BTL FLEXI 12 ECG

USER'S MANUAL

CONTENTS

1   GENERAL CHARACTERISTIC

The BTL Flexi 12 ECG is an ECG system (hereinafter referred to as 'ECG system') composed of the portable handheld BTL Flexi 12 ECG acquisition device (hereinafter referred to as 'device') and the 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. /Prietaisas įrašo paciento EKG duomenis per EKG paciento kabelį ir pacientui pritaikytus elektrodus. Šie EKG duomenys vienu metu perduodami į programą per Wi-Fi tinklą tolesnei analizei ir pateikimui. -punktas 4

1.1   INTENDED USE

The BTL Flexi 12 ECG is intended for acquisition, processing, recording, analysis and presentation of ECG data 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 ECG examinations are performed. The BTL Flexi 12 ECG is not intended for home use.

1.4   PATIENT PROFILE/paciento profilis

The BTL Flexi 12 ECG can be used on all adult and paediatric patients without limitation of age, gender, weight, height, etc./BTL Flexi 12 EKG gali būti naudojamas visiems suaugusiems ir vaikams neribojant amžiaus, lyties, svorio, ūgis ir kt. punktas 1

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 is not advised and considered a 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 may generate electric shock.

Use the ECG system under safe operating environment as specified in the manual. The system must not be used around flammable anaesthetics or oxidizing 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 damage, 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 the 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 for applicable ECG standards. 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 must comply with the applicable standards and its discharge must correspond to what 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 coming 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 the section "Troubleshooting" in this manual for any uncertainties. Contact the 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 must 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 - using cables not supplied with this equipment can lead to a serious injury. Use only patient cables that are shipped 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 the 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 the colour markings provided on the ECG leads.

Power adapter and battery

The "docking station" or the "device" is connected to the AC 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 the charging station.

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

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

If the battery leaks and gives off an unusual smell, power off immediately and stop using the device. Contact the authorized BTL service department for attention and support.

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

To avoid loss of data, it is recommended to back up 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 distance between the equipment and the 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 about help.
- Use a shielded and properly grounded I/O cable and power cable to ensure compliance of this unit with 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

Symbol	Description
⚠	Caution
⚠	Warning
👤	Type BF applied part
♥	Defibrillation-proof type CF applied part
📖	Read the manual and follow its instructions before using the device
🗑	Electrical and electronic equipment waste
🏭	Name and address of the manufacturer
📅	Date of manufacturing
SN	Serial number
LOT	Batch code
REF	Catalogue number
IPX2	The Ingress Protection code for this device is IPX2 Protection against solid foreign objects - no specified protection Protection against liquid - against vertically falling drops of water, if the case is tilted up to 15 degrees from vertical
===	DC Voltage In
⏚	Chassis – connection of sensitive electrical circuits to the chassis
CE	CE mark

4 SYSTEM OVERVIEW

This section of the manual describes the ECG system components and its physical characteristics in detail.
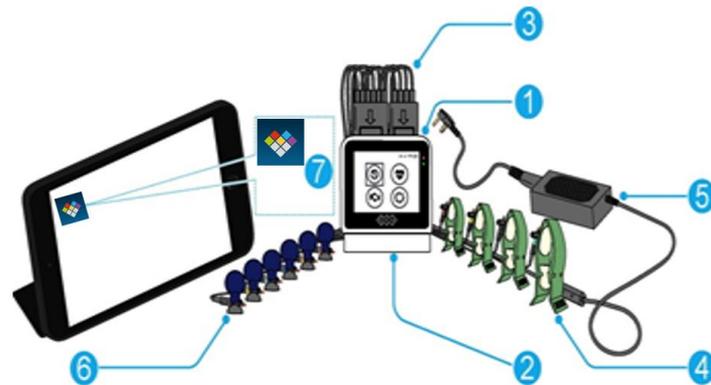
1. BTL Flexi 12 ECG device for ECG acquisition with display with touch panel for 12L waveform view only.
2. Docking station for charging.
3. Patient Cables (6L and 4L cables)
4. Electrode set - clamp
5. Power adaptor. Can be connected to the docking station or to the device for charging.
6. Electrode set - bulb
7. BTL CardioPoint Flexi application (Installed on recommended tablet 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 the 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 an edge of the table, safe enough to prevent accidental drop of the device or the docking on the operator.

⚠️ In the event of any fluid spillage on the device, move the device immediately away from the spillage area. Thoroughly wipe and dry all wet surface of the device including patient cable holder area. Allow sufficient time for the device to dry before reuse.
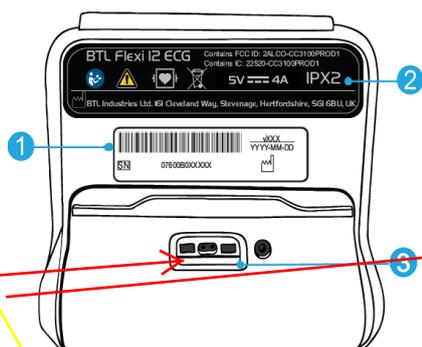
4.1 BUTTONS
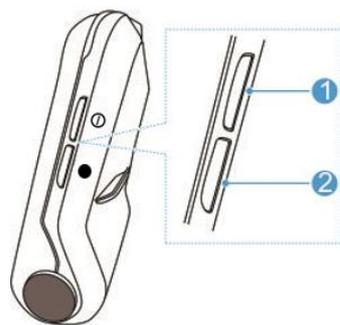
1. On/off button
2. Record/back button

	Operation	Recording screen	Other screens
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 recording screen

4.2 DEVICE LABELS AND CHARGING POINT

krovimui visada naudokite medicininės klasės maitinimo adapterį, pateiktą kartu su EKG sistema įrenginio baterija. Įkrovimui naudojant kitas priemones ar laidus galite sugadinti įrenginį ir įkrovimo stotį.- punktas 11

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 the charging station.

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

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

4.3 INDICATORS
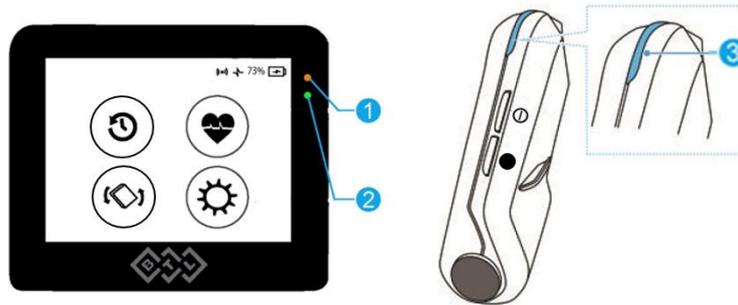
1. Battery status
   a. Low battery capacity: Permanent blinking (when battery capacity is less than 10%)
   b. Battery charging: Permanent orange light
   c. Battery failure: Permanent blinking
   d. Battery fully charged (when charger connected): Off.
2. Switch-on indicator (indicates that the device is ready for use)
3. Signalization status. Some of the signalization, like WiFi connection and disconnection, can be accompanied by a sound indication.

Battery indication

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

A fully charged battery can last up to 8 hours under normal usage conditions. The battery requires approximately 2 hours and 45 minutes of charging to reach >90% capacity in a turn-off condition.

Visiškai įkrauta baterija gali veikti iki 8 valandų normaliomis naudojimo sąlygomis.-punktas10

Symbol	Battery status
⚡	Charger connected
▮▮▮▮	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 the power adapter can also be used to alternatively connect the device to AC mains.

When a battery failure occurs, it is recommended to contact the BTL Authorized service. Such a situation is indicated by the LED and on-device display as well.

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

⚠️ If excessive device temperature is observed while using 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.

⚠️ For continuous usage of the device for longer durations of more than 2–6 hours it is recommended to operate the device in environment with temperature around 35 °C.

4.4   PATIENT CABLES

Cable holder area
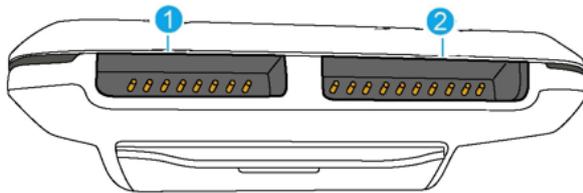
1.   4-lead patient cable holder area

2.   6-lead patient cable holder area

Patient cables/paciento kabelis - punktas 20.1
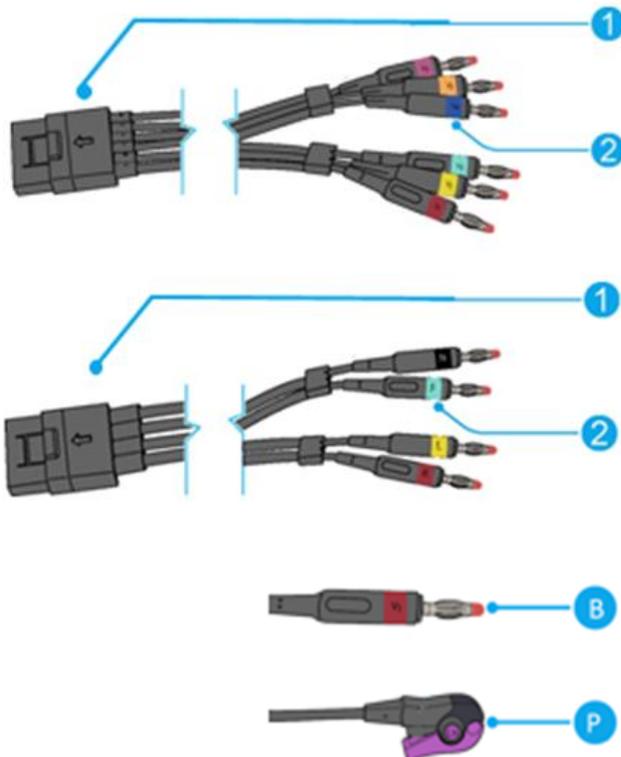
1.   Device side connection – 6-lead and 4-lead type cables/Prietaiso pusės jungtis – 6 ir 4 laidų tipo kabeliai

2.   Electrode side connection – 6-lead and 4-lead type cables/Elektrodo šoninė jungtis – 6 laidų ir 4 laidų tipo kabeliai

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

⚠   Warranty for a patient cable is 6 months in normal use. Typical normal use is 30 ECG examinations 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 a device in the list of recommended devices.

Recommended list of tablet devices:

Mobile device	Supported operating system
Apple iPad Air (3rd generation)	iOS 10 and above
Apple iPad Mini (5th generation)	iOS 10 and above
Apple iPad Pro 9.7"	iOS 10 and above
Apple iPad (2019)	iOS 10 and above

Backup battery charging

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

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

Installation of application

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

First time connection – application to device

1. Switch on the device using power **on-off button**. Check the device name in device settings (Menu > Settings > About).

2. Search and connect to the device with the name in Wi-Fi settings of the tablet device, using the default password **"12345678"**.

3. Start the application on the tablet device. Entering the ECG device serial number is required when using the application for the first time. The device serial number is written on a label on the back of the device. It is then required to create a user account. When the application is launched, the recording screen with

    the icon Connected to: appears. The device name shows which device is connected.

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

⚠️ A connection failure may occur due to weak Wi-Fi signal due to interference or an obstacle. Reposition both the device and the tablet to get higher signal strength and repeat the steps to connect the application to the device.

The device enables to choose the Wi-Fi communication channel manually from Settings > Connection > Advanced > Wi-Fi Channel Selection. Default setting = Channel 1.

6 CONTROLS DESCRIPTION

This section of the 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
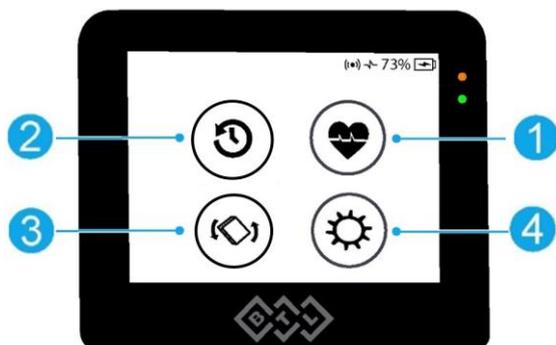
1. Recording screen
2. History screen
3. Rotate display 180°
4. Settings

6.2 RECORDING SCREEN – DEVICE/ĮRAŠYMO EKRANAS – PRIETAISAS
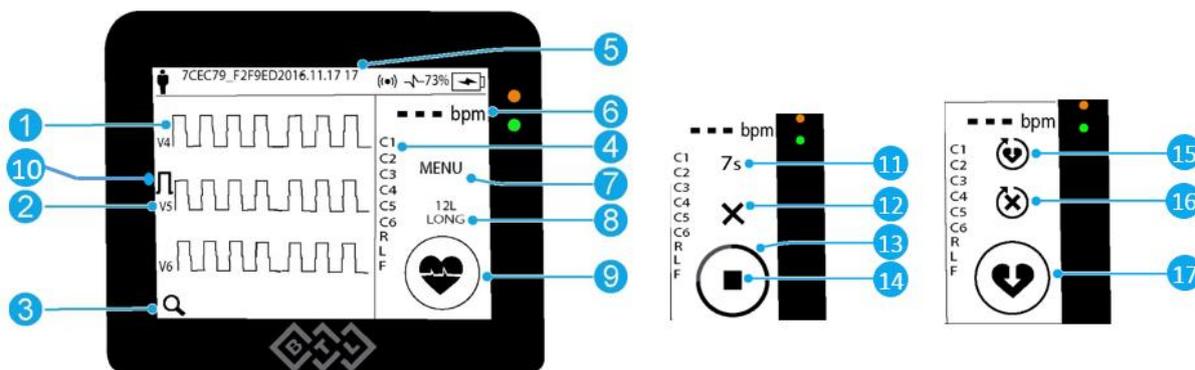
1. ECG signal /EKG signalas - punktas 15.1
2. Derived lead name (V1 – V6, I, II, III, aVR, aVL, aVF)
3. Rotate ECG signal layout (switch between 1, 3 or 12 leads with different sensitivity and speed)
4. Physical lead name (IEC or AHA, per device setting).
5. Top Row (See chapter 6.2.1)
6. Patient's heart rate in real time/paciento širdies ritmas realiuoju laiku-punktas 15.2
7. Menu button
8. Examination type – 12L ECG / 12L Rhythm
9. Record an ECG/EKG įrašymo mygtukas - punktas 15.3
10. Calibration pulse
11. Recording time/įrašymo laikas - punktas 15.4
12. Cancel recording
13. Recording progress bar
14. Stop recording
15. Save ECG and repeat recording
16. Delete ECG and repeat recording
17. Save ECG

The operator is obliged to consult with the patient if they are fitted with pacemaker and add this information into the 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 on a waveform screen can be shown as a square wave when no input signal is present or in case of bad signal quality due to lead disconnection or improper patient preparation.

Pace pulse is detected only when all leads are connected to the

Patient. **6.2.1** **Top row of recording screen /ekrano viršus**

1. Patient details (Allows user to add/modify patient name and patient ID)/Informacija apie pacientą (leidžia vartotojui pridėti / pakeisti paciento vardą ir paciento ID)-punktas 15.6
2. Number of ECG records pending import to tablet application
3. Online transmission in progress
4. Battery status/baterijos indikatorius - punktas 15.5

6.2.2 Record Review

After recording a strip, it is possible to preview last 10 seconds of ECG record by double-tapping the recording screen.

6.3 HISTORY SCREEN – DEVICE

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

Managing ECG history

The History screen lists ECGs that are recorded with the ECG system. Each ECG has a proper status. Use

to record ECG for the same patient.

| Status	Description
Recorded	ECG strip recorded with no connection to the application and stored in the internal memory of the device
Sent	ECG strip exported to the application (no confirmation that ECG was successfully imported)
Delivered	ECG strip successfully imported to the application (confirmed that ECG strip was successfully imported)
Delivery Error	Export of ECG strip was not successful

6.4 SETTINGS – DEVICE

1. BTL Adaptive Workflow – Contains settings of a special feature called BTL Adaptive workflow. This feature allows optimizing system workflow for user needs.
2. Connection – Contains settings and information related to Wi-Fi connection.
3. Recording – Contains settings related to ECG recording with the system.
4. History – Contains settings related to managing internal storage and displaying stored ECG records.
5. General – Contains general settings.
6. About – Contains information about the device.

History protection feature allows locking the history section with a numeric password for better security of the patient's data. It can be turned on here: Settings >History>Advanced>History protection

Advance settings lock feature allows locking parts of settings which should be changed only by the administrator to avoid unwanted changes and issues in the system. It can be turn on here: Settings > General > Advanced settings lock

6.5 LOGIN SCREEN – APPLICATION
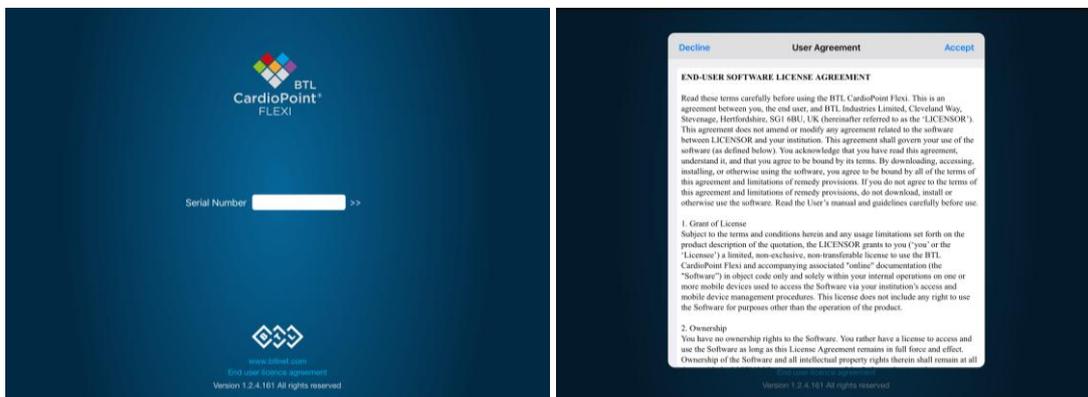
It is required to enter the device serial number and accept the user agreement at the first application launch.

It is required to create a user account at the first login. The login screen is used to create a user using a valid email ID and password during the first login.

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

6.6 RECORDING SCREEN – APPLICATION

Recording screen

1. Patient details
2. Heart rate
3. Leads system
4. Patients screen
5. Record – initiate ECG recording
6. Device connection status
7. Application settings
8. Speed and sensitivity settings
9. Filter settings

ECG recording, review and evaluation screens

1. Cancel recording
2. Recording progress bar
3. Delete ECG and repeat recording
4. Save ECG
5. Save ECG and repeat recording
6. Print ECG report
7. Enter medical finding
8. Close evaluation
9. Report preview

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

6.7 PATIENTS CARD SCREEN – APPLICATION
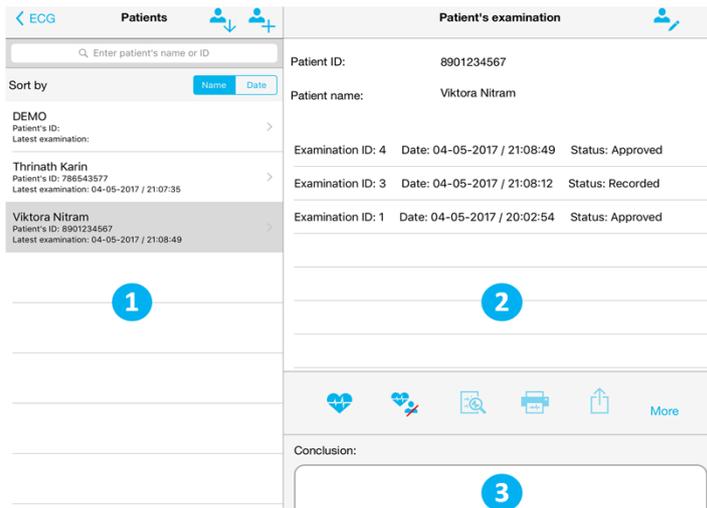
1. List of patients

2. List of selected patient recordings

3. Medical findings

⚠️ Login setup or Email account configuration on a tablet is essential to email the ECG.

⚠️ Disconnect the device and connect the tablet to a printer to print the ECG.

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

6.8 SETTINGS – APPLICATION
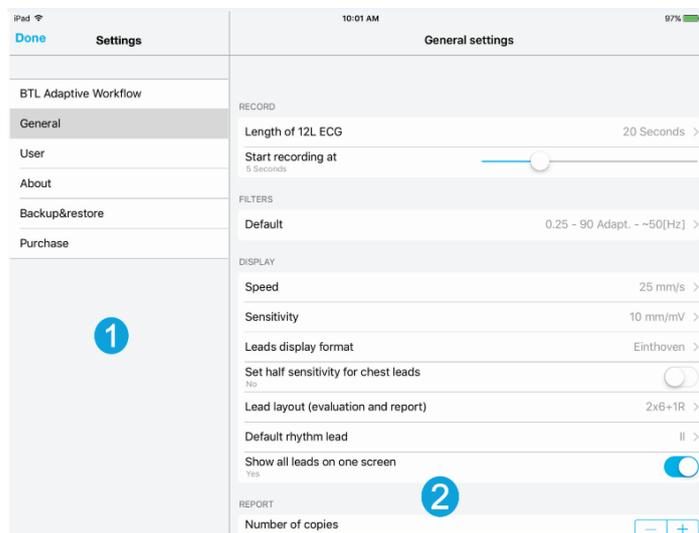
1. List of settings

2. Detailed settings

List of settings:

- BTL Adaptive Workflow – Contains settings of a special feature called BTL Adaptive workflow. This feature allows optimizing system workflow for user needs.
- General – Contains settings and information related to application and recording control.
- User – Contains settings related to managing application user and facility details.
- Purchase – Allows to purchase premium application features
- Backup&restore – Contains features to create and/or restore backup
- About – Contains information about the application.

7 ECG RECORDING WITH THE SYSTEM

7.1 POSITIONING OF ELECTRODES

Patient preparation – The ECG quality is particularly dependent on the contact between the electrode and patient's skin.

To keep the contact as good as possible please follow the principles mentioned below:
- the skin should be warm and the patient relaxed
- cleanse the skin with alcohol before fastening the electrode
- apply sufficient layer of gel on the electrode

⚠️ Unprepared skin may lead to a loose 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 patient's body and the device in the following sequence of lead placement.
- First, fasten the N (RL in AHA marking) electrode to patient's 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)
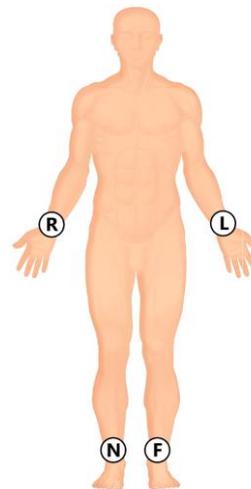
Chest Electrodes

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
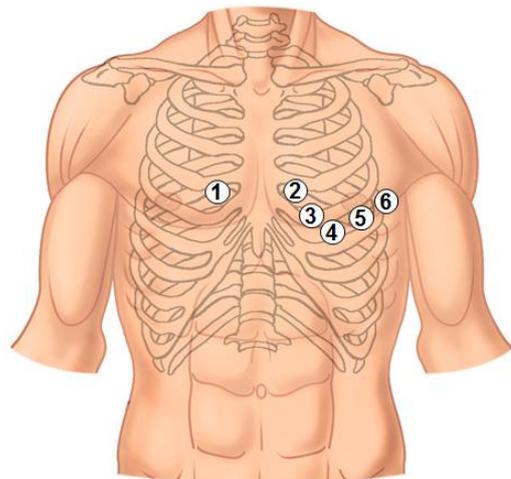
7.2 CONNECTING THE APPLICATION TO THE DEVICE

Follow the sequence in chapter 5 to connect the application to the device for the first time. The application connects to the device automatically on start-up, with WiFi enabled in tablet. If multiple devices are available, choose and connect to the required device from WiFi device list in the Tablet settings.

Note: The device can also work in an offline mode (no connection between the device and the application). Recorded ECG is stored to device internal memory. Such ECG can be managed on device history screen. All these ECG records are stored in status "recorded" in order to easily recognise which ECG is to be imported to the application manually once connection is established.

7.3 ENTER PATIENT INFORMATION AND START RECORDING

NOTE: Some of the features mentioned in chapters 7.3 – 7.5 are available only after a purchase. The purchase is available in application Settings>Purchase.

1. Access patients screen using icon in the application.

2. Create a new patient with button or choose an existing patient from the list on the screen.

3. Start ECG recording for selected patient using on the patients screen of the application. Observe patient details on the recording screen of the application and on the device display.

4. Check ECG signal quality on the device display/Patikrinkite EKG signalo kokybę įrenginio ekrane-punktas 12

Lead colour/laidų spalvos	Leads quality status/laidų kokybiškas prijungimas
Grey/pilkas	Connection is good enough for recording/Ryšys pakankamai geras įrašymui
Orange/orandžinis	Improve lead connection with skin/pagerinkite sąlytį su oda
Red/raudonas	Lead is disconnected/laidas atjungtas

Note: ECG recording can be started without entering patient details using . Patient's name is automatically generated as **YYYY.MM.DD HH:MM:SS Unknown** (tablet device date and time). This generated name can be changed on the patients screen to a real name after the recording.

*Note***:** If ECG recording is started from the device without entering patient details in a mode when the device is not connected to the application (offline mode), general name format is displayed **YYYY.MM.DD HH:MM:SS Devicename**. Such ECG can be imported manually (follow the sequence in chapter 7.6). The same can be edited later in the application and linked to an existing patient in the patients list.

Use on the device history screen to record ECG for prevously recorded ECG in online mode. At that moment, the ECG record has the same name. Such ECG can be imported manually (follow the sequence in chapter 7.6).

⚠ The tag "**NOT OPERABLE**" is shown on the waveform screen on the tablet if the ECG signal exceeds the specified signal range. Review and correct patient's skin preparation.

7.4 ECG RECORDING AND REVIEW

1. When you find the ECG signal ready for recording, press ![icon] to initate recording. ECG recording can be started from the device or application.

   *Note***:** ECG recording started from the application cannot be cancelled from the device.

   Note: When the device history has reached the maximum count of 90 ECGs, the system will automatically delete the oldest "delivered" ECG on the history screen. If there are no records with a "delivered" state in history, a warning will pop up on the device display to prompt you to make storage space by manually deleting records on the history screen. This warning pop-up can be disabled/enabled in Menu>Settings>History>Advanced>Warn before deleting undelivered records.

2. Observe progress of ECG recording in the progress bar icon ![icon] on the device and in the application.

3. Check the ECG preview in the application and save the ECG by pressing ![icon] .

4. The user also has an option to press ![icon] to save the current ECG and immediately record one more ECG for the same patient.

5. Button ![icon] deletes a recorded ECG, but enables recording a new ECG for the same patient again immediately.

6. Evaluation screen enables you to type medical findings, preview and to print an ECG report

7. Use ![icon] to close the evaluation screen

Saved ECGs can be seen on the patient screen in the application.

Recording during defibrillation/įrašas per defibriliaciją

The equipment is protected against any damage of cardiac defibrillator discharge to ensure recovery as required by the test standards. As for the test standards, the recovery of ECG trace to return does not exceed 5 seconds after defibrillation./ Įranga apsaugota nuo bet kokių širdies defibriliatoriaus iškrovos pažeidimų, kad būtų užtikrintas reikiamas atsigavimas pagal bandymo standartus. Kalbant apie bandymo standartus, EKG pėdsakų atkūrimas iki grįžimo neviršija 5 sekundžių po defibriliacijos.-punktas 14

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

Refer to the List of accessories for approved electrode details.

7.5 PRINTING AND SHARING ECG/EKG SPAUSDINIMAS IR DALINIMASIS

Select a patient and his ECG to be shared or printed on the patient screen of the application.

- Press ![icon] to print using a wireless printer connected to the tablet.

- Press ![icon] to share the ECG.

Note: **The** ECG can be shared either as a PDF report or as an XML file. The share format can be changed in the application settings./Pastaba: EKG galima bendrinti kaip PDF ataskaitą arba kaip XML failą. Bendrinimo formatą galima pakeisti programos nustatymuose.-punktas16

7.6 MANAGING ECG HISTORY

Importing ECG to the application

- Press on the patient screen to import ECG from the device memory to the application.
- Application lists ECG status as 'recorded', 'sent' and 'delivery error'
- Select an ECG to be imported

Note: Select 'Display including delivered' to view ECGs with the status 'delivered'.

Managing ECG

When you select a patient and an ECG on the patients screen in the application, by choosing the following actions are possible:

1. Hide/Unhide an ECG using 'Hide examination'. Hidden ECGs can be seen after enabling this in the application settings.

2. Assign an examination to another patient in the patient list.

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 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.

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".
- ECGs taken in an extremely disturbing environment or while the patient is moving. In such an event, switch to the "User Filter" and set another combination.

This setting consists of the following filters:/ Šį nustatymą sudaro šie filtrai: - punktas 17

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

No Filter

This setting does not include any filter and the transferred band is, in this case, 0.05 Hz - 170 Hz.

Strict Filter

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

Mains

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

1. **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.

2. **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.

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 the one appearing as a result of the patient's breathing.

1. **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. due to static charge) the signal returns to zero very slowly, taking up to 12 seconds.

2. **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. due to static charge) the signal returns to zero, taking up to 4 seconds.

3. **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.

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 of it.

⚠️ 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 eliminated as well.

1. **90 Hz Adaptive**

   This filter is recommended as default for most ECGs. The filter smoothly retunes its resulting cut-off frequency so as to permanently preserve the useful signal components. The unprocessed signal is monitored by the curvature analyser. The output of the analyser smoothly sets the output cut-off frequency of the filter. In the area of rapid changes (typically QRS), the frequencies are transferred at 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.

2. **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.

3. **25 Hz**

   This filter suppresses all frequencies higher than 25 Hz. This setting may influence the recorded ECG, 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.

4. **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 the BTL authorized service department for further assistance, in-case the following troubleshooting solutions do not solve your problem.

Trouble in connecting the application to the device:

→ The **application is not able to connect to the device, even when in the device signal range.** → Interference from an external device. Move away from interference and try reconnecting.

→ The **application is out of the device signal range.** → Move the tablet closer to the device signal range and try reconnecting.

 Indication of Signal Strength in the tablet application.

→ It is **not possible to see the device name in the tablet settings - WiFi device list.** → The device is switched off or in the offline mode. Switch on the device or disable 'Work offline' in device settings > connection.

→ The **device is listed in the tablet settings - WiFi device list, but it is unable to connect.** → Identify the WiFi address of the connected tablet application. The details can be found in device settings > connection. Disconnect and try reconnecting.

The device is not charging:

→ The **device is not charging with a power adaptor connected.** → Broken power adaptor or loose connection. Check the LED glow on the adaptor. If it is fine, clean the device area before connecting. If any foreign particle is observed, reconnect the adaptor to the device and check for charging indication.

→ The **device is connected to the power adaptor, there is a damaged battery indication on the device display.** → Broken battery, contact the BTL Authorized service for further assistance.

Factory reset:

→ The **device is hanged and doesn't switch off**→ Broken device, contact the BTL Authorized service for further assistance.

→ The **device doesn't respond to operator actions in a normal-use scenario.** → Re-initialize the system by Factory reset in settings > General > Factory settings > Reset to factory settings.

⚠ Backup all data to the tablet application before a factory reset of the device.

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

ECG signal quality:

→ **Noise observed in ECG signal in the device and on the application display** → improper skin preparation or loose connections to the patient or damaged patient cable; check skin preparation, connection and cable, reconnect / replace damaged lead wires and recheck signal quality. In case of further noise in signal, change filter settings and recheck ECG signal quality.

Device overheat:

→ **Overheat shutdown after short usage (<1 hour of usage under recommended operating conditions).** → Allow the device to cool in operating condition for 30 minutes to 1 hour. If the problem persists and repeats, contact the 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 a cleaning procedure!

Recommended intervals for inspection of the device are 24 months after installation and subsequently each 12 months. The intervals may differ according to the local regulations. The inspection shall be performed according to the 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 the 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 with 2% detergent solution or other mild cleaning agents.

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

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 the 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 to clean 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 with 2% detergent solution or other mild cleaning agents.

⚠️ Usage of harsh cleaning agents with chemicals like alcohols, ammonium chloride, sodium hypochlorite 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 equipment packaging for safe transportation.
Store the device indoors only, in a dust-free environment.

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

11 ACCESSORIES/priedai - punktas 20.1; 20.2

The ECG system is not designed for use with other medical devices or accessories except for those stated specifically in this manual.

The following is a list of accessories that can be supplied with the equipment:

- 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 connector/ BTL Flexi 12 EKG paciento krūtininis 6 laidų kabelis su užspaudžiama jungtimi-punktas 20.1

- BTL Flexi 12 ECG patient cable limb 4-lead with pinch connector/BTL Flexi 12 EKG paciento galūninis 4 laidų kabelis su užspaudžiama jungtimi punktas 20.1

- Charger for the BTL Flexi 12 ECG acquisition device

- Wi-Fi dongle

- Docking station

- Belt strap

- Belt strap plate for connection between the BTL Flexi 12 ECG and belt strap

- Extremity AgCl electrodes

- Chest AgCl electrodes

- Universal self-adhesive ECG electrodes (disposable, for pinch connector)-Universalūs lipnūs EKG elektrodai (vienkartiniai, suspaudimui) - punktas 20.2

12 TECHNICAL PARAMETERS

Device name	BTL Flexi 12 ECG
General characteristics device	
Display dimension and resolution/ekrano išmatavimai ir rezoliucija	2.8", 240 x 320 dots(taškai) - punktas 6
Overall dimension (mm)	82 x 87 x 25
Weight/svoris	150 g - punktas 7
Keyboard/klaviatūra	Touch panel on device/Įrenginio jutiklinis ekranas - punktas 8
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/derivacijų(kanalų)skaičius - punktas 2	12 Leads (I, II, III, aVR, aVL, aVF, V1, V2, V3, V4, V5, V6) - 12 derivacijų
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)/Įrašo trukmė (įrenginyje)	
ECG 12L	10 s; 12 s; 15 s; 20 s
Storage/saugykla(vidinė talpa)	Maximally 90 ECG on device/maksimaliai 90 ECG įrenginyje - punktas 9 Maximally 6000 ECG on application.
Filters-filtrai - punktas 17	
Mains filter (Hz)	50; 60
Drift (Hz)	0.05; 0.25, 0.6
Myo (Hz)	20; 25; 35; 90
Detection of pacemaker/Širdies stimuliatoriaus aptikimas -punktas 13	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-condensing
Atmospheric pressure	700 hPa to 1060 hPa
Transport and storage conditions	
Temperature	-10 °C to +55 °C
Relative humidity	10 % to 85 %, Non-condensing
Atmospheric pressure	650 hPa to 1100 hPa
Power supply	
Mains voltage	100–240 V ~
Frequency	50–60 Hz
Protection class	Class I
Input impedance	>2.5 MΩ
Ingress condition	Comply with the IPx2 requirement as per standard IEC 60529.
Battery/akumuliatorius-punktas 11	Li-Ion battery, 3200 mAh capacity, 3.6 V/ličio baterija 3200mAh talpa, 3.6V
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 170 Hz
Sampling frequency/ekg analizės dažnis punktas 3	1000 Hz
Storing frequency	500 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 artefacts 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.

Guidance and manufacturer's declaration – Electromagnetic Emissions		
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.		
Emissions test	**Compliance**	**Electromagnetic environment - guidance**
RF emissions CISPR 11	Group 1	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.
RF emissions CISPR 11	Class B	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.
Harmonic Emission IEC 61000-3-2	Class A	
Voltage Fluctuations / Flicker Emission IEC 61000-3-3	Complies	

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.

	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
Conducted RF EN 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 V	Portable and mobile RF communications equipment should be used no closer to any part of the device, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** $d = 1{,}2\sqrt{P}$
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 the equipment marked with the following symbol: $(((\cdot)))$

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.

13 MANUFACTURER

BTL Industries Ltd.
161 Cleveland Way
Stevenage
Hertfordshire
SG1 6BU
United Kingdom

E-mail: sales@btlnet.com

For service, please contact the service department at service@btlnet.com.

Date of last revision: 11th September 2019

ID: 076-80MANEN02103

$C\epsilon$ 1434