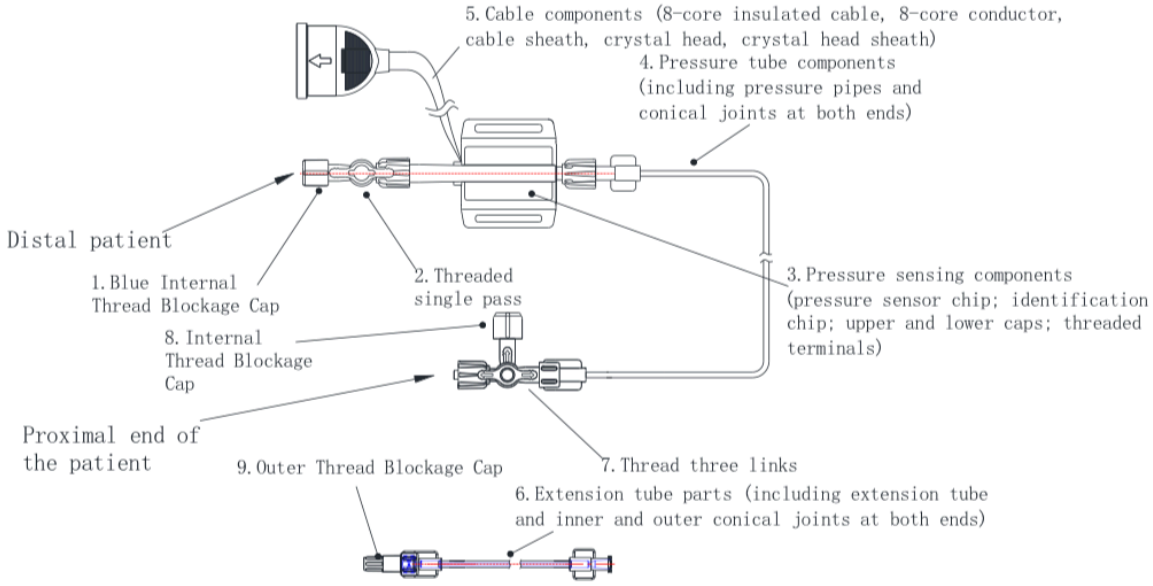

Fig 1.structure diagram of the Blood Pressure Transducer

No	Name
1	Blue internal thread plug
2	one-way Stopcock
3	Pressure sensing component(pressure sensor chip; identification chip; top, bottom cover; thread terminal)
4	Pressure Tube component(including Pressure Tube and the Luer tapers at both ends)
5	cable component(8-core insulated cable, 8-core conductor, cable sheath, crystal connector, crystal connector sheath
6	Extension Tube component (including extension Tube and the Luer tapers at both ends)
7	three-way Stopcock
8	Internal thread
9	External thread plug

【Application Range】

This product is used to obtain aortic pressure.

Note: The obtained aortic pressure is used for the calculation of Coronary arteriography Fractional Flow Reserve (caFFR) by the ASC15 Coronary artery analysis system manufactured by Suzhou RainMed Medical Technology Co., Ltd.

Note: Only for qualified by training medical technicians to operate on adult patient。

【Contraindication】

- Patients with abnormal coagulation function should use with caution.
- Patients with hemorrhagic disease should use with caution.

【Main Material】

Polyvinyl chloride, polycarbonate, polypropylene, polycarbonate + high density polyethylene, acrylonitrile-butadiene-styrene copolymer

【Method of Use】

All operations shall be performed in accordance with the requirements of aseptic operations.

1. Ensure the connection between the IBP lead line and the analyzer is reliable, and turn on the analyzer to preheat.

2. Open the package and take out the blood pressure transducer.

3. Check all components to make sure all joints are tightly connected.

Note: excessive tightening of the joint may break the joint, causing leakage, air bubble embolism, backflow or loss of blood pressure waveforms.

Note: air or air bubbles in the Tube may affect the measurement results.

4. Connection between sensor and analyzer

a. Connect the sensor cable to the IBP lead wire of the analyzer.

b. Check whether the joints are fully connected and locked.

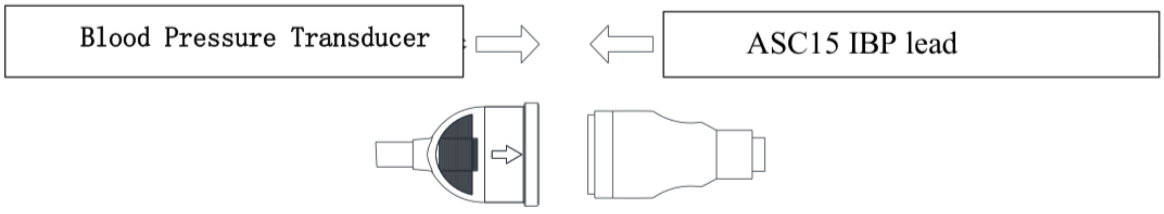

Fig 2. Connection of Blood Pressure transducer connector

5. Prepare a disposable sterile syringe, inhale stroke-physiological saline solution (if anticoagulation is needed, heparin can be added), then remove the external thread plug at the proximal end of the patient, put the proximal and distal end of the patient in the same height, inject normal saline from the distal end of the patient to flush the tube, discharge all the air in the tube. Then close the threaded one-way, remove the syringe, and twist the blue internal thread plug cap.

Warning: If the liquid contains air (namely there is air in the syringe that is not fully discharged), air may enter the pressure monitoring tube when the liquid runs out.

Warning: air bubbles should not be emptied by pressurization (slowly injected with normal saline) In the process of emptying air bubbles and judging whether bubbles are emptied, pressurization is not feasible (should be by means of slowly injecting normal saline).so as to prevent the small air bubbles compressed (which are recognized to the naked eye) from being neglected, and the air embolism will be formed after entering the blood.

Note: If there is air or bubbles in the pipeline, the measurement results will be affected.

6. Rotate the threaded tee handle near the patient, connect the blood pressure sensor with the direction of

the side hole where the inner thread plug cap is located, and close the end outlet of the threaded tee.

7. Zero calibration of the Blood Pressure Transducer.

a. Connect the blood pressure sensor to the triple junction, remove the internal threads on the proximal threads of the patient and plug the clogging, so that the blood pressure sensor can be connected to the atmosphere.

b. Keep the pressure stable. Then zero calibration is carried out according to the zero calibration operation method of the analyzer.

c. After successful zero calibration, and re-screw the internal thread to stop the leaking. Open the proximal threaded tee of the patient to connect the blood pressure sensor with the triple tee.

Note: if the zero calibration is not successful, please check whether the cable connection, analyzer, etc. are normal.

Note: The pressure sensing parts of the blood pressure sensor should be at the same level as the heart when zeroing.

8. After the system is normally zero calibrated, the pressure measurement shall be carried out as required.

【Precautions】

- To avoid disturbance of reading, please don't wring the tubes.
- In order to ensure the accuracy of the equipment, the analyzer should be preheated for no less than 1 minute before the blood pressure sensor is connected to the analyzer.

【warning】

- **This product should be operated by experienced medical staff or under their direct instructions. And please note that the integrity and effectiveness of the product should be checked.**
- **No bubbles shall be found in the tube during the use of the product, otherwise the measurement accuracy will be affected.**
- **This product shall be used in a sterile environment.**
- **This product is a disposable, please do not reuse it.**
- **This product is sterilized by ethylene oxide; do not use it if the package or the product is damaged.**
- **The effective period of sterilization of the blood pressure transducer is 2 years; the product must be used before the expiration date.**
- **Please do not use the product in the environment with high magnetic field intensity (such as MRI).**
- **Expired products shall not be used, and shall be recycled in accordance with hospital or local environmental regulations.**
- **The blood pressure transducer can only be connected to the ASC15 analyzer produced by Suzhou RainMed Company.**
- **Using vacuum device to eliminate air bubbles is not recommended. It may make the liquid mixed with or discharge air.**

【Notes】

- This product should be stored without corrosive gas in a dry and well ventilated room. Avoid direct sunlight exposure.
- To ensure the effectiveness and safety, understand in detail the method of use and the function of the product before use.
- Medical staff shall use the product according to the requirements of the manual and it shall not be used for other purposes.
- During blood pressure test, patients should try to keep calm, for patient’s motion would affect the precision of the measuring result.
- Do not change the product structure while using the product.
- Patients identified with hemorrhagic diseases should be treated with caution.

- Do not use the product if there is any abnormal condition such as product contamination, damage, or missing parts etc.）。

【Potential complications】

Adverse events or complications associated with the use of the disposable blood pressure transducer include, but are not limited to:

Minor blood loose

Misdiagnosis

Delay treatment

Air embolism

Leakage

Fatal allergic reactions and infections

Poisoning, local or systemic infection, all kinds of severe allergic reactions

Bleeding

Thrombosis

Infection

Burn

Patient injury or damage

Electric shock

Pollute environment

Scratched。

【Product Specification and Basic Parameter】

According to the classification of Annex IX Rule 10 of MDD 93/42/EEC: this product is a Class IIa appliance.

According to EN 60601-1:2006+A1:2013

1) By the classification of the Type of Protection Against Electric Shock: not applicable;

2) By the classification of the Degree of Protection Against Electric Shock: CF-type application part;

3) By the classification of IP protection level: IPX0;

4) AP or APG-type equipment: non-AP or APG-type equipment ;

5) By the operation mode, not applicable;

6) Rated voltage and frequency of equipment: not applicable;

7) Equipment input power: not applicable;

8) If the equipment has the application part of protection against defibrillation effect:

CF-type defibrillation-proof application part;

9) If the equipment has the signal output or input part: not applicable;

10) Permanently installed or non-permanently installed equipment: non permanently installed equipment.

Measurement range	-30～300 mmHg
Maximum overvoltage	-400～4000 mmHg
Sensitivity	5μV/V/mmHg±1%
Sensitivity temperature error	±1%
Zero-pressure offset	±20 mmHg
Disturbance deflection	±75 mmHg
Thermal shift offset	±0.3 mmHg/°C
Offset drift	≤2 mmHg(8 hours)
Accuracy	(±1mmHg±1%reading)(when-30 ~ 50mmHg)
	±3%reading(when 50 ～300 mmHg)
Frequency response	＞200Hz(only for blood-pressure transducer part,based on15%passband)
Supply voltage	2～10VDC
Excitation impedance (inputimpedance)	1200Ω～3200Ω
Output impedance	285Ω～315Ω
Sensor symmetry	1.0±0.05
light sensitivity	±1mmHg

Note: Those parameters above are obtained at ambient temperature of 23±2℃ and excitation voltage of 6VDC.

Operating temperature		+15℃～+40℃
Storage temperature		-25℃～+70℃
Atmospheric pressure		56.7kPa ～113.0kPa
Humidity		10% ~90%，not under condensation condition
Transportation Conditions	**Temperature**	-25℃～+70℃
	Humidity	10% ~90%，not under condensation condition
	Pressure	56.7kPa ～113.0kPa
Except for geomagnetic field, there should be no external magnetic field; no mechanical vibration		

【Electromagnetic Compatibility】

This product is in conformity with the requirements of EN 60601-1-2:2015 Medical Electrical Equipment-Part1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests (IEC 60601-1-2:2014).

【Packaging and Sterilization Method】

This product's interior package uses blister packs.

This product is sterilized by ethylene oxide.

【Shelf-life】

The shelf-life of the device is two years.

This product is aseptic and pyrogen-free if the single package is not unpackaged and not damaged.

【Disposal Measure】

This product is disposable. After operation, it should be destroyed by the hospital after sterilization under high-temperature condition. It shouldn't pollute the environment.

【Symbol and Label】

Symbol	Symbol
	Attention! Please refer to the attached documents.
	Model number
	Lot number
	Production date
	Expiration date or service life
	Not reusable
	No DEHP
	CF-type defibrillation-proof application part
	Don't use if the package is damaged
	No pyrogenic
	Refer to the product manual
	Up
	Keep dry
	Keep away from heat(solar radiation)
	Fragile goods
	Maximum stacking weight 20kg

[Assurance and responsibility]

This product and its every component have been designed, produced, tested, and packaged with utmost care. The warnings written in the product manual are a part of the product manual. Suzhou RainMed Medical Technology Co., Ltd. is responsible for its products within their shelf life, but consumers must operate them according to the product manual strictly. Suzhou RainMed Medical Technology Co., Ltd. refuses to assume the responsibility of purchasing products for particular purposes and their applicability. Suzhou RainMed Medical Technology Co., Ltd. will assume the responsibility of any results caused by its products directly, indirectly, occasionally and secondarily. All the limits on warranty and responsibility are not contrary to any force by law. If some terms are identified invalid or contrary to existing law by court, then others are not affected and still valid. These invalid terms will be replaced by those which can assure Suzhou RainMed Medical Technology Co., Ltd. of its legitimate interests. No individual shall have the right to constrain the warranty and responsibility held by Suzhou RainMed Medical Technology Co., Ltd.

【Registrant/ manufacturer】

Name of Registrant/ Manufacturer: Suzhou RainMed Medical Technology Co., Ltd.

Domicile of Registrant/ Manufacturer: Room NW -05 -502, Northwestern Nanopolis Suzhou, No. 99, Jinjihu Avenue, Suzhou Industrial Park, Jiangsu Province, China.

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【After-sale service】

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