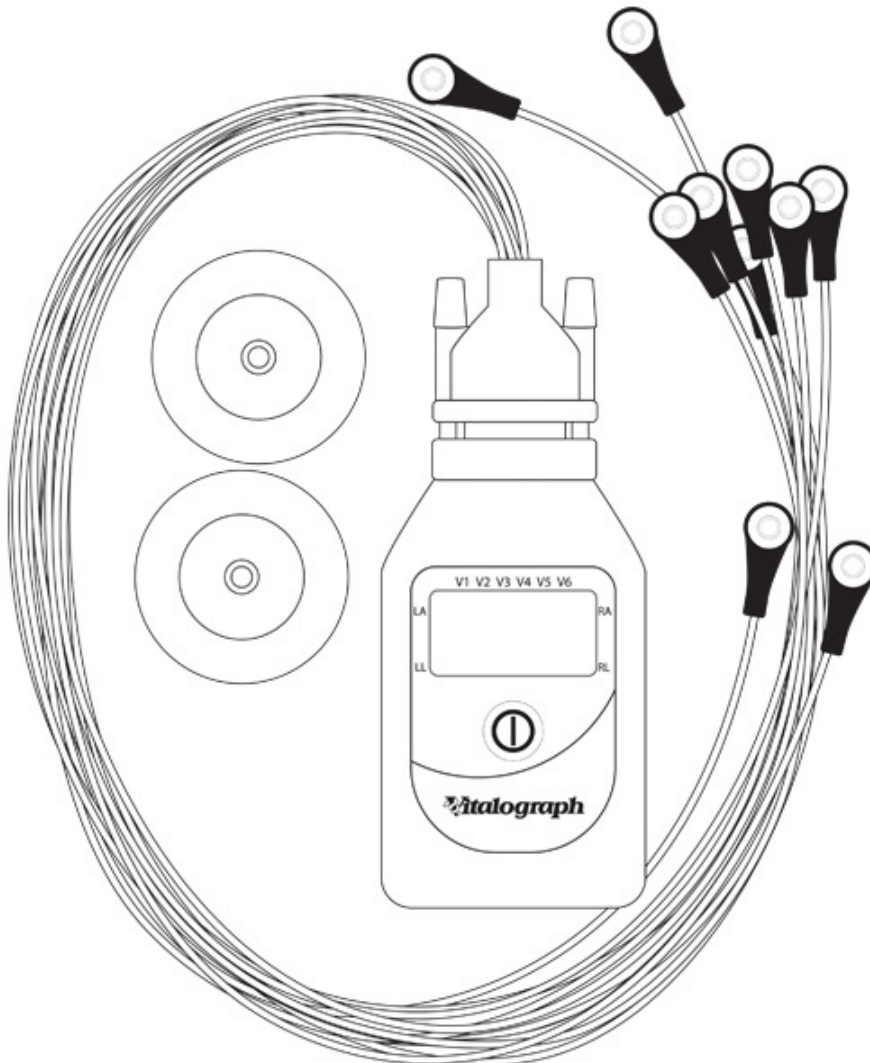


**Vitalograph<sup>®</sup>****ECG****BT12 ECG**

# User Training Manual

**CE**  
0086



**Vitalograph Ltd. UK**

Maids Moreton, Buckingham,  
MK18 1SW  
England

**Tel:** (01280) 827110

**Fax:** (01280) 823302

**E-mail:** sales@vitalograph.co.uk

**www.vitalograph.co.uk**

**Vitalograph Ltd. International**

Maids Moreton, Buckingham,  
MK18 1SW  
England

**Tel:** +44 1280 827120

**Fax:** +44 1280 823302

**E-mail:** sales@vitalograph.co.uk

**www.vitalograph.eu**

**Vitalograph GmbH**

Rellinger Straße 64a,  
D-20257 Hamburg,  
Germany

**Tel:** +49 40 547391-0

**Fax:** +49 40 547391-40

**E-mail:** info@vitalograph.de

**www.vitalograph.de**

**Vitalograph Inc.**

13310 West 99th Street,  
Lenexa, Kansas, 66215,  
USA

**Toll Free:** 800 255 6626

**Tel:** (913) 730 3200

**Fax:** (913) 730 3232

**E-mail:** vitcs@vitalograph.com

**www.vitalograph.com**

**Vitalograph (Ireland) Ltd.**

Gort Road Business Park,  
Ennis, Co. Clare, V95 HFT4,  
Ireland

**Tel:** +353 65 6864100

**Fax:** : +353 65 6829289

**E-mail:** sales@vitalograph.ie

**www.vitalograph.ie**

**Vitalograph Ltd. Hong Kong /China**

Unit 2001, Floor 20, Block A,  
New Trade Plaza, 6 On Ping Street,  
Shatin  
Hong Kong

**Phone:** +852 2117 2678

**Fax:** : +852 2117 2679

**E-mail:** sales@vitalograph.cn

**www.vitalograph.cn**

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## 1. DESCRIPTION OF THE VITALOGRAPH BT12 ECG

The BT12 ECG measuring unit is an active medical product and in connection with a receiving unit serves as a mains-independent, wireless ECG device which can be worn on the body for the following purposes:

- Measurement of an ECG
- Measurement of the heart rate with optical and acoustical signals when preset values are exceeded or fallen short of
- To supports a diagnosis from a physician
- Documentation of ECGs

The ECG measuring unit can be used in the clinical area and in a doctor's practice. The subject or relative – after being instructed accordingly – can operate the device for patient monitoring at home. The ECG measuring unit is not suitable for intracardial use.



*Figure 1: BT12 ECG Measuring Unit*

The measured ECG is transferred via a Bluetooth interface to an external receiver unit such as a PC running monitor software. Here, the data may be displayed specific to a subject, saved, commented, printed out and revised by expert personnel.

The main components for the Vitalograph BT12 ECG are shown in Figure 2.

**Warning: No modification of this equipment is allowed. Any unauthorised changes to the ECG device may compromise product safety and/or data and as such Vitalograph cannot be held responsible and the device will no longer be supported.**

### 1.1 Indications for use

The BT12, hereafter referred to as the “BT Device”, is a battery powered device capable of acquiring and transmitting a standard electrocardiogram (EKG) to be applied by medically trained persons for the purpose of cardiac monitoring and diagnosis performed by medical professionals. The collected data is not interpreted by the BT device as this is done by the monitoring device operated by medical professionals.

The collected data is processed by the BT device and then transmitted via a standard wireless link to a monitoring device, such as a PC or hand-held device for display, review, printing, saving and post event processing by medical professionals. Use of the BT device is not restricted to the adult population, but is also intended for infants weighing less than 10Kg(22lbs).














Measurements taken by the BT device are only significant if considered in connection with other clinical findings. No therapy or drugs can be administered based solely on ECG data derived from the BT device. The BT device is not intended for monitoring critical patients and is not intended for intracardial use

Federal law restricts this device to sale by or on the order of a physician.



















## 2. CONTRAINDICATIONS, WARNINGS, PRECAUTIONS AND ADVERSE REACTIONS



Read this User Training Manual carefully, it is a component of the device and must be available at all times. Only use the device for the described purpose (see Section 1.1). Please also observe the User Training Manual of the PC software used with the measuring unit PN 07402.

### 2.1 General

	<i>The ECG measuring unit may only be used by persons who can guarantee that it will be used properly based on their training/education or knowledge e.g. instruction.</i>
	<i>If original accessories are not used, this could result in function failures and bio-compatibility cannot be assured. Observe that in such cases, any warranty or liability claims are void when neither the accessories recommended in the User Training Manual nor the original replacement parts are used.</i>
	<i>The ECG measuring unit is not suitable for use in rescue helicopters or ambulances.</i>
	<i>Observe section 5 "CLEANING AND DISINFECTION" to avoid contamination.</i>
	<i>Only allow repair work be done by the manufacturer or other expert personnel.</i>
	<i>Before each use, visually inspect the device, the electrode cables and the adhesive electrodes. If there is any externally visible damage or if the self-test fails the device may no longer be used.</i>
	<i>The ambient conditions specified in the technical data are to be complied with.</i>
	<i>The ECG measuring unit may not be submerged in liquids or have liquids poured on it, be intentionally sprayed or be exposed to rain.</i>
	<i>The ECG measuring unit may only be opened by authorized expert personnel. If the device is opened without permission, the warranty is void.</i>
	<i>The manufacturer is not liable for the function of the ECG measuring unit if the device is improperly maintained by the owner/operator or if it is treated in a way which doesn't correspond with its proper use in accordance with this user manual.</i>
	<i>The signals output by the measuring unit do not meet the alarm standard for medical electrical devices, DIN EN 60601-1-8.</i>
	<i>To guarantee patient safety, the receiver unit and peripheral devices are to be operated outside of the patient's immediate surroundings, i.e. with a minimum distance of 1.5 m to the patient.</i>
	<i>All parts of the measuring unit, including accessories, which come into contact with the patient during intended use, meet the requirements of the applicable standards with regard to bio-compatibility.</i>

### 2.2 Operating the device

	<i>The ECG measuring unit, especially the electrodes and electrode cables, may only come into contact with healthy patient skin.</i>
	<i>Wear the ECG measuring unit on a piece of clothing or carry it in its pouch (accessory).</i>
	<i>While the ECG is recording, don't make any changes to the electrodes or the device as this may result in faulty measurements.</i>
	<i>The ECG measuring unit is a defibrillation-proof application part of type BF. The device is not suitable for direct leads to the heart. When using a defibrillator, the ECG electrodes and the defibrillator must not come into contact.</i>  <i>Note: When using a defibrillator, make sure that no one has a conducting connection to the patient. Burns or other injuries could result.</i>
	<i>It is not possible to operate High Frequency devices, e.g. surgical devices, in combination with the ECG measuring device.</i>
	<i>When monitoring critical patients, an alternative ECG system should be kept readily available in the event of a device fault or failure.</i>
	<i>Avoid tensile loads on electrode cables.</i>
	<i>Only use bio-compatible and CE-approved ECG electrodes with the ECG measuring unit.</i>
	<i>Always observe the user instructions for the used electrodes.</i>
	<i>Magnetic and electric fields can influence the function of the device. Keep the recommended separation distance between the ECG measuring unit and devices which emit High Frequency radiation (e.g. cell or mobile phones) to ensure correct operation (see Section 12 "Technical Specifications").</i>
	<i>Observe that when the measuring unit is switched on, the electromagnetic radiation it emits can influence other electric devices around it. Keep the recommended separation distance between the ECG measuring unit and other devices to ensure there is no interference (see Section 12 "Technical Specifications").</i>
	<i>The ECG measuring unit may not be operated in potentially explosive atmospheres.</i>
	<i>Check the signal limit settings before every monitoring phase.</i>
	<i>When using the BT12 during a stress ECG, it is required that the patient be under constant observation.</i>
	<i>The ECG measuring unit may not be used without supervision on children under the age of 3 or mentally confused patients. There is a risk that the electrodes could be aspirated.</i>
	<i>Wireless transmission errors could occur if heat therapy devices are operated in the immediate vicinity.</i>
	<i>If the patient has a cardiac pacemaker, there could be errors in the heart rate calculations.</i>
	<i>In rare cases the measuring unit may heat up in rare cases due to a short circuit in the batteries. Turn off the ECG measuring unit immediately and remove the batteries. Stop using the device and have it repaired before</i>

	<i>using it again.</i>
	<i>Make sure that the Bluetooth monitor to which the measured data is transmitted is invisible to other Bluetooth end devices. Otherwise, there could be errors in the data transmission.</i>
	<p><i>BT12 operate safely and effectively in an environment where BT devices and WLAN devices coexist. But some restrictions have to be considered. We recommend using the BT12 device together with a maximum of two other BT ECG devices within the range of each BT ECG device. Furthermore, any WLAN sender or receiver (e.g. WLAN USB dongles for PCs) should be placed more than 1 meter away from the BT12 and the BT receiver (BT USB dongle for PCs) respectively. Otherwise, BT12 will lose data packets. The user is responsible for ensuring that data transmission is not corrupted by too many wireless senders or receivers in the vicinity.</i></p> <p><i>Refer to the appendix at the end of this User Training Manual for a troubleshooting guide on pairing the Vitalograph ECG.</i></p>

### 3. MAIN COMPONENTS OF THE VITALOGRAPH BT12 ECG

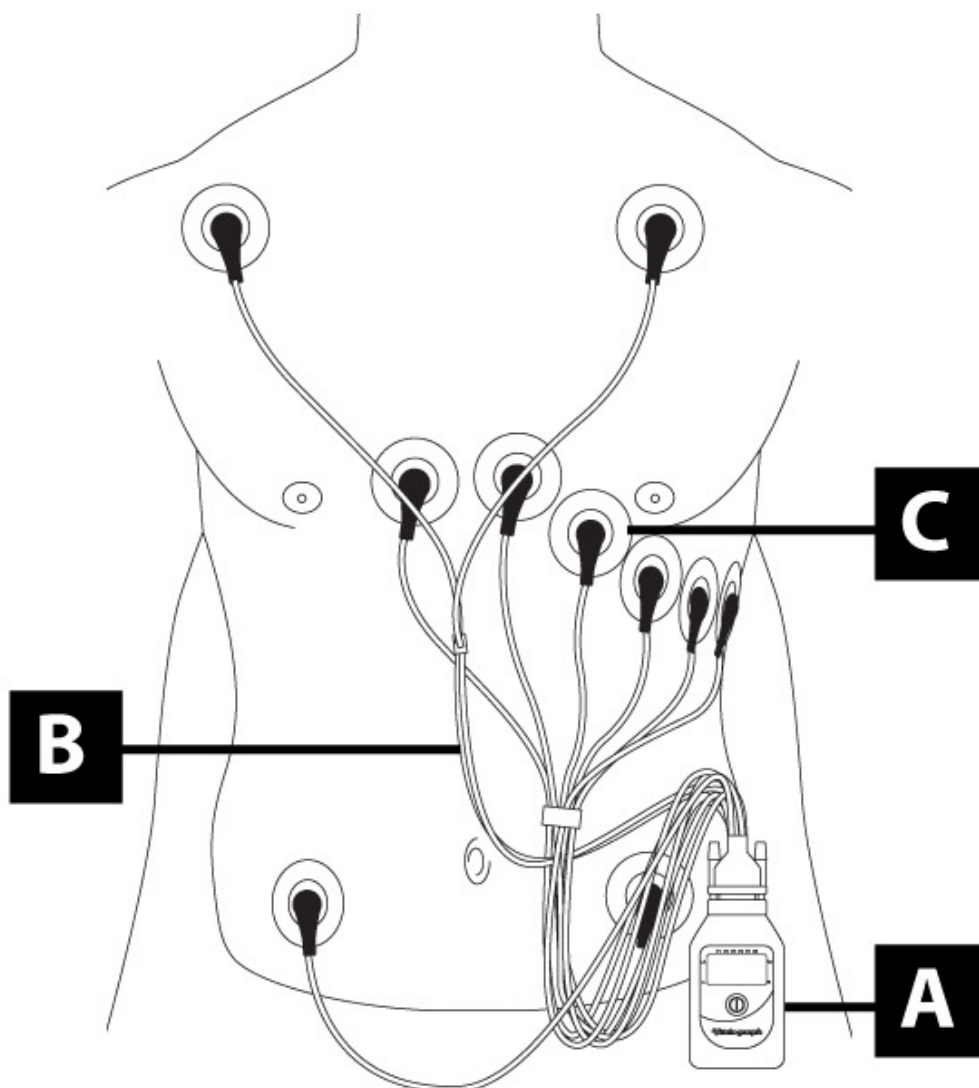


Figure 2



A	ECG device
B	Electrode cable
C	Electrodes

## 4. FEATURES OF THE VITALOGRAPH BT12 ECG

The Vitalograph BT12 device features include:

- Capable of acquiring and transmitting standard 12 lead ECG
- Battery powered
- Small, portable design with integrated clip to allow for attachment to clothes/belt
- Heart rate monitoring with results displayed on the integrated LCD
- Wireless connectivity to monitoring software to allow display, review, printing, saving and post event processing of data

## 5. GETTING THE VITALOGRAPH BT12 ECG READY FOR USE

### 5.1 Unpack device

Remove all components of the Vitalograph BT12 ECG device carefully from the packaging. Check them against the contents list to ensure that they are all present and check them for damage. If any are missing or damaged do not use the device. Contact the distributor or the manufacturer directly for replacement parts.

**ATTENTION : Packaging material can pose a suffocation danger. Keep it away from children and dispose of it properly.**

### 5.2 Power Management

The ECG measuring unit requires two AA alkaline batteries or two AA NiMH rechargeable batteries for operation. The operating time depends on the quality of the selected batteries. With the BT12, runtimes between 9 and 13 hours can be achieved.

Power source	Manufacturer	Device runtime	Device runtime BT12
Alkaline LR6 AA	TDK, Duracell	15 hours	9 hours
Varta photo rechargeable NiMH AA batteries	Varta	20 hours	13 hours

To insert the batteries, open the battery compartment cover and insert the batteries according to the shown polarity inside the battery compartment. Close the battery compartment cover.



*Figure 3: Opened battery compartment with inserted batteries*

The battery status for the activated device is visible on the battery icon at the bottom left of the screen. It is recommended to change the batteries when the display shows no bars and the battery icon flashes. In measuring mode, the ECG measuring unit is designed for between 9 to 13 hours of operation, depending on the type of batteries used.

**ATTENTION: Dispose of used batteries according to the valid regulations of your country.**

### 5.3 Clip

The device can be worn on the patient's clothing with the clip. To fasten the device to clothing, push the clip in a loop of clothing or on a belt.



*Figure 4: ECG measuring unit with clip*

### 5.4 Electrodes and electrode cable

Make sure the ECG adhesive electrodes are applied carefully. A disturbance-free ECG is only guaranteed if the electrodes are correctly positioned with good skin contact.

- Adhesive electrodes are intended for one-time use only
- Always observe the user instructions for the used electrodes

- Shave off any excess hair which could prevent good electrode contact
- The application positions (see section 5.5) must be clean and dry
- Remove the foil from the adhesive electrodes
- The electrodes may only be applied to healthy skin
- Do not use any electrodes past their expiration date or if the gel is dried out
- Make sure that electrodes are exchanged according to manufacturer specifications
- Press the electrodes firmly onto the patient's skin at the corresponding places, depending on the desired lead

For an optimal measured result, it is recommended that the original ECG cable which was included in delivery be used. If a cable is used other than the original ECG cable included in delivery, there can be no guarantee that it will function correctly.

**ATTENTION : The electrode cable can pose a strangulation danger, always attach the device to clothing/belt or pouch as instructed and do not use without supervision on children under the age of 3 or mentally confused patients.**

**ATTENTION : The electrodes can pose a suffocation/aspiration danger, do not use without supervision on children under the age of 3 or mentally confused patients.**

## 5.5 Electrode position

The following table provides an overview of the electrodes and neutral electrodes, their positions, as well as their ID and color code in accordance with DIN EN 60601-2-27 and ANSI/AAMI EC11.

System	CODE 1 electrodes		CODE 2 electrodes		Position on the surface of the body
	ID	Color Code	ID	Color Code	
Extremities	R	Red	RA	White	Right Shoulder
	L	Yellow	LA	Black	Left Shoulder
	F	Green	LL	Red	Left Hip
	N	Black	RL	Green	Right Hip (neutral electrode)
Chest wall acc. to Wilson	C1	White/Red	V1	Brown/Red	In the IV intercostal space on the right sternal border
	C2	White/Yellow	V2	Brown/Yellow	In the IV intercostal space on the left sternal border
	C3	White/Green	V3	Brown/Green	On the 5th rib between C2 and C4
	C4	White/Brown	V4	Brown/Blue	In the V intercostals space on the left midclavicular line
	C5	White/Black	V5	Brown/Orange	On the front left axial line at the level of C4
	C6	White/Purple	V6	Brown/Purple	On the left midaxillary line at the level of C4

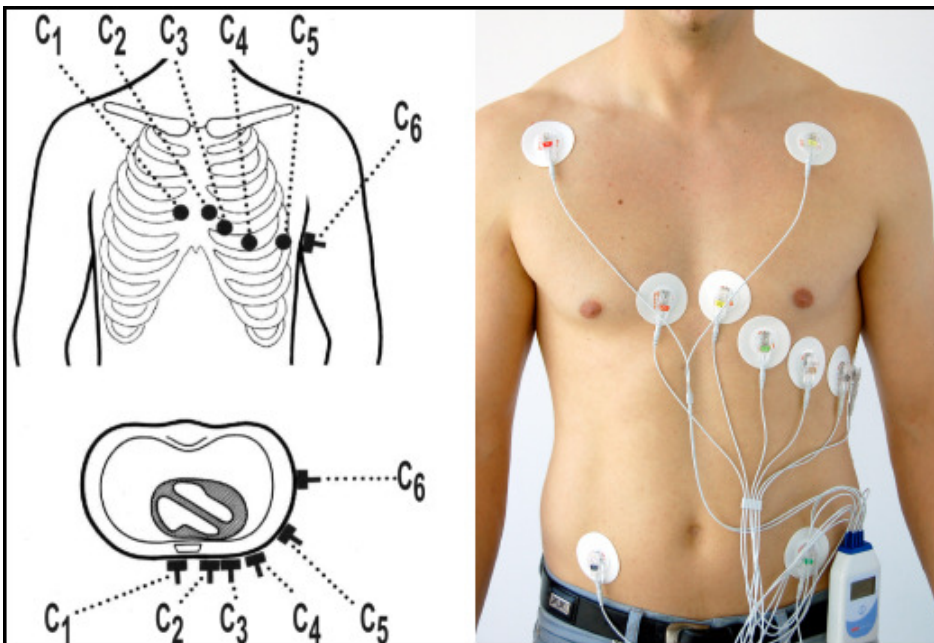


Figure 5: Positions of the chest wall leads

## 5.6 Functional Check

Every time the ECG measuring unit is switched on, it carries out an integrated self-test. Error conditions in the electronics or program run are indicated on the display with “Err” and an error code.



Figure 6: Display of error codes

Visually inspect the ECG measuring unit before every use. If any external damage to the device or the electrode cables is noted or if the integrated self-test fails, do not continue to use it. Contact the distributor or manufacturer to have the device repaired or replaced, please refer to the contact information at the start of this manual.

## 6. OPERATING THE VITALOGRAPH BT12 ECG

### 6.1 Pairing the ECG device

The first time a connection is established with a monitor such as a PC running appropriate software, the ECG measuring unit is paired to this monitor. If the Bluetooth driver requests a PIN number during this pairing operation, enter “1111”.

To avoid data transmission errors and to deny access to unauthorized parties, the ECG measuring unit is no longer visible to other Bluetooth devices after this pairing. This pairing can be broken by following the instructions below -

1. Turn on the device by pressing the power button.
2. Once the device is on press and hold the power button for 20 seconds.
3. The device will emit beeps during this process, 1 x long beep after 3 seconds and 2 x short beeps after 20 seconds and then it switches off. After switching on again the ECG measuring unit is visible to other Bluetooth devices and may be paired to a new monitor.

Refer to section 17. Appendix for a complete troubleshooting guide on pairing the ECG device.

## 6.2 Preparing the ECG recording

Examine the ECG measuring unit and the electrode cable for externally visible damage. If any damage is noted, have the unit repaired or replaced before using it. If the ECG cable for the BT12 shows any signs of damage, replace it before using it.

Before using the ECG measuring unit, make sure that the expiration date of the adhesive electrodes you are using has not elapsed and observe the user instructions for the electrodes.

Attach the electrodes to the corresponding places on the body of the patient (see Section 5.5). Then fasten the electrode cable via the contact option for the snaps on the electrodes.

## 6.3 Switching the ECG measuring unit on/off

To switch on the ECG measuring unit, press the power button for 3 seconds. On power on the device carries out an automatic self-test. If an error code appears on the display follow the instructions in Section 6.7 below and Section 8. Fault Finding. The ECG measuring unit is ready for operation when the battery symbol and the loudspeaker symbol appear on the display.

**CAUTION:** Do not use the device if an error code is displayed, see section 6.7 for a complete list of error codes.

Briefly pressing the power button with the device switched on activates the backlighting of the display. This switches off automatically after 5 seconds.

Pressing and holding the power button switches the ECG measuring unit off. An acoustic signal sounds when it does so.

## 6.4 Electrode contact


Fasten the electrodes to the patient (see Section 5.4 and 5.5). The ECG measuring unit automatically checks the contact quality and indicates a poor electrode contact by flashing the respective point on the display. If one or more points flash check the contact of the corresponding electrode(s) and replace if necessary. The ECG transmission begins when all electrodes are connected. If one of these four electrodes R, L, F and N is removed or falls off during recording, the ECG signal transmission is interrupted. The recording is not interrupted if one of the V leads comes loose.

## 6.5 Heart rate monitoring

The ECG measuring unit monitors the heart rate of the patient continuously after correctly applying the electrodes. The heart rate is shown on the display, labeled "BPM". In limited display mode, only the heart symbol flashes at the same rate as the heartbeat. If the preset limits are exceeded or fallen short of, the device will emit a sound to indicate this. The volume of this can be adjusted to 5 different levels or muted.

**NOTE:** The sound volume should be set so that it can't be missed.

## 6.6 ECG data transmission

The receiving unit establishes the wireless connection to the ECG measuring unit via the interface. Once the connection has been established, there is a short beep on the ECG measuring unit. An existing connection is indicated on the display by the "Radio active"  symbol. If the connection is lost because the user moves out of range of the receiver it will emit a sound and the corresponding symbol disappears from the display.

**NOTE:** If there is no data transfer within five minutes of activating the device the ECG measuring unit switches off again automatically.

**NOTE:** The range of the wireless transmission is approximately 10 m. Ensure that there are no obstacles between the ECG measuring unit and the receiver unit to maintain a stable connection.

**NOTE:** If the Bluetooth connection is interrupted for longer than 15 minutes the ECG measuring unit switches off

automatically.

With the monitor software, ECG data can be shown online on the PC. In addition, measured values can be saved and revised (not available in every monitor software version). Observe the user instructions for the respective monitor software.

## 6.7 Displays and signals

The ECG measuring unit can be operated in two different display modes:

- In the complete display mode, the heart symbol flashes at the same rate as the heartbeat and the heart rate is displayed as a number value.
- In limited display mode, the heart rate is not displayed. Only the heart symbol flashes. Instead of the heart rate, the following characters appear on the display: “???”.

A crossed-out loudspeaker symbol indicates that the sound is muted. The charge status of the power source is indicated by a battery icon showing three bars for full batteries and no bars/icon flashing for discharged batteries.

If the ECG measuring unit detects an R wave, it emits a brief sound. This output can be deactivated via the receiver of the ECG data. Furthermore, the heart symbol flashes on the display at the rate of the detected R wave.

The electrode connections are displayed by points. An open electrode is indicated by a respectively flashing point and a connected electrode by a continuously illuminated point. Data transmission on the monitor only starts when all electrodes are connected. If one of the electrodes loses contact, the device emits a warning sound. If the disconnected/failed electrode is R, L, F or N the ECG signal transmission is interrupted until the electrode has been replaced or correctly attached. The recording is not interrupted if one of the V leads comes loose.

If the measured heart rate is above or below the set limits the device will emit two short warning sounds.

The “Radio active” symbol indicates if there is a Bluetooth connection to the P.C. When the wireless connection is established, the device emits a short sound. In the case of a broken connection e.g. if the patient moves out of the monitor’s receiving range, the device emits a pulsing sound for one minute.

All acoustic signals, except for the sound output for a detected R wave, can be muted by pressing the power button briefly. After 3 minutes, the signal sounds automatically again if the cause is still present. Muting only applies for the currently occurring signal. All other signals can still sound. If an event signal sound is muted, the crossed-out loudspeaker symbol is illuminated on the display.

All acoustic outputs, except for warning signals when the connection is terminated can be permanently deactivated by configuring via the PC monitor software.

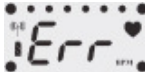




**ATTENTION:** If the sound output is permanently deactivated via the monitor software, no alarm is sounded when an electrode falls off or when the pulse thresholds are exceeded/fallen short of.

The display has backlighting, which can be activated by a short press of the power button and switches off automatically after 5 seconds.



Figure 5: Labeling of the display

The following table offers a list of all occurring acoustic and optical signals which can be output by the ECG unit.

Signal	Acoustic Signal	Optical Signal
Open electrode	At the rate of the flashing icon	Flashing of the corresponding point on the display
Closed electrode	-	Illumination of the corresponding point on the display
Leaving range	Longer pulsating sound for 1 minute	Radio symbol on display is deactivated
Exceeding or falling short of the configured threshold for the heart rate	Two brief sounds, one per second	
R wave detected	Brief sound	Heart symbol flashes briefly
Switching off the device	After pressing button for 2 seconds, a 2-second sound	-
Error message	-	
Data memory full	-	
Data memory almost full	-	
Radio active - Bluetooth is connected	-	
Crossed out loudspeaker - audio is muted	-	

## 7. CLEANING INSTRUCTIONS

### 7.1 Maintenance

To maintain the ECG measuring unit change the batteries as required. See also Section 5.1.

Remove the batteries if storing the device for a long period of time without using it to avoid damage to the device.

An annual service is recommended. Service and repairs should be carried out only by the manufacturer or by Service Agents specifically approved by Vitalograph.

### 7.2 Disposal

The device must be taken to separate collection at the product end-of-life. Do not dispose of these products as unsorted municipal waste. Please note, that batteries must be disposed of separately.

### 7.3 Cleaning and disinfection of the surface of the device

Ensure the ECG measuring unit is turned off prior to cleaning/disinfecting. The device is not intended to be waterproof and as such must not be submerged, have liquids poured or sprayed on it.

To clean, wipe the housing with a soft, moist cloth.

For disinfection use Incidin® Foam oder Mikrozyd® AF Liquid or equivalent. Please refer to the specific manufacturers instructions for use prior to disinfecting.

**CAUTION:** *Never submerge the device in disinfectant or other liquids as it may cause damage to it.*

## 7.4 Cleaning and disinfecting the electrode cable

To clean the electrode cable, rub the cable off with a soft, moist cloth. Only use a mild cleaning agent to avoid damage. Make sure you don't pull too hard on the cables.

For disinfection, rub the cable off with a cloth soaked in Incidin® Foam or Mikrozyd® AF Liquid. Please refer to the specific manufacturers instructions for use prior to disinfecting.

**CAUTION:** *Never submerge the cable in disinfectant or other liquids as it may cause damage to it.*

## 7.5 Electrodes

If disposable adhesive electrodes are used, dispose of these immediately after use.

## 8. FAULT FINDING GUIDE



<b>Malfunction</b>	<b>Possible causes</b>	<b>Rectification</b>
The ECG device will not turn on	Dead batteries, reversed batteries.	Exchange batteries for fully charged ones. Check the polarity of the inserted batteries.
The measuring unit cannot be detected by other Bluetooth devices.	It is already paired with another device.	Switch the device on and then press the power button for at least 20 seconds until it beeps. The device is now ready to be paired again and is visible to other Bluetooth devices after switching on again.
	Issues caused by conflict with USB 3.0 hard drives/flash drive, internal built in BT antenna, too many BT devices or incorrect BT dongle used.	There are several issues that may cause an issue with detection/pairing, see section 17. Troubleshooting guide for pairing the BT12 for details on resolving all known issues.
You are prompted to enter a PIN number during pairing.	The ECG device is being newly paired with a monitor.	Please enter "1111" during this process.
After switching on, the display continuously shows an error code.	PCBA fault.	Switch off the device. Take out the batteries and put them back in. Afterwards, switch on the device again. If the error code is still present stop using the device and contact Vitalograph.
The "Radio active" symbol does not appear on the display or disappears from the display during use.	The wireless connection cannot be established or has been broken.	Reduce the distance to the receiver unit (<10m) and remove any existing obstacle. If necessary, carry out pairing again. See section 17. Troubleshooting guide for pairing the BT12 for details on resolving all known issues.
Displaying too few channels for desired 12-channel use.	Incorrect configuration.	Configure the ECG measuring unit for 12-channel use
No warning sounds for critical events.	Loudspeaker is muted or is defective.	Check the configuration of the loudspeaker. Muting is indicated on the display by the crossed-out loudspeaker symbol. If the sounds are enabled and the warning sounds are still missing it is likely a defective speaker, contact the manufacturer.
Pulse frequency is not shown on the display.	The ECG device is in limited display mode.	Check the configuration of the display mode and reconfigure if required.
One or several electrode contact points flash despite all electrodes being connected.	The electrode contact is poor. The cable is defective.	Check the positioning and the skin contact of the electrodes. Press the electrodes on firmly. If necessary, shave any hair or clean the skin. Replace the electrode. Use electrode gel/spray to improve contact. If the above measures do not resolve the issue the cable could be defective. Replace the ECG cable.
Device sounds 2 seconds on, 2 seconds off, for 1 minute.	Wireless connection has been interrupted.	Reduce distance (<10m) to the receiver unit and/or remove any obstacles.
Device emits a sound at the same frequency as the flashing of the electrode contact points.	An electrode has come loose during measurement.	Check the electrode contact and replace the electrode if necessary.

If there are errors which cannot be rectified immediately using the solutions above, contact Vitalograph. Stop using the device to avoid greater damage.

Electrode cables and the fastening clip can only be replaced by the manufacturer/dealer.

## 9. CUSTOMER SERVICE








Service and repairs should be carried out only by the manufacturer or by Service Agents specifically approved by Vitalograph.

For the names and addresses of approved Vitalograph Service Agents or to arrange training, please refer to the contact information at the start of this manual.

## 10. CONSUMABLES AND ACCESSORIES

Cat. no	Description
41384	2 x 1.5V AA non-rechargeable batteries
41301	Electrodes

## 11. EXPLANATION OF SYMBOLS

Symbol	Description
	Defibrillator-proof application part of type BF
	Application part of type BF
	Disposal according to electronic scrap ordinance
	Radio symbol
	Manufacturer
	Date of manufacture
	Speaker/audio muted

## 12. TECHNICAL SPECIFICATIONS

Feature	Value
Product class in acc. with 93/42/EWG (MDD)	Ila
Dimensions W x H x D in cm	6.1 x 10.6 x 2.3
Weight, incl. cable	210 g incl. batteries (154 g without batteries)
Temperature range - Operation - Storage (without batteries)	T = 0...50 °C T = 0...50 °C
Air pressure range	700...1060 hPa
Power supply	2 * AA batteries (1.5 V) or rechargeable batteries (1.2 V)
Current consumption at 3 V - Operation - Stand-by	148 mA (BT12) 37 mA (BT12)
Data transmission	Wireless, standard Bluetooth 2.1
Intermediate data memory (data saving mode)	Is sufficient for at least 6 minutes of ECG
Classification in acc. with 60601-1 - Type of protection against electric shock - Degree of protection against electric shock	Device with internal power supply Type BF
Electromagnetic compatibility (EMC) in acc. with 60601-1-2 - Noise suppression - Immunity to interference	EN 55011 EN 61000-4 parts 2, 3, 6, 8
Degree of protection against penetration of water	IPX3
Variants	BT12: 12-channel, 3 leads acc. to Einthoven, 3 acc. to Goldberger, 6 Wilson leads
Electrodes	Standard clip ECG electrodes, bio-compatible, CE marked, single use.
Signal output	Pulse frequency exceeded/fallen short of. Missing signal / connection termination Electrode loss
Sound pressure level of a signal can be regulated over 5 levels	37 dB – 55 dB
Product liability	Annual service recommended for product life of 5 years.
Wireless transmission	Approved in accordance to R&TTE directive transmitter module marked by CE, manufactured by MITSUMI incorporated to OEM product.

### 13. CE MARK



Marking by the symbol 0086 indicates compliance of the Vitalograph BT12 ECG to the Medical Devices Directive of the European Community. Such marking is indicative that the Vitalograph BT12 ECG meets or exceeds the following technical standards:

**Guidance and Manufacturer's Declaration – Electromagnetic Emissions**

The **BT12** is intended for use in the electromagnetic environment specified below. The customer or the user of the **BT12** should assure that it is used in such an environment.

<b>Emissions Test</b>	<b>Compliance</b>	<b>Electromagnetic Environment – Guidance</b>
RF Emissions CISPR 11	Group 1	The <b>BT12</b> uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF Emissions CISPR 11	Class B	The <b>BT12</b> 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 Emissions IEC 61000-3-2	not applicable	
Voltage Fluctuations/ Flicker Emissions IEC 61000-3-3	not applicable	

**Guidance and Manufacturer's Declaration – Electromagnetic Immunity**

The **BT12** is intended for use in the electromagnetic environment specified below. The customer or the user should assure that it is used in such an environment.

<b>Immunity Test</b>	<b>IEC 60601 Test Level</b>	<b>Compliance Level</b>	<b>Electromagnetic Environment</b>
Electrostatic Discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV 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 IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	not applicable	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV line(s) to line(s) ±2 kV line(s) to earth	not applicable	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 IEC 61000-4-11	<5% UT (>95% dip in UT) for 0.5 cycle 40% UT (60% dip in UT) for 5 cycles 70% UT (30% dip in UT) for 25 cycles <5% UT (>95% dip in UT) for 5 sec	not applicable	Mains power quality should be that of a typical commercial or hospital environment. If the user of the <b>BT12</b> requires continued operation during power mains interruptions, it is recommended that the <b>BT12</b> be powered from an uninterruptible power supply or a battery.
Power Frequency (50/60 Hz) Magnetic Field IEC 61000-4-8	3A/m	3A/m (50/60Hz)	Power frequency magnetic fields should be at levels characteristic of a typical commercial or hospital environment.

**NOTE:** U<sub>T</sub> is the a.c. mains voltage prior to application of the test level.

<b>Recommended Separation Distances Between Portable and Mobile RF Communications Equipment and the BT12</b>			
The <b>BT12</b> is intended for use in an electromagnetic environment where radiated radio frequency (RF) signals are controlled. The customer or the user of the <b>BT12</b> can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the <b>BT12</b> as recommended below, according to the maximum output power of the communications equipment.			
<b>Rated Maximum Output Power of Transmitter W</b>	<b>Separation Distance According to Frequency of Transmitter M</b>		
	<b>150 kHz to 80 MHz</b> $d = (3,5 / \sqrt{V_2}) \sqrt{P}$	<b>80 MHz to 800 MHz</b> $d = (3,5 / E_1) \sqrt{P}$	<b>800 MHz to 2,5 GHz</b> $d = (7 / E_1) \sqrt{P}$
0,01	0,12	0,12	0,23
0,1	0,37	0,37	0,74
1	1,17	1,17	2,33
10	3,69	3,69	7,38
100	11,67	11,67	23,33

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.

Medical Devices may be affected by cellular telephones and other personal or household devices not intended for medical facilities. It is recommended that all equipment used near the Vitalograph product comply with the medical electromagnetic compatibility standard and to check before use that no interference is evident or possible. If interference is suspected or possible, switching off the offending device is the normal solution, as is required in aircraft and medical facilities.

Medical electrical equipment needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided,

Portable and mobile RF communications equipment can affect medical electrical equipment.

## 14. FDA NOTICE

Caution: Federal Law restricts this device to sale by, or on the order of a physician.

## 15. DECLARATION OF CONFORMITY

Product: Model 4130 Vitalograph BT12 ECG

Vitalograph hereby ensures and declares that the above product associated with this user manual, is designed and manufactured in accordance with the following QMS regulations and standards:

- European Medical Devices Directive {MDD} 93/42/EEC, as amended.

This device is classified as IIa per Annex IX of the MDD also meets the provisions of the Essential Requirements, Annex I, via compliance with Annex II of the Medical Devices Directive as per Article 11, section 3a, excluding point 4 of Annex II.

- FDA Quality System Regulation {QSR} 21 CFR 820.
- EN ISO 13485: 2012. Medical devices. Quality management systems. Requirements for regulatory purposes.



Certifying Body: British Standards Institute {BSI}.

{For 93/42/EEC and CMDR}.

BSI Notified Body #: 0086

Certificate Nos. CE 00772, CE 85553, MD 82182

Signed on behalf of Vitalograph (Ireland) Ltd.

A handwritten signature in black ink, appearing to read 'B. R. Garbe'.

B. R. Garbe.

Group Managing Director

## 16. GUARANTEE

Subject to the conditions listed below, Vitalograph Ltd. and its associated companies, (hereinafter called the Company) guarantee to repair or at its option replace any component thereof, which, in the opinion of the Company is faulty or below standard as a result of inferior workmanship or materials.

The conditions of this Guarantee are:

This Guarantee shall only apply to hardware defects which are notified to the Company or to its accredited distributor within 1 year of the date of purchase of the equipment, unless otherwise agreed in writing by the Company.

Software (meaning computer software, or user installable modules) is guaranteed for 90 days from the date of purchase.

The Company warrants that the software when correctly used in conjunction with the hardware will perform in the manner described in the Company's literature and user manuals. The Company undertakes to rectify at no expense to the customer any software failure notified within the period stated above, provided that the failure can be recreated and the software has been installed and used in accordance with the user manual. Notwithstanding this clause, the software is not warranted to be free of errors.

This Guarantee does not cover any faults caused by accident, misuse, neglect, tampering with the equipment, use of consumable items or parts not approved by the Company, or any attempt at adjustment or repair other than by personnel accredited by the Company, nor does it cover reinstatement of any configuration changes caused by the installation of any software.

If a defect occurs please contact the supplier from it was purchased for advice. The Company does not authorize any person to create for it any other obligation or liability in connection with Vitalograph® equipment.

This Guarantee is not transferable and no person, firm or company has any authority to vary the terms or conditions of this guarantee.

To the maximum extent permitted by law, the Company does not accept liability for any consequential damages arising out of the use of, or inability to use any Vitalograph® equipment.

This Guarantee is offered as an additional benefit to the Consumer's statutory rights and does not affect these rights in any way.

## 17. APPENDIX

### Troubleshooting Guide for Pairing Vitalograph BT12 ECG BT Device

#### INITIAL CHECKS

1. Disconnect any USB 3.0 external USB hard drives from the PC/Laptop as they can interfere with any Bluetooth signal and, in this case, the Bluetooth signal between the BT12 device and the computer. Other USB 3.0 Bluetooth devices such as flash drives also have potential to cause interference and should be disconnected. This is not unique to our device and further information can be found here;  
[www.bluetoothandusb3.com/the-explanation](http://www.bluetoothandusb3.com/the-explanation)
2. Some Laptops or PC's may have an internal built-in Bluetooth adapter. It should be possible to pair the BT12 ECG device to the computer without the need for the supplied external Startech USB BT adaptor dongle. Reference NOTE 1 on how to turn this On/Off.
3. Section 2. Contraindications, warnings, precautions and adverse reactions above indicates that "The user is responsible for ensuring that data transmission is not corrupted by too many wireless senders or receivers in the vicinity." Please also review BT12 ECG Regulatory Notice 07651. Possible sources of interference are other devices which share the 2.4Ghz frequency band such as mobile phones, cordless phones, microwave ovens, fluorescent lighting, wireless cameras or security systems, baby monitors, wireless speakers, remote-control toys, wireless pointing devices, wireless networking devices, Wi-Fi base station, wireless video.
4. BT12 Regulatory Notice 07651 and Section 2. Contraindications, warnings, precautions and adverse reactions above also indicate that "If interference is suspected or possible, switching off the offending device is the normal solution, as is required in aircraft and medical facilities"
5. Remove All Barriers: Certain building materials can get in the way of weaker signals like Bluetooth. Metal, bulletproof glass, concrete, plaster, marble and brick are examples of signal blocking materials. So, if you're really struggling with interference, your first step should be to move your Bluetooth devices away from these materials. That means no physical barriers between you and your devices, and definitely no metal desks! (Ensure that BT12 ECG device is within line of sight to Startech BT adaptor dongle on PC/Compact if possible)

#### BT12 ECG DEVICE/CONNECTION CHECKS

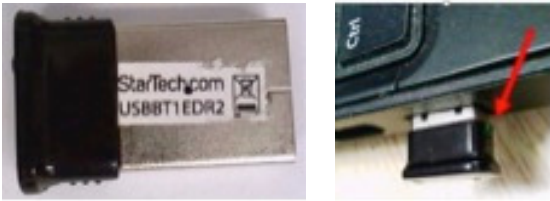
1. Verify BT12 ECG device battery charge status. Replace the batteries when the BT12 ECG device display "battery symbol" flashes or shows no more bars.



2. Ensure that BT adaptor dongle being used is Startech USBBT1EDR2. This should be clearly marked on the device



label (reorder part # for dongle is 67201). Is the BT adaptor dongle connected and operating? A flashing green LED indicator on the dongle shows the power or standby status of adapter.



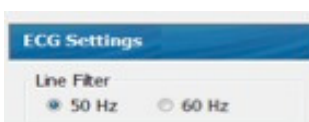
3. Ensure that the correct Bluetooth drivers are installed on the PC. The operating system needs to have the Microsoft Generic Bluetooth Radio Driver and the Microsoft Bluetooth Enumerator Driver installed. Reference NOTE 2 on how to check this.
4. Ensure BlueSoleil drivers are uninstalled. Reference NOTE 3
5. If the BT adaptor dongle is connected and the dongle LED indicator is not flashing green, then please try a replacement dongle (reorder part # for dongle is 67201).
6. If the above have been checked and the BT12 device does still not pair, reset the BT12 and the BT connection. Reference NOTE 4

#### Recording Issues

1. Low Battery issues - Verify BT12 ECG device battery charge status. Replace the batteries when the BT12 ECG device display "battery symbol" flashes or shows no more bars

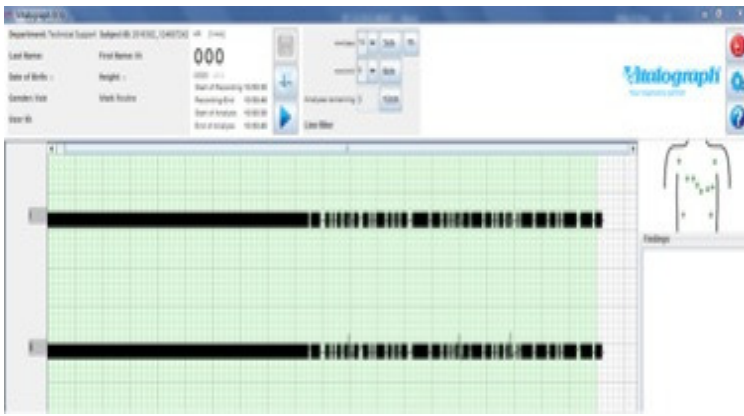


2. Set Spirotrac line filter to the correct mains power frequency for the country/location by opening Spirotrac and going to Tools\Options \ECG



3. Black bars on the Spirotrac display could indicate faulty electrode contact, transmission interference or too much distance between the patient and PC. Check the electrode contact, and, if necessary, apply contact spray again where the skin and electrodes come into contact. Reduce the distance between the patient and PC. During a recording, the radio symbol on the BT12 ECG device may flash or disappear from the BT12 display to indicate the wireless connection has been interrupted. Black bars may appear on the ECG recording. To resolve the issue, reduce the distance between the BT12 device and the BT adaptor dongle by moving closer to the PC/Compact (Ensure that BT12 device is within line of sight to BT adaptor dongle on PC/Compact if possible)



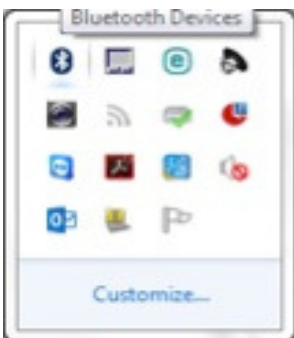


4. Using Multiple devices - We recommend using the BT12 device together with a maximum of two other BT ECG devices within the range of each BT ECG device. Section 2. Contraindications, warnings, precautions and adverse reactions above includes the following information: - “ and BT12 operate safely and effectively in an environment where BT devices and WLAN devices coexist. But some restrictions have to be considered. We recommend using the BT12 device together with a maximum of two other BT ECG devices within the range of each BT ECG device. Furthermore, any WLAN sender or receiver (e.g. WLAN USB dongles for PCs) should be placed more than 1 meter away from the BT12 and the BT receiver (BT USB dongle for PCs) respectively. Otherwise, BT12 will lose data packets. The user is responsible for ensuring that data transmission is not corrupted by too many wireless senders or receivers in the vicinity.”

## NOTE 1 – ENABLE/DISABLE INTERNAL BT ADAPTOR

To enable / disable internal built-in BT adapter - go to Taskbar “show hidden icons” to bring up icons screen (NB: If there is no Bluetooth icon, there is no built-in Bluetooth adaptor on the computer so in this case, the external Startech Dongle must be used)

Verify BT12 ECG device battery charge status. Replace the batteries when the BT12 ECG device display “battery symbol” flashes or shows no more bars.



Right Click on Bluetooth icon and select Turn Adapter On /Off option as required



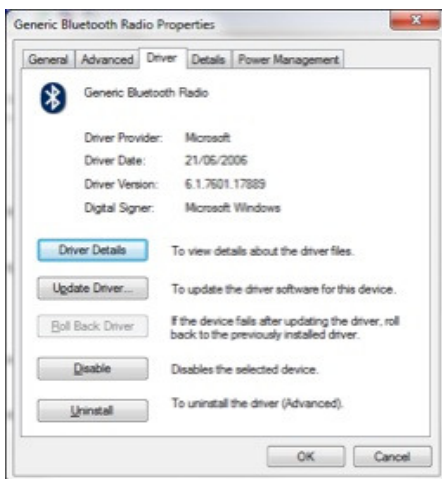
## NOTE 2 – CONFIRM MICROSOFT DRIVERS ARE USED WITH BT ADAPTOR

To confirm/check if these drivers are installed:

1. Connect the Bluetooth adapter
2. Open Windows Device Manager
3. Expand the “Bluetooth Radios” tree node. There should be two drivers listed “Generic Bluetooth Radio” and “Microsoft Bluetooth Enumerator”



4. To confirm the drivers are Microsoft drivers, right-click the driver, choose 'Properties' and choose the Driver tab. The provider must be listed as Microsoft for both.



## NOTE 3 – UNINSTALL BLUESOLEIL DRIVERS

Uninstall any BlueSoleil entries from Control Panel “Programs and Features” as these will create a driver conflict.

Windows 7 Users

1. Click on Start at the bottom left of the screen
2. Select Control Panel ? Uninstall a program link.
3. Search for BlueSoleil in the list, right-click it and select Uninstall.
4. Follow the instruction to finish the removal.
5. Restart your computer.

Windows 8 Users

1. Hover the mouse pointer in the lower right corner to see Win8 side menu.
2. Go to Settings > Control Panel > Uninstall a program link.
3. The rest are the same as those on Windows 7.

## NOTE 4 – RESET BT ADAPTOR AND DRIVERS

To reset the BT12 connection and the Bluetooth adaptor, please follow the steps below:

1. Connect the Bluetooth adapter
2. Open Windows Device Manager
3. Expand the "Bluetooth Radios" tree node. Right click on "Generic Bluetooth Radio", select the option to uninstall, then right click on "Microsoft Bluetooth Enumerator" and select uninstall.



4. Disconnect Bluetooth adapter
5. Restart PC
6. Remove pairing for BT12 device by powering device on, then pressing and holding the power button until 2 confirmation beeps are heard (about 20 seconds).
7. Connect Bluetooth dongle and allow drivers to install automatically, restart PC is requested
8. Power on BT12
9. Launch Spirotrac
10. Pair ECG (Tools – Options – ECG – Add/Pair) Verify that BT12 ECG device serial number listed on the BT12 ECG device serial number label is the same as the BT12 device serial number listed in the device configuration field in Spirotrac Tools\Options\ECG. If the serial numbers do not match, then you have paired with another BT12 device that is also within range.



Clinical risk / safety impact information and rational for non-generation of FSCA:

The potential reportability and potential for a Field Safety Corrective Action (FSCA) has been reviewed. An FSCA is not required in this instance. The communicated information does not present a safety issue.

#### ABOUT VITALOGRAPH

Having served the respiratory market for almost half a century, Vitalograph is a world-leading provider of respiratory, diagnostic, screening and monitoring devices. Vitalograph continue to make pioneering contributions to effective respiratory measurements and enhanced quality of life. Vitalograph products are widely used in primary and secondary care environments, as well as in occupational health, sports medicine and in the home. Represented in over 113 countries through highly trained authorised distributors, Vitalograph has its head office in Buckingham, England and has offices in Germany, Ireland, Hong Kong and the United States.

For more information on Vitalograph visit [www.vitalograph.eu/](http://www.vitalograph.eu/) or e-mail [sales@vitalograph.co.uk](mailto:sales@vitalograph.co.uk)