

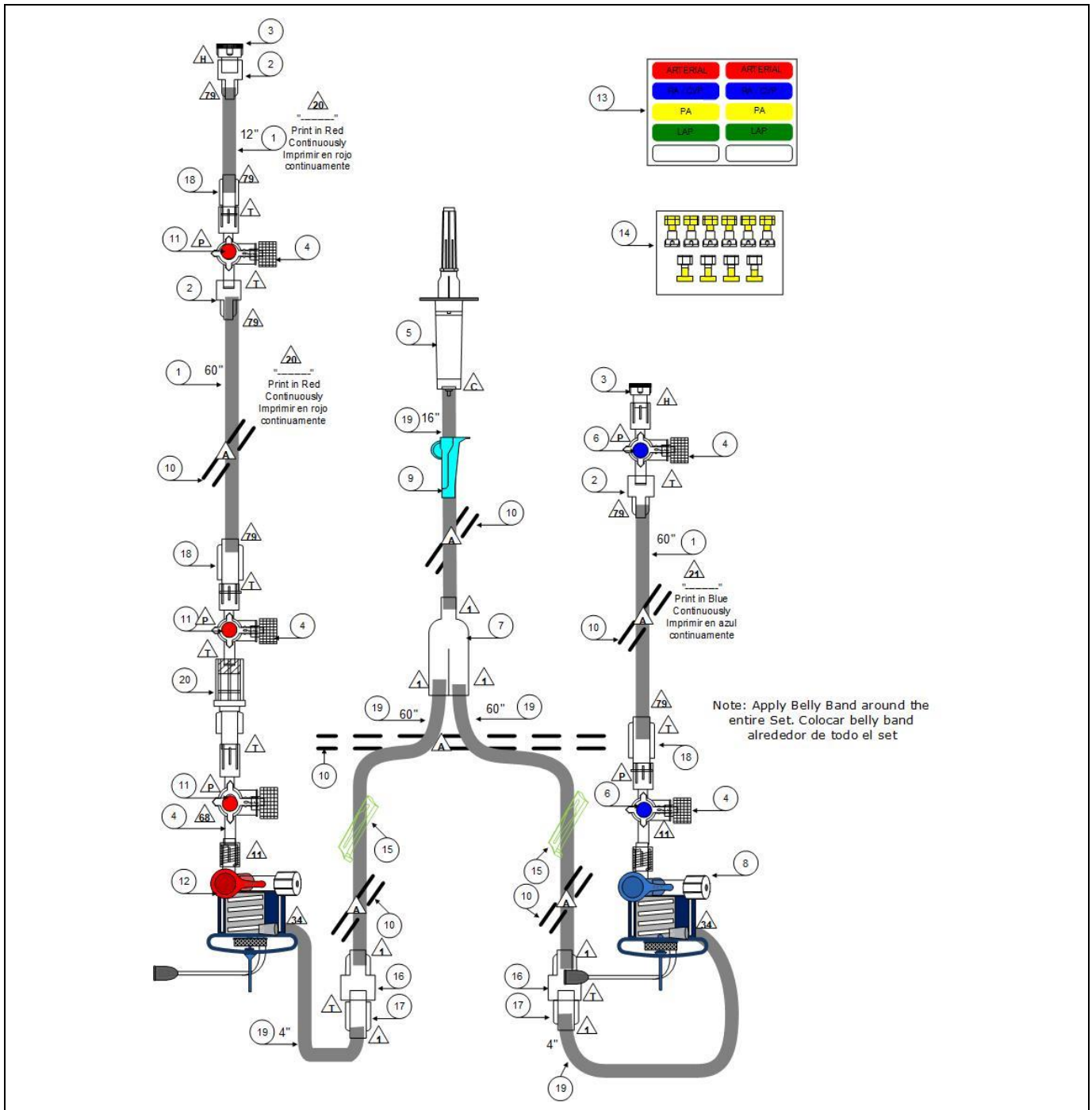
PRODUCT TECHNICAL DATASHEET

ITEM REF:	011-46106-13	REVISION:	19
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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 Maneadero 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	Bifurcated Transpac® IT Monitoring Kit w/03 ml Flush Device, Adaptor Rotating Male/Female and Macrodrop®						
PRIMING VOLUME (ml)	33.5	LENGTH (cm)	878,84	WEIGHT (g)	150.44	CASE QTY	10

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ITEM SPECIFIC DATA	MRI Compatibility	No metal components
	Chemical Compatibility	Lipids & Common Chemotherapeutics
	Luer Compatibility	ISO 80369-7 Compliant.
	Sterilization and Shelf Life	ETO; 3-Year Expiration

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LIST OF COMPONENTS <i>(Latex and DEHP Free)</i>	1	TUBING, HIGH PRESSURE	PVC
	2	MALE LUER, WINGED, PC, UV POCKET	POLYCARBONATE
	3	COVER, VENTED, WHITE, RG	ABS
	4	STOPCOCK, CAPCOVER SUBASSEMBLY	ABS
	5	DRIP CHAMBER, 20 DROP NON-VENTED, 15 MICRON FILTER	ABS PVC POLYPROPYLENE
	6	PLUG, STOPCOCK INDICATOR, BLUE	HDPE
	7	2-WAY CONNECTOR	PCTG
	8	TRANSDUCER, INTEGR 3 ML WIT	SILICONE SANTOPRENE POLYPROPYLENE ADHESIVE HDPE POLYCARBONATE COPPER PVC SILICONE RUBBER
	9	CLAMP, ROLLER, LIGHT BLUE	ABS
	10	LATEX FREE COHESIVE BELLY BAND	TAPE
	11	PLUG, STOPCOCK INDICATOR, RED	HDPE
	12	TRANSDUCER, INTEGR 3 ML RED	SILICONE SANTOPRENE POLYPROPYLENE ADHESIVE HDPE POLYCARBONATE COPPER PVC SILICONE RUBBER
	13	LABEL, PATIENT LINE	STOCK/BACKING LABEL
	14	SPARE PARTS	ABS LOW DENSITY POLYETHYLENE
	15	SLIDE CLAMP II, POLY. GR, RG	HDPE
	16	MALE LUER, PC	POLYCARBONATE
	17	CONN. WINGED FEM. LUER	PVC
	18	FEMALE LUER, WINGED, PC, UV POCKET	POLYCARBONATE
	19	TUBING	PVC
	20	ADAPTOR, ROTATING MALE/FEMALE	POLYCARBONATE RUBBER

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MATERIAL COMPLIANCE AND BIOCOMPATIBILITY	Product has met the requirements of ISO 10993-1 and related standards 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 met the requirements of 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	<ul style="list-style-type: none"> • 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 amoebocyte 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 AND PRODUCT CERTIFICATION	Quality System complies to:	ISO 13485:2016
	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