AFT 1000

Digital Holter recorder

USER GUIDE

Software version 1.64 et +

CE

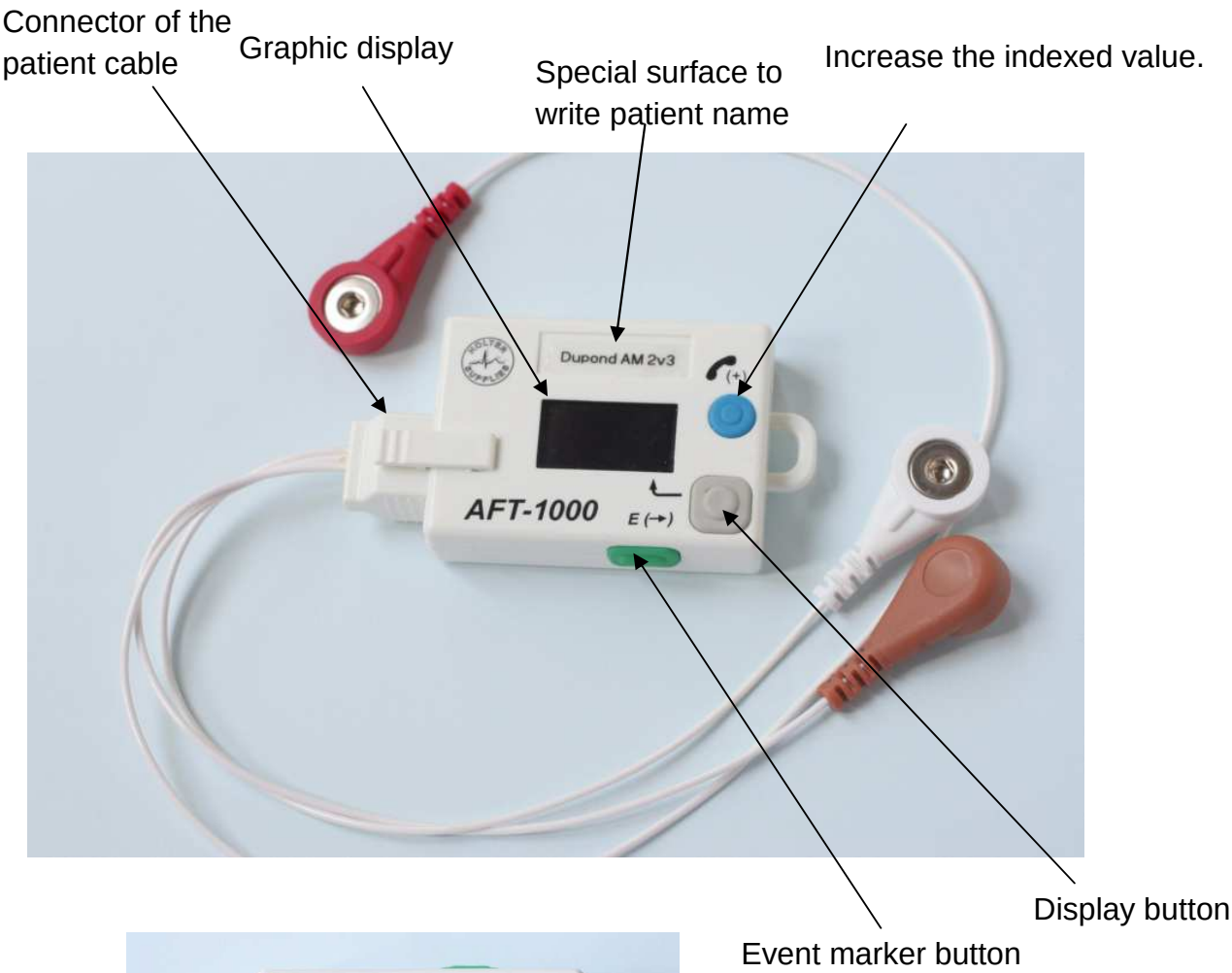
0459 1st year CE : 2008

réf.: AM710_GBA4_09A

I. Introduction

The **AFT1000** is an ECG (Electrocardiogram) Holter recorder using an internal flash memory.
The AFT1000 records 1, 2 or 3 tracks of ECG in standard quality (250Hz/10µV) or in High Quality (1000Hz/2,5µV).
The recorded data are transferred via a USB2 "High Speed" (480Mbauds) cable to a PC running the “Quick Reader®” software giving a general overview of the recording and able to analyze it (rhythm, ST segment elevation, QT interval,…).

II. General description



Back view with the battery (AAA) case open

Description of symbols present on the case

The following symbols are printed on the case of the AFT1000:

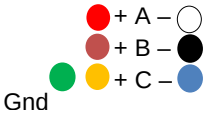
Indicates that the device is B type (IEC 60601-1).

Indicates that the user must refer to the AFT1000 user's manual before handling the part of the device with this symbol.

CE mark: the AFT1000 complies with EC directive 93/42/EEC.

End of live: don't throw it away but return it to your distributor.

Manufacturer



Colors of the ECG cables: A channel, input + and -, B and C channels.
Gnd = ground to connect to patient reference electrode.

EQUIPMENT PRESENT IN THE PACKAGING:

In standard configuration, the device is delivered with:

- An ECG cable 2 channels 3 leads.
- This manual is in electronic format ("pdf"), in the memory of the recorder, in the folder "Guides".
- The Setup program for Quick Reader (Setup.exe) is present in the memory of the recorder in the folder "QuickReader". The software has it's own guide. Look at if there is a new version of this software on the Download page of Holter Supplies web site.
- An After Sales Service file to fill in case of failure (directory SAV).

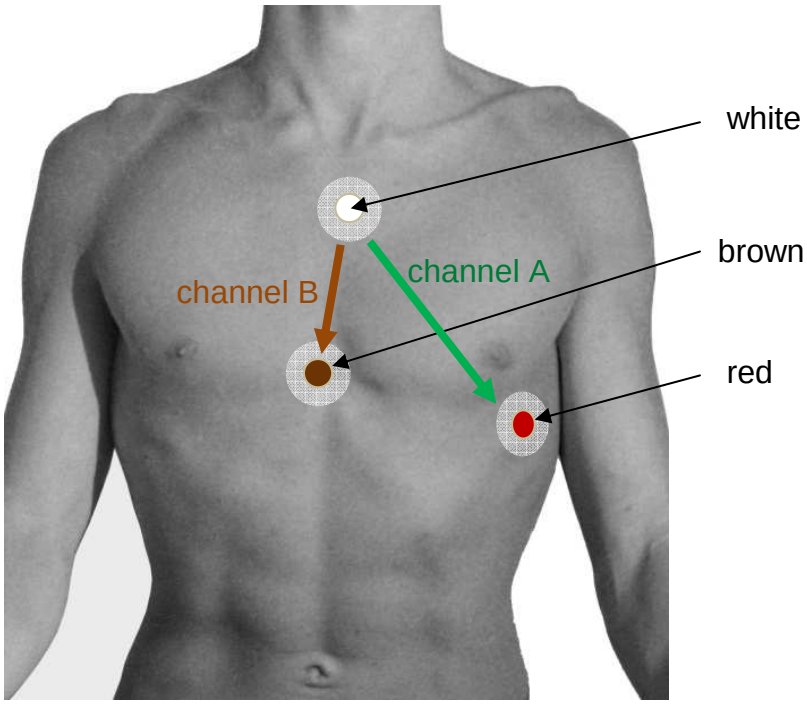
The USB2 cable (ref.: RFU-00A for standard or RFU-00B for AFT1000+) is delivered separately. The pouch and lanyard are delivered in separate packaging (ref.: PCT03-100-B with lanyards PCT05-010-A).

III. Electrodes placement

The electrodes placement, except the case of single lead, follows the usual Holter recommendations. At the end, the user verifies the ECG displayed on the screen of the device. To ensure a good quality of the recording, special care must be taken when preparing the patient's skin, placing the electrodes and connecting the leads. Gently rub the patient's skin and clean it to obtain a **good electrode-skin contact** and reduce impedance.
ATTENTION : if the patient has a pacemaker, use a cable "250/1000Hz" (RFT00-2L3-1000, 2L5-1000 or 3L7-1000) and set it to 1000Hz to properly record the pulses generated (see Adjustment screen, chapter V).

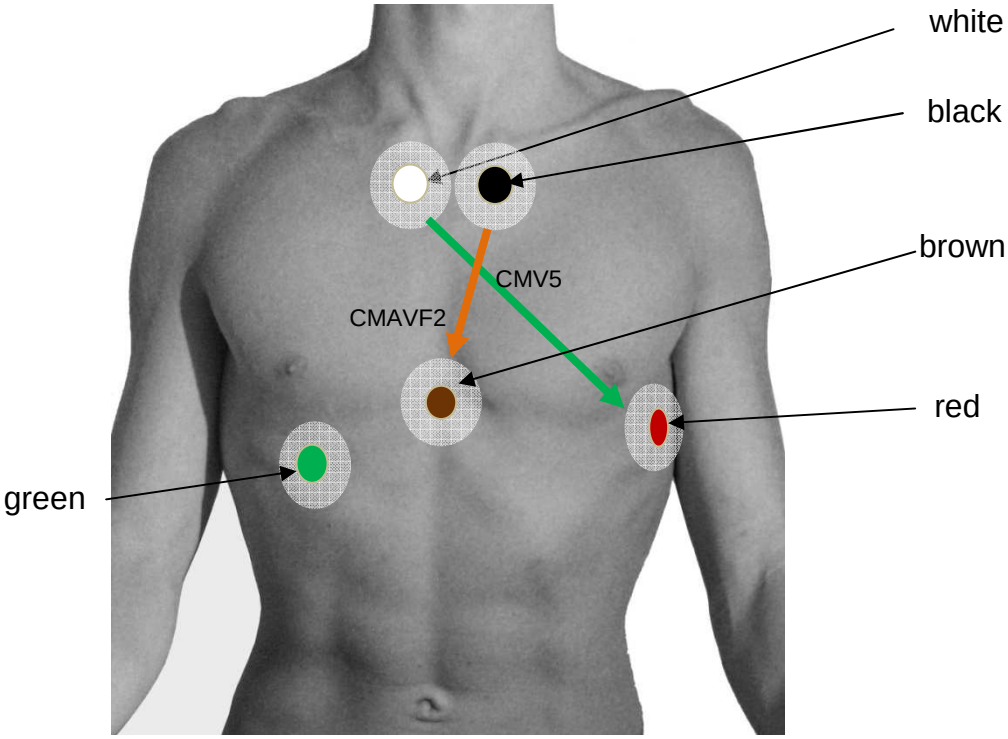
2 channels recording 3 electrodes. Cable : *RFT00-2L3-250 or RFT00-2L3-1000*

Place the electrode with the red connector (A+) over a rib at V5, the electrode with the brown connector (B+) over the xiphoid at the bottom of sternum and the electrode with the white connector (common -) on the manubrium.



2 channels recording 5 electrodes 250 or 1000Hz. Cable RFT00-2L5-1000

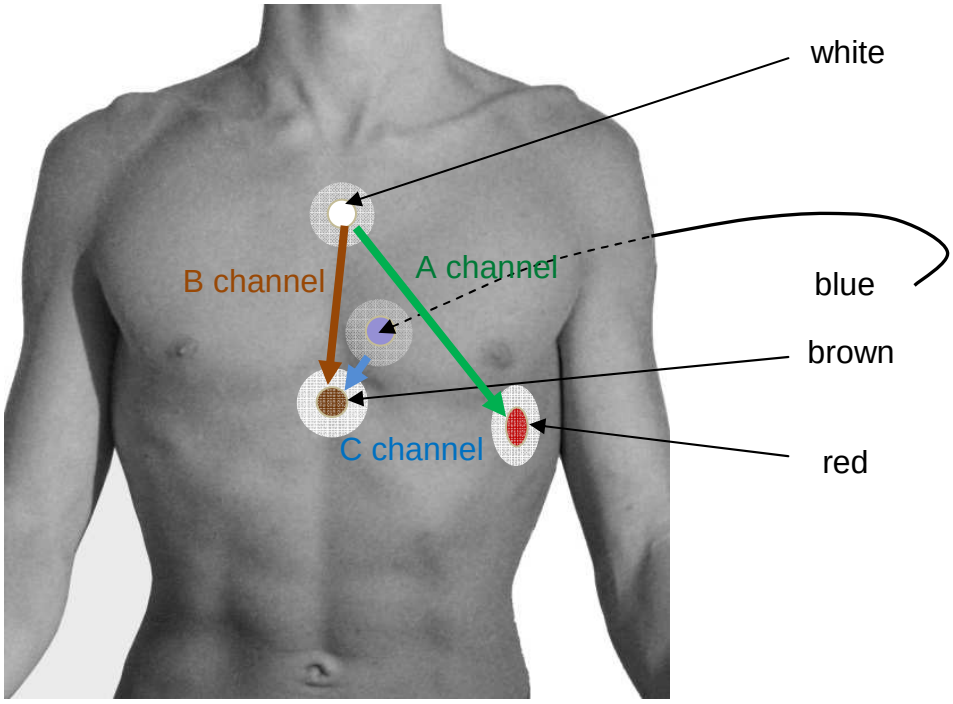
Place the white connector (A -) on the manubrium and the red connector (A+) over a rib at V5.
The black connector (B -) is also placed on the manubrium, at the left of the white one, and the brown connector (B+) over the xiphoid at the bottom of sternum.
The Ground electrode with the green connector is placed over a rib on the right side of the chest.



The **switch between 250Hz / 1000Hz** is done in the adjustment screen. See chapter V.

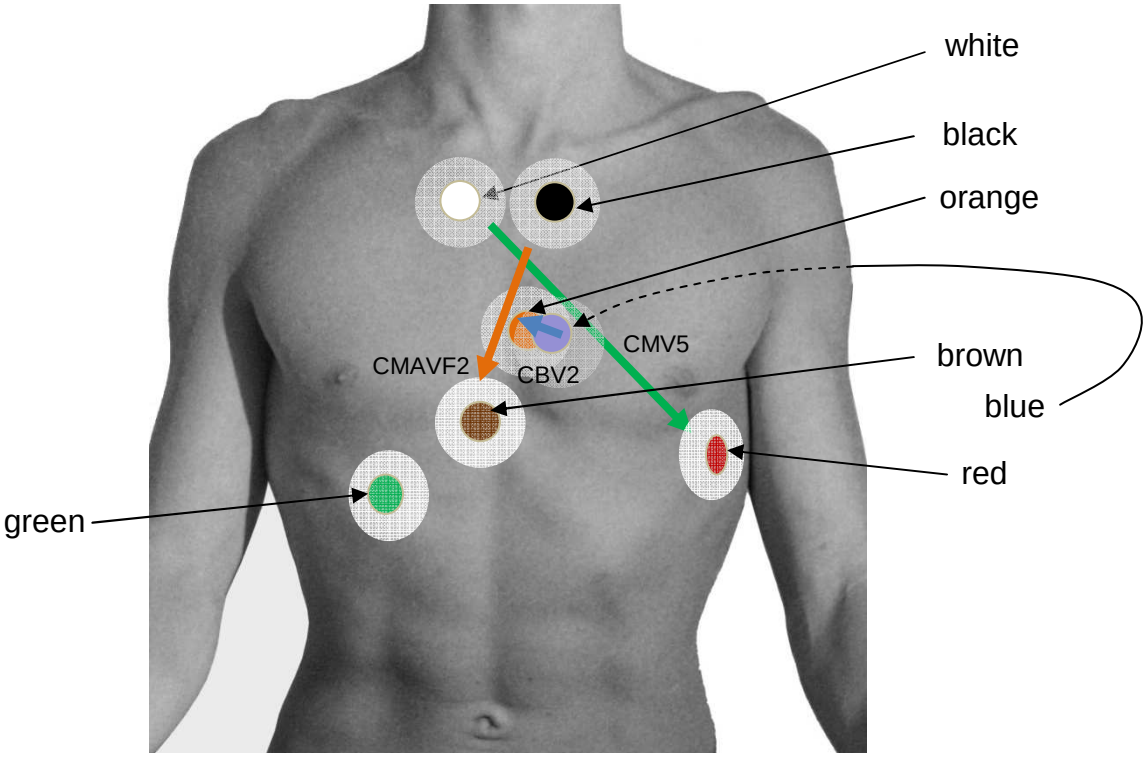
3 channels recording 4 electrodes 250Hz. Cable RFT00-3L4-250

This configuration is the same as the 2 channels recording 3 electrodes, with an antero-posterior lead more. The blue connector (C-) is placed posteriorly and paravertebrally facing V2.



3 channels recording 7 electrodes, 250 or 1000Hz. Cable RFT00-3L7-1000

It is the same as the 2 channels recording with 5 electrodes with a CBV2 anteroposterior lead close to the Z axis. The blue electrode (C-) lies posteriorly and paravertebrally facing V2. The orange electrode (C+) is placed on V2.

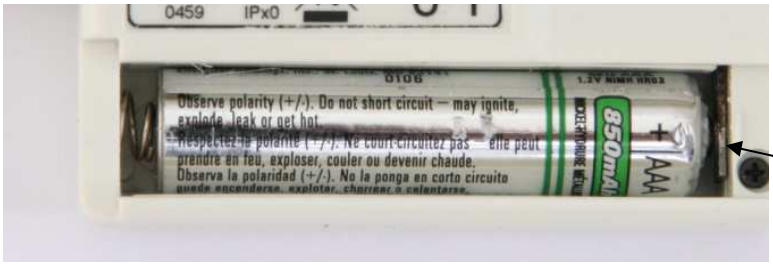


The **switch between 250Hz / 1000Hz** is done in the adjustment screen. See chapter V.

IV. Starting the recorder

Put the battery:

Open the battery case, at the back of the device. Install a new alkaline battery AAA (or a rechargeable battery) and respect the polarity as indicated in the battery case (see below).



Install and close the battery cover until the Index is positioned on "O" (OFF).

The autonomy is function of the battery voltage (for a recorder working around 23°C with 2 channels in standard mode, with a moderate usage (<5/day) of the display).

1,20V	1,24V	1,28V	1,35V	1,50V
10%	25%	50%	67%	100%
24h	5 days	11 days	15 days	22 days

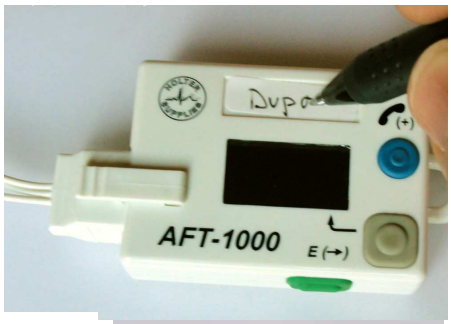
The NiMH AAA batteries (800mAh) give an autonomy of 10 days with a standard 2 channels.

ATTENTION :

In normal use, don't remove the battery between two recordings. If the recorder stands without battery during more than 5 minutes, it can loose the date and the time. For stopping it during long periods, it is recommended to withdraw the battery. When it will be power up, it will be then necessary to adjust the time and the date.

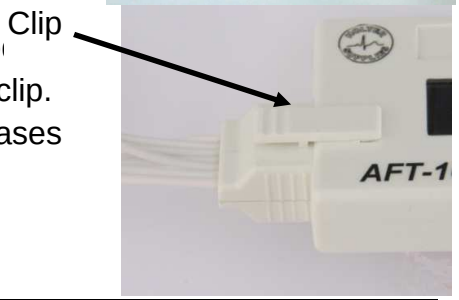
Write the patient's name

- Whether stick a identification label of the patient in the pouch.
- Whether write it with a erasable pen.
- Whether write it in the memory of the recorder (p.8)
- Whether on Quick Reader (v.2.03 or +) and transfer in AFT.



Connect the patient cable

Press the terminal of the ECG cables on the tips of the electro
then insert the connector in the recorder until it is locked by its clip.
The connector is unplugged by pushing the lever which releases the clip.

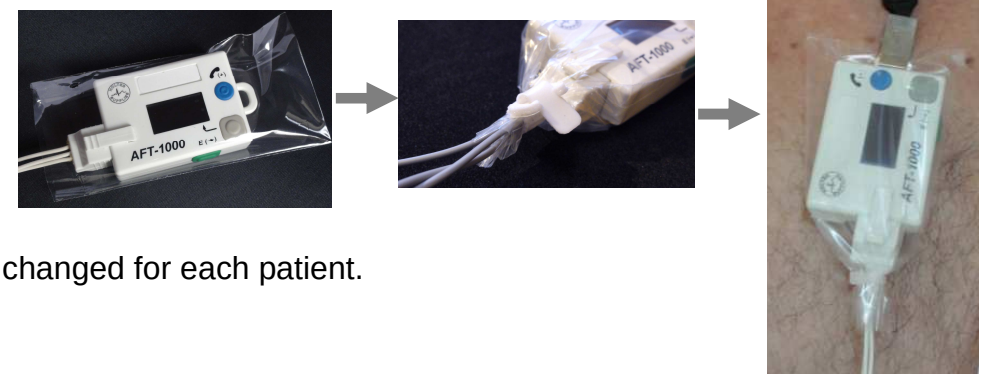


DURATION OF RECORDING (days)

ECG Cable :	2 tracks - 250Hz	2 tracks- 1000Hz	3 tracks - 250Hz	3 tracks-1000Hz
AFT1000-01-A	**10 d.**	**2 d.**	**6 d.**	**1,6 d.**
AFT1000-01-B	**22 d.**	**5 d.**	**14 d.**	**3,6 d.**

Place the recorder in a disposable protective pouch

PCT03 economic
& lanyards **PCT05**

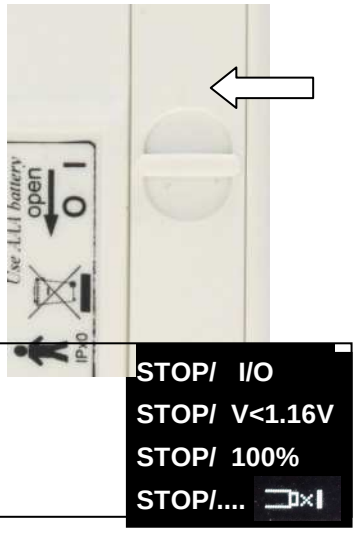


The pouch must be changed for each patient.

Switch on the recorder

Put the index on "I": move the battery cover by pushing the central beam. The recorder switches on and displays the main display after a memory check

Message explaining the reason for which the last recording stopped.



Normal stop by cover — STOP/ I/O
Low battery stop : — STOP/ V<1.16V
Full memory stop : — STOP/ 100%
Bad battery contact : — STOP/....

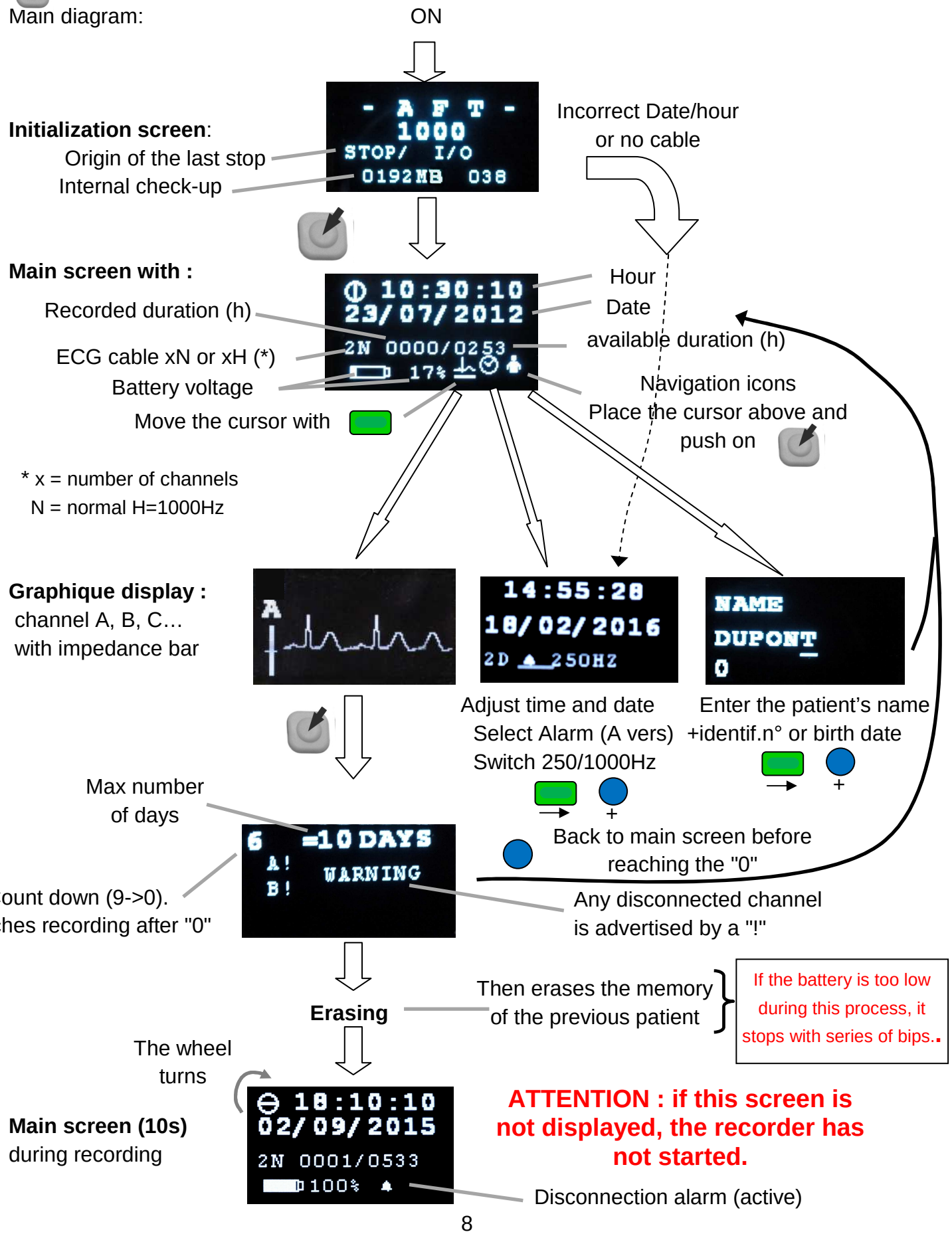
If the ECG connector is not plugged in, the recorder displays the screen for time and date adjustment. In case of problem, a message is displayed (see p.9).
In case of not start, verify that the battery has a enough voltage (> 1.20V with 10% displayed)

***ATTENTION**: If the recording is not launched, and without any action during 2 minutes, the recorder stops. In this case, the device is completely halted and the possible patient name lost. To restart, you need to put the index on "O" during around 2 seconds, then to put it on "I".*

V. Menu of the AFT1000

Except the time, date, selection of disconnection alarm and if case the sampling frequency, there is not anything to set in the adjustment screen. The only one button to use is the button "Display" which commands the next screen in the menu.

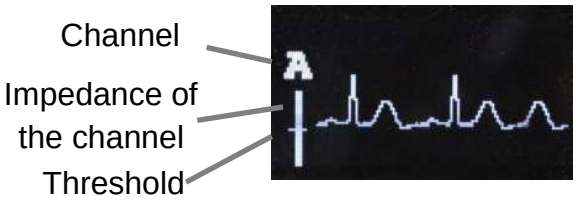
Main diagram:



During the recording, the button commands the display of the main screen. In this case, the wheel turns.

IMPEDANCES MEASUREMENT:

The AFT1000 permanently checks the impedance of the cables and the electrodes.



More the connection is good, higher is the line of impedance.

The vertical line must be above the threshold, otherwise there is a faulty electrode or a cable failure.

ADVICE BEFORE LET THE PATIENT GO : *Read Recommandations for the patient (cf.Chap.VII)*

Before to shut down the display, the device emits 3 notes to confirm the correct starting of the recording. If the disconnection alarm is selected (Chp.V) and in case of bad impedance, the recorder emit warning beeps during the first 30s of recording. After these 30s, it will emit a beep every 30 seconds, except during the night (11pm to 8am). The patient can inhibit this alarm by pressing the blue button (cf.Chapitre VII).

You can verify a last time that the recorder is properly recording: press to see the main screen with the turning wheel, and if you press a second time, you verify the quality of the ECG signal for each channel. Your patient can go.

SECURITY AGAINST DATA ERASING:

If, during the recording, (minimum 10mn), one stops the recording and restarts it later, the recorder displays a "restart" screen with few right arrows, which means a new recording will be set after the previous. *There is no lost of any recorded data.* During the reading, there will be several sessions separated by stopping intervals.

The connexion of a USB cable (for the transfer of data to the PC) reset this security. The recorder will start normally.

SECURITY AGAINST A LOW BATTERY VOLTAGE:

The recorder measures the battery voltage and detects a drop under a critical value. The threshold is fixed at 1.16V. The low voltage detection stops the device in full security and the previous recorded data are saved.

Stop the recorder

To stop the recorder at the end of the recording, place the index of the battery cover on "O".

The device can also stop spontaneously on low battery voltage, a memory full or a bad contact with the battery. To clean the recorder, see **Care of the Device (chap.IX).**

ERROR MESSAGES:

During the check up and when the recorder starts, several messages can be displayed in case of problem:

V=1,15V<1.20V : battery voltage too low to record 24h. Change the battery.

ERROR 32 hard failure of the flash memory : return the recorder to After Sales Services.

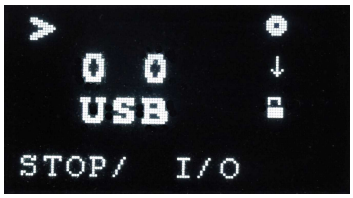
BLOCK LOST : failure of the flash memory which loose one or several blocks of 128k bytes. This allows to make recording but you must program a return for repairing.

VI. Data transfer:

After the device stopped, and after setting **the index of the battery cover on "O"**, you can process to the transfer of the data to a PC under Windows (XP, Vista, 7..),which has a minimum of 1 Gigabyte of memory, 10 Gigabytes free on the hard disk, and a USB "2 High Speed" connector (see Quick Reader specifications).
The software Quick Reader must be previously installed: you will find the Setup in the memory of the recorder, in the directory Quick Reader. Version = 2.05L or more.
First**, remove the ECG connector** and **plug the USB cable** inside the receptacle of the ECG connector. Then, the screen displays "USB + 0 0". The last line remembers why the recorder stopped last time (see p.7).
If the recorder was not stopped, an error message **"STOP REC"** is displayed.

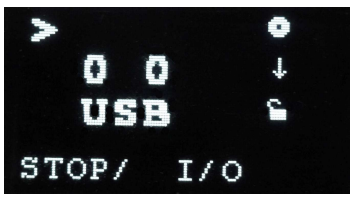
If you must install Quick Reader®, call the Windows Explorer® to find the unit corresponding to the recorder "AFT1000". Double click on the folder "QuickReader", then on the "Setup.exe" program. Follow the instructions.
When Quick Reader is installed, you call it by a double click on the icon present on the desktop.
We recommend to read the manual displayed when you click on the icon "?".
The transfer starts when you click on the download icon. 
The transfer is done at a very high rate (max=480Mb).
If you had written the patient's name on the case, enter it in the identification dialog box, then erase it with the special eraser.
The end of the transfer is indicated by a message: you must then disconnect the recorder from the USB cable.
If you need to make another transfer to another PC, it is possible because the data are not erased until a new record starts.

Avoid intrusions of the PC in the flash memory during the USB download.
The USB screen displays a closed lock, corresponding to a write protect setup of the flash memory. There is no more risk to see a virus, or a large volume of data writing on the flash memory to compromise the functioning of the recorder.



In rare cases, a *spontaneous alteration of the flash memory* can occur, which impedes Windows to read this memory : the download stops with a message as "An unexpected error occurs…" (depending of the Windows version and language).
In this case, Windows refuses to read memory if it cannot access it in writing mode.

One can just ask to « Start again » the reading procedure after having open the lock by a push on the blue button, as it is indicated on the screen. During the download, Windows supports error correction by modifying the memory configuration. Verify after this,



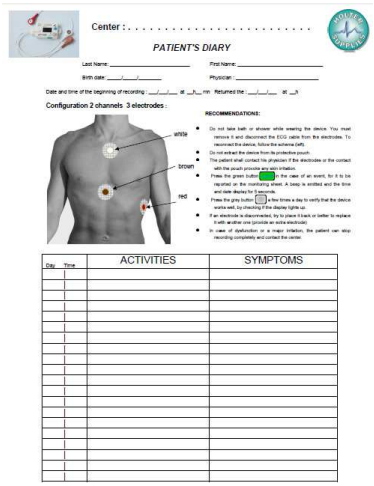
that the correction doesn’t interfere with the internal management by checking the memory of the recorder (start -> main screen or time adjust screen).
A sudden hard drive failure can happen ! Don't forget to secure your download data on the PC: create an copy of each record in a second hard disk of the PC (internal of external) or by write on a flash memory or a DVD with all the last data.

VII. Recommandations for the patient

The patient must be informed of several points:

- The patient should never take any shower or bath while the device is wear. This will damage the device.
- The patient shall from time to time take off the device and disconnect ECG cable from the electrodes, without switching off the device, in order to take a shower or bath : one must explain to him how to disconnect the snap fastener without pull the cables. If an electrode doesn't stick properly, the patient must use a new one: so it is necessary to tell him how to position the electrodes, give to him enough electrodes for the recording period and tell him how to connect the ECG cable. You will find a schema of electrodes positioning in the folder "Guide" in the memory of the recorder. The use of a belt with permanent electrodes simplifies a lot this procedures.
- If the patient temporarily removes the device, he shall never switch it off or extract it from the pouch.
- The patient shall contact his physician if the electrodes or the contact with the pouch provoke any skin irritation.
- In case of symptom or for any activity having direct effect on the heart, the patient must push on the Event button (green): the time of the push is then recorded. The patient can read the time and the date that are displayed during 5s and report them on his diary sheet with comments.
- The patient should daily make sure that the device is recording. If he has not used the Event button, he can push on the Display button and verify the display of the main screen with the wheel rotating. In case of problem, he should immediately contact his physician or the technician.
- The patient must avoid proximity of radio or radar antenna: this can perturb excessively the ECG signal.

It **is strongly recommended to print and give to him the Patient’s diary** document present in the recorder. To do this easily, make a copy of this file on the desk: you will have just to click on it for opening in a pdf reader and call “print”.


Center : . . . . . .

PATIENT'S DIARY

Last Name: First Name:

Birth date: Physician:

Date and time of the beginning of recording: Returned the:

Configuration 2 channels 3 electrodes :

RECOMMENDATIONS:

white

brown

red

Day	Time	ACTIVITIES	SYMPTOMS

VIII. Technical spécifications

ECG features:

- Recording ..... without compression (delta 8 bit optimized)
- Channels ..... 1 to 3 channels
- Resolution..... 12 bit, 10µV & 2,5µV (1000 H.Q.* model)
- Sampling frequency ..... 250Hz & 1000Hz (H.Q.)
- Band pass ..... 0.05Hz - 80Hz (400Hz H.Q.) -3dB
- Amplitude:..... ± 5 mV
- Storage ..... Internal flash memory 0,5 to 1 Gigabytes
- Spikes of pace-maker detection ..... during reading, on 1000Hz signal

Electrical specifications:

- Input impedance ..... 40MΩ between two poles
- Common mode rejection..... >60dB from 10 to 120Hz.
- Consumption..... <3mW (mean value)
- Power ..... 1 x battery 1,5V AAA

Environment recording:

- Battery voltage..... resolution 10mV, 1 measure / 10s
- Temperature ..... resolution 0.1°C, (±3°) 1 measure / 10s
- Spatial position (optional)..... acceleration X, Y, Z 1 measure./ 10s
- Leads impedances..... permanent measurement.

Physical:

- Dimensions..... 41 x 65 x 14,5mm and 41,5 x 65 x 14.5 for the +.
- Weight *with battery* 42g
- Enclosure..... Molded polycarbonate plastic
- Display..... OLED 128x64 pixels.
- Protection against water (without pouch) : IPX0

IX. Precautions for use and maintenance

Transport

The AFT1000 is packed in the packaging for delivery.
If you want to repack and carry or deliver the AFT1000 after its first usage, we recommend putting all the parts back to their initial position..

End of life

When the device is out of order, it should be returned to your distributor for appropriate recycling.
The batteries should be recycled as appropriate.
ECG cables and pouch can be thrown away, since they do not contain specific dangerous material.
The AFT1000 parts and accessories do not contain mercury nor mercury compounds.

Conditions for use and storage of the device

The following table shows the conditions for use, storage and transportation of AFT1000

	Température	Humidité	Pression
Operating	10° to 45°C	10% to 95% non condensing	700 hPA to 1060 hPa
Storage and Transportation	-20° to 65°C	5%* to 95% non condensing	500 hPA to 1060 hPa

During long duration storage (few months) the battery must be removed from the device.
The AFT1000 is not protected against chocks from defibrillator, the high-frequency current and magnetic fields.

! **WARNING**: If a patient wearing an AFT1000 recorder needs to be defibrillated, it is mandatory that the recorder's electrodes be removed before the defibrillator is used.

! **WARNING**: The AFT1000 shall not be used in environments with flammable aesthetic mixtures with oxygen or nitrous oxide.

WARNING: The recorder can be disturbed by strong electrostatic discharges, particularly if it is out of its protective pouch. A so strong discharge can induce a "reset" and then stopping the current recording or, more, a breakdown of the device.

! If a "reset" occurs, the program restarts and the mains screen is displayed, as usual. The best to do in this case is to stop the device (index on "O") and to avoid to restart a new recording before download the data to the PC: the last data would be erased.

Electromagnetic compatibility

The use of portable and mobile RF communication equipment (ex. cellular phones, radio, radar...) can affect the event recorder since the recorded ECG signal may be disturbed due to electromagnetic interference.

The device shall not be used in presence of ionizing radiations (X rays, gamma rays, …) that could cancel the internal memory and the internal flash card.

Tables about electromagnetic emission and immunity of the recorder are reported in the annex of that manual.

Care of the device

It is advised to test regularly the ECG cables with the tester of cables TCB00-04-A which can be fixed in the suitcase.

An annual servicing is advised to control functioning of the recorder and to keep it as reliable as possible. The pole + of the battery must be kept clean. Ask to your distributor a maintenance contract.

The surface of the case and the patient cables can be cleaned with a slightly damp cloth or one wet with soapy water. Detergents, aggressive products (as Dakin for instance), or solvent as alcohol or acetone must not be used.

Maintenance :

If the device doesn't function properly, look at the Guide for maintenance in the file of the recorder. Never open the device in any case (see Warranty).

You can make a "reset" of the device in case of failing to work properly or to erase the flag preventing erase of the last record. You have access to the reset button through an eye present in the case receiving the ECG connector, along the right side, at half height. Insert a tool (paper clip for instance) to switch on the reset.

ATTENTION: never make a "reset" during erasing or recording: there is a risk to corrupt the flash memory. This reset gives also access to test programs which need special accessories to run. However, several tests can corrupt the internal memory: we recommend to not use these tests if you are not a technician trained to this device.

X. Warranty

AFT1000 guaranteed for parts and labour during two years from the date of delivery.

The accessories as the ECG cables are not guaranteed after their first use.

After-sales service is available after the warranty has expired.

! **WARNING**: the warranty is only valid under the condition that no attempts have been made to open or repair the device, or to write or erase the flash memory - as virus -. The warranty will be void if the device or accessories have been used contrary this user's manual recommendations, particularly if it is worn without protective pouch, if it receives electric discharges, chocks, mechanical strain, excessive pressure or humidity as defined by the standards applicable to this device.

US only CAUTION: Federal law restricts the sale of this device by or on the order of a physician.

XI. Annexe 1

Guidance and manufacturer's declaration - electromagnetic immunity			
The AFT1000 is intended for use in the electromagnetic environment specified below. The customer or the user of the AFT1000 should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment — guidance**
Electrostatic Discharge (ESD) EC 61000-4-2	±6 kV contact ±8 kV air	on USB inputs ±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%.
Electric fast Transient/burst IEC 61000-4-4	±2 kV for power Supply lines lines ±1 kV for input/output lines	Non applicable	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV differential mode ±2 kV common mode	Non applicable	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips On power supply input lines IEC 61000-4-11	N.A.	Non applicable	Mains power quality : the device is powered by a battery.
Power frequency (50/60 Hz) Magnetic field IEC 61000-4-8	3 A/m	3A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

Guidance and manufacturer's declaration - electromagnetic immunity			
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Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment — guidance**
Conducted RF Radiated RF IEC 61000-4-3	3 Vrms 3 V/m 80 MHz to 2,5 GHz	3 V/m	Portable and mobile RF communications equipment should be used no closer to any part of the AFT1000, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** $d = 1.2\sqrt{P}$ 80 MHz to 800 MHz $d = 2.3\sqrt{P}$ 800 MHz to 2,5 GHz where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, [a] should be less than the compliance level in each frequency range.[b] Interference may occur in the vicinity of equipment marked with the following symbol: 
NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies. NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			
[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the AFT1000 is used exceeds the applicable RF compliance level above, the AFT1000 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the AFT1000. [b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.			

Guidance and manufacturer's declaration - electromagnetic emissions		
The AFT1000 is intended for use in the electromagnetic environment specified below. The customer or the user of the AFT1000 should assure that it is used in such an environment.		
Emissions test	***Compliance***	***Electromagnetic environment - guidance***
RF emissions CISPR 11	Group 1	The AFT1000 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 AFT1000 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	Non applicable	
Voltage fluctuations flicker emissions IEC 61000-3-3	Non applicable	

Recommended separation distances between portable and mobile RF communications equipment and the AFT1000

The AFT1000 is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the AFT1000 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the AFT1000 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**		
	150 kHz to 80 MHz $d = 1.17\sqrt{P}$	**80 MHz to 800 MHz** $d = 1.17\sqrt{P}$	**800 MHz to 2,5 GHz** $d = 2.33\sqrt{P}$
0,01	0.12	0.12	0.23
0,1	0.38	0.37	0.74
1	1.2	1.17	2.33
10	3.70	3.70	7.37
100	11.70	11.70	23.30

For transmitters rated at a maximum output power not listed above, the recommended separation distance *d* in metres (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.

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Note: These data are indicatives and don't engage Holter Supplies: depending of the hardware and software versions, several points can change and functioning be different from those indicated. We invite the user to verify the functioning of his device with its ECG cables and its battery.
You can also look at our web site www.holtersupplies.com.