



APC Medical Ltd.
MODEL 4170 BEDSIDE™
SINGLE-CHAMBER
EXTERNAL PULSE GENERATOR

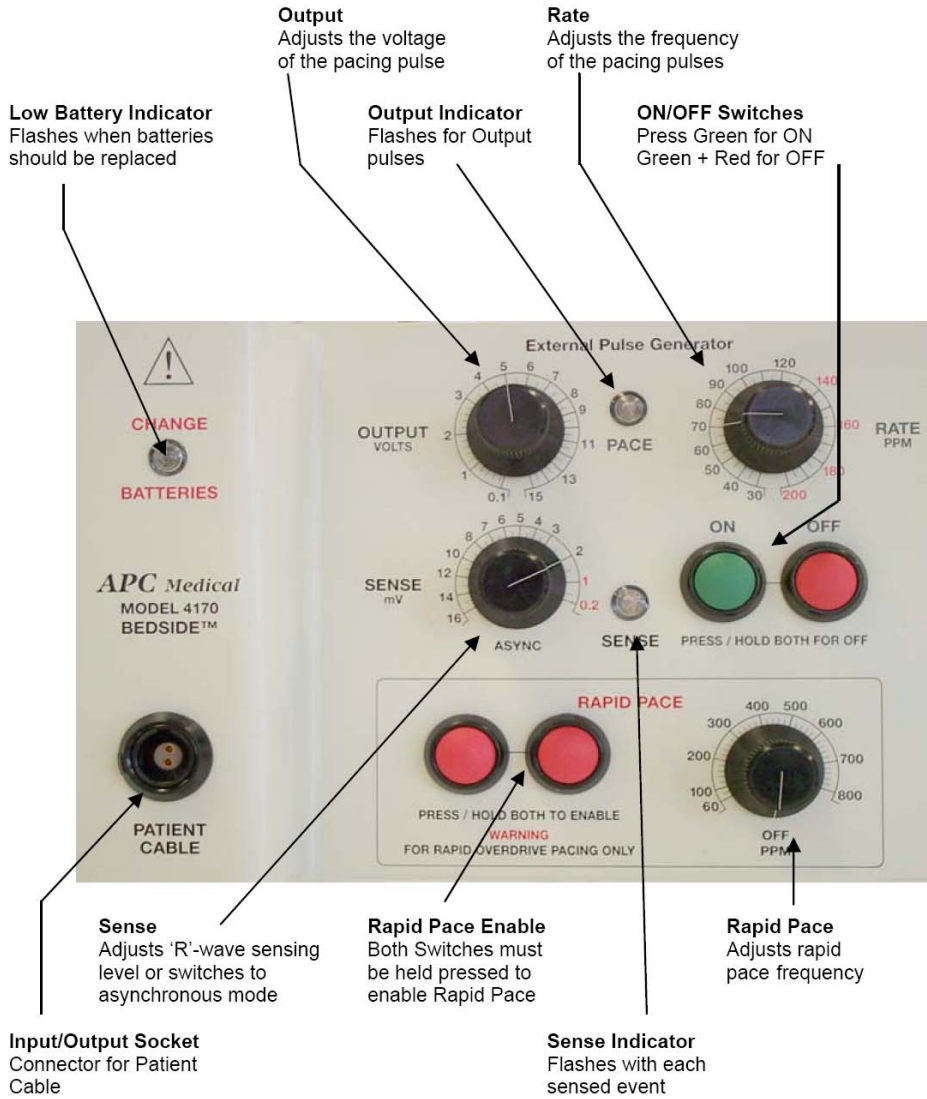


INSTRUCTION MANUAL

CAUTION: Federal Law (U.S.A) restricts
this device to use by or on the order
of a physician

P/N 03-016-001 Rev 2

© 2003 Pace Medical, Inc.



Key to BEDSIDE External Pulse Generator Controls and Features
Figure 1

Contents

1.	System familiarization	4
1.1	Introduction	4
1.2	Parts supplied	5
1.3	Specifications	6
1.4	Indications and contraindications	7
2.	Features and controls	8
2.1	Function indicators	8
2.1.1	Pacing	8
2.1.2	Sensing	8
2.1.3	Battery replacement	8
2.1.4	Interference	8
2.2	Controls	9
2.2.1	Sensitivity	9
2.2.2	Output	9
2.2.3	Rate	9
2.2.4	On/Off and Off Keys	9
2.2.5	Rapid stimulation	9
2.3	Collet terminals	9
3.	Operating instructions	10
3.1	Lead placement	10
3.2	Connecting the lead to the Bedside using the extension cable	10
3.3	Determination of pacing threshold	11
3.4	Determination of sensing threshold	12
4.	Precautions	13
5.	Equipment care	14
6.	Troubleshooting	15
6.1	Interference	15
6.2	High rate protection	15
6.3	Battery depletion and replacement	16
6.4	Miscellaneous clinical problems	17
7.	Accessories / Parts	18
8.	Miscellaneous	19
8.1	Additional information	19
8.2	Limited warranty	20
9.	Storage	21
10.	Care of the extension cable	22
11.	Classifications / certifications	23

1. System Familiarization

1.1 Introduction

The Model 4170 Bedside External Pulse Generator is a temporary cardiac pacemaker with internal power source, which offers short-term pacing support for a patient with myocardial infarction or temporary heart block.

The Model 4170 Bedside may be operated in either the R-wave inhibited (demand) or asynchronous mode with rate continuously variable within the range of 30 - 200 ppm. It also has rapid stimulation capability up to a rate of 800 ppm accessible from separate controls. **Activation of rapid stimulation will automatically change the unit to an asynchronous mode of operation, unless the sensitivity control has previously been switched to the ASYNCH position.**

WARNING: RAPID STIMULATION CAPABILITY IS INTENDED FOR SHORT-TERM, HIGH RATE ATRIAL PACING ONLY.
--

The output and sensitivity control scales are expanded at the lower settings to facilitate approximate threshold measurement.

In the presence of an excessive level of electrical interference (EMI), the pulse generator will automatically switch from its normal demand mode of operation to a temporary asynchronous pacing mode at the selected pacing rate. Normal function is resumed when the level of interference is reduced below the level of detection or stops completely.

Should an electronic component failure occur in the unit, the rate is limited to 285ppm in the Model 4170. Rate limiting is disabled during rapid stimulation.

1.2 Parts supplied

BEDSIDE External Pulse Generator

Two 9 volt alkaline batteries (IEC Type 6LR61)

Instruction manual

Extension cable

1.3 Specifications (@ 20°C ± 2°C and 500 Ohms ± 1%)

Mode of Operation	Demand or Asynchronous
Voltage output (continuously variable) Accuracy ± 10% or 0.05V	0.1 - 15 V
Pulse rate (continuously variable) Accuracy ± 7.5%	30 - 200 ppm
Rapid Stimulation (continuously variable) Accuracy ± 7.5%	60 - 800 ppm
Pulse duration (fixed) Accuracy ± 10%	1.8 ms
Interference rate (asynchronous)	Selected rate
Inhibit sensitivity (continuously variable) Accuracy ± 20%	0.2 to 16 mV
Refractory period Accuracy ± 10%	250 ms
Dimensions (millimeters)	178 x 137 x 112
Weight (with two batteries)	1.6kg

Recommended conditions for:

Operation: +10°C (+50°F) to +40°C (+104°F); RH 30% to 70%

Transport/Storage: -20°C (-4°F) to +60°C (+140°F); RH less than 95%

Exceeding the transport and storage temperature range may result in damage to a Model 4170 Bedside External Pulse Generator.

1.4 Indications and Contraindications

The Bedside External Pulse Generator may be used in any clinical situation in which the use of a temporary pacemaker on a patient provides therapeutic or diagnostic value, or serves a prophylactic purpose. Specifically, indications for temporary pacemakers include, but are not limited to, the following: intermittent or complete heart block associated with asystole or bradycardia, symptomatic sinus bradycardia, surgically-induced heart block and heart block accompanying an acute myocardial infarction.

There are no known contraindications to the use of temporary cardiac pacing as a therapeutic or prophylactic modality. Nevertheless, certain relative contraindications may exist in any given patient. Among others, the application of asynchronous pacing in competition with an intrinsic rhythm may provoke arrhythmias in electrically unstable individuals.

CAUTION: When clinically indicated, supplemental monitoring of a patient should be considered during temporary cardiac pacing.

WARNINGS

A Bedside External Pulse Generator which has been subjected to conditions of transport or storage at temperatures below 10°C (50°F) or above 40°C (104°F), should be allowed to sit at room temperature (about 20°C or 68°F) for an hour before being placed in use on a patient.

Before handling a Bedside external pulse generator, patient cable(s), or indwelling lead(s), steps should be taken to equalize the electrostatic potential between the user and the patient; e.g. by touching the patient at a site remote to the pacing lead.

Continuous ECG and blood pressure monitoring is necessary prior to pacing, during any pacing procedure, and in the immediate post-operative phase. Equipment for defibrillation, I.V. infusion, endotracheal intubation and oxygen administration must be immediately available.

2. Features and controls

2.1 Function indicators

Light Emitting Diodes (LEDs) are used to indicate pacing, sensing, when the battery should be replaced, and the presence of detected interference.

2.1.1 Pacing

The amber/green Pace LED flashes once for every pulse delivered by the Bedside.

2.1.2 Sensing

The amber/green Sense LED flashes once for every sensed spontaneous R-wave whenever the sensitivity control is set to other than the ASYNCH position.

2.1.3 Battery replacement

The red Battery LED flashes simultaneously with the flashing of the amber/green Sense or Pace LEDs to indicate low battery condition. IN THIS CONDITION, THE UNIT WILL CONTINUE TO PACE NORMALLY, BUT THE BATTERIES SHOULD BE REPLACED AS SOON AS POSSIBLE.

2.1.4 Interference

If the unit is in the presence of detected interference; i.e. a signal repeating more frequently than 10Hz, both the Sense and Pace LEDs will flash. The Sense LED will flash RED in response to the interference signal. The Pace LED is flashing to indicate continued pacing in an asynchronous mode at the rate indicated by the rate setting.

2.2 Controls

All controls are located on the face of the Bedside and are protected by a transparent cover.

2.2.1 Sensitivity

This control adjusts the R-wave sensing level. It is continuously variable from 0.2 to 16 mV. There is also an ASYNCH position at the full counter-clockwise detent. Selection of the ASYNCH position will incapacitate sensing.

2.2.2 Output

This control adjusts the amplitude of the pacing pulse over the calibrated range of 0.1 to 15 volts. The Bedside has a constant voltage output.

2.2.3 Rate

This control adjusts the frequency at which pacing pulses are generated over the continuously variable range of 30 to 200 ppm. There are also separate rapid stimulation controls for high rate atrial pacing only.

2.2.4 On/Off and Off switches

Pressing the On/Off switch will turn the Bedside on and pressing the On/Off and Off switches simultaneously will turn it off.

2.2.5 Rapid stimulation

An independent set of controls is provided for implementation of this junction. Select the rate desired with the rate control knob and begin rapid stimulation by pressing the two rapid stimulation activation keys simultaneously.

2.3 Output connector

The Model 4170 is provided with a Redel® P-Series recessed connector port for the attachment of the extension cable. The connector on the extension cable is a recessed pin design which is of a style commonly found on high quality instruments and medical equipment. The port on the Bedside and the connector on the extension cable are keyed to ensure proper orientation.

Avoid contamination of the port or cable connector with blood or other body fluids. If it is necessary to clean the connector, use only isopropyl alcohol. Do not use any other chemical cleaner.

3. Operating instructions

3.1 Lead placement

When positioning the lead in the heart, it is recommended that the intracardiac ECG be monitored so that S-T segment elevation, indicating contact with the myocardium and impaction, can be noted.

WARNING: When handling indwelling leads, the connector pins or exposed metal should not be touched or allowed to come into contact with electrically conductive or wet surfaces.

3.2 Connecting the lead to the Bedside using the extension cable

With the Bedside off, plug the cable connector into the receptacle on the front of the Bedside. The cable connector is keyed and will only insert into the receptacle with proper polarity. On the distal end of the cable are two collet terminals and two 2mm recessed pin sockets. With bipolar, transvenous electrodes or leads where only one electrode is in contact with the myocardium, connect the proximal or skin electrode to the indifferent (+) red terminal and the distal or contacting electrode to the active (-) black terminal (with heartwires in a bipolar configuration, connect one lead to the indifferent (+) red terminal and one lead to the active (-) black terminal). Do not over-tighten the terminal caps. To unplug the extension cable from the Bedside, pull back gently on the connector sleeve of the extension cable to release the locking mechanism.

For transvenous leads having 2mm recessed pin connectors, fully insert each connector pin into its socket, observing polarity. For transvenous leads having exposed male pin connectors, connect to the collet terminals as described above.

CAUTION: Never attempt to connect a cardiac pacing lead or heartwire directly to the connector port of a Bedside. Damage to the contacts within the connector may result. The extension cable must always be used.

3.3 Determination of pacing threshold

With the Bedside on and pacing the patient, set the controls as follows **(taking any special requirements of the patient into account)**:

- a) Set the pulse **rate** control to a value higher than the patient's spontaneous rate.
- b) Set the **output** control to **4V** (higher if needed).
- c) Turn the **sensitivity** control to **2mV** or other setting required by the patient's condition to ensure continuous sensing. The Pace LED will be flashing to show that pacing pulses are being generated at the preset rate.
- d) Turn the **output** control counterclockwise until cardiac stimulation ceases and then slowly turn the control clockwise until pacing resumes. This point is the stimulation threshold.
- e) For reliable capture, increase the **output** control to a value three to four times the stimulation threshold. If necessary, readjust the pulse **rate** control to the minimum pacing rate required for the patient.

3.4 Determination of sensing threshold

This test can only be performed if the patient has an intrinsic rate above the minimum rate of the Bedside (30ppm). To ensure reliable detection of the patient's R-wave, the sensitivity level should be set as follows, **(taking any special requirements of the patient into account)**:

- a) With the Bedside **on**, set the **sensitivity** control to **1 mV** or any lower value which may be required by the patient's condition to ensure continuous sensing.
- b) Set the **rate** control to a value below the patient's spontaneous rate.
- c) Set the **output** control fully counterclockwise to **0.1V**.
- d) Turn the **sensitivity** control counterclockwise until the Sense LED stops flashing (but not into the ASYNCH position). When this occurs, note the sensitivity setting.
- e) For reliable R-wave detection, increase the sensitivity two to three-fold; i.e. if the noted setting determined in d) is **6 mV**, the recommended setting is **2 - 3 mV**.
- f) Increase the pacing **rate** control to the desired level and return the **output** control to its prior setting or three to four times the pacing threshold, as determined in 3.3 e).

4. Precautions

The controls on the Bedside External Pulse Generator should be operated only by qualified medical personnel.

The Bedside is protected from damage caused by defibrillatory discharges, but care should be exercised in the placing of defibrillator paddles well away from the pacing leads.

Great care should be exercised when using diathermy in association with any cardiac pacing system. Adequate monitoring must be used.

Line-powered monitoring equipment should be avoided when pacing, since even minute leakage currents flowing through the heart may cause ventricular fibrillation. If line-powered equipment is used, the manufacturer of the equipment, or person(s) responsible for safety within your organization should be consulted on the safest method of connection.

The Bedside external pulse generator described in this information manual is not waterproof and it must not be immersed in cold sterilizing solutions. Additionally, it must not be sterilized using ethylene oxide, steam autoclaving or gamma irradiation techniques. See section 5.

The Bedside external pulse generator is a life-support device. Section 6.3 of this manual describes the routine for battery replacement. This is the only recommended user-serviceable item. In general, it is recommended that repair operations be performed by the specially-trained, Company technicians

Whenever an extension cable is used, it should be connected to the pulse generator prior to connecting the pacing lead to the extension cable. After making all connections, turn the Model 4170 on. Failure to follow this instruction could result in the delivery of a pacing pulse into the vulnerable portion of the T-wave.

5. Equipment care

A clean, soft cloth moistened with 70% isopropyl alcohol or a dilute solution of a mild, non-abrasive detergent and water may be used to clean the Bedside External Pulse Generator. **A Bedside must NOT be immersed in a cleaning solution.**

The Bedside must not be sterilized by ethylene oxide, steam autoclaving or irradiation.

NOTE: The Bedside and its extension cable should be routinely inspected for signs of physical damage or contamination, particularly damage or contamination that may have a detrimental effect on the electrical isolation properties of these devices. If such damage or contamination is identified, the Bedside should be returned to the Company for repair. The extension cable should be promptly replaced. See sections 7 and 8 of this instruction manual.

6. Troubleshooting

6.1 Interference

The Bedside External Pulse Generator is designed to reject interference frequencies outside of the R-wave bandpass. Detected signals which repeat with a frequency equal to or greater than 10Hz will cause reversion to the interference mode.

When operating in the sensing (demand) mode, an excessive level of electrical interference, for example, from diathermy or microwave ovens, will cause the pulse generator to switch automatically to asynchronous pacing at the rate set on the **rate** control and both the Sense and Pace LEDs will flash. To further emphasize this operation, the color of the Sense LED will change from amber/green to red. Normal function is resumed when the level of interference is sufficiently reduced.

6.2 High rate protection

Should an electronic component failure occur in the unit, the maximum high asynchronous rate is limited to 285 ppm, unless the unit is being operated in its rapid stimulation mode.

6.3 Battery depletion and replacement

All Bedside External Pulse Generators are designed to operate on two 9V alkaline batteries (IEC type 6LR61). Spare batteries should be kept available at all times. It is recommended that new batteries be used with each patient. Two fresh 9V batteries will typically last approximately three weeks. Low battery condition is signaled by a flashing red Low Battery LED during sensing or pacing. **When this occurs, the batteries should be replaced without delay even though the Bedside will continue to operate for at least 24 additional hours.**

Once the Bedside has been operating for a minimum of 10 minutes, it will typically continue to function for 15 seconds after battery removal, if battery replacement is made within 12 hours of the first indication of low battery. This time may be reduced dramatically, if the rate and output settings are at high levels. If replacement is delayed, operating time without batteries will gradually decline. Batteries may also be changed one at a time, thereby lengthening the time available for battery replacement, while continuing pacing support.

In general, however, it is recommended that batteries not be changed while the pulse generator is in use on a patient. By temporarily substituting another unit, a battery change can be carried out without risk that a patient may accidentally be left without pacing support; e.g. if a battery is dropped.

To change the batteries, open the battery compartment and remove and replace each battery, observing polarity. Ensure that the contact terminals are clean. As an additional safety precaution, the battery and contact terminals should be checked for corrosion at regular intervals. Close the battery compartment cover securely.

6.4 Miscellaneous clinical problems

Additional minor device operating problems: A failure to tighten the cable terminals adequately or to properly insert the cable connector into the Bedside may lead to intermittent pacing and/or sensing. Improperly set output and/or sensitivity controls may lead to the appearance of intermittent or complete failure to pace or sense. Inappropriate asynchronous operation may be due entirely to the sensitivity control being turned to the ASYNCH position, or as noted earlier, interference from EMI.

These normal and minor pacing complications should be considered prior to concluding that a more serious device malfunction is occurring. Repair, if needed, should be referred to a qualified biomedical technician or equivalent, or to the Company.

7. Accessories / Parts

Accessories supplied with a Bedside External Pulse Generator are available from the Company individually. No catalog number is required. A simple description of the accessory needed is usually adequate.

Similarly, certain parts of a Bedside itself; for example, the clear control panel cover, may be ordered by post or by calling the company at the appropriate location listed on the following page.

Model 5265 - Re-sterilizable extension cable, 2.5 meters long, universal patient connector.

8. Miscellaneous

8.1 Additional information

For further information about the Model 4170 Bedside External Pulse Generator and other pacing products available, contact:

APC MEDICAL LTD.
68-70 Tewin Road
Welwyn Garden City
Herts. AL7 1BD
England
Tel.: (01707) 327641
Fax: (01707) 333117

or

PACE MEDICAL, INC.
391 Totten Pond Road
Waltham, MA 02451
U.S.A.
Tel.: (781) 890-5656
Fax: (781) 890-4894

8.2 Limited warranty for Pace Medical, Inc. (the Company) BEDSIDE external pulse generators

The Company, warrants the Bedside External Pulse Generator to be free from defects in materials and workmanship for one year from the date of delivery when operated in accordance with the written Operating instructions which accompany the equipment.

This Warranty extends to the original purchaser of the equipment only and not to any subsequent purchaser.

The Company's obligation under this Warranty shall be limited to repair or replacement of part or parts found to be defective during the Warranty period. All expendable items, such as Extension Cables, and Batteries are not covered by this Warranty.

The equipment as sold may embody design or performance modifications not reflected in applicable literature. However, the Company warrants that such modifications will not reduce the design performance of the equipment.

Any repair or calibration to the circuitry during the period of the Warranty will invalidate the terms of the Warranty unless performed by Company personnel.

9. Storage

A Bedside external pulse generator should be stored in a location which is clean and dry. The temperature of the storage area should be within the range -20°C to 60°C (-4°F to 149°F).

Always remove the batteries from a Bedside external pulse generator which is to be stored for a significant length of time. Life of the alkaline batteries to be used with the Bedside will be extended if they are maintained in normal refrigeration and rotated at least once annually.

NOTE: It is recommended that a Bedside external pulse generator be allowed to come to ambient temperature prior to use following prolonged storage at temperatures outside of the specified range of operating temperature; i.e. 10°C to 40°C (50°F to 104°F).

10. Care of the Extension Cable

The Model 5265 extension cable provided with this product has been designed to provide a prompt and secure means of interconnecting the Bedside external pulse generator and an implanted temporary lead system.

The extension cable has a universal connector (see section 3.2) at one end and a REDEL® shielded, two pin, locking connector at the other. In addition to color coding, this cable is marked (+) or (-).

As supplied, the cable is NON-STERILE. It may be cleaned using 70% isopropyl alcohol or mild detergent followed by rinsing with water. Air dry thoroughly. Have a qualified technician test cable continuity. Sterilize by steam autoclaving at 121°C for 30 minutes.

Ethylene oxide sterilization will do no more harm to the cable than steam sterilization, but no specific method can be recommended.

Do not attempt to resterilize an extension cable using gamma irradiation.

11. Classifications / Certifications

The Model 4170 Bedside external pulse generator is classified as a Type CF defibrillation-proof applied part and bears the international symbol identifying it as such shown below:



Additionally, the Model 4170 Bedside external pulse generator bears the CE Mark to indicate compliance with the requirements of Annex I of Council Directive 93/42/EEC, known as the "Medical Device Directive".



Manufactured By:

Pace Medical, Inc.
391 Totten Pond Road
Waltham, MA 02451
U.S.A.

Manufactured For:

APC Medical Limited
68 – 70 Tewin Road
Welwyn Garden City
Herts. AL7 1BD

England