INSTRUCTIONS FOR USE

FIAB®

4427 Easypace

CE 2797

CONTENTS

1. INTRODUCTION

This manual forms an integral part of the product and must be stored for future reference. It cannot be reproduced or photocopied, even partially, without prior authorisation from ***FIAB***. The use of the documentation material is reserved exclusively for the Customer.

The present manual contains all the indications which should be observed in order to guarantee correct use of the device. It is therefore recommended reading the entire contents of this manual while observing the machine turned on and functioning, in the aim of fully understanding its operation and gaining sufficient knowledge of its use in clinical procedure.

1.1. Classification, standards and regulations

With regard to electrical safety the external *4427 Easypace* pacemaker is classified as an electromedical device with an internal power supply of the CF type seeing that it is destined for application directly to the heart.

The heart stimulator *4427 Easypace* is manufactured in compliance with the European standards in force:

- EN 60601-1 “Medical electrical equipment - Part 1: General requirements for safety.” File 4745 C (1998-12)
- EN 60601-2-31 "Medical electrical equipment - Part 2: Particular requirements for the safety of external cardiac pacemakers with internal power source". File 2689 E (1995-11)
- EN 60601-2-31/A1 "Medical electrical equipment - Part 2-31: Particular requirements for safety of external cardiac pacemakers with internal power source". File 5226 (1999-07)
- EN 60601-1-2 "Medical electrical equipment - Part 1: General requirements for safety - Collateral standard: Electromagnetic compatibility - Requirements and tests". File 6977 (2003-07)
- EN 14971 "Medical devices - Application of risk management to medical devices." (2002-05).
- MDD 93/42/CEE.

FIAB also declares that the information contained in this manual is complete and congruous with the technical, functional and safety specifications of the device. Any suggestions regarding errors detected or any eventual improvements will be greatly appreciated.

FIAB shall only accept all liability for the effects of safety, reliability and performance of the device if:

- repairs, calibrations or modifications of the device or one of its parts or any accessories supplied with the device are be carried out by personnel either belonging to the ***FIAB*** Technical Assistance Service or trained and explicitly authorised by the same;
- the environment and the system in which the device is used is compliant with the relative safety prescriptions;
- the device being used is compliant with these instructions for use.

2. CAUTIONS AND WARNINGS

Indicated here below are the precautions to be taken for the correct use of the heart stimulator *4427 Easypace*. Further information can be found in other sections of this manual.

The manufacturer shall hold responsible for the safety, reliability and performance of the unit provided the following indications are strictly observed.

- The device must be used by physicians with extensive knowledge of cardiac stimulation.
- The device must only be used in compliance with these instructions for use. It is necessary to read every part of this manual, if possible in front of the device which is turned on and operating, in order to fully understand its functioning.
- Before each use, especially if prolonged, it is firmly recommended replacing the main (alkaline) batteries. The battery replacement will be indispensable if the stimulator has been turned off after the request to change batteries.
- In the case of prolonged use it will be necessary to make periodic checks of the stimulation parameters (sensing and pacing thresholds).
- It is indispensable to continuously monitor the patient during stimulation. In emergency situations it will also be necessary to have a defibrillator on hand and ready for use.
- The programming of a low value for the sensing threshold increases the probability of the *4427 Easypace* operations being influenced by muscular tremors. The device may interpret false signals as spontaneous cardiac activity, with consequent inhibition of the stimulation.
- All the automatic functions offered by the 4427 device have been implemented to help the User make a rapid search for the correct parameters. However, it will always be the physician’s responsibility to evaluate the suitability of these values in each specific case.
- In order to use components in contact with the Patient that have to be connected up to the device, follow the instructions supplied with the same.
- In general, an endocavitary or epimiocardiac electrode connected to any type of electro-medical device represents a pathway for direct current with low resistance towards the myocardium. The risk of inducing threatening ventricular arrhythmias resulting from the dispersion of alternate current increases considerably when a device

supplied by the mains is connected to a derivation system. The utmost care must therefore be taken in earthing devices supplied from the mains and used in the vicinity of the Patient.

- The heart stimulator *4427 Easypace* may also be used within another system consisting of other equipment. In this case the ascertaining of the compliance of the equipment chosen and the specific system with the electrical safety and electromagnetic compatibility provisions in force will be the responsibility of the designer and manufacturer of the same.

  In this eventuality it is always recommended taking great care in connecting all the other equipment used in the procedure (electrocardiographs or polygraphs, monitors, etc.) up to the equipotentiality node of the electrical system.
- It is also necessary to avoid touching any metallic parts of the terminals with bare hands and/or letting them come in contact with wet or electrically conductive surfaces.
- As it is always good practice to equalise the potential between User and Patient, the User is advised to touch the patient in a area that is not too close to the stimulation derivations.
- Keep all possible sources of static electricity away from the stimulation system.
- The presence of an electrocatheter in contact with the heart wall may allow for the radiofrequency generated by an electrotome to reach the heart wall itself, producing possible arrhythmias or burns to the myocardium.
- Devices that generate ionising radiations (cobalt machines, linear accelerators, etc.) could damage the electronic components inside the stimulator, especially following an accumulation of a considerable quantity of radiations. In case of use in the above-mentioned conditions it will be necessary to provide an efficacious shield for the stimulator plus continuous monitoring of the Patient.
- The stimulator is protected from defibrillation discharges at the input. It is however recommended wherever possible disconnecting the electrocatheter from the device before defibrillating.

- Before each use in heart surgery, check that the locking jaws of the two sockets of the heart surgery cable F7818/30 close evenly and firmly on the terminals. In case of doubt do not use the device and contact ***FIAB***.

- Before each use check the integrity of the device and all its accessories. Particular attention must be paid when inspecting the cables and connectors. In case of doubt do not use the device and contact ***FIAB***.
- Before each use check the compatibility of the pin of the electrocatheter with the socket of the device.

  In the event of using electrocatheters not fitted with protected pins, but instead with pins with male contacts with a diameter of less than 2 mm, it is recommended using the heart surgery cable F7818/30 with screw-on sockets in order to allow for stimulation.
- Insert the terminals of the electrode fully into each socket without forcing, following the indications in chapter 10 - "Connection to the patient and Instruction for use".
- Before each use check that the transparent protective cover of the keypad is correctly inserted and that there are no breaks or tears. This protection must always be put back into place after setting the parameters.
- Should the device be dropped, check its correct functioning and in case of doubt contact ***FIAB*** before reusing. If there is any apparent mechanical damage avoid using the device and contact ***FIAB***.
- **All operations to open the device, gain access to the internal parts, and repair the same must only ever be carried out by authorized *FIAB* personnel.**
- The environment where the device is used must be compliant with the safety regulations.
- The device must never be immersed in water or any other liquids.
- It will be necessary to remove the batteries from their compartment if the stimulator is stored for prolonged periods (longer than 4 weeks).
- After storing the 4427 device in environments with temperatures and/or humidity unsuited to its use, before using again wait until a suitable temperature and humidity have been reached as indicated on the “characteristics” card.
- Product not sterile and not sterilizable: the hygienic conditions of the device cannot be guaranteed in the event of being placed inside a sterile field.
- In order to avoid damaging the device it must not be sterilized. To clean the device and the accessories follow the indications in chapter 12.
- The accessories supplied with the device are not sterile.

IT IS RECOMMENDED HAVING THE 4427 DEVICE CHECKED AT LEAST ONCE A YEAR BY OUR MEASURING LABORATORY.

2.1. Electromagnetic compatibility – guidance and manufacturer's declaration

The 4427 Easypace, like any other medical electrical equipment, needs special precautions regarding EMC and needs to be used according to the information provided below.

It's important to understand that other devices (particularly portable and mobile RF communications equipment) can affect a medical electrical device. The 4427 device should not be used adjacent to or stacked with other equipment. In particular the stimulator must never be used in the presence of high frequency therapeutic and diagnostic energy sources (e.g.: electrotomes, diathermy devices, RMN etc.) which could cause malfunctioning, temporary inhibitions of the stimulation, or asynchronous stimulation.

Electromagnetic emissions

The 4427 device is intended for use in the electromagnetic environment specified below. The User of the *4427 Easypace* should assure that it is used in such an environment.

Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1 Class B	The 4427 device 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.
Harmonic emissions IEC 61000-3-2	Not applicable[(a)]	The 4427 device is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Voltage fluctuation/flicker emissions IEC 61000-3-3	Not applicable[(a)]	

Electromagnetic immunity

The 4427 device is intended for use in the electromagnetic environment specified below. The User of the *4427 Easypace* should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Electrostatic discharge (ESD) IEC 61000-4-2	± 6 kV contact ± 8 kV air	Compliant	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 61000-4-2	± 2 kV for power supply lines ± 1 kV for input/output lines	Not Applicable[(a)]	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	Not Applicable[(a)]	Mains power quality should be that of a typical commercial or hospital environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5% U_T (>95% dip in U_T) for 0,5 cycle 40% U_T (60% dip in U_T) for 5 cycle 70% U_T (30% dip in U_T) for 25 cycle 5% U_T (>95% dip in U_T) for 5 s	Not Applicable[(a)]	Mains power quality should be that of a typical commercial or hospital environment. If the User of the *4427 Easypace* requires continued operation during power mains interruptions, it is recommended that the 4427 device be powered from an uninterruptible power supply (UPS) or a battery.
Power frequency (50/60Hz) magnetic field IEC 61000-4-8	3 A/m	Not Applicable[(a)]	Power frequency magnetic fields shold be at levels characteristic of a typical location in a typical commercial or hospital environment.
Conduced RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz outside ISM bands[(b)] 10 Vrms 150 kHz to 80 MHz in ISM bands[(b)]	Not Applicable[(a)]	Portable and mobile RF communications equipment should be used no closer to any part of the 4427 device, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.
Radiated RF IEC 61000-4-3	10 V/m 80 MHz to 2,5 GHz	10 V/m[(1)]	**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 recommended separation distance in metres (m).[(c)] Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[(d)] should be less than the compliance level in each frequency range.[(e)] Interference may occur in the vicinity of equipment marked with the following symbol: 

NOTES:

(a) The *4427 Easypace* device is not mains powered but has an internal power source. U_T is the a.c. mains voltage prior to application of the test level.

(b) The ISM (industrial, scientific e medical) bands between 150 kHZ e 80 MHz are 6,765 MHz to 6,795 MHz; 13,553 MHz to 13,567 MHz; 26,957 MHz to 27,283 MHz and 40,66 MHz to 40,70 MHz.

(c) The compliance levels in the ISM frequency bands between 150 kHz and 80 MHz and in the frequency range 80 MHz to 2.5 GHz are intended to decrease the likelihood that mobile/portable communications equipment could cause interference if it is inadvertently brought into patient areas. For this reason, an additional factor of 10/3 is used in calculating the recommended separation distance for transmitters in these frequency ranges.

(d) Field strengths from fixed transmitters, such as base station 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 *4427 Easypace* is used exceeds the applicable RF compliance level above, the 4427 device should

be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the 4427 device.

(e) Over the frequency range 150 kHz to 80 MHz, field strength should be less than 10 V/m.

(1) **WARNING!**

An electro-magnetic interference shielding system is embedded in the device in order to detect noise signals with frequencies above 300 ppm: during VVI stimulation and with such interferences, the unit will be set to V00 mode while the User is notified by means of an "EMI" warning on the display; the devices switches to the VVI mode again once the interference is over (see § 11.4).

Besides that an electro-magnetic field, with frequency within the range (80 - 1000 MHz) and rate below 300 ppm, with an high sensitivity set on the device, could override the protection system: in that case the device won't switch to V00 mode causing random loss of the pacing pulse, for no longer than 2 pacing periods; the complete functionality is regained when the interference is over. The afore mentioned event can be considered extremely rare. In case of a VVI mode use it's recommended to check that in the environment where the device will be used there are no interferences like the one just described, especially if the Patient is not constantly monitored. If not it's advisable to find and possibly remove the source of the interference before proceeding. If the removal of the source is not feasible it's recommended to pace in V00 mode.

A method of spotting the presence of the interferences is based on a pre-procedure check: before the procedure set the device to *sensing* mode, preferably connecting it to a 500 Ω load. If such electromagnetic fields are present in the environment, the ECG will detect an activity similar to the spontaneous one and will show the correspondent ppm.

Recommended separation distances between 4427 device and portable and mobile RF communication equipment

The *4427 Easypace* is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The User of the 4427 device can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communication equipment (transmitters) and the 4427 device, as recommended below, according to the maximum output power of the communications equipment.

	Separation distance according to frequency of transmitter (m)	
	80 MHz to 800 MHz	**800 MHz to 2.5 GHz**
Rated maximum output power of transmitter (W)	$d = 1{,}2\sqrt{P}$	$d = 2{,}3\sqrt{P}$
0,01	0,12	0,23
0,1	0,38	0,73
1	1,2	2,3
10	3,79	7,27
100	12	23

NOTE:

- At 80 MHz and 800 MHz the separation distance for the higher frequency range applies.
- These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Data reported in this chapter are valid for the device used in the manner and with accessories stated in this instructions for use. The use of accessories other than those specified may result in increased emissions or decreased immunity.

3. DESCRIPTION

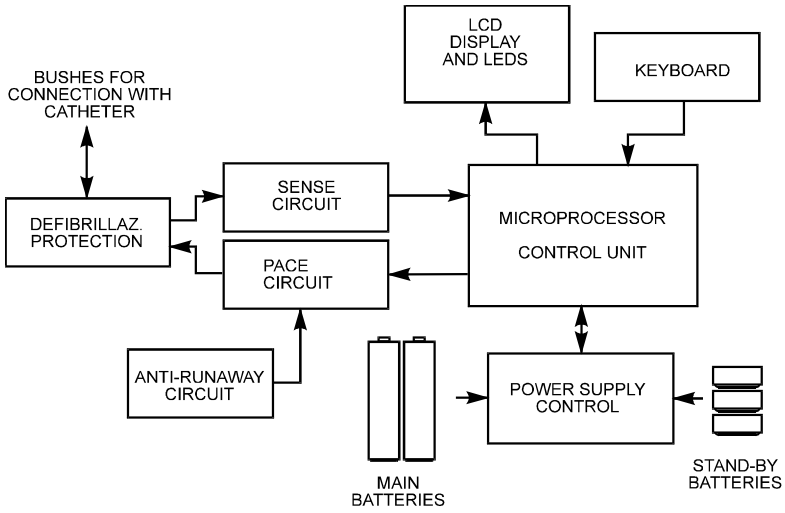
External *4427 Easypace* pacemaker is a compact, single-chamber, temporary heart stimulator to be used in the pathologies of spontaneous generation and conduction of impulses.

The unit's main characteristics are :

- synchronous and asynchronous modes of operation
- fully microprocessor operated control allowing a high precision setting of stimulation parameters and a complete and continuous check for correct operation of the unit
- back-lighted LCD display
- AUTO and EMERGENCY keys for a quick start-up of both synchronous and asynchronous stimulation with safety parameters
- stimulation capability with quadruple rate and decreasing ramp to reduce tachycardia events
- stand-by batteries for replacement of main batteries without interrupting the stimulation
- a large number of safety functions: self-test at power on; on-line control of the batteries level; turn-on inhibition with low battery charge; check for run-away and lead connection; protection against defibrillation discharges and electromagnetic interference. Dangerous situations are signalled to the operator by an acoustic alarm and a suitable display message
- easy and safety connection of Patient cable or lead to sockets
- protected sockets coloured black for the – and red for the +; these are compatible with protected pins fitted with Ø 2 mm electrical- contacts

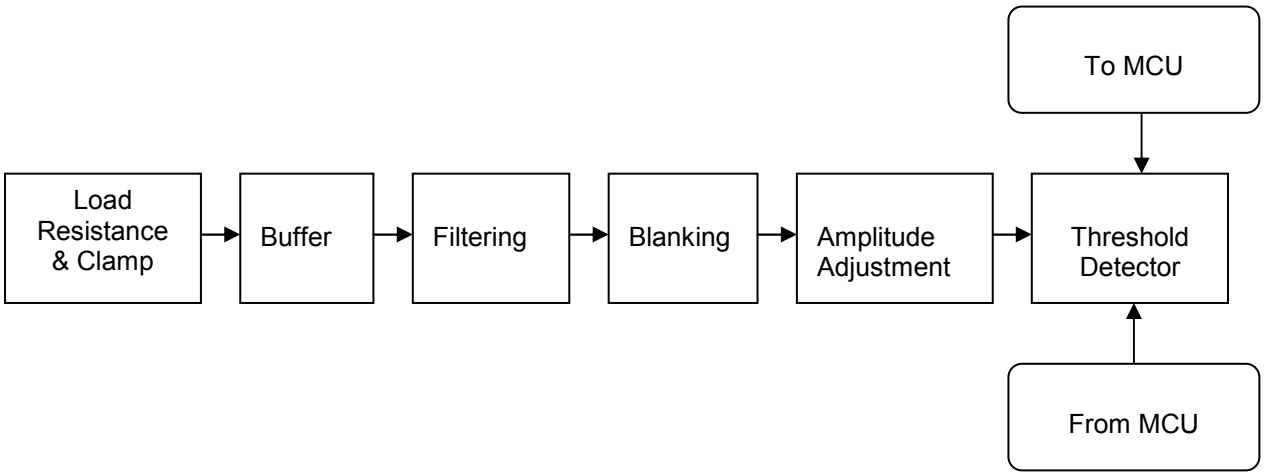
3.1. Block Diagram

The figure below is a block diagram of the heart stimulator *4427 Easypace*.



Cardiac signal enters the unit through the lead and the connecting socketes. A suitable circuit provides for the protection against the defibrillator discharge.

The sense channel consists of a chain of amplifiers and filters - schematically illustrated in the figure below - for the cardiac signal acknowledgement:



The current (mA) controlled output stimulation is governed by the microprocessor according to values entered via the keyboard and visualised on the display. The stimulation impulse is followed by a short period of electrode depolarisation obtained through a short-circuit of the two catheter poles.

4. USE

Heart stimulator *4427 Easypace* is a versatile unit easy to use for single-chamber temporary intracardiac stimulation. In particular it is recommended in:

- extreme bradycardia;
- paroxysmal atrial-ventricular block;
- interruption of paroxysmal tachycardia from atrial flutter;
- atrial-ventricular blocks of various types prior to implantation or replacement of a definitive pacemaker.

5. POSSIBLE COMPLICATIONS

Complications likely to occur upon using heart stimulator *4427 Easypace* are the following:

- muscle stimulation causing contractions and pain;
- breaking or displacement of the catheter causing intermittence or lack of stimulation
- erroneous setting of stimulation parameters causing capture failure;
- erroneous adjustment of the stimulation rate causing induction and tachycardia;
- erroneous setting of sense parameters causing the stimulation to loose synchronism or be inhibited.

5.1. Contraindications

There are no contraindications in relation to the use of *4427 Easypace* for temporary cardiac stimulation during a therapy or arrhythmia prevention. However the Patient's state of health or the presence of electromagnetic interference can limit the choice of modes and stimulation parameters.

The stimulator is provided with numerous and redundant safety circuits whose simultaneous failure - unsigned to the User - is an event very unlikely to occur. However, it is recommended that the use of the heart stimulator *4427 Easypace* be restricted to authorised medical staff and always accompanied by ECG monitoring.

6. TECHNICAL FEATURES

Manufacturer	*FIAB SpA Via Costoli, 4 - 50039 Vicchio, Florence (ITALY)*
Model	*4427*
Class and Type	*Portable unit with internal power supply*
Applied part	*Type CF, protected against defibrillator discharges*
Conditions for use	*Device for continuous functioning*
Compliance to directives	*EN 60601-1 "Medical Electrical equipment - Part 1: general requirements for safety" File 4745 C (1998-12)* *EN 60601-2-31 "Medical Electrical equipment - Part 2: particular requirements for the safety of external cardiac pacemaker with internal power source" File 2689 (1995-11)* *EN 60601-2-31/A1 "Medical Electrical equipment - Part 2-31: particular requirements for the safety of external cardiac pacemaker with internal power source" File 5226 (1999-07)* *EN 60601-1-2 "Medical Electrical equipment - Part 1: general requirements for safety - Collateral standard: electromagnetic compatibility - Requirements and tests" File 6977 (2003-07)* *EN 6060-2-31 Electro-medical equipment - Part 2: rules for safety of external cardiac stimulators with internal power supply* *MDD 93/42/CEE*
Destination for use	*Single-chamber temporary intracardiac heart stimulator*
Sensitivity	*Adjustable with continuity by the couple of SENSE keys*
Maximum sensitivity	***(*)*** *0.75 mV ± 5%, both for positive and negative polarities*[(1)]
Detectable spontaneous rate	*30÷300 ppm; the value is shown on the display during STAND-BY and VVI modes*
Post-stimulation refractory period (APRP)	*3/8 stimulation period*
Blanking width	*48 ms*
Input impedance	*Approx. 30 kΩ*
Input filtering	*Pass band filter tuned for recognition of R wave*[(1)]
Sense signalling	*By flashing of the green LED at each recognition of R wave*
EMI signalling	*Acustic (emission of a tone) and visual (turning on of LCD) for detected rate values which exceed 300 ppm*
Amplitude of stimulation impulse	*Varying between 0.4 and 40 mA (by steps of 0.4 mA up to 10 mA, and then by steps of 2 mA)*
Maximum available current	*40 mA @ 300 Ω, 25 mA @ 500 Ω*
Waveform of the stimulation impulse	*Rectangular*
Length of stimulation impulse	*1.4 ms ± 10%*
Local depolarisation	*Short-circuit of 16 ms length after the stimulus*
Post-sense refractory period (ASRP)	*200 ms*
Hysteresis	*0 ms*
Stimulation rate	*30÷180 ppm, with 1 ppm steps variation. High rate stimulation (up to 720 ppm) for burst and ramp*
Anti-runaway	*200 ppm, with warning circuit independent of the microprocessor*
Pace signalling	*By flashing of the red LED for each stimulus emitted*
Stimulation output	*Black/red safety sockets for 2 mm pins* *The neutral socket is of red colour; the active socket is black*
Stimulation method	*Asynchronous (V00) and on demand (VVI) - A00, AAI (0,75 mV - see* ***(*)****)* *In the VVI mode, detected rate values which exceed 300 ppm are interpreted as disturbance condition: the 4427 Easypace indicates EMI and change over V00 mode at the set rate* *In the V00 mode, the sense signal is ignored and does not inhibit the stimulation*
Additional functions	*BURST x4 (quadruple of set frequency rate stimulation)* *RAMP (decreasing frequency rate of 8 ppm/stimulus)* *EMERGENCY (V00, 72 ppm, 20 mA)* *AUTO (VVI, automatic adjustment of sense, amplitude and frequency rate)*
Special and safety functions	*device self-test at power on* *Stand-by mode for setting stimulation and sense parameters under no-stimulation condition* *Protection against defibrillator discharges* *Integrity checking of Patient connection during stimulation mode* *Continuous checking of batteries charge level*

Default parameters at power on	*Upon completion of self-test, the stimulator is set on mode Stand-by: frequency rate 72 ppm, amplitude 10 mA, sense threshold 1 mV*
Display	*liquid crystals type LCD, with back illumination, for monitoring stimulation and sense parameters. 20 sec after the last key pressure, the display goes off, to be switched on again at a touch of any key*
Keyboard	*thermoformed, with EMI shielding, for setting stimulation and sense parameters*
Power supply Switch on Switching on signals Max. input Autonomy Signalling of batteries discharge	*2 main batteries: AA size 1.5 V alkaline (type LR6)* *3 stand-by batteries: 1.4 V type PR44 or NR44 or 3 batteries of 1.5 V type D375H* *On /Off button* *Acustic (emission of a tone) and visual (turning on of LCD)* *11 mA* *Main batteries: > 10 days prior to low warning; at least 12 hours of residual autonomy afterwards* *The replacement can be done (within 120 seconds) without the necessity of turning off the device* *Stand-by batteries:> 350 main batteries replacements; batteries life > 12 months* *When these batteries are dead, the replacement of main batteries is prevented with the unit in operation (self-test of charge level)* *Acoustic and visual, with no variation of sensing and pacing set parameters*
Operating conditions Storage and transportation conditions (for 4 weeks max.)	*Temperature: +10 to +40 °C* *Relative humidity: 30% to 70% RH uncondensed* *ATM. pressure: 700 mbar to 1060 mbar* *Temperature: 0 to +50 °C* *Relative humidity: 20% to 80% RH uncondensed* *ATM. pressure: 500 mbar to 1060 mbar* *Packaging designed to prevent mechanical deterioration following the batteries*
Dimensions Weight	*130 x65 x 32 mm* *Approx. 210 g (including batteries)*

Note: (1) the accuracy of the measurements of the sensing values parameters has been calculated by using a triangular signal 2 ms/13 ms (14708-2 Annex F)

The accuracy of the stimulation parameters has been calculated with a load of 500 Ω.

6.1. Graphic symbols

Symbol	Meaning
	caution, consult the attached documentation
	defibrillator-protected apparatus of CF type (Cardiac Floating, suited for direct cardiac applications)
	keyboard lock / unlock

NOTE: in heart stimulator 4427 the protection against the defibrillator discharge is inside the device.

7. MATERIALS AND ACCESSORIES

QUANTITY	DESCRIPTION	CODE
2	Elastic strips	*60002300*
2	1,5 V alkaline battery, pen type (LR6)	*26000010*
3	1,4 V Stand-by battery, type PR44 or NR44 (or 1,5 V type D357H).	*26000003*
1	Transparent cover	*40202700*
1	Protecting case	*40209800*
1	Sterile bipolar cable for heart surgery F7818/30 (only on request)	*68518440*
1	Sterile extension cable F7817/30 (only on request)	*68518430*

Electrocatheters for temporary stimulation avaiable from the range of ***FIAB***

REF SPIKE 2S	REF SPIKE LC 2S/6F	REF SPIKE LC 2S/5F	REF SPIKE LC 2S/4F	Extension cable REF
62166S	52166S	52165S	52164S	**F7817/30B**
62126S	52266S	52265S	52264S	**F7818/30B**
62106S	52366S	52365S	52364S	**F7817/30**
62266S	52466S	52465S	52464S	**F7818/30**
62226S	52126S	52125S	52124S	
62206S	52226S	52225S	52224S	
62366S	52326S	52325S	52324S	
62326S	52106S	52105S	52104S	
62306S	52206S	52205S	52204S	
62466S	52306S	52305S	52304S	

WARNING !

*Using extension cables or others accessories, pay attention to the total length (extension cable length + electrocatheter length) isn't longer than 3 m. Otherwise radiated RF could be increased or EMC immunity could be decreased (cf. 11.4 and 2.1 - **EMC immunity**).*

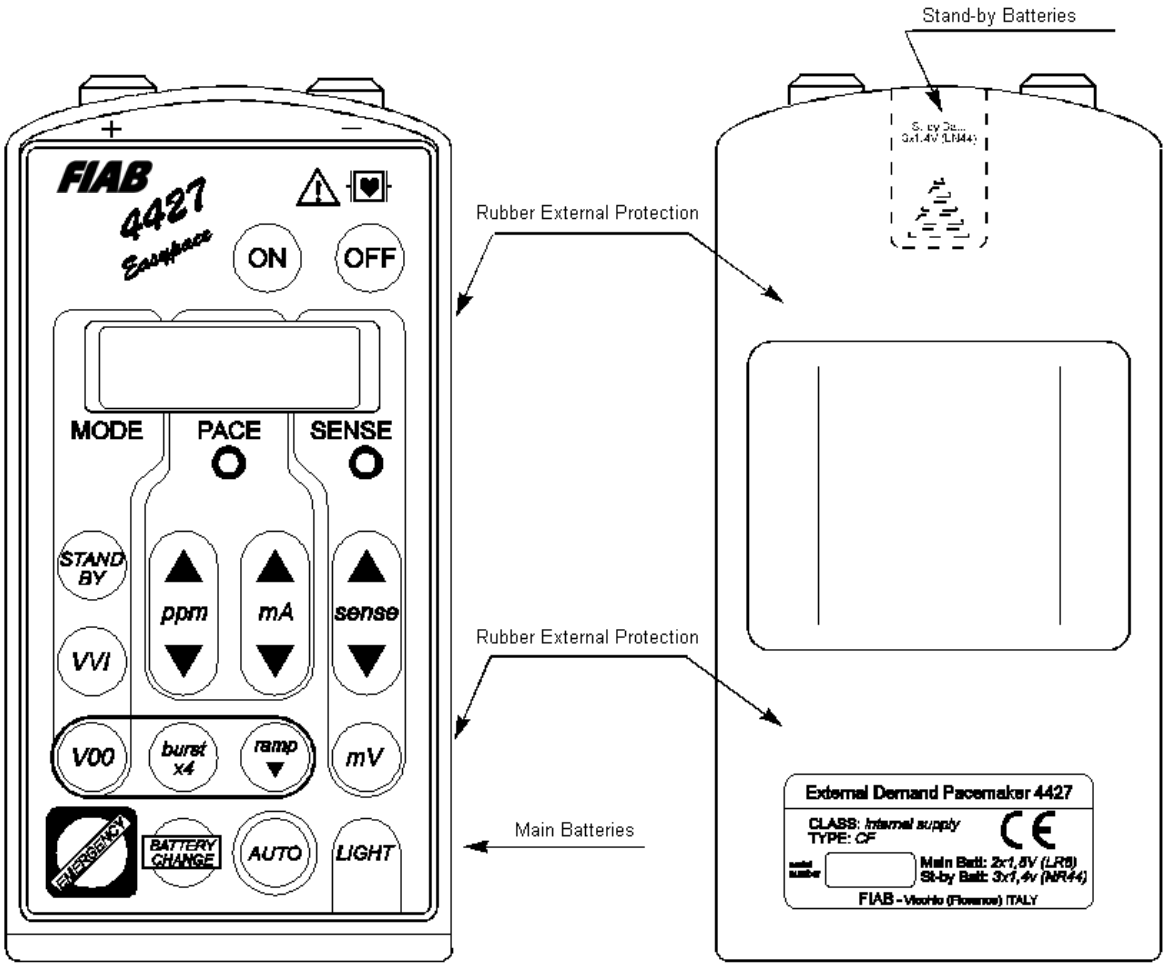
*Therefore the use of listed **FIAB** extension cables is recommended only with SPIKE LC 2S/4F electrodes.*

8. CUSTOMER INTERFACE

8.1. Commands and Controls

The figure below is an ensemble view of the heart stimulator *4427 Easypace* showing the following details:

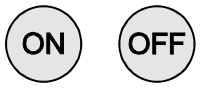
- ON/OFF switches;
- LCD display for parameters setting and monitoring;
- signalling LED for stimulation (red) and sense (green);
- keyboard for setting the operation mode and regulating the stimulation impulse and sense threshold;
- dedicated keys for quick access to stimulation, battery replacement and display illumination;
- rubber external protection;
- doors for access to main and stand-by batteries housing.



Illustrated in the next part of this section are the unit's operational functions and controls.

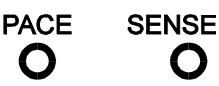
8.2. Description of keyboard and display

The keyboard *of 4427 Easypace* has thermoformed keys providing an accentuated sense of touch. Moreover, the pressing down of any key is confirmed by a short acoustic signal.



The **ON** and **OFF** keys are for turning the stimulator on and off. The on condition of the unit is signalled by the display (during the STAND-BY mode of operation) and by the blinking of the LED (during the V00 and VVI modes which include turning the display off).

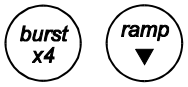
The device can be switched off only by a prolonged pressure of the **OFF** key.



The emission of a stimulation pulse takes place upon entering one of the two operating modes V00 and VVI and is signalled by the blinking of the red LED **PACE**.

The capture of a spontaneous impulse occurs, instead, after the correct adjustment of the threshold (cf. later on) and is signalled (in the STAND-BY or VVI mode) by the blinking of the green LED **SENSE**.

The stimulator operating modes STAND-BY, VVI and V00 are selectable by a touch of the relevant keys. The specific operations to be carried out for each of these modes will be described in detail later in this manual.



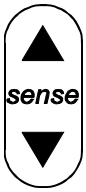
As graphically indicated on the keyboard, the burst and decreasing ramp programs can only be activated in the mode V00 by pressing at the same time the keys **V00** and ***burst x4*** or **V00** and ***ramp*** ▼.

Both functions are active only until the two keys (**V00** + ***burst x4*** or **V00** + ***ramp*** ▼) are kept pressed. When one is released, the stimulator returns to the previous program V00 at the set rate.

Two automatic programs are also available for a quick entry into the asynchronous mode V00 by a touch of the red key ***EMERGENCY*** and into the synchronous mode VVI by pressing ***AUTO***. Both modes also allow the operator to adjust with precision all the set parameters. For a detailed illustration of the EMERGENCY AND AUTO programs, reference is made to the relevant paragraph.

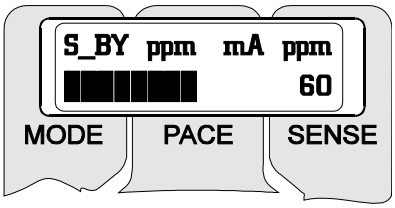
The adjustment of the stimulation rate is made by acting on the pair of keys ***ppm*** ▲ and ▼ whose thus set value is shown on the display. The variation of the rate by steps of 1 ppm takes place more quickly if the relevant key is kept pressed. Keys ***ppm*** ▲ and ▼ are active in all the operation modes, V00 and VVI included.

The current (mA)-operated variation of the impulse is made by pressing keys ***mA*** ▲ and ▼; also in this case the keys are active in all the operating modes and the set value is visualised on the display. The variation step of the current is 0.4 mA in the range of 0÷10mA, and then of 2 mA up to the maximum value of 40 mA.



In the STAND-BY and VVI modes the active keys are ***sense*** ▲, ▼ and ***mV***, for the adjustment, respectively, of the sensitivity threshold of spontaneous activity and for the visualisation of the threshold level (in mV).

For the mode VVI to be performed correctly, careful adjustment of the sensitivity level should be made beforehand, when operating in the STAND-BY mode. At power on, the default threshold is 1 mV. The keys ***sense*** ▲ and ▼ act on the amplification of the input signal. Accordingly, an increase of the sensitivity will be obtained by pressing the key ***sense*** ▲ (which will cause the threshold to go down to the minimum value of 0.75 mV) whereas a decrease of the same sensitivity will be set by the key ***sense*** ▼. The capture of the spontaneous impulse is signalled both by the blinking of the green LED of sense, and by the appearance on display of the spontaneous rate value which is updated after each impulse. To graphically show the amplification level being reached, the second line of the display is replaced - when using the sensitivity adjustment keys - by a bar indicating the volume (see figure at the side). At the end of setting, the display will resume its usual configuration.



For a final verification of the threshold level being set, press the ***mV*** key to allow it to be visualised in place of the spontaneous ppm figure, normally shown on the display - the visualisation of the threshold value being active for the time this key is depressed. A release of the same key causes the display to resume its normal configuration.

CAUTION !

*For a correct synchronism it is recommended not to set a limit of the threshold, but to reduce the latter by approx. 20% (by acting on key **sense** ▼) in order to prevent possible fluctuation of spontaneous activity level.*

In case of prolonged use of the stimulator, provision is made for replacing the batteries during operation by pressing the key ***BATTERY CHANGE***. The effect of such action is to shift the supply power for the stimulator from the main (two AA size) to the stand-by (three auxiliary) batteries for a period of 120 seconds. For the replacement of the main and stand-by batteries, see the relevant paragraph of this manual.

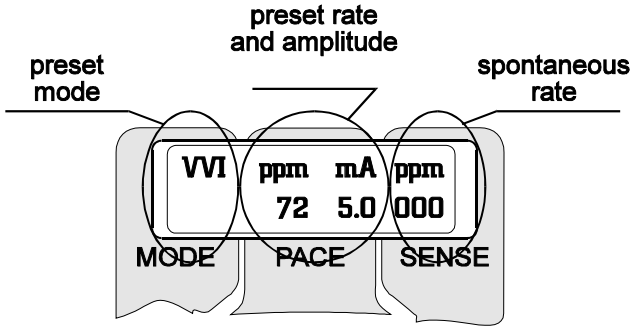
After replacing the batteries, the return to the main supply is made either by waiting for the remaining time to elapse, or by pressing ***BATTERY CHANGE*** for a few seconds.

CAUTION !

Pay much attention to the polarity of batteries upon their insertion. The stimulator is protected against damages caused by improper polarity. However, in case of replacement during the stimulation, the unit would be turned off upon resuming power from the main batteries.

Provision is also made for illuminating the display by means of the key ***LIGHT***, in case the unit is used under poor light conditions.

The LCD display allows two lines of 16 characters each to be visualised. As illustrated in the figure below, these lines report both the stimulation parameters and the data relevant to the Patient's spontaneous activity:



The field referring to the operating mode may be S-BY, VVI or V00. When in the V00 mode only, the program ***burst x4*** is activated it will cause **x4** to appear on the second line of the display, while program ***ramp*** ▼ will show **Ramp** on the same line.

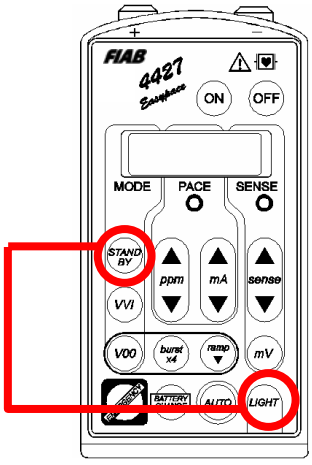
The set values for the frequency and amplitude of the stimulating current are indicated in the middle of the display under the symbol **ppm** and under **mA**, **respectively**.

The last field, visible only in STAND-BY and VVI modes, refers to the spontaneous rate and to the sensitivity threshold. In case of spontaneous activity capture (signalled by a blinking of the green LED) the corresponding rate will be displayed under the symbol **ppm**. Pressing the ***mV*** key will cause the set threshold to be indicated in mV.

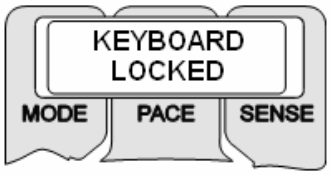
NOTE: In order to save the battery life, under normal operating modes (V00 and VVI), the display is made to go off after 20 seconds from the last key-pressure. The display will be on again following a pressure of any key.

8.3. Keyboard lock

Apart from using the transparent cover, another function is also available which allows for locking the emission of commands from the keyboard in order to prevent accidental modifications to the parameters or involuntary activation of other functions.
This function is activated by pressing both the "***STAND BY***" and "**LIGHT**" keys together for several seconds.



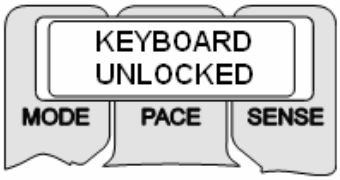
When the keyboard lock function is activated, the message "***KEYBOARD LOCKED***" appears on the display and disappears after 3 seconds.



From this moment all the function keys will be inhibited, with the exception of "***EMERGENCY***", "***LIGHT***" and "***OFF***". The device will show the operating parameters on the display and the keyboard locking status will be shown with the message "**KEYBOARD LOCKED**" every time one of the locked keys is pressed.
In the case of the display being turned off (cf. **NOTE** in paragraph 8.2), whenever any of the keys are pressed, the operating parameters will be displayed once again, and by pressing the key once more the message "**KEYBOARD LOCKED**" will appear.

When the "***EMERGENCY***" key is pressed, the asynchronous stimulation will immediately be activated with the default parameters set (72 ppm – 20 mA), even when the keyboard is locked. It will be necessary to unlock the keyboard if any of these parameters need to be changed.

To unlock the keyboard press the combination "***STAND BY***" and "***LIGHT***" again until the message "***KEYBOARD UNLOCKED***" appears on the display.



A quick reference about keyboard lock / unlock function is provided on the back side of the device.

9. OPERATING MODES

Described in the next chapter are the three modes - with relevant options - in which the *4427 Easypace* is able to operate.

9.1. STAND-BY mode

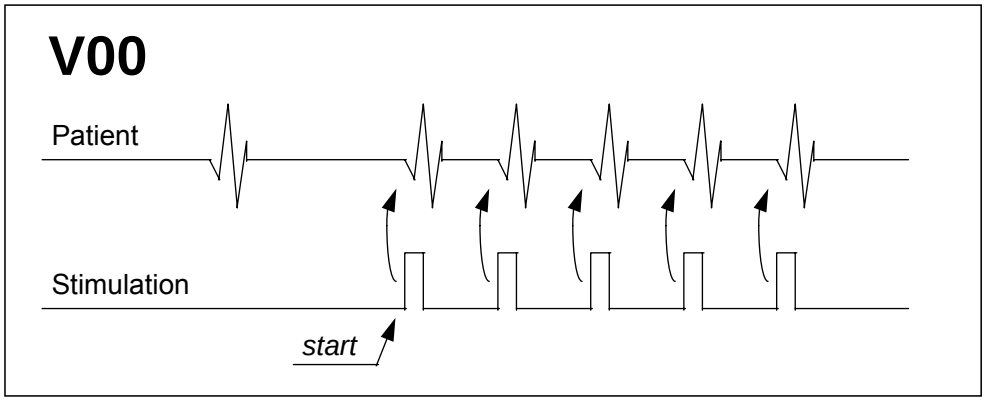
The STAND-BY mode is intended for setting stimulation and sense parameters under no-stimulation condition. This is the operational configuration obtained upon completion of the self-test procedure following the unit's power-on.
Preset values are:

- frequency *72 ppm;*
- current *10 mA;*
- sense threshold *1 mV.*

Afterwards, the mode may be used for the temporary breaking off of the stimulation without loosing the parameter values being set.

9.2. V00 (A00), BURST x4 and DECREASING RAMP mode

V00 - This asynchronous stimulation function allows a pacing to be set independent of the presence of a spontaneous activity, as shown in the figure below:

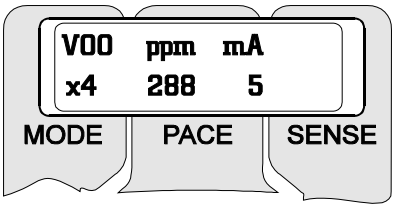


The stimulation is started by simply acting on the ***V00*** key and is made to terminate by pressing (for 1÷2 seconds) the ***STAND BY*** key. The stimulation is instead shifted to the synchronous mode by pressing ***VVI***.
The amplitude and rate of the stimuli can be modified at any moment without interrupting the stimulation. The corrected value of the modified parameter is constantly indicated on the display.

The stimulus emission is signalled by a blinking of the red LED ***PACE***, and takes place only if the set amplitude is other than 0 mA. The efficacy of the stimulation can be checked by using a normal monitor for ECG signals. In case the stimulation has no effect, increase the stimulus amplitude or check for the correct positioning of the electrode.

As under all the other stimulation modes, 20 seconds after no key has been pressed the display goes off to prolong the life of the batteries but the stimulation at the set rate can still be monitored by the blinking of the LED ***PACE***. Pressing any key will cause the display to be on again.

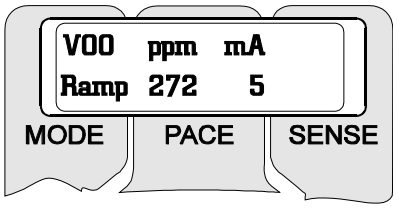
BURST - The burst function, which is activated by pressing at the same time **V00** + ***burst x4***, is selected for generating an asynchronous stimulation at a rate four times the set one and which lasts as long as this keys is pressed.



The display appears as shown in the figure on the left (in case of a set rate of 72 ppm).

Releasing the ***burst x4*** or **V00** key, causes the stimulation to return to the previous rate values.

DECREASING RAMP - The decreasing ramp function, which is activated by pressing **V00** + ***ramp*** ▼ at the same time, is selected for generating an asynchronous stimulation at a rate which decreases starting from a value four times the set one. The 8 ppm decrement of the stimulation rate is 8 ppm after every stimulus and the actual value, updated all the time, is indicated on the display (which, in the illustrated example, refers to a set rate of 72 ppm with updated value after 2 stimuli - at 288 and 280 ppm).



The ramp terminates at the originally set rate and the stimulation goes on at such rate.

Again, with the release of the ***ramp*** ▼ or **V00** key, the stimulation is resumed at the previous rate values.

CAUTION !

The stimulation in the V00 mode, may interfere with the spontaneous cardiac activity of the Patient because of lack of synchronism. It is therefore recommended in case of a total absence of spontaneous activity.

The use of asynchronous modes RAMP and BURST x4 is fundamentally recommended for atrial tachyarrhythmia treatment. These modes can be used, ***only after physician's judgment****, in case of ventricular tachyarrhythmia. During this procedure it is recommended to have a defibrillator at hand when using the heart stimulator.*

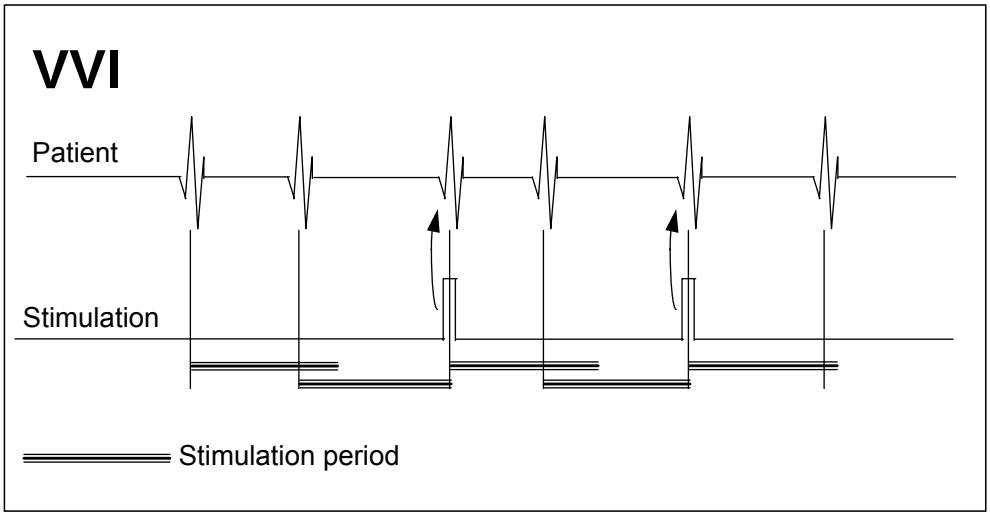
CAUTION !

It is crucial to check the efficacy of the stimulation and the correct setting of pace parameters through an ECG monitor.

In case of a prolonged use of the stimulator, a periodic check by the doctor, to assess the constant correctness of such parameters, is necessary.

9.3. VVI mode (AAI ref. *(*)* table § 6 - TECHNICAL FEATURES)

This is a demand function which enables the unit to intervene only in case the spontaneous rate is lower than the one set by keys ***ppm*** ▲ and ▼, as shown in the figure below:



External stimulator *4427 Easypace* acts as a common, implantable pacemaker with a basic period equivalent to the escape interval (that is, with no hysteresis).

For a correct synchronism function it is necessary to make an accurate adjustment of the unit's sensitivity threshold by acting on keys ***sense*** ▲ and ▼ as described above. Proceed as follows: starting from a setting with a high value of sense (several sense bars switched on) and a safe capture, slowly decrease such setting by checking the synchronisation green LED. After reaching the minimum value at which this synchronisation is maintained, increase by approximately two bars to allow for some margin.

CAUTION !

A correct setting of the sense threshold is crucial for a proper operation in VVI mode.

Too high a value of such threshold, may give rise to capture failure and consequent, unnecessary and potentially dangerous stimulation.

Vice versa, a threshold too low is not to be recommended as minor activities or simple disturbances may be interpreted as cardiac activities and cause stimulation inhibition.

Also in this operating mode, the stimulation starts as soon as the mode is activated by a pressure on the ***VVI*** key and terminates when exiting the same mode by a prolonged pressure on the ***STAND BY*** *key*.

As indicated above, shifting to asynchronous stimulation, and adjustments of rate and amplitude of the stimulus, are possible without interrupting the stimulation.

The stimulator activity is indicated by a blinking of the LED as follows:

- red LED - stimulus emission (only if the amplitude is other than 0 mA);
- green LED - spontaneous beat and inhibition of stimulation.

In case of inefficient stimulation - as verified with the aid of an ECG monitor - increase the amplitude of the stimulus or check for the correct positioning of the electrode.

Also in this mode the display is turned off, in order to prolong the battery life, if no keys have been pressed for 20 seconds. The stimulator activity can still be checked by the blinking of key ***PACE*** or ***SENSE***. Pressing any key will cause the display to be switched on again.

CAUTION !

It is indispensable to check the efficacy of the stimulation and the correct setting of pace and sense parameters by means of an ECG monitor.
In case of prolonged use of the stimulator, doctor should check periodically the device, to assess the constant correctness of these parameters.

9.4. EMERGENCY mode

It is possible to generate an immediately asynchronous stimulation (both during synchronous mode and in STAND-BY mode), set up with safe parameters (rate: 72 ppm; amplitude: 20 mA), pressing the ***EMERGENCY*** key at any moment.

This key is provided for safety reasons and for allowing the physician to carry out rapid and safe stimulation in the case of an emergency. The amplitude of 20 mA, which is more than sufficient in the event of endocavitary stimulation, may not be sufficient in the case of epimiocardiac stimulation, in cases with a particularly high threshold. By using the specific key **mA** the value may however be increased until a stable harnessing value is obtained.

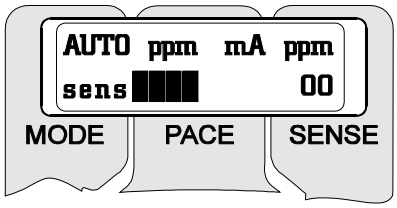
The operating mode is an asynchronous V00 (as indicated on the display), it is possible to stop the stimulation by pressing *(for 1÷2 seconds)* ***STAND-BY***, then to shift the synchronous stimulation by pressing ***VVI*** and to adjust the parameters without interrupting the stimulation itself.

Also in this case the display will be turned off after 20 seconds from the last pressure of a key.

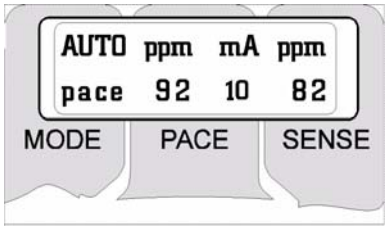
9.5. AUTO mode

The operating mode “pacing”, which is activated by pressing key ***AUTO***, is the synchronous VVI but, in this case, a preventive setting of all the necessary parameters is not necessary, as this is accomplished by the stimulator itself.
The key ***AUTO*** is active only in the STAND-BY mode and has no effect when pressed in the V00 mode.
The algorithm for the automatic setting of sense and pace parameters generates the following sequence:

1. setting the sensitivity threshold by rapid adjusting steps. The display appears as shown in the figure on the right. In case of no spontaneous impulse for about 2 seconds, the *4427 Easypace* sets itself to 72 ppm, 20 mA and 1.1 mV threshold, thereby ending the program.



2. Temporary setting the stimulation rate (based on the impulses detected during the sensitivity threshold setting) as follows:
   - < 50 ppm ⇒ 56 ppm
   - 50÷110 ppm ⇒ spontaneous rate increased by 1/8 (e.g.:72 ppm becoming 81 ppm)
   - >110 ppm ⇒ stimulation with safety parameters (VVI, 72 ppm, 20 mA, 1.1 mV of sense)
3. stimulating in VVI mode with 10 mA amplitude; subsequently adjusting the amplitude with 20 or 30 mA values depending or not on the capture of the cardiac activity. During the stages indicated on points 3 and 4, the display appears as in the figure on the right.



4. Setting of the stimulation rate (as far as the 50÷100 ppm range of spontaneous rates is concerned) to a value of 1/8 lower than the spontaneous one being detected (e.g.: spontaneous 72 ppm becoming 63 ppm).
   The setting of the rate is performed in such a sequence (first $rate_{spont}$ + 1/8, then $rate_{spont}$ - 1/8) as to ensure the capture while assessing the stimulation threshold and, afterwards, to set a surveillance value.

Upon completion of the automatic settings, the operating mode is a synchronous VVI (as shown on the display) which, accordingly, allows either to stop the stimulation by pressing (for 1÷2 seconds*)* ***STAND-BY***, or to shift to the asynchronous stimulation by pressing ***V00*** or to adjust all the parameters without interrupting the stimulation itself.

At any moment, during the program, it is possible to interrupt the automatic settings and start the manual stimulation by pressing the relevant keys ***VVI***, ***V00*** or ***EMERGENCY***.

Also in this case the display will be turned off after 20 seconds from the last pressure of a key.

CAUTION !

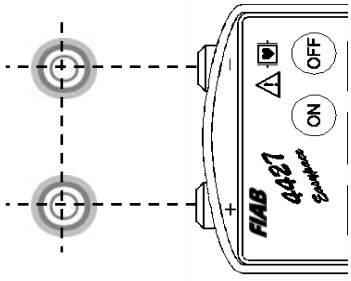
The algorithm for the automatic setting of stimulation and sensitivity parameters is designed to face most of the possible rhythm phatology. However, it is recommended not to use it with Patients exhibiting marked arrhythmia because of possible uncertain results.

In any case, it is indispensable that the doctor – who is the only person responsible for the procedure - will carry out a final check on the set values.

10. CONNECTION TO THE PATIENT AND INSTRUCTIONS FOR USE

10.1. Connection to the Patient

The *4427 Easypace* comes with protected outlet sockets, the geometry of which is illustrated in the following figure, and is capable of accepting 2 mm pins, both protected and unprotected.



To avoid any problems in connecting up to the Patient, it is necessary to make sure that the protected pins of the electrocatheters used have a geometry compatible with that of the outlet sockets of the device so that their insertion can be carried out with ease. They must also guarantee good electrical connection and mechanical stability.

The protected pins of the electrocatheter or extension cable must have the following characteristics:

- An insulator with a minimum internal diameter of 4,5 mm and a maximum external diameter of 6,2 mm. (recommended thickness 0,8 mm).
- An internal contact with a diameter of 2mm.

The electrocatheters manufactured by *FIAB* that guarantee full compatibility with the outlet sockets of the 4427 device belong to the "Spike-S" and "Spike-LCS" families.

In the event of having to make a connection between an epicardium needle it will be necessary to use the sterile bipolar cable F7818/30 for heart surgery that is fitted with screw-on sockets.

WARNING !

Use of the F7818/30 bipolar cable for heart surgery

1. *The cable is fitted with pints at one end that are easy to insert into the outlet sockets of the 4427 device. The only precaution to be taken is that of observing the correct insertion in to the matching colours. At the other end there are two screw-on sockets, one red and the other black, for housing the Patient connection terminals. In order to ensure that the procedure is performed in maximum safety it is recommended making the connection of the Patient terminals to the cable sockets before connecting the corresponding pins to the stimulator. Always observe the recommendation in point three above.*
2. *The cable sockets are designed to receive terminals with a diameter varying from a minimum of 0.5 mm to a maximum of 2.0 mm. For an ideal coupling it is necessary for the jaw openings of the socket to have the same or a slightly larger diameter than that of the terminal to be inserted. In order to adjust the diameter of the opening remember that it can be increased (up to 2 mm) by rotating the socket protection in an anticlockwise direction, and decreased (down to 0.5 mm) by rotating in the opposite direction.*
3. *The epicardium needle usually has a diameter of approximately 1 mm. Before inserting it into the socket it is recommended checking that its opening has been suitably adjusted. Moreover, in order not to compromise the efficacy of the locking system, it is recommended inserting the needle by keeping it aligned with the axis of the socket and subsequently tightening it securely in order to guarantee an efficacious and mechanically sure electrical contract. Finally, it is recommended protecting the residual metallic parts of the needle that protrude from the insulated lining of the socket with the special hood, if foreseen, supplied with the needle used, like for example with the FIAB MyopaceT, TZ and P epicardium needles.*

10.2. Instructions

A correct use of the stimulator *4427 Easypace* requires the following instructions to be strictly observed:

1. Always replace the main batteries before re-using the stimulator (cf. 11.5), especially for an extended period of time. This operation may be suppressed only if you are certain of the optimal level of the battery charge and in case of a very short period of utilisation (for example as stand-by for replacement of a pacemaker).
2. Connect the Patient to an ECG monitor for his/her continuous monitoring. If possible, keep a defibrillator ready for use in the vicinity of the Patient.
3. Check the compatibility of the pins of the electrocatheter to be used as described above. Before commencing the clinical procedure it is good practice to check that the sockets of the device ensure a correct hold and good electrical contact.
4. Turn on the stimulator and wait for the outcome of the self-test (cf. 11.1). In case of positive result, the unit will set itself to STAND-BY MODE with 72 ppm, 10 mA and 1.0 mV threshold. A detailed description of the self-test procedure is dealt with later on in this manual.
5. Insert the pins of the electrocatheter as far as they will go, observing the correct polarity (the indifferent, or positive pole of the stimulator is the one corresponding to the red socket, while the active, or negative pole is the one corresponding to the black socket; the shape of the stimulation is negative rectangular).
6. If it is necessary to use the F7817/30 extension cable, first insert its pins into the respective sockets of the stimulator as far as they will go, and only after this, introduce the pins of the electrocatheter into the sockets of the extension cable itself, observing the polarity.
7. If it is necessary to use the F7818/30 heart surgery cable, first make the connection with the Patient and then introduce the pins of the cable itself into the respective sockets of the stimulator.
8. After having made the connection use the specific elastic strips supplied in order to attach the stimulator to the Patient’s arm (if required by the specific clinical protocol), and for greater safety take all measures for ensuring that the pins will not be accidentally disconnected.
9. Set the pace and sense parameters with precision, as described in this manual. Finally, select the set asynchronous (V00) or synchronous (VVI) mode.

10. Continuously monitor the Patient to change the set values or to put a dislodged catheter in place, as necessary.

> ***CAUTION !***
>
> 
>
> *The lead allows a low-resistance contact with the heart. It is thus indispensable that the catheter sockets be not touched with bare hands nor with metal or wet objects.*

11. SPECIAL SAFETY FUNCTIONS

11.1. SELF-TEST program and error messages

Whenever the *4427 Easypace* is turned on, the controlling microprocessor carries out a fast but complete self-test of it. This includes a check for the correct operation of the CPU, internal and external logic, memory, timer and charge levels of main and stand-by batteries.

Messages on display may be as indicated in the table below:

MESSAGE	MEANING AND ACTION
TEST IN PROGRESS	Test is under way. Wait for completion thereof
TEST OK	Positive test. The unit is ready for use
TEST FAIL N.#	Test failed. The unit is out of order. Do not use it and contact *FIAB* Technical Service
MAIN BATTERY LOW	Insufficient charge of the main batteries. Replacement of batteries is indispensable before proceeding with normal activity
STAND-BY BATTERY LOW	Insufficient level of stand-by batteries. Replacement of main batteries is inhibited. After a few seconds, necessary to read the message, the normal activity can be resumed.

Should the unit be turned off after a MAIN BATTERY LOW message, a suitable circuit would prevent the unit to be turned on afterwards unless the same batteries are replaced.

11.2. Checking the lead connection

The unit is provided with a sentinel circuit intended to check the connection or disconnection between the catheter and the *4427 Easypace*, by measuring the voltage at the terminals of the stimulation sockets. Such measurement is carried out only for impulses with amplitude in the range of 2.8 to 20 mA.

Any dangerous situation is signalled by a “beep” sound at intervals of 2 seconds, and by a flashing **DANG** message on display.

CAUTION !

The testing circuit which verifies the catheter connection is not able to detect a poor contact with the heart wall, which is cause for inefficient stimulation .
It is thus indispensable to carry out periodic checks of the stimulation threshold in case of prolonged use of the stimulator.

11.3. Checking the maximum stimulation rate

The stimulator has been designed to provide rates - the period of which is controlled by a quartz-microprocessor - whose maximum value is 180 ppm.

In case of microprocessor failure - and in order to avoid any dangerous high-rate stimulation - provision has been made for a suitable anti run-away circuit, disengaged by the microprocessor and calibrated to a rate of 200 ppm, capable of limiting the stimulation rate.

The circuit is automatically cut off at a pressure of keys ***burst x4*** and ***ramp*** ▼, to prevent the high rates that can be reached in these modes of operation.

11.4. Protection against electro-magnetic interferences

The *4427 Easypace* is provided of an embedded Patient's spontaneous heart activity detection circuit calibrated on the ventricular impulse. However, owing to the high sensitivity of the stimulator and to the interference which, in some cases, may reach a remarkable level, the rare possibility exist that some electromagnetic interferences, with morphological characteristics as those of cardiac signals, could be considered as spontaneous heart activity, with consequent unwanted inhibition of the stimulation.

In order to reduce such eventuality when operating in the VVI mode, the stimulator is provided with a program performing an automatic check of noise presence with a rate higher than the device measurable maximum frequency. Therefore impulses with rate higher than 300 ppm (impulses at intervals of less than 200 ms) are considered interference.

In such case the stimulation mode automatically shifts from VVI mode to V00 mode with the parameters of stimulation set up before. The User is warned of electromagnetic interference by means of two signals, acoustic (a “beep” every 5 seconds) and visual (indication of EMI on the display).

Consequently impulses with rate below 300 ppm (periods exceeding 200 ms), being in the frequency range of the heart spontaneous activity, cannot be interpreted as noises, Therefore the solution in these cases is to remove the source of the interference or shift to the V00 mode.

Before beginning the procedure it is advisable to:

- check the contact between electrocatheter and the sockets;
- check the state of the electrocatheter itself;
- optimize the device sensibility in order to assure a steady harnessing value of spontaneous heart activity and an effective noise rejection;
- make sure that no electromagnetic fields or interferences are present in the environment where the 4427 device (cf. § 2.1 - **Electromagnetic immunity** - note (1) **WARNING**!).

11.5. Checking the charge and replacing the batteries

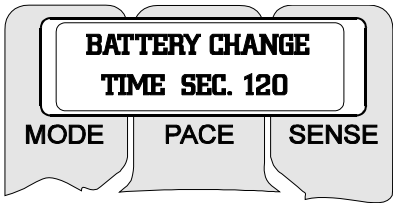
Assessment of the main and stand-by batteries charge is made during the self-test (see the relevant paragraph) and during normal operation.

Under normal operating conditions, with fresh alkaline batteries, the stimulator has an autonomy of at least 10 days. By the moment the microprocessor detects an insufficient charge level of the main batteries, the remaining autonomy is at least 12 hours, during which time it is possible to replace the main batteries as described here below. The insufficient charge level is signalled both by a “beep” sound, at intervals of 4 minutes, and by the message “LOWB” appearing on the display.

When acting on ***BATTERY CHANGE*** in order to activate a replacement of the main batteries, the microprocessor - before shifting the supply to the stand-by batteries - carries out an instantaneous test on the charge level of the latter and, if found insufficient -

inhibits the replacement of the main batteries and prompts the User with the message "BATTERY CHANGE NOT POSSIBLE".

As indicated above, the replacement of the batteries during the unit's operation is made by pressing the ***BATTERY CHANGE*** key. This allows shifting the stimulator supply from the main (two AA-size) to stand-by (three auxiliary) batteries for 120 seconds. The display appears as in the figure on the left with updated information, given every second, about the time left over for the operation, while the normal stimulation activity goes on according to the established program.



During the 120 seconds available, it is easy to remove the sliding side cover, take out and replace the main batteries by respecting the polarity (indicated both on the batteries seat and on the cover's contacts) and re-close the cover.

During the 120 seconds it is easy to take off the rubber cover protection and the side emergency battery cover. Take off and change STILO battery respecting polarity indicated both on batteries housing and on electric contact on the cover. After replacing of battery, close the slide cover and insert the rubber cover protection to his original position.

After replacing the batteries, the return to the main supply is made either by waiting for the remaining time to elapse, or by pressing ***BATTERY CHANGE*** for a few seconds.

CAUTION !

Pay much attention to the polarity of batteries upon their insertion. The stimulator is protected against damages caused by improper polarity. However, when the replacement is made during the stimulation, the unit would be turned off upon resuming power from the main batteries.

It is recommended to use alkaline batteries (as indicated in § 6) unless the autonomy could be lower than indicated.

The replacement of the stand-by batteries must be made by skilled personnel, explicitly authorized by ***FIAB***, and never during the use of the unit.

11.6. Protecting against defibrillator discharges

The stimulator is provided with a protection circuit able to fend off defibrillator discharges. The recovery time after defibrillation discharge is about 10 seconds.

CAUTION!

The stimulator is provided with a low-impedance sense circuit which limits the applicable protection.

It is therefore recommended, whenever possible, to disconnect the lead from the unit before defibrillating. Otherwise, carefully check for the proper operation of the defibrillator and always take a second defibrillator at easy reach for a prompt substitution, as necessary.

12. MAINTENANCE

12.1. Controls

It is advisable a periodic check by the User on the device functions, its accessories and the state of connections. If any failures or bad state of connections are detected, do not use the device but contact ***FIAB***. Moreover it is necessary having the 4427 device checked at least once a year by our measuring laboratory. Our technicians will do the following actions:

- replacing stand-by batteries;
- functioning's check;
- electrical safety test;
- certified final inspection.

12.2. Cleaning

The User should take care of the cleaning of the unit to meet ordinary sanitary requirements. For the cleaning of the external parts of the unit and accessories, it is recommended using ethyl alcohol or Citrosil®. Belts can be washed with water and soap at a temperature of 40 °C.

For the cleaning of the parts in contact with the Patient, reference is made to the relevant instructions.

Dear Customer,

*Thank you for having placed your trust in **FIAB** by purchasing this product. Together with our technical staff we have taken every measure to provide you with a quality device. Before leaving the factory all testing has been conducted that is necessary for guaranteeing full compliance of the product with the standards foreseen by the regulations in force. Enclosed with the instructions you will also find the Compliance Certificate and the results of the electrical safety test which we invite you to keep with care. **FIAB** subjects all its products to strict quality and safety tests, however if in spite of all precautions taken your device should present any defects, please directly contact our Technical Assistance Department.*

TERMS OF THE GUARANTEE

***FIAB** guarantees that this product is free from material and manufacturing defects. This guarantee shall be valid for 24 months from the date of purchase. Should any defects be detected in the device over this period, **FIAB** shall carry out repairs free of charge according to the conditions illustrated below.*

***FIAB** reserves the right to replace the defective device free of charge with another device with the same or superior features.*

*It is recommended promptly notifying the **FIAB** Quality Assurance Department of any signs of malfunctioning, defects or accidents occurring to this device.*

GUARANTEE CONDITIONS

The guarantee, which is in force from the purchasing date, shall be acknowledged if the guarantee certificate contained in the packaging is correctly filled in and sent to our company within 30 days from the purchasing date.

*In the event of failure to forward the certificate within the above-mentioned term, the Customer must be able to demonstrate to **FIAB**, with suitable and verifiable documentation (copy of the invoice, etc.), that the device is still covered by the guarantee.*

Any defects detected must be communicated to FIAB within 60 days of being discovered.

*The guarantee shall be invalidated in the event of technical intervention by personnel not explicitly authorised by **FIAB** and/or tampering with the device.*

EXCLUSIONS

*The guarantee does not cover the following: periodic servicing, maintenance, repairs or replacements of parts subjected to normal wear and tear (like batteries, displays, etc.) – delivery and transport costs, damage caused by transport of the product from the Customer's address to the **FIAB** assistance centre and vice-versa – damage deriving from negligence and incorrect use – causes not attributable to **FIAB**, like for example: accidents, acts of God, natural calamities (lightning, floods, earthquakes), fires or public disorder.*

Reimbursement of damage, even economic, deriving from the failure of this device to function, is explicitly excluded.

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