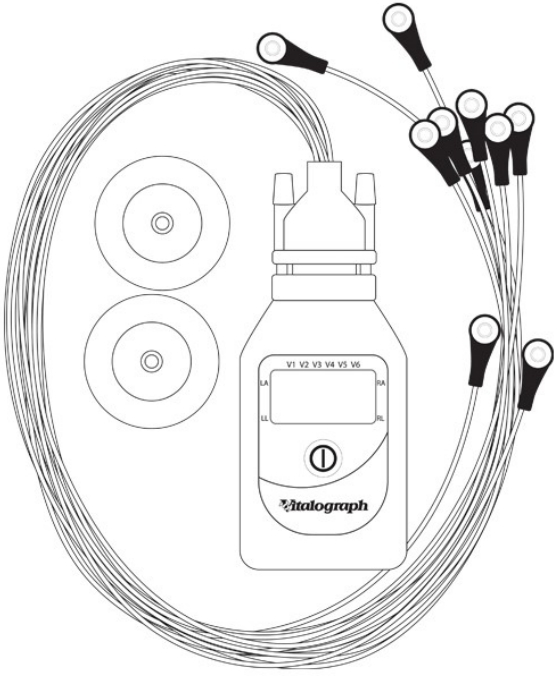
BT12 ECG

MODEL 4130



Instructions for Use

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1. Main Components of the BT12 ECG

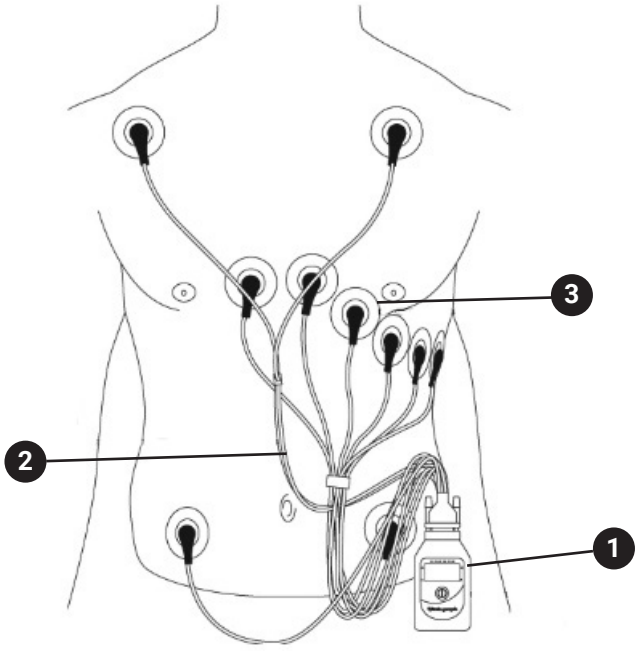

Figure 1 Main Components

1	BT12 ECG Device
2	Electrode cable
3	Electrodes

1.1. Features of the BT12 ECG

- Ability to acquire and transmit standard 12 lead ECG
- Battery powered, small, portable design allowing for attachment to clothes/belt
- Heart rate monitoring with results displayed on integrated LCD
- Wireless connectivity to monitoring software allowing data display, review, printing, saving and post event processing

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2. Setting Up the BT12 ECG

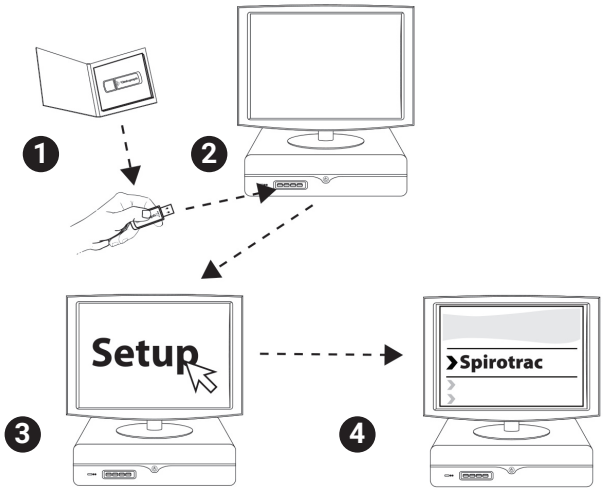

Figure 2

1. Remove Vitalograph® USB drive from packaging.
2. Insert USB drive into USB port on computer.
3. Browse USB Drive and click Setup.
4. Select Install Spirotrac. Follow on-screen instructions to complete installation. Further details are provided in the Spirotrac Instructions found under User Manual on the installation menu.

2.1. Pairing the BT12 ECG device

The first time the BT12 ECG is used in conjunction with Spirotrac PC software a Bluetooth pairing needs to be established. If the Bluetooth driver requests a PIN number during pairing, enter “1111”. For details on connecting the BT12 ECG with Spirotrac® software refer to the Spirotrac Instructions.
To avoid data transmission errors and to deny access to unauthorized parties, the BT12 ECG device is no longer visible to other Bluetooth devices after this pairing.
To **undo** a pairing:

1. Press the power button to turn on the device.
2. Then press and hold the power button for 20 seconds.
3. The device will emit beeps: 1 x long beep after 3 seconds and 2 x short beeps after 20 seconds. It then switches off.
4. Switch ECG unit on. It is now visible to other Bluetooth devices and may be paired to a new PC.

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2.2. Clip

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

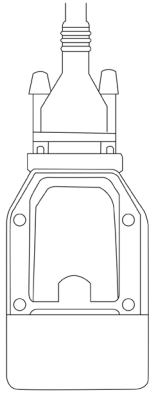

Figure 3 BT12 ECG with clip

2.3. Electrodes and electrode cable

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

- Always observe the user instructions of the electrodes.
- Shave off any excess hair which could prevent good electrode contact.
- The application positions must be clean and dry.
- Remove the protective layer from the adhesive electrodes.
- The electrodes may only be applied to healthy skin. Press the electrodes firmly onto the patient's skin at the corresponding places, depending on the desired lead.

2.4. Electrode position

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

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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/Arm
	L	Yellow	LA	Black	Left Shoulder/Arm
	F	Green	LL	Red	Left Hip/Leg
	N	Black	RL	Green	Right Hip/Leg (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

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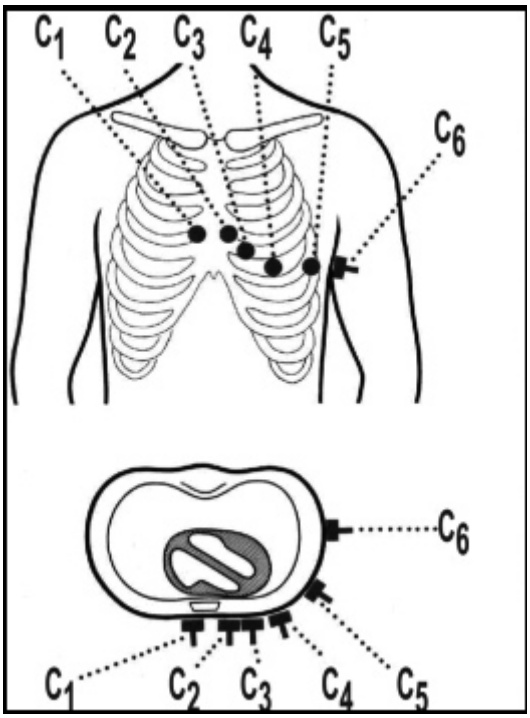

Figure 4 Positions of the chest wall leads

2.5. Functional Check

Every time the BT12 ECG is switched on, it carries out a self-test. Errors are shown on the display with 'Err' and an error code.

Figure 5 Display of error codes

Visually inspect the BT12 ECG before every use.
Do not use the device if there is any visible external damage to the device or the electrode cables, or if the integrated self-test fails. Contact the distributor or manufacturer to have the device repaired or replaced. Refer to the contact information at the start of this manual.

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3. Operating Instructions

1. The BT12 ECG device works with Vitalograph Spirotrac software. Spirotrac software must be installed on the PC to begin testing. Refer to Spirotrac Instructions for Use for details on:
   - Installing Spirotrac software
   - Entering Subject Data
   - Conducting an ECG test
   - Printing a Report

3.1. Preparing the ECG recording

Before using the BT12 ECG ensure that the expiration date of the adhesive electrodes you are using has not elapsed and the gel has not dried out. Attach the electrodes to the corresponding places on the patient's body (see Electrode position). Fasten the electrode cable via the contact option for the snaps on the electrodes.

3.2. Switching the BT12 ECG on/off

To switch on the BT12 ECG, press the power button for 3 seconds. The device will carry out an automatic self-test. If an error code appears on the display, follow the trouble shooting guide in Section 6. The BT12 ECG is ready for use when the battery symbol and the loudspeaker symbol appear on the display. 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 BT12 ECG off. This is accompanied by a signal sound.

3.3. Electrode contact

Fasten the electrodes to the patient. The BT12 ECG automatically checks the contact quality and indicates any 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. If one of the R, L, F and N electrodes are removed or falls off during recording, the ECG signal transmission will stop. The recording will not stop if one of the V leads comes loose.

3.4. Heart rate monitoring

The BT12 ECG monitors the heart rate of the patient continuously after correctly applying the electrodes. Heart rate is shown on the display, labelled "BPM".

3.5. ECG data transmission

The receiving unit establishes a wireless connection to the BT12 ECG via the interface. Once connection has been established, a short beep will sound.

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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 BT12 ECG switches off again automatically.*

Note: *The range of the wireless transmission is approximately 10 m. Ensure that there are no obstacles between the BT12 ECG and the receiver unit to maintain a stable connection.*

Note: *If the Bluetooth connection is interrupted for longer than 15 minutes the BT12 ECG switches off automatically.*

3.6. Displays and signals

Figure 5 Display

1	Electrode Connection Status
2	Radio Active Status
3	Battery Status
4	Heart Rate Status
5	Heart Rate Value

The electrode connections are displayed by points (Figure 5). An open electrode is indicated by a respectively flashing point and a connected electrode by a continuously illuminated point. Data transmission on the device 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 stops until the electrode has been replaced or correctly attached. The recording does not stop if one of the V leads comes loose.

The “Radio active” symbol indicates if there is a Bluetooth connection to the PC. When 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 Bluetooth connection range, the device emits a pulsing sound for one minute.
The battery status is indicated by a battery icon showing three bars for full batteries and no bars/icon flashing for discharged batteries.
The BT12 ECG displays the heart rate as a numeric value and a heart symbol flashing at the same rate as the heartbeat.
A crossed-out loudspeaker symbol indicates that sound is muted. If the BT12 ECG detects an R wave, it emits a brief sound. This sound can be deactivated via the receiver of the ECG data. The heart symbol flashes on the display at the rate of the detected R wave.
All sounds, 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.
The display has backlighting, which can be activated by a short press of the power button and switches off automatically after 5 seconds.
The acoustic and optical signals are:

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
Bluetooth 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	-	

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Signal	Acoustic Signal	Optical Signal
Data memory full	-	
Data memory almost full	-	
Radio active - Bluetooth is connected	-	
Crossed out loudspeaker - audio is muted	-	

4. Power Management

The BT12 ECG requires two AA alkaline batteries or two AA NiMH rechargeable batteries for operation. Operating time depends on battery quality. 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 batteries, open the battery compartment cover and insert batteries according to the polarity shown inside the compartment. Close the compartment cover.

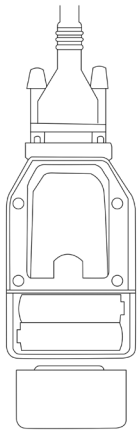

Figure 6: Opened battery compartment with inserted batteries

The battery status for the activated device is shown on the battery icon at the bottom left of the screen. Batteries should be changed when the display shows no bars and the battery icon flashes. In measuring mode, the BT12 ECG is designed for between 9 to 13 hours of operation, depending on the type of batteries used.

5. Cleaning & Hygiene

5.1. Maintenance

To maintain the BT12 ECG, change the batteries as required (See Section Power Management). If storing the device for a long period of time without use, remove batteries 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 approved by Vitalograph.

5.2. Cleaning and disinfecting the device

Ensure the BT12 ECG is turned off prior to cleaning/disinfecting. The device is not waterproof and as such must not be submerged, have liquids poured or sprayed on it. For disinfection, wipe the housing with a 70% isopropyl alcohol impregnated cloth, found in medical facilities and hospitals.
CAUTION: *Submerging the device in disinfectant or other liquids will damage it.*

5.3. Cleaning and disinfecting the electrode cable

To clean the electrode cable, rub the cable 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.

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For disinfection, rub the cable with a 70% isopropyl alcohol impregnated cloth, found in medical facilities and hospitals.

CAUTION: Submerging the cable in disinfectant or other liquids will damage it.

6. Fault Finding Guide

Problem Fault	Possible causes	Solution
The BT12 ECG will not turn on.	Reversed batteries. Dead batteries.	Check the polarity of the inserted batteries. Exchange batteries for fully charged ones.
The BT12 ECG is not detected by other Bluetooth devices.	It is already paired with another device. 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.	Switch the device on. 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. See Appendix Troubleshooting guide for pairing the BT12 ECG and resolving all known issues.
You are prompted to enter a PIN number during pairing.	The BT12 ECG device is being newly paired.	Enter PIN “1111”.
After switching on, the display continuously shows an error code.	Internal electronics 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.

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Problem Fault	Possible causes	Solution
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 Troubleshooting Guide for details on resolving all known issues on pairing the BT12 ECG.
No sounds are emitted from the device	Loudspeaker is muted or is defective.	If the loudspeaker symbol is crossed out, sounds are muted. If sounds are enabled and the warning sounds are still missing, speaker may be defective. Contact Vitalograph.
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 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 not resolved by above, 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 PC and/or remove any obstacles.

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Problem Fault	Possible causes	Solution
Device emits a sound at the same frequency as the flashing of the electrode contact points.	An electrode has come loose during measurement.	Check electrode contact and replace 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.

7. Customer Service

Service and repairs should be carried out only by the manufacturer, or by Service Agents approved by Vitalograph. Contact information for approved Vitalograph Service Agents may be found at the start of this manual.
Any serious incident that has occurred in relation to the device should be reported to Vitalograph or its Authorized Representative and the Regulatory Authorities of the country. Refer to the Vitalograph contact information at the start of this manual.

8. Consumables and Accessories

Cat. No	Description
41384	2 x 1.5V AA non-rechargeable batteries
41301	Self-Adhesive Electrodes (Qty 30)
70200	Spirotrac V software
41530	Bluetooth Adaptor

9. 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 according to the regulations for your country. If disposable adhesive electrodes are used, dispose of these immediately after use.

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10. 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
	Class II
VA	Power rating
V	Direct current
	Instructions for Use; operating instructions
	Fragile, handle with care
	Keep Dry
	Do not re-use
	Non sterile

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Symbol	Description
	Recycle
	QR code - matrix bar code. All information in the bar code is included in the text under it

11. Description of the Vitalograph BT12 ECG

The BT12 ECG is an active medical product when used with a receiving unit serves as a mains-independent, wireless ECG device which can be worn on the body for:

- Measurement of ECG and heart rate
- To support a diagnosis from a physician
- Documentation of ECGs

The device can be used in the clinical area and in a doctor's practice. It is not suitable for intracardial use.
The measured ECG is transferred via Bluetooth to an external receiving unit such as a PC with suitable software. The data may then be displayed for a specific subject, saved, commented, printed out and revised by expert personnel.

11.1. Indications for Use

The BT12 ECG is a battery powered device capable of acquiring and transmitting a standard electrocardiogram to be used for the purpose of cardiac monitoring and diagnosis performed by medical professionals.
The collected data is processed by the BT12 ECG and then transmitted via a standard wireless link to a monitoring device, such as a PC or hand-held device, for display and processing by medical professionals. The collected data is not interpreted by the BT12 ECG as this is done by the monitoring software operated by medical professionals.
The BT12 ECG is intended for use on persons of all ages including infants weighing less than 10Kg (22lbs). The BT12 ECG is not intended for monitoring critical patients and is not intended for intracardial use. Measurements taken by the BT12 ECG are only significant if considered in connection with other clinical findings. No therapy or drugs can be administered based solely on data derived from the BT12 ECG.
Federal law restricts this device to sale by or on the order of a physician. The device is intended for use by medical professionals trained in ECG. Apart from this instruction manual, there are no other training requirements for the medical professional.

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12. Technical Specification

Product	Vitalograph BT12 ECG
Model	4130
Product class in acc. with 93/42/EEC	IIa
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)
Operating temperature range	Temp = 0 to 50 °C, Humidity = 25 to 95% RH
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
EMC Standards	EN60601-1-2:2007
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	Missing signal / connection termination Electrode loss
Sound pressure level of a signal can be regulated over 5 levels	37 dB – 55 dB

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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.
PC Requirements	Bluetooth capability or USB port for Bluetooth Adaptor. Refer to the Spirotrac Instructions For Use for further PC requirements of Software.
Sample Rate	500Hz
Digital Resolution	2.6 µV

13. Contraindications, Warnings, Precautions and Adverse Reactions

13.1. General

1. No modification of this equipment is allowed. Any unauthorised changes to the Vitalograph BT12 ECG may compromise product safety and/or data and as such Vitalograph cannot be held responsible and the device will no longer be supported.
2. The BT12 ECG is not designed as a sterile device. Always follow the safety guidelines given by the manufacturer of cleaning and disinfectant chemicals.
3. Service and repairs should be carried out only by the manufacturer or by Service Agents approved by Vitalograph.
4. Maintenance must not be performed while the device is in use by a subject.
5. Non-medical equipment must be kept outside the subject environment i.e. any area in which intentional or unintentional contact between the subject and parts of the system, or some other persons touching part of the system, can occur.
6. The BT12 ECG 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.
7. Use of accessories and cables other than those provided could result in function failures, and bio-compatibility cannot be assured. Any warranty or liability claims are void when neither the accessories recommended nor the original replacement parts are used.
8. The BT12 ECG is not suitable for use in rescue helicopters or ambulances.
9. Observe the Cleaning & Hygiene section to avoid contamination.
10. Before each use, visually inspect the device, the electrode cables and

the adhesive electrodes. If there is any visible damage externally, or if the self-test fails, the device may no longer be used.

11. The BT12 ECG should not be submerged in liquids or have liquids poured on it, be intentionally sprayed or be exposed to rain.
12. The BT12 ECG may only be opened by authorized expert personnel. If the device is opened without permission, the warranty is void.
13. The manufacturer is not liable for the function of the BT12 ECG 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 these instructions.
14. The signals output by the BT12 ECG do not meet the alarm standard for medical electrical devices, DIN EN 60601-1-8.
15. 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.
16. All parts of the BT12 ECG, including accessories, which come into contact with the patient during intended use, meet the requirements of the applicable bio-compatibility standards.

13.2. Operating the device

1. While the ECG is recording, do not make any changes to electrodes or device as this may result in faulty measurements.
2. The BT12 ECG 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. Note: When using a defibrillator, make sure that no one has a conducting connection to the patient. Burns or other injuries could result.
3. Do not operate High Frequency devices, e.g. surgical devices, in combination with the BT12 ECG.
4. When monitoring critical patients, an alternative ECG system should be kept readily available in the event of a device fault or failure.
5. Avoid tensile loads on electrode cables.
6. Only use bio-compatible and CE-approved ECG electrodes with the BT12 ECG.
7. Always observe user instructions for the used electrodes.
8. Magnetic and electric fields can influence the function of the device. To ensure correct operation keep the recommended separation distance between the BT12 ECG and devices which emit High Frequency radiation (e.g. cell or mobile phones).
9. When the BT12 ECG is switched on, the electromagnetic radiation emitted can influence other electric devices nearby. Keep the recommended separation distance between the BT12 ECG and other devices to minimize interference The BT12 ECG should not be operated in potentially explosive atmospheres.

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10. If using the BT12 during a stress ECG, the patient must be under constant observation.
11. The BT12 ECG should not be used without supervision on children under the age of 3 or mentally confused patients. The electrodes can pose a suffocation/aspiration danger.
12. The electrode cable can pose a strangulation danger, always attach the device to clothing/belt or pouch as instructed.
13. Wireless transmission errors may occur if heat therapy devices are operated in the immediate vicinity.
14. If the patient has a cardiac pacemaker, there may be errors in the heart rate calculations.
15. In rare cases the BT12 ECG may heat up due to a short circuit in the batteries. Turn off the BT12 ECG immediately and remove the batteries. Stop using the device and arrange repairs.
16. BT12 operates 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 with no more than 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, the BT12 device 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.

14. CE Notice

Marking by the symbol CE 2797 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.		
Emissions Test	**Compliance**	**Electromagnetic Environment – Guidance**
RF Emissions CISPR 11	Group 1	The **BT12** 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.

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Guidance and Manufacturer's Declaration – Electromagnetic Emissions		
RF Emissions CISPR 11	Class B	The **BT12** 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.			
Immunity Test	**IEC 60601 Test Level**	**Compliance Level**	**Electromagnetic Environment**
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.

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Guidance and Manufacturer's Declaration – Electromagnetic Immunity			
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 **BT12** requires continued operation during power mains interruptions, it is recommended that the **BT12** 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: *UT is the a.c. mains voltage prior to application of the test level.*			

Recommended Separation Distances Between Portable and Mobile RF Communications Equipment and the BT12

The **BT12** is intended for use in an electromagnetic environment where radiated radio frequency (RF) signals are controlled. The customer or the user of the **BT12** can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the **BT12** 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 = (3,5/ V2) √ P	**80 MHz to 800 MHz** d = (3,5 / E1) √ P	**800 MHz to 2,5 GHz** d = (7 / E1) √ P
0,01	0,12	0,12	0,23
0,1	0,37	0,37	0,74
1	1,17	1,17	2,33

Recommended Separation Distances Between Portable and Mobile RF Communications Equipment and the BT12			
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.

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15. FDA Notice

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

16. EU Declaration of Conformity

Product: 4130 Vitalograph BT12 ECG

Vitalograph hereby ensures and declares that the above product associated with these instructions for use, 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.

- EN ISO 13485 Medical devices. Quality management systems. Requirements for regulatory purposes.

Certifying Body: British Standards Institute {BSI}.
BSI Notified Body #: 2797
Certificate Nos. CE 00772, MD 82182

CE 2797

Signed on behalf of Vitalograph (Ireland) Ltd.

Frank Keane.
CEO, Vitalograph Ltd.

17. Guarantee & Free Five Year warranty

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:

1. This Guarantee shall only apply to hardware defects which are notified to the Company or to its accredited distributor within two years of the date of purchase of the equipment, unless otherwise agreed in writing by the Company. Registration is not required for this base two year guarantee.
2. An extended five year warranty from date of purchase, is available by registering the products serial number at www.vitalograph.com/warranty within thirty days of purchase.
3. Software (meaning computer software, or user installable modules) is guaranteed for 90 days from the date of purchase.
4. 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.
5. 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.
6. 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.
7. This Guarantee is not transferable and no person, firm or company has any authority to vary the terms or conditions of this guarantee.
8. 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.
9. This Guarantee is offered as an additional benefit to the Consumer's statutory rights and does not affect these rights in any way.

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18. APPENDIX

18.1. Troubleshooting Guide

18.1.1. Initial Checks

1. Disconnect any USB 3.0 external USB hard drives from the PC/ Laptop as they can interfere with the Bluetooth signal. 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 the BT12 and further information can be found here: www.bluetoothandusb3.com/the-explanation
2. Some Laptops or PC's may have an internal built-in Bluetooth adapter that may be used instead of the supplied external USB BT adaptor dongle. Reference NOTE 1 on how to turn this On/Off.
3. Possible sources of interference are other devices which share the 2.4 GHz 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, and wireless video. If interference is suspected or possible, switching off the offending device is the normal solution.
4. Remove All Barriers: Certain building materials can get in the way of wireless signals like Bluetooth. Signal blocking materials include metal, bulletproof glass, concrete, plaster, marble and brick. If interference is a problem, your first step should be to move your Bluetooth devices away from these materials. There should be no physical barriers between you and your devices, and definitely no metal desks. (Ensure that BT12 ECG device is within line of sight to BT adaptor dongle on PC/Compact if possible)

18.1.2. BT12 ECG Device/Connection Checks

1. Check the status of the batteries in the BT12 ECG. Replace batteries when the "battery symbol" flashes (Figure 5 *Display*) or shows no more bars.
2. If a BT adaptor is used ensure it is the Asus USB-BT400. This should be clearly marked on the device label (reorder part # for dongle is: 41530).
3. Ensure the correct Bluetooth drivers are installed on the PC. Reference NOTE 2 on how to check this.
4. Ensure BlueSoleil drivers are uninstalled. Reference NOTE 3
5. If the above have been checked and the BT12 device does still not pair, reset the BT12 and the BT connection. Reference NOTE 4

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18.1.3. Recording Issues

1. Set line/noise filter to the correct mains power frequency for the country/location.
2. Black bars on the Spirotrac display may 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 (Figure 5 *Display*) or disappear from the BT12 display indicating 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 the BT12 is within line of sight to BT adaptor dongle on PC/Compact if possible.
3. Using Multiple devices - We recommend using the BT12 device with no more than 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 BLUETOOTH ADAPTOR

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

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

NOTE 2 – CONFIRM CORRECT DRIVERS ARE USED WITH BT ADAPTOR

To confirm/check if 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 as below. If not install the drivers provided with the Bluetooth adaptor.

Bluetooth Radios

|-- Intel(R) Wireless Bluetooth(R)

|-- Microsoft Bluetooth Enumerator

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NOTE 3 – UNINSTALL BLUESOLEIL DRIVERS

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

1. Select Control Panel > Uninstall a Program link.
2. Search for BlueSoleil in the list, right-click it and select Uninstall.
3. Follow onscreen instructions to finish removal.
4. Restart computer.

NOTE 4 – RESET BT ADAPTOR AND DRIVERS

To reset the BT12 connection and the Bluetooth adaptor:

1. Connect the Bluetooth adapter.
2. Open Windows Device Manager.
3. Expand the “Bluetooth Radios” tree node. Right click on each driver and select the option to uninstall.
4. Disconnect Bluetooth adapter.
5. Restart PC.
6. Remove the Bluetooth pairing (see section Pairing the BT12 ECG device)
7. Connect Bluetooth dongle. Ensure that the drivers provided with the Bluetooth Adaptor are installed. Restart PC when requested.
8. Power on BT12 ECG.
9. Launch Spirotrac.
10. Pair BT12 ECG (see section Setting Up the BT12 ECG).

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