BTL FLEXI 12 ECG

USER'S MANUAL

BEFORE YOU START

Dear customer,

Thank you for purchasing BTL technology. All of us at BTL wish you every success with your system. We pride ourselves on being as responsive as possible to our customers' needs.

Your suggestions and comments are always welcome since we believe an ongoing relationship with our customers is critically important to our future product line.

While we would like you to start using your new equipment right away, we encourage a thorough reading of this manual in order to fully understand the operational features of the system.

Please visit our corporate website at http://www.btlnet.com for the latest information on BTL products and services.

Again, thank you for being a BTL customer.

BTL Industries Limited

CONTENTS

1 GENERAL CHARACTERISTIC

BTL Flexi 12 ECG is an ECG system (hereinafter referred to as 'ECG system') composed of portable handheld BTL Flexi 12 ECG acquisition device (hereinafter referred to as 'device') and BTL CardioPoint Flexi software application (hereinafter referred to as 'application') running on a tablet.

The device records ECG data of a patient through ECG Patient Cable and Electrodes, applied to the Patient. These ECG data are simultaneously transmitted to the application via Wi-Fi network for further analysis and presentation.

1.1 INTENDED USE

The BTL Flexi 12 ECG is intended for acquisition, processing, recording, analysis and presentation of 12-lead simultaneous resting ECG for diagnostic purposes.

1.2 USER PROFILE

The BTL Flexi 12 ECG shall be used by medically educated personnel. The user shall be familiar with all safety precautions, operating procedures and maintenance instructions given in this User's Manual.

1.3 OPERATING ENVIRONMENT

The BTL Flexi 12 ECG is intended to be used primarily in hospitals, but it can also be used in clinics, medical centres or wherever the resting ECG examinations are performed. The BTL Flexi 12 ECG is not intended for home-use.

1.4 PATIENT PROFILE

The BTL Flexi 12 ECG can be used on all adult and paediatric patients without limitation of age, gender, weight, height, etc.

1.5 INDICATIONS

The indications for electrocardiography include, among others, assessment of presence, absence or condition change of:

- arrhythmias,
- conduction defects,
- chamber enlargement,
- myocardial hypertrophy,
- myocardial ischemia,
- myocardial necrosis,
- pericardial inflammation,
- electrolyte disturbance,
- neurohumoral influence.

1.6 CONTRAINDICATIONS

There are no known contraindications for resting ECG examinations.

1.7 POSSIBLE SIDE EFFECTS

There are no known possible side-effects for resting ECG examinations.

2 SAFETY PRECAUTIONS

Read the user's manual carefully and become familiar with all its safety requirements, operating procedures and maintenance instructions before using the ECG system. It is prohibited to use the ECG system and its accessories in any manner that is not in accordance with the user's manual.

Any other application of data and reports, other than its intended use are not advised and considered misuse of the ECG system. The ECG system is not intended for Direct Cardiac Application and home use.

The ECG system and accessories should be kept away from any liquids to avoid accidental spillage on components. Penetration of liquid in the device may cause it to malfunction or it may generate electric shock.

Use the ECG system under safe operating environment as specified in the manual. The system must not be used about flammable anaesthetics or oxidize fluids (O2, N2O, etc).

Do not operate the ECG system with any external devices generating magnetic and electrical fields and high-frequency signals. This may cause undesirable mutual interference and will hamper the functioning of the ECG system.

Thoroughly inspect the ECG system before each use. Check for any physical damages, loose connections, distorted display and any other inconsistency or abnormality. Stop using the ECG system if the behaviour differs from the function described in this manual or the labelling on the device / accessory is unclear for use. Try to determine and solve uncertainty by referring to section "Troubleshooting". Immediately contact authorized BTL service department for additional support.

It is not recommended to use the ECG system together with other devices than stated in this User's Manual.

The ECG curves displayed by the acquisition device are informative only and do not fulfil the requirements per applicable ECG standard. Always use the BTL CardioPoint Flexi SW application for analysis of patient data.

The device does not carry any risk to patients with cardiac pacemakers.

Device and Defibrillation Precautions

The ECG system is designed for use with the defibrillator. The used defibrillator has to comply with the applicable standards and its discharge must correspond to that which is described in the applicable standards. The ECG system is resistant to defibrillation only if the original BTL patient cable is used.

Stay away from the patient or patient cables during defibrillation procedure. A defibrillator may generate electric shock and come in contact may cause serious injury or death.

The device should be used in accordance with the operations described in this manual.

Use "Docking station" or "Power Cord & Power Adapter set" provided along with the ECG system to charge device's battery. Do not use any other non-approved cables or means for charging. This may cause damage to the device. Refer to section "Troubleshooting" in this manual for any uncertainties. Contact authorized BTL service department for additional help.

Parts and Accessories

Patient Cables

Use only parts and accessories supplied along with the ECG system. Any external part related to the ECG system has to meet the safety requirements according to the applicable standards.

Do not touch exposed ends of lead wires or connector pins and patient simultaneously. Ensure that the accessible ends of the leads do not meet other conductive materials.

Always clean and disinfect reusable leads and connectors with recommended chemicals before patient use. Failure to do so may cause transfer of infection between patients.

High-Frequency burns - Use of cables not supplied with this equipment can lead to serious injury. Use only patient cables that ships with this equipment.

Ensure that the ECG leads are securely connected to the device. Obey the marking on the socket for proper connection. Loose or improper connection cause inaccuracies in acquiring and processing ECG data.

Periodically inspect the ECG Leads. Do not use any damaged or broken leads. Contact authorized BTL service department for replacement of damaged leads.

Always follow IEC or AHA standard guidelines while connecting the ECG leads to the electrodes placed on patient's skin. Follow color markings provided on ECG leads.

Power Adapter and Battery

The "Docking station" or "Device" is connected to the A.C power supply through a power adapter. Use the medical grade power adapter supplied along with the ECG system for charging the device's battery. Using other means or cables for charging may damage the device and charging station.

Check if the parameters of the mains, A.C voltage and Frequency etc. correspond to the requirements of the ECG system per section "Technical Parameters". Do not connect the system in case of any non-compatibility. Refer to section "Troubleshooting" in this manual for making appropriate adjustments in the device. Contact BTL authorized service department for additional help.

A faulty adapter or battery replacement should be attended only by BTL authorized service department. Using non-approved batteries or adapter and replacement done by unauthorized personnel can damage the device.

If battery leaks and gives off an unusual odour, power off immediately stop device usage. Contact BTL Authorized service for attention and support.

Electric Shock — Improper connection of the system or device may cause electric shock. To avoid the risk, the device must only be connected to supply mains with protective earth.

Do not position equipment in a way that makes it difficult to disconnect the device when using an appliance coupler, mains plug, or another separable plug as a means of isolation.

Application on Tablet

Follow recommended installation procedure. Acquiring and installing the application from any other sources is strictly prohibited and can damage the functioning of the ECG system.

To avoid loss of data, it is recommended to backup acquired ECG data and patient information from the application.

FCC & ISED Compliance Statement

This device complies with Part 15 of the FCC Rules.

Operation is subject to the following two conditions:

(1) This device may not cause harmful interference, and
(2) This device must accept any interference received, including interference that may cause undesired operation of the device.

FCC Caution!
Any changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate this device.

Part 15B compliance statements for digital devices:

NOTE: This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to Part 15 of the FCC rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses, and can radiate radio frequency energy, and if not installed and used in accordance with the instruction manual, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. However, if this equipment does cause interference to radio or television equipment reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the separation between equipment and receiver.
- Connect the equipment to an outlet on a circuit different from that to which the receiver is connected.
- Consult the dealer or an experienced radio/television technician for help.
- Use a shielded and properly grounded I/O cable and power cable to ensure compliance of this unit to the specified limits of the rules.

ISED Statements

This Class B digital apparatus complies with Canadian ICES-003. This device complies with Industry Canada license-exempt RSS standard(s). Operation is subject to the following two conditions:

1. This device may not cause interference, and
2. This device must accept any interference, including interference that may cause undesired operation of the device.

Le présent appareil est conforme aux CNR d'Industrie Canada applicables aux appareils radio exempts de licence. L'exploitation est autorisée aux deux conditions suivantes:

1. l'appareil ne doit pas produire de brouillage, et
2. l'utilisateur de l'appareil doit accepter tout brouillage adioélectrique subi, même si le brouillage est susceptible d'en compromettre le fonctionnement.

Attention!

Toute modification ou modification non expressément approuvée par la partie responsable de la conformité pourrait annuler l'autorisation de l'utilisateur d'utiliser cet appareil.

REMARQUE: Cet équipement a été testé et s'est déclaré conforme aux limites d'un appareil numérique de classe B, conformément aux règles ISED. Ces limites sont conçues pour fournir une protection raisonnable contre les interférences nuisibles dans une installation résidentielle. Cet équipement génère, utilise et peut émettre de l'énergie radiofréquence, et s'il n'est pas installé et utilisé conformément au mode d'emploi, il peut causer des interférences nuisibles aux communications radio. Cependant, il n'y a aucune garantie que des interférences ne se produiront pas dans une installation particulière. Toutefois, si cet équipement cause des interférences à la réception de l'équipement de radio ou de télévision, ce qui peut être déterminé en allumant et éteindre l'équipement, l'utilisateur est encouragé à essayer de corriger les interférences en prenant une ou plusieurs des mesures suivantes:

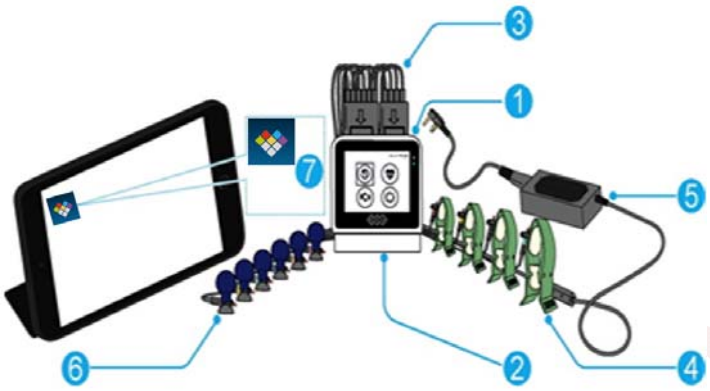
• Réorientez ou déménagez l'antenne de réception.
• Augmenter la séparation entre l'équipement et le récepteur.
• Connectez l'équipement à une prise de courant sur un circuit différent de celui auquel le récepteur est connecté.
• Consultez le revendeur ou un technicien en radio / télévision expérimenté pour obtenir de l'aide.
• Utilisez un câble d'E / S blindé et correctement mis à la terre et un câble d'alimentation pour assurer la conformité de cet appareil aux limites spécifiées des règles.

3 USED SYMBOLS AND MARKINGS

	Caution
	Warning
	Type BF applied part
	Defibrillation-proof type CF applied part
	Before the use of the device read the manual and follow its instructions
	Waste electrical and electronic equipment
	Name and address of the manufacturer
	Date of manufacture
	Serial number
	Batch code
	Catalogue number
IPX2	The Ingress Protection code for this device is IPX2. Protected against solid foreign objects no special claim Protection against liquid is against falling drops of water, if the case is disposed up to 15 degrees from vertical.
	DC Voltage In
	Chassis – connection of sensitive electrical circuits to the chassis

4 SYSTEM OVERVIEW

This section of manual describes the ECG system components and its physical characteristics in detail.

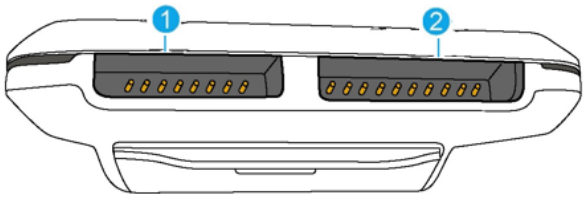


1. BTL Flexi 12 ECG Device for ECG Acquisition with Display with touch panel for 12L waveform view only.
2. Docking Station for Charging.
3. Patient Cables (6L and 4L cables)
4. Electrode set - Clamp
5. Power Adaptor. Can be connected to Docking station or Device for charging.
6. Electrode set - Bulb
7. BTL CardioPoint Flexi Application (Installed on recommended devices)

This product meets the applicable national or international RF exposure guidance (SAR guideline) when used normally held near the body or when worn or carried, at a distance of 1.5 cm or more from the body. The SAR guideline includes a considerable safety margin designed to ensure the safety of all persons, regardless of age and health.

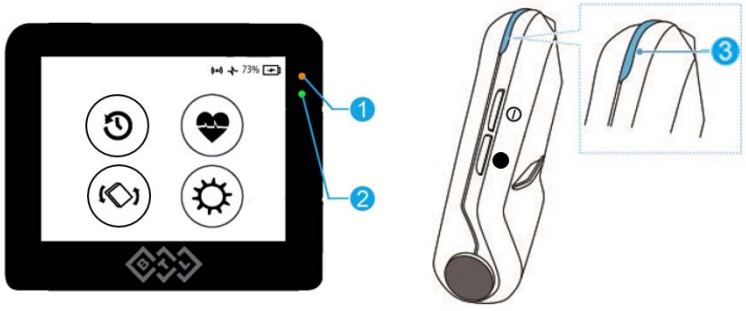
Always install the Docking station away from edge of the table, safe enough to prevent accidental drop of device or docking on operator.

In the event of any fluid spillage on the device, move the device immediately away from the spillage area. Thorough wipe and dry all wet surface of device including patient cable holder area. Allow sufficient time for device to dry before reuse.



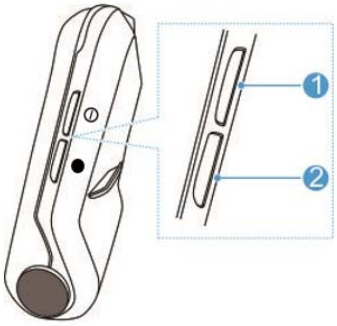
1. 4L Patient Cable Holder area
2. 6L Patient Cable Holder area

Indicators



1. Battery status
    a. Low battery capacity: Two orange color short blinks in every two seconds
    b. Battery charging: One orange color long blink in every five seconds
    c. Battery charged to 100% capacity: Permanent orange light
    d. Battery not charging even after connecting to AC mains: Five short orange color blinks in every ten seconds
2. Switch-on indicator
3. Signalization status. Some of the signalization like WiFi connection and disconnection can accompany with a noise indication.

Buttons



1. On/off button
2. Record/back button

	Operation	Recording screen	Other screen
On/off button	Short press	Display off	Display off
	Long press	Device off	Device off
Record/back button	Short press	Record	Back
	Long press	No function	Back to ECG screen

Battery indication

An internal rechargeable battery powers the device during its operation. The device also serves as inbuilt protection circuit to protect the battery against overcharging and short-circuits. The battery symbol and numerical value on the screen indicate the remaining battery power.

A fully charged battery can last up to 6 hours under normal usage condition. Battery requires approximately 8 hours of charging to reach > 90 % capacity in turn off condition.

Symbol	Battery status
	Charging
	100–76 %
	75–51 %
	50–26 %
	25–11 %
	10–0 %
	Indication that battery is damaged or removed

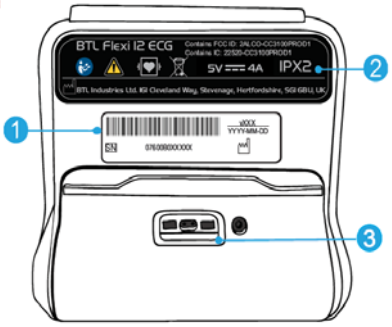
The device can also be powered directly from AC Mains when the battery failure occurs or in case the battery is not present in the device. In such case, the device is connected directly to AC mains through a medical grade power adapter. A docking station connected to power adapter can also be used to alternatively connect the device to AC mains.

When battery failure occurs, it is recommended to contact service. Situation is indicated by LED and on device display as well.

Usage during charging without internal rechargeable battery or no battery condition will lead to patient data loss, in the event of any power failure from the mains.

If excessive device temperature is observed during usage of the device, stop using the device and switch off the device for at least 30 minutes to allow cooling of the device before the next use.

Device labels and charging point



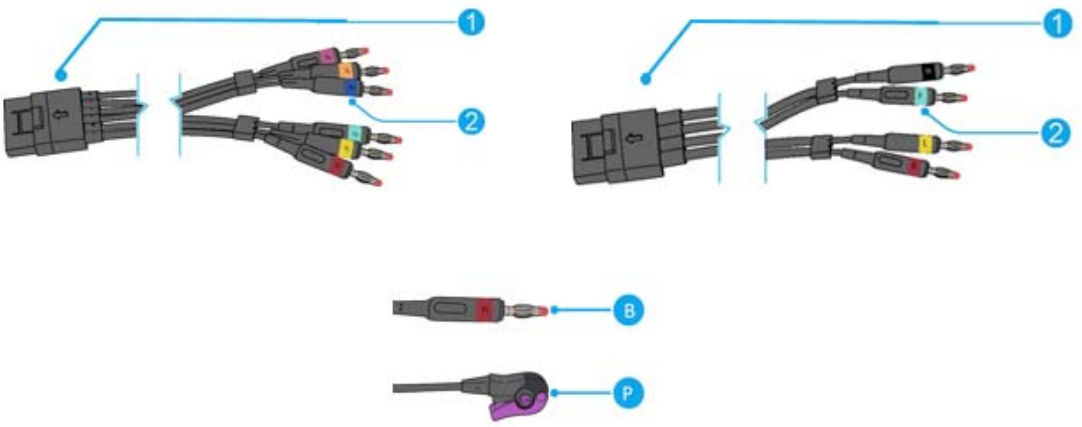
1. Serial label
2. Device rating label
3. Connection point for charging

Always use the medical grade power adapter supplied along with the ECG system for charging the device's battery. Using other means or cables for charging may damage the device and charging station.

For disposal of the device follow local environmental guidelines concerning disposal and recycling instructions.

Do not dispose the battery by fire. Explosion hazard – batteries may explode in fire.

Patient cables



1. Device side connection – 6L and 4L type cables
2. Electrode side connection – 6L and 4L type cables

B Banana type connection for reusable electrodes.
P Pinch or snap type connection for disposable electrodes.

Warranty for patient cable is 6 months in normal use. Typical normal use is 30 ECGs exams per day with proper cleaning as specified in this manual.

5 SETUP AND START UP

Unpack the device from the packaging to setup the device and accessories. Install the application on the recommended list of devices.

Recommended list of tablet devices:

Mobile device	Supported operating system
Apple iPad Air 2	iOS 10
Apple iPad Mini 4	iOS 10
Apple iPad Pro 9.7”	iOS 10

Backup battery charging

The device contains an internal backup battery which is supplied in a semi-charged state. After the device is purchased, we advise you to charge the device before first use.

Charge the device completely before any scenario of long non usage over 3 months.

Installation of application

Search and install the application from Application store in tablet device.

First time connection – application to device

Switch on the device using power **on-off key**. Check the Device Name in Device Settings.

Search and connect to Device name in WiFi settings of Tablet device, using default password **“12345678”**.

Start the application in the tablet device. Connection to Device Name can be observed in the opening screen of the application.

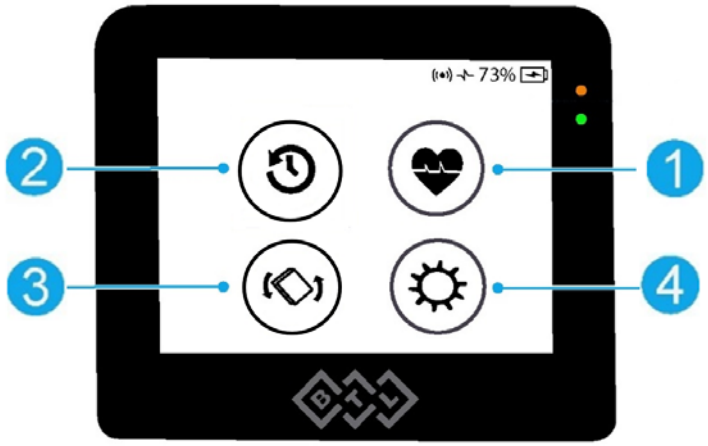
It is important to connect the device to the tablet application before the first use or usage after a long time to synchronize date and time between the device and the tablet application.

A connection failure may occur due to weak Wi-Fi signal as a result of interference or obstacle. Reposition both device and tablet to get strong signal strength and repeat the steps to connect application to device.

6 DESCRIPTION OF CONTROLS

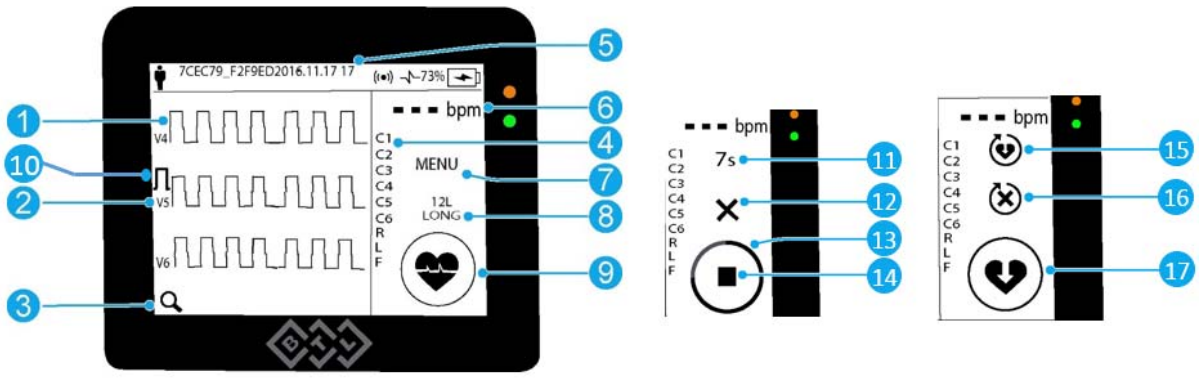
This section of manual explains the user interface of the device and the application. The buttons and functionalities symbols appearing on the screen can be operated by touch actions.

6.1 MENU SCREEN - DEVICE



1. Waveform Screen
2. History Screen
3. Rotate Display 180°
4. Settings

6.2 WAVEFORM SCREEN - DEVICE



1. ECG Waveforms – 1, 3 or 12 leads
2. Derived lead name – V1 – V6, I, II, III, aVR, aVL, aVF
3. Rotate Waveform Layout
4. Physical lead name (IEC or AHA, per device setting.). **Gives Lead signal quality status. Grey = OK, Orange = Noisy, Red = Disconnected.**
5. Top Row – See Chapter 6.3
6. Patient's Heart rate
7. Menu Button

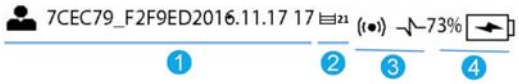
8. Examination type – 12L Automat / 12L Long
9. Record ECG Examination
10. Calibration Pulse.
11. Recorded time
12. Cancel Recording
13. Recording Progress Bar
14. Stop Recording
15. Save Record and Do another ECG
16. Cancel Examination and Do another ECG
17. Save Record

Operator is obliged to consult with the patient if he is fitted with pacemaker and add this information in patient's profile. In an event of consistent pace pulse detection in a patient, every pace pulse is represented as a red line in the top line of the waveform screen for indication only.

All recorded Patient Data will be lost in case the ECG recording is cancelled by the user.

ECG lead in a waveform screen can be shown as square wave when no input signal is present or in case of bad signal quality due to lead disconnection or improper patient preparation.

6.3 TOP ROW OF WAVEFORM SCREEN

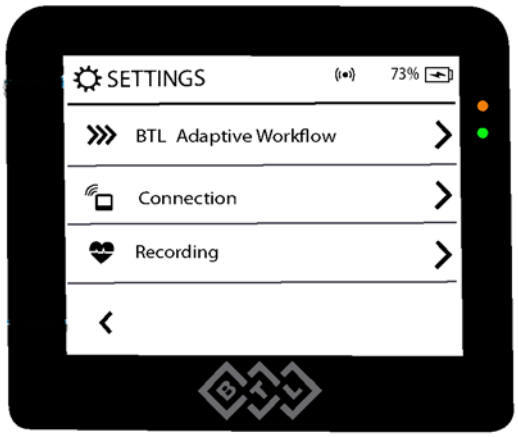


1. Patient Details
2. Number of offline records pending import to tablet application.
3. Online Transmission
4. Battery Status

6.4 HISTORY SCREEN - DEVICE

1. ECG Records
2. Back
3. Record another ECG for the listed patient.

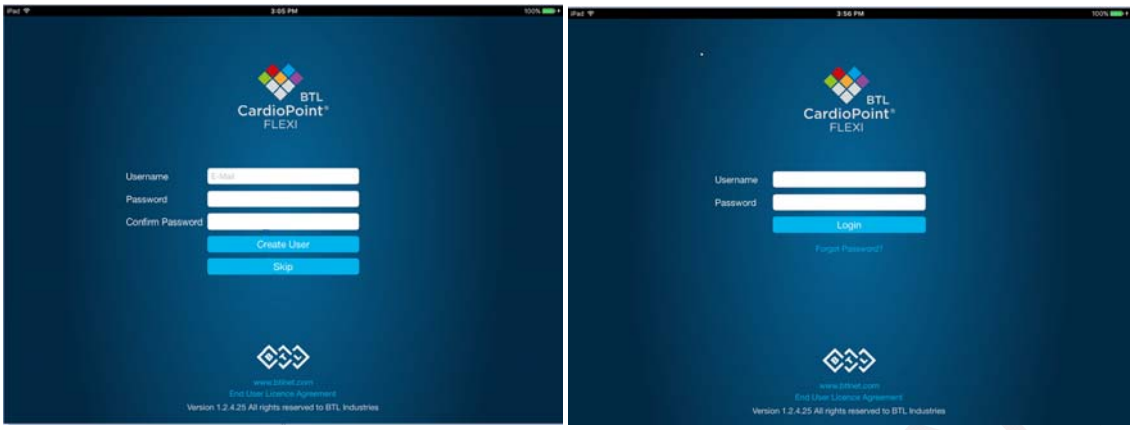
6.5 SETTINGS - DEVICE



1. **BTL Adaptive Workflow** – Select Default opening screen, Examination type, Choice to preview & save record
2. **Connection** – Select Access point mode, Workoffline mode, WiFi Communication Channel. Check Password, Device Alias Name and Check connected Host details.
3. **Recording** - Select Half sentivity for V leads, default values of lead layout, Length of ECG record, Lead type IEC or AHA.
4. **History** – Select default Patient Name in History. Choice to warn deletion of old record, Clear History of records.
5. **Device Settings** – Select default device settings like Display Brightness, Sound, Language, Power Save mode (display off), Demo mode and Reset to Factory Settings.
6. **About** – Firmware version Details.

Invalid Password Message will appear on the tablet when wrong password is entered.

6.6 LOGIN SCREEN – APPLICATION

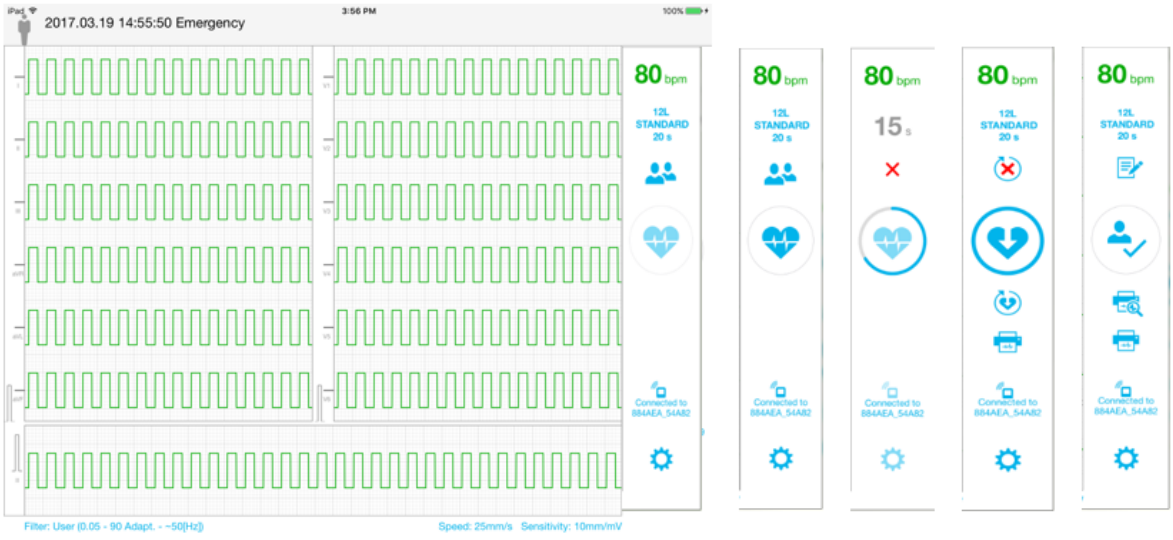


Login Screens – Used to Create User using valid Email ID and Password during First login.

Skipping of user login has potential to give access to Patient details in History Records.

"Failed to login, please check your username/password and try again" message will appear on the tablet when wrong password is entered.

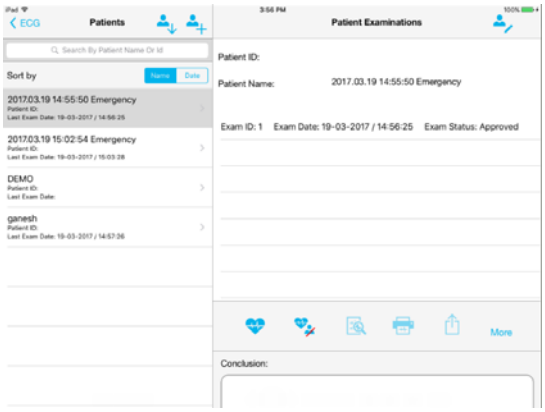
6.7 RECORDING SCREEN – APPLICATION



ECG Screens – Used to navigate to Patient Settings; App Settings; Record ECG; Cancel; Record Status; Save; Save and Record another ECG record; Cancel and Record another ECG record; Add notes to ECG Record; Shows connected Device status; ECG waveform layouts; Patient Details; Heart Rate; Filter Settings; Speed and Sensitivity Details.

ECG lead in a waveform screen can show square wave when no signal is received from device due to disconnection or bad signal quality.

6.8 PATIENT SCREEN – APPLICATION



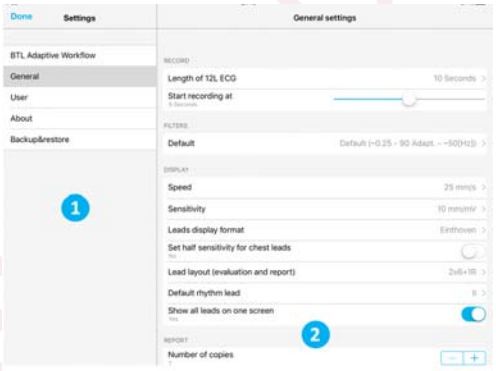
Patient Screens – Used to Add New Patient; Start ECG for the patient; View Patient ECG record; Associate a ECG record to a patient; Edit Patient Details for an Emergency Patient record; Preview, Print a ECG Record; Email a ECG record.

Login setup **or** Email account configuration in tablet is essential to email the ECG record.

Disconnect the Device and connect the tablet to Printer to Print the ECG Record.

Application uses the Email account configured by the user on Tablet PC to email / backup the reports. User is responsible to make sure only secure applications and accounts are configured on the tablet device used for installation of the application.

6.9 SETTINGS – APPLICATION



1. List of settings
2. Detailed settings

6.9.1 List of settings:

1. **BTL Adaptive Workflow** – Contains settings of special feature called BTL Adaptive workflow. This feature allows optimizing system workflow to user needs.
2. **General** – Contains settings and information related to application and recording control.
3. **User** – Contains settings related to managing application user and facility details.
4. **About** – Contains information about device.
5. **Backup&restore** – Contains features to create and/or restore backup.

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7 ECG RECORDING WITH THE SYSTEM

7.1 POSITIONING OF ELECTRODES

Patient preparation – Quality of the ECG record is particularly dependent on the contact between the electrode and the patient's skin.

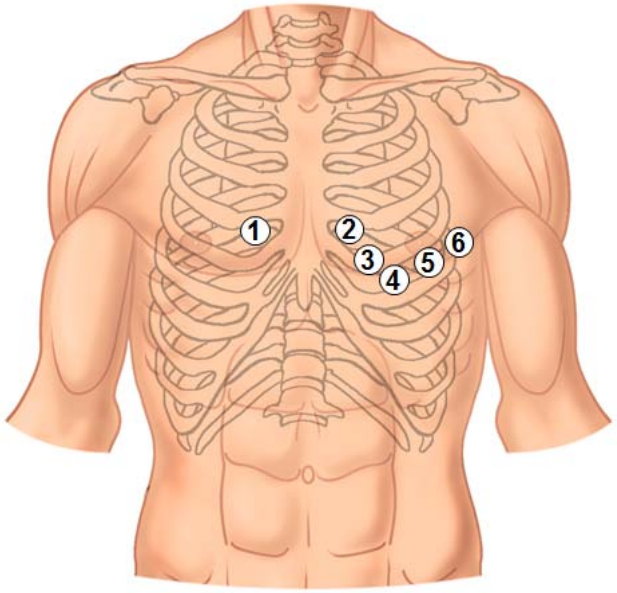
To keep the contact as good as possible please follow below mentioned principles:

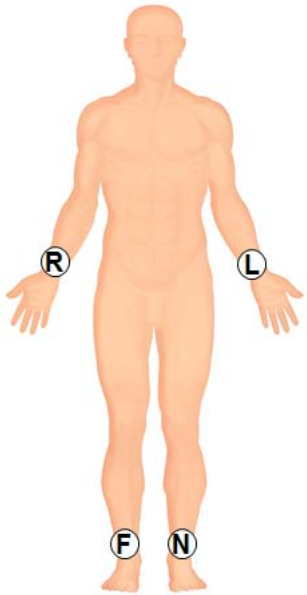
- the skin should be warm and the patient relaxed
- before fastening the electrode cleanse the skin with alcohol
- apply sufficient layer of gel on the electrode

An unprepared skin may lead to loosening electrode placement resulting in distorted waveforms and failed ECG examination.

Electrode Placement – Connect the 6L and 4L patient cable to the device. Connect the electrodes to the patient body and device in the following sequence of lead placement.

- First fasten the N (RL in AHA marking) electrode to the right leg
- Then fasten the other limb electrodes R, L, F (RA, LA, LL in AHA marking)
- Finally fasten the chest electrodes





Limb Electrodes

IEC			AHA			
N		black	RL		green	Right leg (on the inside)
R		red	RA		white	Right arm (on the inside)
L		yellow	LA		black	Left arm (on the inside)
F		green	LL		red	Left leg (on the inside)

Chest Electrodes

IEC		AHA		
C1	red	V1	red	4th intercostal space (between ribs 4 and 5) to the right of the sternum
C2	yellow	V2	yellow	4th intercostal space (between ribs 4 and 5) to the left of the sternum
C3	green	V3	green	In the middle between leads C2 and C4
C4	brown	V4	blue	5th intercostal space (between ribs 5 and 6) in the mid-clavicular line
C5	black	V5	orange	5th intercostal space (at the same level as C4) on the left anterior axillary line
C6	violet	V6	violet	5th intercostal space (at the same level as C5) on the left midaxillary line

7.2 CONNECTING APPLICATION TO DEVICE

Follow the sequence in chapter 5 to connect the application to device first time.
Application connects to device automatically on startup, with WiFi enabled in tablet.

If multiple devices are available, choose and connect to the required device from WiFi device list in Tablet settings.

7.3 ENTER PATIENT INFORMATION, REVIEW SIGNAL AND START EXAMINATION

Access Patients screen using  icon in application. Create New Patient or choose existing patient list in this screen.

Start ECG examination for selected patient using  in Patients screen of application.

Observe Patient details in Waveform Screen of Application and Device Display.
Note: If ECG examination is started from device without entering patient details in Offline mode, General Name format which is displayed **DDMMYYYYHHMMSS<Aliasname>**. The same can be edited later in application and linked to existing patient in patient list.

Check ECG signal quality in Device display.
ECG examination can be started in device or application.
Note: Examination started in application cannot be cancelled in device.

"**NOT OPERABLE**" tag is show in the waveform screen in the tablet if the ECG signal exceeds the specified signal range. Review and correct patient skin preparation.

7.4 RECORD, REVIEW OF HISTORY

Observe ECG progress in Progress bar  icon in device and application.

Check the ECG record preview in application and save the record by pressing the Save & reset  icon in place where ECG examination was initiated. This sequence is skipped if auto-save is enabled. User also has option to Save & do one more  OR Cancel and do one more  .

Saved ECG can be seen in the History List of Device and in Patient Screen in application.
Offline saved ECG records can be imported to application after reconnection in online mode.

Recording during Defibrillation: The equipment is protected against any damage of cardiac defibrillator discharge to ensure recovery as required by test standards. As per test standard, the recovery of ECG trace to return does not exceed 5 seconds after defibrillation.

The signal input from the patient to acquisition module is defibrillation proof. It is not necessary to remove the ECG electrodes from device, prior to defibrillation, in case of use of non-polarizing electrodes.

Refer List of accessories for approved electrode details.

7.5 PRINTING AND SHARING ECG RECORDS

Select a patient and his record to be shared or printed in Patient Screen of the application.

Press  to print to the wireless printer connected to the tablet.

Press  to email to email id requested by patient.
Note: Valid email id used for User registration will be used to send this email.

7.6 MANAGING HISTORY OF RECORDS

In Device History list, press  to initiate ECG for the selected patient.
When device History has reached the Max 30 record count, system automatically delete the oldest ECG record in history (device memory). However, automatic warning can be set in Menu>Settings>Warn before deleting the oldest record. Then, operator is warned to make storage space by deleting records in History.

In application Patients Screen when you select a patient and an ECG record, following actions are possible. Hide – Unhide records using <More> Hide examination. Hidden records can be seen after enabling the same in application Settings Screen.

In application Patients screen when you select a ECG record with generic Patient name. Assign it to a patient in patient list by <More> Assign Examination option.

8 FILTERS

This chapter describes the filters, their setting and the influence on the ECG signal waveform. The present configurations are described first and the individual types of filters are defined at the end of the chapter.

The setting of the filters for printing or display has no influence on the shape of the averaged complex or on the diagnostics results.

We strongly recommend becoming well-acquainted with this chapter of the User's Manual. You will avoid many possible, subsequent complications and misunderstandings that could result from using the wrong filters settings.

8.1 PREDEFINED FILTERS

The program includes predefined filters to help you with the setting of the ECG signal filtering. Get acquainted with their setting, description and properties before you start working with the program.

8.1.1 Default filter

This setting contains a set of filters, which gives the best results for most examinations.

Exceptions:

- Patients with a pacemaker implanted. If you want to keep the shape of the pulses obtained from the pacemaker, switch to the "User Filter" and switch off the "Myo Filter".
- Records taken in extremely disturbed environment or while the patients is moving. In such an event, switch to the "User Filter" and set another combination.

This setting consists of the following filters:

- Mains: 50 Hz Adaptive
- Drift: 0.25 Hz
- Myo: 90 Hz Adaptive

8.1.2 No Filter

This setting does not include any filter and the transferred band in this case is 0.05 Hz - 160 Hz.

8.1.3 Strict Filter

This setting includes the set of filters that most suppress the interference in the ECG signal. However, it also can suppress the most useful parts of the ECG signal that could be important for the further diagnosis. This filter may also cause slight widening of the QRS complex, a reduction of its amplitude and a distortion of the ST segment and T wave, for example. Before each recording of the ECG signal, carefully consider using this filter!

This setting consists of the following filters:

- Mains: 50/60 Hz Adaptive
- Drift: 0.6 Hz (0.3 s)
- Myo: 25 Hz

8.2 USER FILTERS

This option will enable you to create your own combination of filters you need for the ECG signal recording. The options include the following:

8.2.1 Mains

This interference comes from the electric mains and shows itself across the entire ECG signal. It manifests itself as very fast oscillation.

No Filter

No filter is used here to suppress the mains interference. The entire signal may be disturbed by interference from the mains frequencies even if the ECG runs on the batteries.

50/60 Adaptive

This filter suppresses the mains interference at frequencies of 50 and 60 Hz. The filter automatically adapts to the exact frequency of the mains, as well as to the current amplitude of the noise. Unlike the “notch” filters, this filter does not distort the QRS complexes. We recommend having this filter switched on permanently; otherwise the entire signal may be disturbed by the mains frequency.

8.2.2 Drift

These filters suppress all slow changes in the ECG signal and are primarily intended for the control of the zero baseline drift such as those as the result of the patient’s breathing.

0.05 Hz

This filter suppresses the frequencies in the ECG signal that are lower than 0.05 Hz. This corresponds to a signal repeating with a period of 3.2 seconds. This filter does not distort the ECG signal being recorded, but in case of a baseline jump (e.g. because of static charge) the signal returns to zero very slowly, taking up to 12 seconds.

0.25 Hz

This filter suppresses the frequencies in the ECG signal that are lower than 0.25 Hz. In case of a baseline jump (e.g. because of static charge) the signal returns to zero taking up to 4 seconds.

0.6 Hz

This filter suppresses the frequencies in the ECG signal that are lower than 0.6 Hz. This frequency corresponds to a signal repeating with a period of 0.3 seconds. This filter can suppress the zero baseline drift the most, but it may also distort the useful signal containing slow changes (typically the ST stage and the amplitudes of peaked T waves of the ECG signal). Set this filter only if the zero baseline drift is unacceptable and cannot be compensated for by any of the above mentioned filters. It is not recommended as the default setting for the recording of all ECG signals.

8.2.3 Myo

These filters serve to suppress the interference originating in the patient’s muscular activity and other electromagnetic interference stretching to the spectrum of the ECG signal. This interference is apparent in the ECG signal as random oscillations in the entire record or a part.

This filter category also filters out pacemaker pulses. If used, these pulses may be strongly reduced or even eliminated. Low-energy pulses, typical for bipolar stimulation, may be totally eliminated as well.

90 Hz Adaptive

This filter is recommended as default for most ECG records. The filter smoothly retunes its resulting cut-off frequency so as to preserve the useful signal components permanently. The unprocessed signal is monitored by the curvature analyzer. The output of the analyzer smoothly sets the output cut-off frequency of the filter. In the area of rapid changes (typically QRS) the frequencies are transferred up to 90 Hz, whereas in the slow areas (for example the T-P segment) the cut-off frequency drops. In extreme cases, it can go as low as 20 Hz. As a result, the distortion of the QRS complex is minimized and the readability of the P waves is maximized.

35 Hz

This filter, with a cut-off frequency of 35 Hz, suppresses all frequency components of the ECG signal higher than 35 Hz. It may reduce the amplitude of QRS, especially in children. It also reduces the amplitude of pacemaker pulses. If, for any reason, you cannot or do not want to use the 90 Hz Adaptive filter, select this option.

25 Hz

This filter suppresses all frequencies higher than 25 Hz. This setting may influence the recorded ECG signal, especially in the area of the QRS complex. It may cause slight widening of the QRS complex and reduction of its amplitude. It also reduces the amplitude of pacemaker pulses. It is not recommended to use this filter as the default setting for all examinations.

20 Hz

This filter suppresses all frequencies higher than 20 Hz. The filter should be used only in extreme cases, such as when the muscular interference is unacceptable and cannot be compensated for in any other way. Please note that this filter may deform (round and widen) any rapid changes in the ECG signal (especially the peaks of the QRS complex), because the most significant frequency components of the QRS complexes lie in the band up to 35 Hz. It also reduces the amplitude of pacemaker pulses. Always check the shape of QRS on the averaged beat.

9 TROUBLESHOOTING

Please contact BTL authorized service department for further assistance, in-case the below troubleshooting solutions do not solve your problem

Trouble in connecting application to Device:

→ **Application not able to connect to Device, even when in range of device signal range** → Interference from External Device. Move away from interference and try reconnection

→ **Application out of Device signal range** → Move the tablet closer to the signal range of device and try reconnection.

 Indication of Signal Strength in Tablet application.

→ **Not able to see Device Name in WiFi Device list of tablet settings** → Device switched off or offline mode, switch on the device or disable Work-offline in Device settings > Connection

→ **Device listed in WiFi Device list of tablet settings, but unable to connect** → Identify the WiFi address of the connected tablet application details in Device Setting > Connection. Disconnect and try reconnection.

Device not Charging:

→ **Device not charging with Power adaptor connected** → Failed Power adaptor or loose connection. Check LED glow on adaptor. If ok, clean device area before connection if any foreign particle is observed, reconnect adaptor to device and check for charging indication.

→ **Device connected to Power adaptor, battery damaged indication on device display**→ Failed battery, contact BTL Authorized service for further assistance.

Factory Reset:

→ **Device hang and doesn't switch off** → failed device, contact BTL Authorized service for further assistance.

→ **Device doesn't respond to operator action in normal use scenario** → Re-initialize the system by Factory Reset in Settings > Device Settings > Factory Reset.

⚠ Backup all data to tablet application before Factory Reset of Device.

Backup all data to Cloud in tablet application before any re-installation of application.

ECG Signal Quality:

→ **Noise observed in ECG signal in device and application display** → improper skin preparation or loose connections to patient or damaged patient cable, Check skin preparation, connection and cable, reconnect / replace damaged Lead wires and recheck signal quality, Noise in Signal, change filter settings and recheck ECG signal quality.

Device Overheat:

→ **Overheat shutdown after short usage <1 hour of usage in recommended operating conditions** → Allow device to cool in operating condition for 30 min to 1hour. If problem persists and repeats contact BTL Authorized service for further assistance.

10 MAINTENANCE

Before any maintenance of the device please switch the device off and disconnect it from the power supply! Never dismantle the device during cleaning procedure!

The recommended intervals for inspection of the device are 24 months after installation, subsequently each 12 months. The intervals may differ according to the local regulations. The inspection shall be performed according to procedure authorized by BTL.

The ECG system does not contain any components that can be repaired or serviced by the user or any unauthorized service personnel. Any attempt to do so can damage the system and hamper its functioning. Please contact authorized BTL service department for service related needs.

Device Cleaning

Keep the device clean. Use lint free soft cloth slightly moistened (drip free) with water or by 2% solution of detergent or other mild cleaning agents.

Use cleaning agents recommended for monitor screens for cleaning of touch panel using a lint free soft cloth slightly moistened (drip free).

Battery Maintenance

Fully charge the battery before each use. It takes approximately 8 (eight) hours to fully charge the battery from zero capacity. Fully charge the battery in the event of any long storage, without use.

Please check the warning list on maximum charge cycle completion. Contact BTL authorized service for further assistance.

Maintenance of Patient Cables and Re-usable Electrodes

Periodically inspect the patient cables and electrodes. Do not use any damaged parts. Contact BTL authorized service department for replacement of damaged leads.

It is recommended cleaning the re-usable electrodes after examination of each patient. For cleaning, use agents which were approved by your local competent health office and are suitable for cleaning and/or disinfection of the ECG accessories.

Use bridges provided on cables for proper routing and to avoid cables getting entangled.

Clean the patient cables regularly before use using a soft cloth slightly moistened with water or by 2% solution of detergent or other mild cleaning agents.

Usage of harsh cleaning agents with chemicals like alcohols, ammonium chloride, sodium hypochloride or any abrasive material might lead to damage of the device, cables and electrode parts.

Drip free cloth is recommended to avoid cleaning agent entry and damage to the device. Ensure dry patient cable holder pocket before reuse.

Transport and Storage

It is recommended to keep the packing of the equipment for safe transportation.
Store the device indoors only in a dust free environment.

After bringing the equipment from cold environment to the operating environment, do not plug it in the mains until the temperatures of equipment become equal to operating temperature

11 ACCESSORIES

The ECG system is not designed for use with other medical devices except for those stated specifically in this manual. The following is a list of accessories that can be supplied with the equipment.

Accessory	Models	
	BTL Flexi 12 ECG	BTL Flexi 12 extra unit for resting ECG
BTL Flexi 12 ECG unit	•	•
BTL Flexi 12 ECG patient cable chest 6-lead with banana plug	•	•
BTL Flexi 12 ECG patient cable limb 4-lead with banana plug	•	•
BTL Flexi 12 ECG patient cable chest 6-lead with pinch	o	o
BTL Flexi 12 ECG patient cable limb 4-lead with pinch	o	o
BTL CardioPoint Flexi	•	o
Charger for the BTL Flexi 12 ECG	•	•
WiFi dongle	o	o
Docking station	•	o
Belt strap plate for connection between the BTL Flexi 12 ECG and belt strap	o	o
Belt strap L 1m length	o	o
Belt strap L 1.6m length	o	o
Extremity AgCl electrodes	•	•
Chest AgCl electrode	•	•
Universal self-adhesive ECG electrode, disposable, for pinch connector	o	o

• … Standard o ... Optional

12 TECHNICAL PARAMETERS

Device name	BTL Flexi 12 ECG
General Characteristics Device	
Display Dimension and Resolution	2.8”, 240 x 320 dots
Overall Dimension (mm)	82 x 87 x 25
Weight	150 g
Keyboard	Touch panel on Device
External Printer	Wireless printer supported by tablet.
Print Speed (mm/sec)	5; 10; 12.5; 25; 50
Sensitivity (mm/mV)	2.5; 5; 10; 20
Print layout	2x6+1R; 4x3+1R; 1x12+0R
Number of Leads	12 Leads (I, II, III, aVR, aVL, aVF, V1, V2, V3, V4, V5, V6)
Number of Displayed Leads	1; 3; 12 in device 12 in tablet application.
Electrode Set	R, L, F, N, C1, C2, C3, C4, C5, C6 or RA, LA, LL, RL, V1, V2, V3, V4, V5, V6
Length of Record (Device)	
Automat	10 s; 12 s; 15 s; 20 s
Storage	Maximally 30 records on device Maximally 6000 records on application.
Filters	
Mains filter (Hz)	50; 60
Drift (Hz)	0.05; 0.25, 0.6
Myo (Hz)	20; 25; 35; 90
Detection of pacemaker	Detects pace pulses of Pulse width: 0.1 ms – 2 ms Pulse amplitude: 2 mV – 250 mV
Operating conditions	
Temperature	10 °C to +40 °C
Relative humidity	30 % to 75 %, Non-condensating
Atmospheric pressure	700 hPa to 1060 hPa
Transport and Storage conditions	
Temperature	-10 °C to +55 °C
Relative humidity	10 % to 85 %, Non-condensating
Atmospheric pressure	650 hPa to 1100 hPa
Power supply	
Mains voltage	100–240 V ~
Frequency	50–60 Hz
Protection class	Class I
Ingress condition	Comply with the IPx2 requirement as per standard IEC 60529.
Battery	Li-Ion battery, 3200 mAh capacity, 3.6 V
Applied part	Type CF
Amplitude resolution	1 µV ±1 % per LSB @ 500 SPS
Dynamic range	AC differential: ±5 mV DC offset: ±300 mV
Frequency range	0.05 Hz to 160 Hz
Common mode rejection	>90 dB (filter off). >100 dB (filter 50/60 Hz on)
WiFi frequency	2.4 GHz
Communication Channel	1 (2412 MHz) to 11 (2462 MHz)
Modulation	DSSS / CCK / OFDM
Effective radiated power	7.92 dBm or 6.198 mW, measured at 11 Mbps

12.1 ELECTROMAGNETIC COMPATIBILITY (EMC)

BTL Flexi 12 ECG complies with IEC 60601-1-2 requirements for “Electromagnetic Compatibility” (EMC). The ECG system, however, may be affected when operated near another medical device or equipment generating high levels of magnetic and electrical fields, resulting in electromagnetic interference. The mutual interference of electromagnetic magnetic fields hampers the effective functioning of the ECG system. The electromagnetic interference is displayed as artifacts on ECG waveforms or distorted data acquisition during ECG examination.

Follow the listed precautionary measures if electromagnetic interference is experienced during ECG examination:

Reposition the device and maintain a safe distance from another device to reduce the mutual interference levels.

Temporarily power off devices generating high levels of electromagnetic fields.

<table>
<tr><th colspan="3">Guidance and manufacturer’s declaration – Electromagnetic Emissions</th></tr>
<tr><td colspan="3">The device is intended for use in the electromagnetic environment specified below. The customer or the user of the device should assure that it is used in such environment.</td></tr>
<tr><th>Emissions test</th><th>Compliance</th><th>Electromagnetic environment - guidance</th></tr>
<tr><td>RF emissions
CISPR 11</td><td>Group 1</td><td>The device uses RF energy only for its internal function. Therefore, its RF emissions are very low and not likely to cause any interference with nearby electronic equipment.</td></tr>
<tr><td>RF emissions
CISPR 11</td><td>Class B</td><td rowspan="3">The device is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.</td></tr>
<tr><td>Harmonic Emission
IEC 61000-3-2</td><td>Class A</td></tr>
<tr><td>Voltage Fluctuations / Flicker Emission
IEC 61000-3-3</td><td>Complies</td></tr>
</table>

Guidance and manufacturer's declaration – Electromagnetic Immunity			
The device is intended for use in the electromagnetic environment specified below. The customer or the user of the device should assure that it is used in such environment.			
Immunity test	**EN 60601 test level**	**Compliance level**	**Electromagnetic environment – guidance**
Electrostatic discharge (ESD) EN 61000-4-2	± 6kV contact ± 8kV air	± 6kV contact ± 8kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient/burst EN 61000-4-4	± 2 kV for power supply lines	± 2 kV for power supply lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge EN 61000-4-5	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines EN 61000-4-11	< 5 % U_T (> 95 % dip in U_T) for 0,5 cycle 40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) for 25 cycles < 5 % U_T (> 95 % dip in U_T) for 5 s	< 5 % U_T (> 95 % dip in U_T) for 0,5 cycle 40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) for 25 cycles < 5 % U_T (> 95 % dip in U_T) for 5 s	Mains power quality should be that of a typical commercial or hospital environment. If the user of the device requires continued operation during power mains interruptions, it is recommended that the device be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field EN 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE U_T is the a.c. mains voltage prior to application of the test level.			

Guidance and manufacturer's declaration – Electromagnetic Immunity			
The device is intended for use in the electromagnetic environment specified below. The customer or the user of the device should assure that it is used in such environment.			
Immunity test	**EN 60601 test level**	**Compliance level**	**Electromagnetic environment – guidance**
			Portable and mobile RF communications equipment should be used no closer to any part of device , including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance**
Conducted RF EN 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 V	$d = 1{,}2\sqrt{P}$
Radiated RF EN 61000-4-3	3 V/m 80 MHz to 2,5 GHz	3 V/m	$d = 1{,}2\sqrt{P}$ 80 MHz to 800 MHz $d = 2{,}3\sqrt{P}$ 800 MHz to 2,5 GHz where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and *d* is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[a] should be less than the compliance level in each frequency range.[b] Interference may occur in the vicinity of equipment marked with the following symbol: 
NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies. NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			
a) Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the device is used exceeds the applicable RF compliance level above, the device should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the device . b) Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.			

Recommended separation distances between

portable and mobile RF communications equipment and the device

The device is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the device can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the device as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter W	**Separation distance according to frequency of transmitter** m		
	150 kHz to 80 MHz $d = 1.2\sqrt{P}$	**80 MHz to 800 MHz** $d = 1.2\sqrt{P}$	**800 MHz to 2,5 GHz** $d = 2.3\sqrt{P}$
	3V	**3V/m**	**3V/m**
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance *d* in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

13 MANUFACTURER

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