

Technical Data Sheet

ProLung® System PL1000

Description:

The ProLung System is a computer-controlled, non-invasive, electrical bioconductance measurement system comprised of an instrument body, a data acquisition probe, and a reference electrode that delivers low level electrical current at specified bilateral anatomic locations on the human body. The integrated computer system provides a screen display of real time measurement during operation, regulates probe performance, and collects and analyzes data.



Indications for Use:

The ProLung System is indicated for use in patients who have undergone computed tomography (CT) in which a pulmonary lesion of indeterminate significance has been detected. The ProLung Test™ is indicated for use as an aid in the risk stratification of such patients for the occurrence of lung cancer. Patients with elevated ProLung Test Scores are at an increased risk of developing lung cancer.

GMDN Codes: P 58514
P 58516

ProLung System package contains:

1 x ProLung Device BS-E2-1000

Outer Material:	GE Lexan 221R
Weight:	4 kg
Dimensions:	34.4 x 33.8 x 8 cm
Storage, memory:	120 GB SSD
Memory:	4 GB DDR3 SDRAM
Ports:	1 HDMI 1 VGA 4 USB 2.0
Type of energy emitted:	Electricity
Electrical rating:	5.5-7.5V DC, 150-500mA, Leakage < 2.5 mA
External Power:	12.0V, 6.0A
Internal Power:	5.5-7.5V, 150-500mA



1 x ProLung Probe BP-E2-1300

Outer Material:	GE Lexan 221R
Weight:	280 g
Dimensions:	18.5 x 3.8 x 4 cm
Carrying case:	Polyethylene, P1032C, PU



1 x Electrode Cable EC-E4-2200

Length:	2 m
Weight:	25 g
Contact resistance:	2 ohm
Insulation resistance:	20M ohm
Molding:	Inner LD-PE, Outer PVC 45P White
Snap:	EKG Electrode Snap
Cable:	UL Cable AWG24x1C+Spiral, PVC Jacket
Connector:	Mini Din 3P Female Insulated, Shell: Nickel Plated



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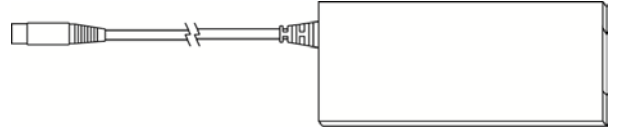
1 x Sponge Cup BS-E5-1128

Sponge cup:	Polystyrene, polypropylene
Height:	3.8 cm
Diameter:	7.9 cm
Weight:	23 g



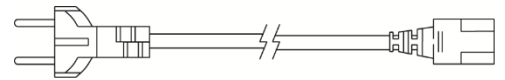
1 x Power Supply BS-E3-1029

Length:	1.83 m
Weight:	0.59 kg
Input connector:	IEC 320 C14
Output connector:	DIN-5, P/N 05GM5M
Power consumption:	<0.5W
Output voltage:	12V
Input voltage:	85 - 264VAC, 100 - 240VAC Nominal
Emissions:	FCC class B, CISP11 class B EN61000-3-2, -3
Immunity:	EN61000-4-2, -3, -4, -5, -6, -8, -11



1 x Power Cord BS-E3-1030

Plug:	CEE 7/7 (BS-E-E3-1030) BS 1363 (BS-UK-E3-1030) Type J (BS-SW-E3-1030) Type B (BS-E3-1030)
Connector:	IEC 320-C13
Length:	1.83 m
Weight:	0.19 kg
Amperage rating:	6A
Voltage Rating:	250V



1 x Monitor BS-L1-0820

Display type:	TFT Color LCD IPS
Aspect ratio:	16:9
Dimensions:	50.7 x 30.6 x 5.7 cm
Weight:	4.3 kg
Resolution:	2MP
Connection:	VGA, DisplayPort, HDMI
Power requirements:	100-240 V
Power consumption:	40 W (<0,5 W in stand-by)
Temperature:	Operating 10°C to 40°C, Storage -20°C to 60°C
Humidity:	Operating 30-75%, Storage 5-85%
Certifications:	CE (MDD 93/42/EEC class I product), CE-2004/108/EC, 2014/30/EU, IEC 60950-1:2005 + A1:2009 (2ND EDITION), IEC 60601-1 2ND ED:1988 + A1:1991 + A2:1995, UL 60601-1 1ST EDITION, CAN/CSA-C22.2 NO. 601.1-M90:2005, IEC 60601-1:2005 + A1:2012, ANSI/AAMI ES 60601-1:2005 + C1:2009 + A1:2012, CAN/CSAC22.2 No. 60601-1-08:2008, DEMKO - EN 60601-1:2006, EN 60601-1-2:2007, EN 60601-1:2006+A11:2011, CCC - GB9254-2008 + GB4943-2001 + GB17625.1-2003, KC, VCCI, FCC class B, ICES-001 Level B, FDA Class I device, RoHS



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1 x Keyboard with Touchpad BS-L1-0810

Keyboard materials:	Silicone rubber, Latex-Free
Dimensions:	38.1 x 15 x 1.5 cm
Weight:	840 g
Connection:	USB
Resistance:	IP 68
Compliance:	CE, FCC, EN-60601
Features:	Sealed, waterproof, immersible
Temperature:	Operating 0°C to 70°C, Storage -20°C to 70°C
Power consumption:	26mA (Max), 300mA (Backlighted)
Model:	ITD 25U Pro-Cart
Height:	136 cm



1 Tower BS-L2-0800

Materials:	Aluminum, sheet steel
Load capacity:	80 kg
Features:	Drawer w/ lock and internal mounting platform USB hub for ProLung Test Scan Key Probe holder Cable winder Push handle Shelf and keyboard drawer 100 mm anti-static castors VESA 75/100 monitor mount



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Electrical Safety Testing

Power Requirements	Power source	Connection to supply mains. Battery provided for connection to patient circuit.
	Inlet voltage	100-240V AC Single Phase 50-60Hz (power supply mains), 12V DC (to Bioconductance Scanner from power supply)
	Inlet Power	72W max (power supply mains)
	Heat emission	Device not intended to supply heat to patient
IEC 60601-1 Compliance	Device Class	Class I externally powered
	Applied Part Class	Type BF
	Operation mode	Suitable for continuous operation
	Protection against liquid penetration	IPX0
Operative Environment Requirements	Temperature range	-20°C / 55°C (ProLung Device) -10°C / 32°C (ProLung Test Kit)
	Humidity	Equipment not to be exposed to humidity for extended periods of time. Use only in a dry, indoor location
	Atmosphere requirements	Not for use in oxygen rich atmosphere, not for use with flammable anesthetics, not for use with flammable agents
Storage and Transportation Environment Requirements	Temperature range	-20°C / 55°C (ProLung Device) -10°C / 32°C (ProLung Test Kit)
	Humidity	Equipment not to be exposed to humidity for extended periods of time. Store and transport only in a dry, indoor location.
Compliance to IEC 60601-1-2	Immunity to power frequency magnetic field, according to IEC 61000-4-8	Compliant at the limit level of 3 A/m
	Immunity to radio frequency electromagnetic field, according to IEC 61000-4-3	Compliant at the limit level of 3 A/m
	Immunity to Electrostatic discharge, according to IEC 61000-4-2	Compliant at 2, 4, 6 kV contact discharge and 2, 4, 8 kV air discharge
	Immunity to radiofrequency continuous conducted according to IEC 61000-4-6	Compliant at the limit level of 3V
	Immunity to fast transient according to EN 61000-4-4	Compliant at the severity level of 1kV
	Immunity to fast transient according to IEC 61000-4-4	Compliant at the limit of 2 kV
	Immunity to voltage dips according to IEC 61000-4-11	Compliant at the limit levels of >95% reduction for 0.5 periods, 60% reduction for 5 periods, 30% reduction for 25 periods
	Immunity to voltage interruptions according to IEC 61000-4-11	Compliant at the limit levels of >95% reduction for 250 periods
	Immunity to lightning surge according to IEC 61000-4-5	Compliant at the limits 0.5-1 kV (Line-Neutral); 0.5-1-2 kV (line-PE and neutral-PE)
	Harmonic current according to IEC 61000-3-2	Compliant
	Voltage fluctuations and flicker according to IEC 61000-3-3	Compliant
	Separation distance from Electromagnetic sources (e.g. Cell Phones)	≥ 0.5 m

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*CE 0120, approved for sale in Europe (EEA & EFTA)
Not currently available for sale in the USA.