BTL 4 ECG



BTL 4	Elite	Pro	Smart
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BATTERY SPECIFICATION

Battery status indication	Buzzer and LED Indication		
Battery type	Li-Ion Battery (2 Packs), 14.52 V, 3250 mAh, 47.19 Wh	Li-Ion Battery (1 Pack), 14.52 V, 3250 mAh, 47.19 Wh	Li-lon Battery (1 Pack), 14.52 V, 3250 mAh, 47.19 Wh
Battery capacity: Printed reports (single page)	> 1200 reports	> 550 reports	> 550 reports
Battery capacity: Manual printing	> 7 hours	> 3.5 hours	> 3.5 hours
Battery capacity: Continuous signal monitoring	> 12 hours	> 6 hours	> 6 hours
Battery capacity: Charging time		240 minutes	

DISPLAY SPECIFICATION

Display	Color & Capacitive Touch (Color depth 16.7M Colours)
Display dimension	7"
Display resolution	1,024 × 600
Displayed data	Heart rate, patient name, patient ID, day time, battery power indicator, notifications, warning messages, scrolling waveforms, blood pressure, weight and height, lead labels, speed, sensitivity and filter settings, profile and lead system settings, hookup advisor, lead off indication, user identification

GENERAL CHARACTERISTICS

Weight of the device	≤ 1.76 kg	≤ 1.57 kg	≤ 1.55 kg
Overall dimension (L x W x H in mm)		234 x 225 x 78 mm	
Start-up time		< 1 min	
Hibernation mode	Y	es, start-up time by 3 seco	nds
Keyboard		Touch Panel	
Lead off indication		On display	

PRINTING

Paper type	Thermal paper with grid
Paper format and size	Paper roll (width 111.5 +/- 0.5 mm, length 22.6 +/- 0.08 m)
Paper tray capacity	1 roll of diameter 45 mm (max 47 mm)
Paper detection	
Printer resolution	Horizontal 40 dots/mm, vertical 8 dots/mm
Print speed (mm/s)	5, 10, 12.5, 25, 50
Sensitivity (mm/mV)	2.5, 5, 10, 20

Amplitude accuracy	±5 %
Printed leads	6, 12
Printing completion speed	Full report < 10 sec.

PERIPHERAL CONNECTIONS

External keyboard	External USB	
Mouse	External USB	
Barcode reader	Standards CodeQr, PDF417, Code128, Code39NC, Code39C; Supporting of ASCII characters	N/A
External printer	For list of compatible printers, please contact BTL S	ales or BTL Service
USB	3 x	
USB specification	5V, 1A	
LAN	1 x	
QRS trigger / TTL Output	N/A	N/A

RECORDING

Number of leads	10 (physical leads)
Number of channels	12
Number of displayed leads	6 / 12
Measured leads	I, II, III, aVR, aVL, aVF, V1, V2, V3, V4, V5, V6
Electrode set	R, L, F, N, C1, C2, C3, C4, C5, C6 or/and RA, LA, LL, RL, V1, V2, V3, V4, V5, V6
Lead off detection, Leads	✓ L, F, C1, C2, C3, C4, C5, C6 or LA, LL, V1, V2, V3, V4, V5, V6 note: RL/N & RA/R needs to be connected for lead detection to work
Display layout	2 x 6 + 0R, 2 x 6 + 1R, 1 x 12 + 0R, 4 x 3 + 0R, 4 x 3 + 1R, 1 x 6 + 0R
Print layout (Auto Profile)	2 x 6 + 1R, 2 x 6 + 0R, 4 x 3 + 1R, 4 x 3 + 0R, 1 x 12 + 0R, 1 x 6 + 0R
Print layout (Manual)	1 x 6, 1 x 12
Print layout (Rhythm)	1 x 1, 1 x 2
Auto profile recording length	10 s, 12 s, 15 s, 20 s
Rhythm profile recording length	30 s, 1 min, 2 mins, 6 mins, 10 mins & 20 mins
Number of records saved	> 3,500 ECG records (10 s)
Number of patients stored	2,000
Number of users stored	100
Number of profiles stored	50
Quick ECG	Start a record without the need of entering patient data

ACQUISITION

Applied part type	Type CF
Applied part	Electrodes & Patient cable
Amplitude resolution	1 μV ±1 % per LSB, 500 SPS

Amplitude inaccuracy (Front end Acqusition data)	< ±1 %
Dynamic range	DC: +/- 300 mV AC: +/- 5 mV
Digital resolution	24 bits
Frequency range	0.049 - 250 Hz
Sampling frequency	1000 SPS Total 8000 SPS
Storing frequency	1000 Hz (Raw data) 500 Hz (after filtering & for printing)
Input Impedance	> 2.5 MΩ >10 MΩ @10Hz
Common mode rejection ratio (CMRR)	> 93 dB for 60Hz (filter off) > 93 dB for 50Hz (filter off) > 110 dB (filter 50/60 Hz on)
Pacemaker detection	Detects pace pulses of Pulse width: 0.1 ms - 2 ms Pulse amplitude: 2 mV - 250 mV (Hardware detection method equivalent to 100.000 SPS*)

DATA PROCESSING

Filters	Mains - None, 50/60 Hz adaptive Myo - 90 Hz adaptive, 20 Hz, 25 Hz, 35 Hz Drift - 0.049 Hz, 0.07 Hz Cubic Spline, 0.25 Hz Adaptive, 0.05 Hz, 0.15 Hz Adaptive; No filter (frequency range User filter; Refiltration	0.05-170 Hz);
ECG interpretation	Interpretation statements for adults and paediatrics patients; Algorithmic and artificial intelligence based interpretation statements; Word interpretation statements	N/A
Heart rate	30 - 300 bpm	
Heart rate accuracy	± 10 % or ±5 bpm whichever is higher	
ST segment visual check	ST maps	N/A
Measurement	RR, P, PQ(PR), QRS, QT, P axis, QRS axis, T axis, C (Bazett, Hodges, Fridericia, and Framingham meth	
Amplitudes	P+, P-, Q, R, R'. R", S, S', T+, T-, J, ST	N/A
Averaged complexes	visualized	N/A
Rhythm analysis	Tachogram, histogram	N/A
	Average HR, Max HR, Min HR, average R-R, Max R-R, N R-R count, SDRR, pRR50	1in R-R,

SAFETY SPECIFICATION

Patient leakage current with earth connection	≤ 10 µA
Patient leakage current without earth connection	≤ 50 µA
Maximum leakage provided by the patient isolation circuitry with 220 V 50 Hz AC operation	≤ 50 µA

^{*} The derived sampling rate for equivalent method was measured for most typical pulse with amplitude 3mV.

Defibrillation protection	400 J
Type of Protection Against Electrical Shock	Class I
Degree of Protection Against Electrical Shock	Type CF defibrillation - proof applied part

DATA EXPORT

Export to hospital informational system standards using compatible SW	HL7 DICOM
Export to file system	PDF format (FAT32 file system)
Export to clinical system	BTL CardioPoint BTL CONNECTin

OPERATING CONDITIONS

Temperature	+10 °C to +35 °C
Relative humidity	30 % to 75 %, Non-condensing
Atmospheric pressure	700 hPa to 1060 hPa
Altitude	up to 3,000 m

TRANSPORT/ STORAGE CONDITIONS

Temperature	-10 °C to +55 °C
Relative humidity	10 % to 85 %, Non-condensing
Atmospheric pressure	650 hPa to 1100 hPa

NETWORK SPECIFICATION

Wi-Fi frequency	2.4 GHz, 5 GHz
Communication channel	1 (2412 MHz) to 11 (2462 MHz) 36 (5180 MHz) to 48 (5240 MHz), 149 (5745 MHz) to 165 (5825 MHz)
Modulation	2.4 GHz band - IEEE 802.11b/g/n : BPSK,QPSK,16-QAM,64-QAM 5 GHz band - IEEE 802.11a/n : BPSK,QPSK,16-QAM,64-QAM
Maximum measured power	2.4 GHz band - 14.3 dBm, measured at 1 Mbps 5 GHz band - 15.1 dBm, measured at 6 Mbps
Wireless standards	802.11a/b/g/n WLAN interfaces Configured manually or via DHCP
Authentication Protocols	open, WEP, WPA-PSK, WPA2-PSK
Ethernet interface	802.3 Ethernet interface via RJ45 connector
Wired standards	10Base-T, 100Base-T, and 1000Base-T LAN x 1 port Configured manually or via DHCP

SECURITY SPECIFICATION

Transfer encryption	Network encryption using TLS 1.2 The device connects only to the user configured server and only authorized user can configure this in the device.
User authentication	Built-in user management (name and password authentication) Active Directory
Data and configuration protection	Defined roles and privileges to each user

REGULATORY SPECIFICATION

IEC 60601-1 IEC 60601-1-2 IEC 60601-2-25 Certification CE with respect to Medical Devices Regulation (MDR) as per European Commission Regulation (EU) No. 2017/745 Compliance with EU General Data Protection Regulation (GDPR)

ADDITIONAL SOFTWARE FEATURES

Entering and editing patient details		
Leads position advisor	Graphically with lead off indication	
Worklist compatibility	⊘	N/A
Signal quality indication	⊘	
User name associated to each ECG record	Yes, printed report and stored examination	
Possibility to write a medical conclusion		

TROLLEY

	BTL Trolley Light
Device fixed on trolley	
Removable device on trolley	
Double castors with foot break	
Storage for accessories	
Patient cable holder	
Weight	< 16 kg

ACCESSORIES AND CONSUMABLES

Accessories included	Patient cable, chest (bulbs) and limb (clamps) electrodes
Consumables	ECG paper roll, ECG gel 500 ml

POWER SUPPLY

Mains voltage	100 - 240 VAC +/- 10%
Frequency	50 Hz, 60 Hz (47-63 Hz)
Total power/watts used by system	1.3A at 115VAC, 0.6A at 230VAC