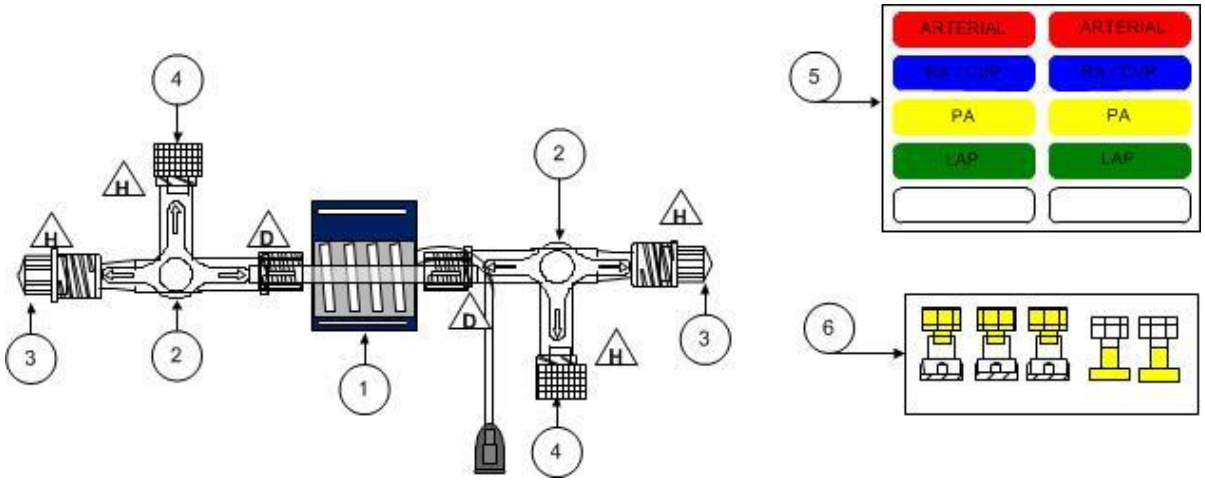
PRODUCT TECHNICAL DATASHEET

ITEM REF:	011-0P544-01	REVISION:	03

icumedical
human connections

LEGAL MANUFACTURER	**ICU Medical, Inc.** 951 Calle Amanecer, San Clemente, CA 92673, USA
IMPORTER	**ICU Medical B.V.** Hofspoor 3, 3994 VZ Houten, The Netherlands
EU AUTHORISED REPRESENTATIVE (EUAR)	**Medical Device Safety Service GmbH (MDSS)**, Schiffgraben 41, 30175 Hannover, Germany
ASSEMBLY SITE	**ICU Medical de Mexico**, S.A. de C.**.,** Avenida Cuarza No. 250, Colonia Rancho Santa Clara, Delegacion Manaedero Ensenada, Baja California, Mexico 22790
CLASSIFICATION CODE	**GMDN** Code: 45275
INTENDED USE	A collection of devices that includes the necessary tubing, pressure transducer(s) and other items [e.g., connectors, stopcock(s), clamps and filters] used for an invasive blood pressure measurement. This set will typically connect directly to the applied invasive catheter and the transducer will provide the electrical signals for display by a patient monitoring system. This device will have physical characteristics appropriate for preserving, to the extent possible, the waveform and fidelity of the measured pressure. This is a single-use device.
ITEM DESCRIPTION	TP ST MONITORING KIT BELGIUM

PRIMING VOLUME (ml)	0.73	**LENGTH (cm)**	17	**WEIGHT (g)**	31	**CASE QTY**	25



ITEM SPECIFIC DATA		**Chemical Compatibility**	Lipids & Common Chemotherapeutics
		Luer Compatibility	ISO 80369-7 Compliant.
		Sterilization and Shelf Life	ETO; 3-Year Expiration
LIST OF COMPONENTS	1	TRANSDUCER, TRANSPAC SINGLE	POLYCARBONATE POLYETHYLENE SILICONE PVC NON-DEHP (NON-FLUID PATH) SANTOPRENE (NON-FLUID PATH)

			ADHESIVE (NON-FLUID PATH) COPPER (NON-FLUID PATH) POLYPROPYLENE CAP (NON-FLUID PATH)
	2	ROBINET, 4-VOIES	POLYCARBONATE HDPE SILICONE LUBRICANT
	3	BOUCHON HYDROPHOBE	POLYPROPYLENE (NON-FLUID PATH)
	4	BOUCHON HYDROPHOBE	POLYPROPYLENE (NON-FLUID PATH)
	5	LABEL, PATIENT LINE	LABEL STOCK (NON-FLUID PATH)
	6	LUER CAPS AND COVERS	ABS (NON-FLUID PATH)
MATERIAL COMPLIANCE AND BIOCOMPATIBILITY	This product is made of non-latex, and non-DEHP components. Product has met the requirements of ISO 10993-1 for biocompatibility.		
PRECAUTIONS	Use aseptic techniques. Single-use only – Do not resterilize. Sterile, Non-Pyrogenic fluid pathway in unopened, undamaged package.		
LABELS AND DIRECTIONS FOR USE	Label and/or DFU contain information for proper use including any warnings or contraindications. Labels are applied on the individual package and on the outside of the cardboard box. Each sales package contains a Direction for Use where applicable.		
PACKING AND PACKAGING	The non-unit packaging is biodegradable as defined by Directive 94/62/EC. Packaging is according to BS EN ISO 11607. The packaging for this product is Latex Free. This item is blister packed or pouched individually using medical grade materials.		
TRACEABILITY	Lot number provides full traceability of all components and manufacturing processes.		
STORAGE	Store in a dry and clean place. Product should be retained in packaging until ready for use.		
DISPOSAL	The user must dispose of the device according to hospital disposal policy.		
PRODUCTION AND ENVIRONMENT CONTROLS	• Product is manufactured in an environmentally controlled room. Floor, surfaces, and environment are monitored according to quality procedures. • Each component is inspected during acceptance (example: visual; dimensional; functional) to verify conformity with the requirements according to quality procedures. • Production and release specific tests are performed according to quality procedures. • Limulus amebocyte lysate (LAL) testing is performed on production samples to verify conformity of the endotoxin charge according to quality procedures. • Bioburden tests are performed on production samples to verify conformity of the microbial charge according to quality procedures.		
	Quality System complies to:	ISO 13485:2016	

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QUALITY SYSTEM AND PRODUCT CERTIFICATION	**Product Certification:**	The product is manufactured in compliance to Council Directive MDD 93/42/EEC as amended.
	CE Certificate Number:	252.702
	Notified Body:	NSAI National Standards Authority of Ireland.
	MDD Device Classification:	Class IIb