

User Manual

DA-2003P

Defibrillator Transutaneous Pacemaker Analyzer



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II. INTRODUCTION

2.1 Features

The DA-2003P Analyzer is a precision instrument for testing defibrillators and transcutaneous pacemakers, and is designed to be used by trained service technicians.

The defibrillator function of the DA-2003P measures the energy output, and ensures that the defibrillator complies with specified requirements. DA-2003P has a built-in load resistance of 50 ohm, which roughly corresponds to the impedance of the human body. The defibrillator pads are placed on the DA-2003P contact plates. Thus, the defibrillator is connected through the load resistance. When the defibrillator is discharged, DA-2003P calculates and displays the energy delivered.

In the pacer function the DA-2003P tests all types of transthoracic pacemakers. The testing is menu driven, and simple to operate. DA-2003P measures and displays a pulse's amplitude, rate, energy and width. It also conducts demand sensitivity tests, measuring and displaying refractory periods, and immunity tests, which determine the pacemaker's susceptibility to 50/60 Hz interference.

2.2 General Information

Temperature Requirements	+15°C to +35°C when operating 0°C to +50°C in storage
Display	
Type	LCD graphic display
Alphanumeric format	6 lines, 40 characters
Data Input/ Output (2)	Parallel printer port (1); Bi-directional RS -232C (1) for Computer control
Power	2 x 9 volt alkaline Battery Duracell® MN1604 (or equivalent) for 20 -25 operational hours, or 240 VAC (Battery Eliminator), 115 VAC for US.
Mechanical Specifications	
Housing	High impact plastic case
Height	9.8 cm 3.9 in.
Width	24.8 cm 9.8 in.
Depth	28.0 cm 11.0 in.
Weight	2.06 kg (with battery) 4.5 lbs
Recommended Printer	HP DeskJet 500C / 550C and Canon BJ -10SX.
Standard Accessories	
110 V or 220 V AC Adapter	(P/N BC20-00429)
Internal paddle-contact adapter	(P/N BC20-00430)
Snap-to-banana adapters (10 pk)	(P/N BC20-00427)
DA-2003P User Manual	
Protective Cover	(P/N BC20-30108)
Additional Accessories	
Defib. paddle adapter (specify defibrillator type)	
Pacemaker External Load Cable (specify pacemaker type)	
Soft Carrying Case	(P/N BC20-30108)
Storage	
Store in the carrying case in dry surroundings within the temperature range specified, without battery. There are no other storage requirements.	
Periodic Inspection	
The unit should be calibrated every 12 months.	

III. SPECIFICATIONS

3.1 Defibrillator Analyzer

1. Energy Output Measurement

High Range

Voltage	<5000 volts
Maximum current	120 amperes
Maximum energy	1000 Joules
Accuracy	± 2 % of reading for >100 Joules ± 2 Joule of reading for <100 Joules
Trigger level	100 volts
Playback amplitude	1 mV/1000 V Lead I
Test pulse	100 + 4 Joules

Low Range

Voltage	<1000 volts
Maximum current	24 amperes
Maximum energy	50 Joules
Accuracy	± 2% of reading for >20 Joules ± 2 Joule of reading for <20 Joules
Trigger level	20 volts
Playback amplitude	1 mV/200 V Lead I
Test pulse	Approx. 4 Joules
Load Resistance	50 ohms ± 1%, non-inductive (<1 µH)
Display Resolution	0.1 Joules
Measurement Time Window	100 ms
Absolute Max. Peak Voltage	6000 volts
Pulse Width	100 ms
Cardioversion	Measured time delay ± 2 ms

Oscilloscope Output

High measure range	1000:1 amplitude-attenuated
Low measure range	200:1 amplitude-attenuated

Waveform Storage And Playback

Discharge can be viewed via ECG outputs and paddles.
Output: 200:1 Time Base expansion.

Sync Time Measurements

Timing window	Starts - 40 ms at each R-wave peak.
Test waveforms	All waveform simulations available.
Delay time accuracy	± 1 ms

Charge Time Measurement

From 0.1 seconds to 99.9 seconds.

2. ECG Wave

ECG General

Lead configuration	12-lead simulation. RL, RA, LA, LL, V1-6
Output impedance	Limb leads 1000 ohms to RL V Leads 1000 ohms to RL

All other signals are in relative proportion to Lead amplitude as follows:
The amplitudes are shown for a Lead I amplitude by 1 mV:

Lead I	1.0 mV (LA - RA)
Lead II	1.5 mV (LL - RA)
Lead III	0.5 mV (LL - LA)
V Lead	1.5 mV (V - 1/3 (LL+LA+RA))

High Level Output (ECG Jack)

1/4" standard phone-jack with an amplitude of 1V/mV of low level Lead II signal

Defibrillator Contact Plates

Same amplitude as Lead I low level ECG.
1 mV between contact surfaces.

Playback

200 to 1 time-base expansion of defibrillator pulse by playback to ECG Leads

Manual ECG Performance Test

DC Pulse	4 seconds 1.0 mV
Square wave	2 Hz 1.0 mV p-p biphasic
Triangular wave	2 Hz 1.0 mV
Sine	0.1, 0.2, 0.5, 10, 40, 50, 60, and 100 Hz
Amplitude	0.5, 1.0, 1.5, 2.0 mV (Lead II)
Accuracy	± 5 % (Lead II 1.0 mV)

ECG Performance Test

Gain/Damping	2 Hz square wave
Frequency Response	
Low Frequency	4 second DC pulse
Band Pass	10 Hz sine
Monitor	-3dB point: 40 Hz sine
Power Line Notch	50 Hz sine
Filter	
Linearity	2 Hz triangle wave

Normal Sinus

Rates	30, 60, 80, 120, 180, 240 and 300 BPM.
Accuracy	±1% of selection
Amplitudes	0.5, 1.0, 1.5 and 2.0 mV (Lead II)
Accuracy	±5 % (Lead II 1.0 mV)

Automatic ECG Rate Test

Arrhythmia Selections

vfib	Ventricular Fibrillation
afib	Atrial Fibrillation
blk II	Second degree A-V block
RBBB	Right Bundle Branch Block
PAC	Premature Atrial Contraction
PVC_E	Early PVC
PVC_STD	PVC
PVCRonT	R on T PVC
mfPVC	Multifocal PVC
bigeminy	Bigeminy
run5PVC	Bigeminy Run of 5 PVCs
vtach	Ventricular Tachycardia

Shock Advisory Test Algorithms

ASYS	Asystole
SVTa_90	Supraventricular Tachycardia
PVT_140	
PVT_160	
MVT_140	
MVT_160	
CVF	Course Ventricular Fibrillation
FVF	Fine Ventricular Fibrillation

3.2 Transcutaneous Pacemaker Analyzer

1. TEST LOAD RANGE

50 to 2300 ohms in step of:
50 ohm up to 200 ohms
100 ohm from 200 up to 2300 ohms
Accuracy 50 - 1300 ohm $\pm 1\%$
1400 - 2300 ohm $\pm 1.5\%$

Oscilloscope Output

50 - 150 ohm 10.24:1 amplitude attenuation
200 - 500 ohm 41:1 amplitude attenuation
600 - 2300 ohm 164:1 amplitude attenuation

2. PULSE MEASUREMENTS

Amplitude 4 to 300 mA (100 ohm load)
Accuracy $\pm 5\%$ or ± 0.5 mA
Max. Amplitude 300 mA all loads
Rate 30 to 800 Pm
Accuracy $\pm 1\%$ or 2 Pm
Pulse width 0.6 to 80 ms
Accuracy $\pm 1\%$ or ± 0.3 ms

3. DEMAND SENSITIVITY TEST

Waveforms Square(SQR), Triangle(TRI), and Havemine (SSQ)
ECG output Amplitude 0 - 4 mV
Resolution 40 μ V
Pacer input (Load depended)
Amplitude (50 ohm) 0 - 10 mV
Resolution (50 ohm) 40 μ V
Amplitude: (≥ 500 ohm) 0 - 100 mV
Resolution: (≥ 500 ohm) 1 mV
Defib. Pads Amplitude 0 - 10 mV
Resolution 0.1 mV
Waveform width 10, 25, 40, 100 and 200 ms
Pacer rate 30 to 120 Pm

Immunity Test

50/60 Hz Interference Signal
ECG output 0 - 4 mV peak in steps of 0.4 mV
Pacer input (Load dependent)
0 - 10 mV peak in steps of 1 mV (50 ohm)
0 - 100 mV peak in steps of 10 mV (≥ 500 ohm)
Defibrillator pads 0 - 10 mV peak in steps of 1 mV

4. Refractory Period Measurement

20 to 500 ms (both Pacing and Sensing) Accuracy: ± 2 ms

IV. INSTALLATION

4.1 Receipt, Inspection and Return

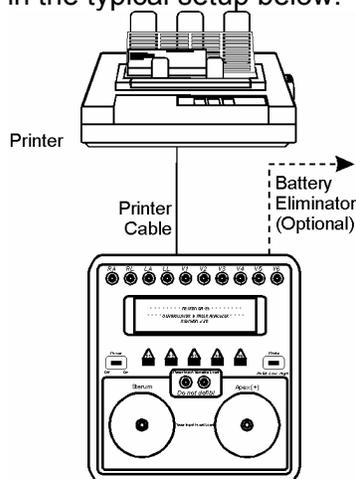
1. Inspect the outer box for damage.
2. Carefully unpack all items from the box and check to see that you have the following items:
 - DA-2003P Defibrillator/Transcutaneous Pacemaker Analyzer
 - 110 V or 220 V AC Adapter
 - Internal paddle-contact adapter
 - Ground contact adapter
 - 10 pack, Snap-to-banana adapter
 - DA-2003P User Manual
3. If you note physical damage, or if the unit fails to function according to specification, inform the supplier immediately. When BC Biomedical or the company's representative, is informed, measures will be taken to either repair the unit or dispatch a replacement. The customer will not have to wait for a claim to be investigated by the supplier. The customer should place a new purchase order to ensure delivery.
4. When returning an instrument to BC Biomedical, or the company representative, fill out the address label, describe what is wrong with the instrument, and provide the model and serial numbers. If possible, use the original packaging material for return shipping. Otherwise, repack the unit using:
 - A reinforced cardboard box, strong enough to carry the weight of the unit.
 - At least 5 cm of shock-absorbing material around the unit.
 - Nonabrasive dust-free material for the other parts.

Repack the unit in a manner to ensure that it cannot shift in the box during shipment.

BC Biomedical's product warranty is on page 26 of this manual. The warranty does not cover freight charges. C.O.D. will not be accepted without authorization from BC Biomedical or its representative.

4.2 Set-up

1. Equipment connection is as shown in the typical setup below.



4.3 Power

1. **Main On/Off Switch.** DA-2003P should remain off for at least 5 seconds before switching on again, in order to allow the test circuits to discharge fully.
2. **Low Battery Power.** If battery power falls below 6.9 volts (± 0.3 volts), the display will show 'Change battery, and reset system'. This means that the battery should either be replaced or the instrument should be connected to a battery eliminator. The main switch has to be switched off and then on again in order to use the instrument.

NOTE
Do not use mercury, air or carbon-zinc batteries.

3. **Changing Batteries.** Open the compartments in the base of the instrument, replace the old batteries with new ones, and close the compartment covers. Use 9-volt alkaline batteries (Duracell® MN1604 or similar).

NOTE
Remove the batteries and disconnect the AC Adapter if you do not intend to use the DA-2003P for an extended period of time.

4. **Battery Eliminator.** BC Biomedical's AC Adapter plug-in power supply transformer allows you to use the DA-2003P anywhere a standard electrical outlet is available. To attach the AC Adapter insert the adapter's small connector into the micro jack labeled "Batt. Elim. 9V DC" on the right rear of the unit. Plug the large connector into the nearest standard electrical outlet.

4.4 Internal Paddles

To be able to test defibrillators with internal paddles, an internal paddle adapter has to be used. These contacts have a banana plug that is attached to the standard paddle contact, and which is protected by a plastic insulation washer.

4.5 Special Contacts

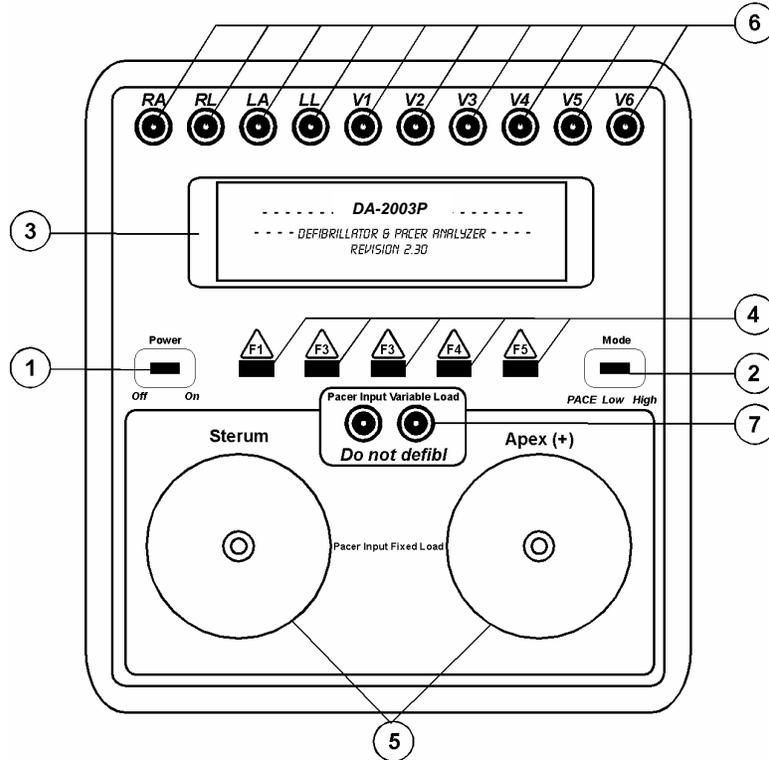
Certain defibrillators (automatic models and those with pacer options) have special contacts that are fastened to the electrodes attached to the patient. BC Biomedical has special adapters to suit the majority of these defibrillators. These are available as accessories. They are more or less the same as the internal pad adapter except that they have a special adapter on the top, which matches the contact on the defibrillator.

Defibrillator paddle adapter (specify defibrillator type)
Pacemaker external load cable (specify type pacemaker type)

V. OPERATING

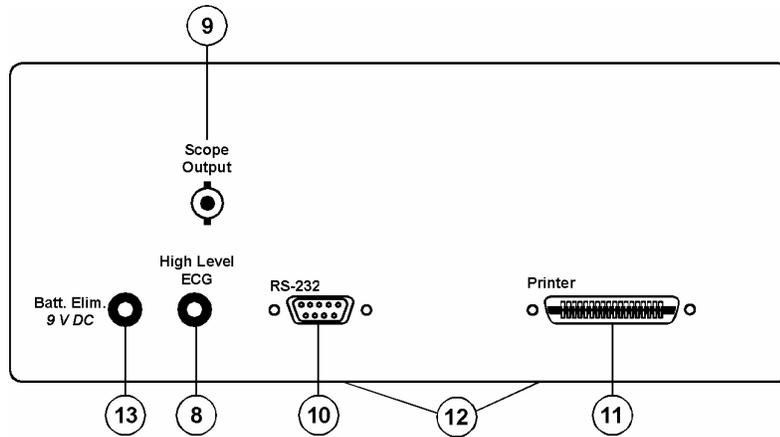
5.1 Control Switches and Connections

Front Panel



- | | |
|------------------------------------|---|
| 1. Power Switch | Turns the power on and off. |
| 2. Mode Switch | Switches between PACE and Low / High ranges of defibrillator energy. |
| 3. LCD Display | Shows messages, test results and function menus. |
| 4. Function Keys | F1 - F5 are used to select the functions shown on the bottom line of the LCD display, i.e., for selecting the function that is directly above the key. |
| 5. Contact Surfaces | The defibrillator's paddles are placed on these so that the discharged energy passes through the instrument in defib. mode and that the pacer signal passes through the instrument with a fixed 50 ohm load in the PACE mode. |
| 6. Low Level ECG Connectors | 10 color-coded 4 mm safety terminals with snap-to-banana adapters. |
| 7. Pacer Input Connectors | The pacer output cables are connected to these so that the pacer signal passes through the instrument with a variable load selectable from 50 to 2300 ohms. |

Rear Panel



8.	High Level ECG Jack	1/4" standard phone-jack for amplitude of 1 V/mV of low level Lead 1 signal.
9.	Oscilloscope Output	BNC-contact for attenuated signal in real time.
10.	RS-232 Serial Port	9-pin D-sub
11.	Printer Outlet Port	14-25 pin D-sub
12.	Location of Batteries	2 compartments in the base of the instrument can be opened to replace the batteries.
13.	Battery Eliminator Socket	Battery contact for connecting 9V 30 mA battery eliminator.

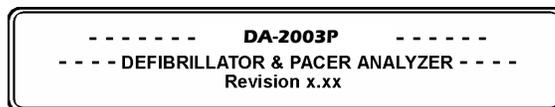
5.2 Menu and Function Keys

The DA-2003P uses display and programmable function keys to provide flexibility and control over the operations. The upper part of the screen displays messages, status and results. The menu bar is at the bottom of the display. The function keys are numbered from F1 to F5.

A function is selected by pressing the key located directly under the Menu Item displayed in the menu bar. A menu unit is written in capital letters. The menu has three pages. The next pages of the menu are selected by pressing **more-2**, **more-3**, or **more-1**.

5.3 Menu and Messages: Defibrillator Mode

1. **Startup Screen.** The following screen will be displayed for 2 seconds after the DA-2003P has been switched on.



2. **Main Menu**

a. Main Menu Bar (Page 1) - Mode switch in Low or High position.

----- STATUS -----		----- RESULT -----		
Wave	: off	Energy	: 0.0 JOULES	
Ampl.	:	Peak U	: 0.0 VOLTS	
Load	: 50 OHMS	Peak I	: 0.0 AMPS	
Oper.	: LOCAL	Delay	: MS	
ECG WAVE	ADV. ALG.	CHARGE TIME	PRINT HEADER	more-2
F1	F2	F3	F4	F5

b. Second Menu Bar (Page 2)

WAVE AMPL.	PLAY PULSE	PERF. WAVE	REMOTE CONTR.	more-3
F1	F2	F3	F4	F5

c. Third Menu Bar (Page 3)

SYSTEM TEST	more-1			
F1	F2	F3	F4	F5

3. **ECG WAVES (F1).**

→ off	180 BPM	PAC	run5PVC	
vfib	240 BPM	PVC_E	vtach	
30 BPM	300 BPM	PVC_STD		
60 BPM 80	afib	PVCRonT		
BPM	blk II	mPVC		
120 BPM	RBBB	bigeminy		
	UP	DOWN	SELECT	CANCEL
F1	F2	F3	F4	F5

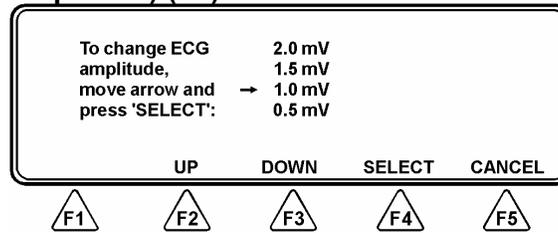
Choose desired wave by pressing **UP (F2)** or **DOWN (F3)**. Save this under 'Wave' in the STATUS field by pressing **SELECT (F4)**. Press **CANCEL (F5)** to cancel selection.

4. **ADV. ALG. (Advisory Algorithms) (F2).**

→ ASYS	PVT_160			
CVF	SVTa_90			
FVF				
MVT_140				
MVT_160				
PVT_140				
	UP	DOWN	SELECT	CANCEL
F1	F2	F3	F4	F5

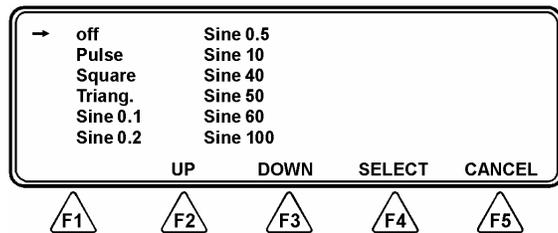
These ECG algorithms are meant to test the analysis and prompting feature of automatic and semi-automatic defibrillators. Choose desired selection by pressing **UP (F2)** or **DOWN (F3)**. Save this under 'Wave' in the STATUS field by pressing **SELECT (F4)**. Press **CANCEL (F5)** to cancel selection.

5. **CHARGE TIME (F3).** Used to test the battery and charging capacitor in the defibrillator. It changes the text 'Delay' to 'Chrg ' in the RESULT field in the main menu.
6. **PRINT HEADER (F4).** Automatically writes a heading for the new test protocol.
7. **WAVE AMPL. (Wave Amplitude) (F1).**



Choose desired amplitude by pressing **UP (F2)** or **DOWN (F3)**. Save this under 'Ampl' in the STATUS field by pressing **SELECT (F4)**. Press **CANCEL (F5)** to cancel selection.

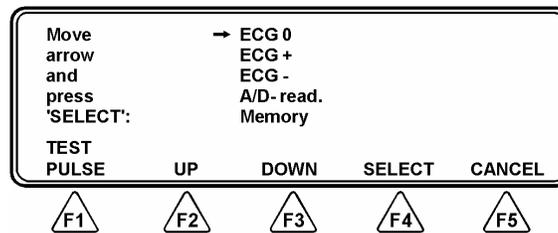
8. **PLAY PULSE (F2)** enables playback of the last discharge.
9. **PERF. WAVE (Performance ECG) (F3).**



Choose desired wave by pressing **UP (F2)** or **DOWN (F3)**. Save this under 'Wave' in the STATUS field by pressing **SELECT (F4)**. Press **CANCEL (F5)** to cancel selection.

10. **SYSTEM TEST (F1) .**

Note
DA-2003P has an internally generated test pulse. The control pulse is set at 1.2 Joules in the Low range and 28.5 Joules in the High range. The test pulse is not a calibration pulse, and should not be used as an indication of the general accuracy of the instrument. The test pulse is a good control for testing functions.

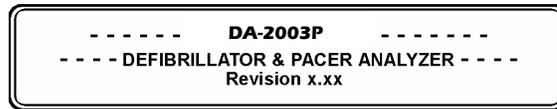


Choose a test variant by pressing **UP (F2)** or **DOWN (F3)** or **TEST PULSE (F1)**. Press **CANCEL (F5)** to cancel selection. For 'ECG0', 'ECG+' and 'ECG-' see Chapter 6, Control and Calibration. For 'A/D-read', see paragraph 7.3.7, page 7-5. Memory' is for factory testing. Also, see paragraph 4.3.5, page 4-3.

11. **REMOTE CONTR. (Remote Control) (F4)** enables communication with a PC with test automation software.

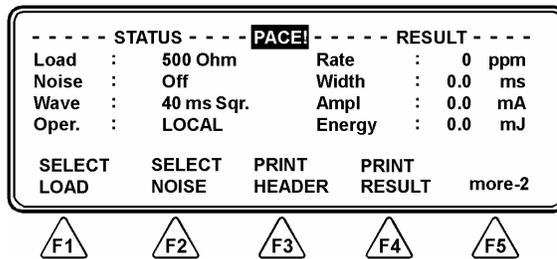
5.4 Menu and Messages: Defibrillator Mode

1. **Startup Screen.** The following screen will be displayed for 2 seconds after the DA-2003P has been switched on.

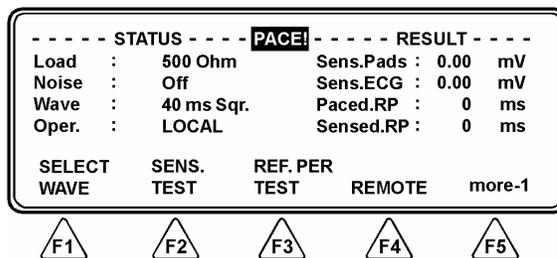


2. Main Menu

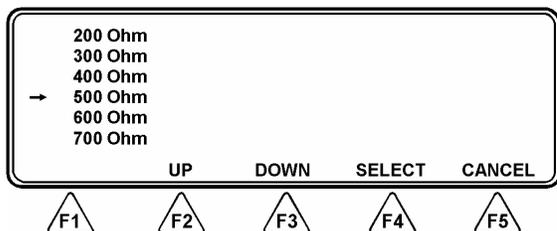
- a. Main Menu Bar (Page 1) - Mode switch in PACE position.



- b. Second Menu Bar (Page 2)

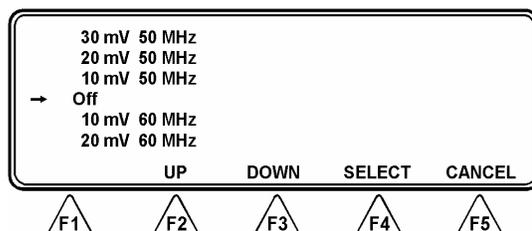


3. SELECT LOAD (F1)



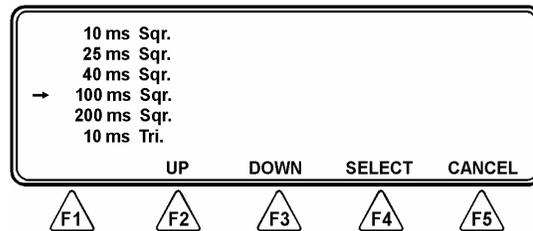
Choose desired PACER load by pressing **UP (F2)** or **DOWN (F3)** and then **SELECT (F4)**. Press **CANCEL (F5)** to cancel selection.

4. SELECT NOISE (F2)



Choose desired noise for the immunity test by **UP (F2)** or **DOWN (F3)** and then **SELECT (F4)**. Press **CANCEL (F5)** to cancel selection.

5. **PRINT HEADER (F3)**. Automatically writes a heading for the new test protocol.
6. **PRINT RESULT (F3)**. Prints the results of measurements.
7. **SELECT WAVE (F2)**



Choose desired waveform for the sensitivity test by pressing **UP (F2)** or **DOWN (F3)** and then **SELECT (F4)**. Press **CANCEL (F5)** to cancel selection.

8. **SENS. TEST (Sensitivity Test) (F2)**. Sensitivity is the QRS minimum amplitude (mV) required to cause the pacemaker to operate in the demand mode. This waveform is delayed from the pacer pulse so that it is outside the pacing refractory period. See 'Sensitivity Measurements' in Chapter 5.
9. **REF. PER TEST (F3)**. Used to test time interval (ms) if the pacemaker is insensitive to any external inputs, the maximum time interval after the generation of a pacer pulse and maximum time interval after a QRS wave. See 'Pacing Refractory Period' and 'Sensing Refractory Period' in Chapter 5.

5.5 Test Result Printouts

1. **Defibrillator Mode**. DA-2003P automatically prints out the test results, via the printer output, after each discharge generated. Select **PRINT HEADER (F4)** if you want to print out a page with a new header.
2. **Pace Mode**. DA-2003P prints out the test results, after the measurements, when you press **PRINT RESULT (F4)** in the Main menu.

VI. DEFIBRILLATOR MODE TESTING

6.1 Introduction

The defibrillator function of the DA-2003P measures the energy output, and ensures that the defibrillator complies with specified requirements. It has a built-in load resistance of 50 ohms, which roughly corresponds to the impedance of the human body. The defibrillator pads are placed on the DA-2003P contact plates. Thus, the defibrillator is connected through the load resistance. When the defibrillator is discharged, DA-2003P will calculate and display the energy delivered.

Defibrillator energy is defined as an integral of the moment of the discharged energy from the defibrillator. The energy is equal to the square of the voltage, divided by the load resistance.

$$E = \int p \, dt = \int V^2 / R \, dt = \int V^2 \, dt / R$$

DA-2003P measures and records the voltage pulse every 100 μ s, 1000 times, for a total time of 100 ms. The squares of the voltages are then summed, multiplied by 100 μ s, and divided by the load resistance, 50 ohms.

$$E = \int_0^{1000} (V^2) \cdot dt / R = \int_0^{1000} (V^2) \cdot 100 \, \mu\text{s} / 50 \, \text{ohms}$$

The unit for energy is 'joule', which is equal to Ws (Watt second).

6.2 Test Preparation

1. If checking ECG monitoring, prompting, or triggering from the ECG, connect the low level or high level ECG connectors to the ten 4 mm AHA color-coded safety terminals or standard phone jack, as appropriate.
2. Switch the DA-2003P on. The following will be displayed in the LCD display for about two seconds:

```

----- DA-2003P -----
----- DEFIBRILLATOR & PACER ANALYZER -----
Revision x.xx
  
```

3. The following main menu will then appear. It will show LOCAL.

```

----- STATUS -----
Wave : off
Ampl. :
Load : 50 OHMS
Oper. : LOCAL

----- RESULT -----
Energy : 0.0 JOULES
Peak U : 0.0 VOLTS
Peak I : 0.0 AMPS
Delay : MS

ECG ADV. CHARGE PRINT
WAVE ALG. TIME HEADER more-2

F1 F2 F3 F4 F5
  
```

6.3 Energy Test

- Select a suitable energy range using the mode switch.
 - Use the HIGH range for normal adult testing.
 - Use the LOW range for low energy testing, where the energy does not exceed 50 Joule and the peak voltage does not exceed 1200 volts.
- Securely place the defibrillator paddles on the DA-2003P contact plates, and discharge the defibrillator. The APEX (+) pad should be connected to the right-hand plate, and the STERNUM pad to the left plate. This ensures correct signal polarity for the oscilloscope output. A reversal of this configuration will not damage the DA-2003P, nor will it give incorrect energy readings. However, the polarity of the oscilloscope output will simply be reversed. The discharge from the defibrillator is transferred to the DA-2003P's load resistance.
- DA-2003P calculates the energy delivered over the load resistance and displays the result in joules under RESULT.

Note
If the maximum voltage for a selected range is exceeded, the LCD display will show 'WARNING! Overload'

----- STATUS -----		----- RESULT -----		
Wave	: off	Energy	: 0.0 JOULES	
Ampl.	:	Peak U	: 0.0 VOLTS	
Load	: 50 OHMS	Peak I	: 0.0 AMPS	
Oper.	: LOCAL	Delay	: MS	
ECG WAVE	ADV. ALG.	CHARGE TIME	PRINT HEADER	more-2
F1	F2	F3	F4	F5

APEX (+) pad → right plate
STERNUM pad → left plate

DA-2003P also shows the energy measured, the maximum voltage and the maximum current in the energy wave. Following the discharge from the defibrillator, DA-2003P shows a playback of the wave from the ECG output. A new pulse can be generated when the LCD display shows 'LOCAL'.

- Following a discharge from the defibrillator, the instrument shows a playback of the wave from the ECG output. The display will thus be in playback mode. When this is shown in one line, DA-2003P automatically prints out the result.
- The discharged pulse can be repeated. To do this press **more-2 (F5)** to advance to page 2 of the main menu.

WAVE AMPL.	PLAY PULSE	SYSTEM TEST	REMOTE CONTR.	more-1
F1	F2	F3	F4	F5

Press **PLAY PULSE (F2)**. The display will show 'Oper: Playback,' and displays the result in joules under RESULT.

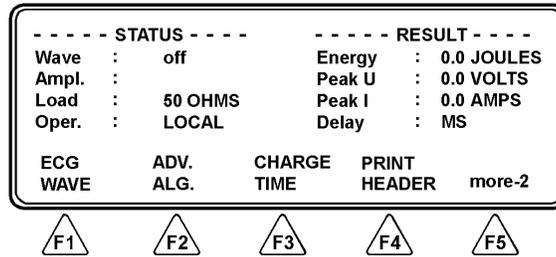
----- STATUS -----		----- RESULT -----		
Wave	: off	Energy	: 0.0 JOULES	
Ampl.	:	Peak U	: 0.0 VOLTS	
Load	: 50 OHMS	Peak I	: 0.0 AMPS	
Oper.	: Playback	Delay	: MS	
ECG WAVE	ADV. ALG.	CHARGE TIME	PRINT HEADER	more-2
F1	F2	F3	F4	F5

Following playback, the apparatus is ready to receive a new discharge from the defibrillator. The display will show 'LOCAL'.

- When testing automatic defibrillators, it is quite common to have to select 'vfib' from the ECG menu 'ECG WAVE' for the 'ventricular fibrillation' wave. Automatic defibrillators typically do not fire without seeing 'v-fib'.

6.4 Cardioversion Test

- Select **ECG WAVE (F1)** from the main menu.

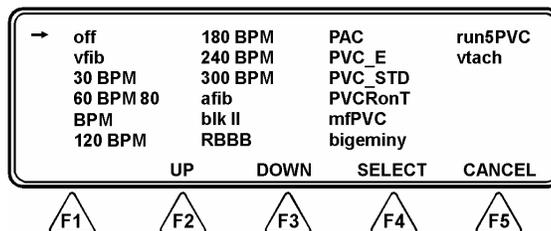


- The ECG Wave menu opens. DA-2003P includes the following ECG wave selection for cardioversion tests, or for the testing of electrocardiograph monitors.

Normal Sine Rates: 30, 60, 80, 120, 180, 240 and 300 BPM.

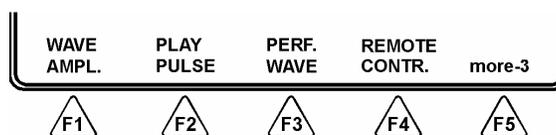
ECG Arrhythmia types as follows:

vfib	Ventricular Fibrillation
afib	Atrial Fibrillation
blk II	Second degree A-V block
RBBB	Right Bundle Branch Block
PAC	Premature Atrial Contraction
PVC_E	Early PVC
PVC_STD	PVC
PVCRonT	R on T PVC
mfPVC	Multifocal PVC
bigeminy	Bigeminy
run5PVC	Bigeminy Run of 5 PVCs
vtach	Ventricular Tachycardia

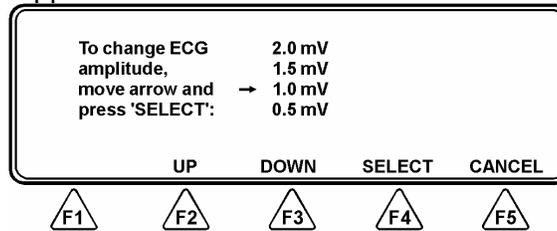


Select a desired wave by pressing **UP (F2)** or **DOWN (F3)**. Save this under 'Wave' in the STATUS field by pressing **SELECT (F4)**. Press **CANCEL (F5)** to cancel selection.

- DA-2003P includes the following ECG wave amplitude options: 0.5 mV, 1.0 mV, 1.5 mV and 2.0 mV. To change wave amplitude select **more-2** on the main menu to advance to page 2. Select **WAVE AMPL. (F1)**.



The Wave Amplitude Menu appears:



Select the desired amplitude by pressing **UP (F2)** or **DOWN (F3)**. Save this under 'Ampl' in the STATUS field by pressing **SELECT (F4)**. Press **CANCEL (F5)** to cancel selection.

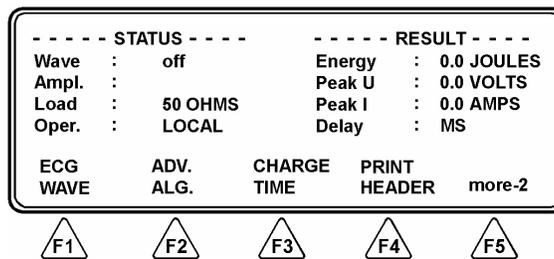
- Set the defibrillator to synchronized cardioversion mode. Discharge the defibrillator over the instrument's load resistance.
- DA-2003P measures the time delay in milliseconds (ms) between the top of the 'R' wave and the discharging of the defibrillator pulse. This delay will be shown in the LCD display as: 'Delay: xxx ms'.

DA-2003P also shows the energy measured, the maximum voltage and the maximum current in the energy wave. Following the discharge from the defibrillator, DA-2003P shows a playback of the wave from the ECG output. A new pulse can be generated when the LCD display shows 'LOCAL'.

6.5 Maximum Energy Charging Time Test

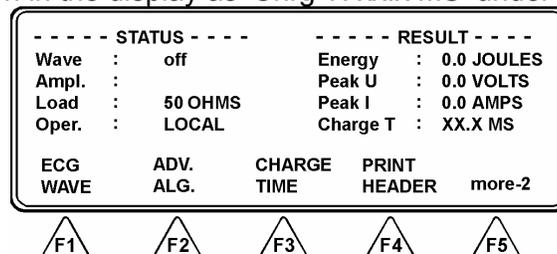
- The charge time function is used to test the battery and the charging capacitor in the defibrillator.
- Set the defibrillator to maximum energy.
- Securely place the defibrillator paddles on the DA-2003P contact plates, and discharge the defibrillator. The APEX (+) pad should be connected to the right-hand plate, and the STERNUM pad to the left plate. This ensures correct signal polarity for the oscilloscope output. A reversal of this configuration will not damage the DA-2003P, nor will it give incorrect energy readings. However, the polarity of the oscilloscope output will simply be reversed. The discharge from the defibrillator is transferred to the DA-2003P's load resistance.
- Select **CHARGE TIME (F3)** from the main menu and the charge button on the defibrillator simultaneously.

APEX (+) pad → right plate
STERNUM pad → left plate



When the defibrillator is charged, discharge it through the instrument.

- Charging time will be shown in the display as 'Chrg T: xx.x MS' under RESULT.

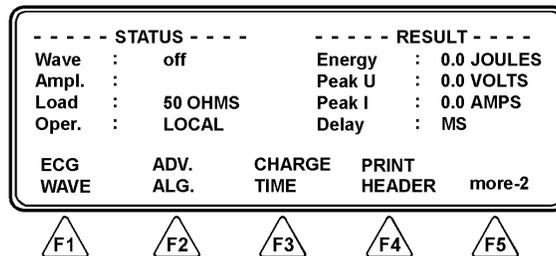


6.6 Shock Advisory Algorithm Test

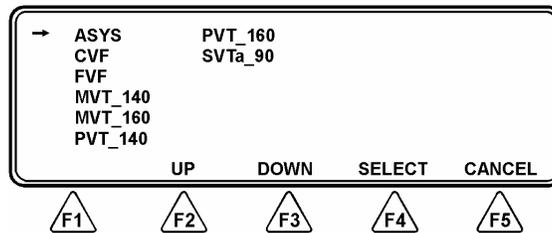
1. This tests the analysis and prompting of automatic and semi-automatic defibrillators. A series of arrhythmia is available for analysis by the defibrillator that should then prompt the user to 'shock' or 'no shock,' in accordance with national and international guidelines, as shown below:

ASYS	No shock
SVTa_90	No shock
PVT_140	No shock
MVT_140	No shock
CVF	Shock
FVF	Shock
PVT_160	Shock
MVT_160	Shock

2. Select **ADV. ALG. (F2)** from the main menu.



3. The Advisory Algorithms Menu opens.



Select the desired rhythm by pressing **UP (F2)** or **DOWN (F3)**. Save this under 'Wave' in the STATUS field by pressing **Select**. Press **CANCEL (F5)** to cancel selection. The ECG signal is output through the low-level ECG connectors, high-level ECG connector, and paddle contact plates on the DA-2003P.

4. Set the defibrillator to analyze the ECG rhythm and operate in the automatic and semi-automatic mode.
5. Records the defibrillator's response.

VII. TRANSCUTANEOUS PACEMAKER TESTING

7.1 Introduction

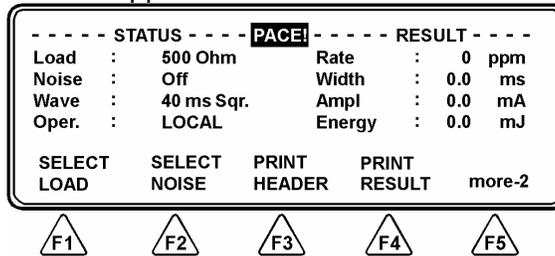
DA-2003P tests all types of transthoracic pacemakers. The testing is menu driven, and simple to operate. DA-2003P measures and displays a pacer pulse's amplitude, rate, energy and width. It also conducts demand sensitivity tests, measuring and displaying refractory periods, and immunity tests, which determine the pacemaker's susceptibility to 50/60 Hz interference.

7.2 Test Preparation

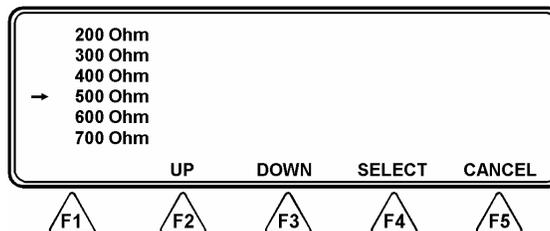
1. Connect the pacer output cables to the pacer input connectors.
2. Switch the mode switch to 'PACE' mode.
3. Turn the DA-2003P on. The following will be displayed in the LCD display for about two seconds:



4. The following main menu will then appear.



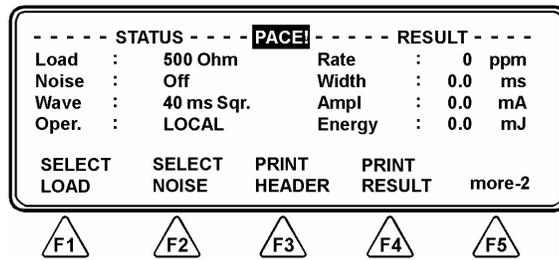
5. Press **SELECT LOAD (F1)**. The following load options will appear:



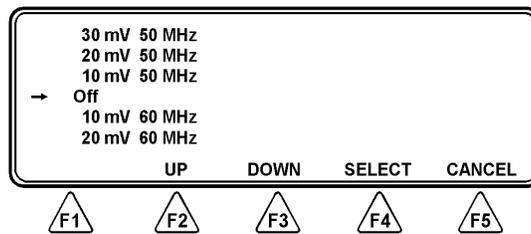
The load range is 50 to 2300 ohms in steps of 50 ohms up to 200 ohms, and 100 ohms from 200 up to 2300 ohms

Select the desired noise form by pressing **UP (F2)** or **DOWN (F3)** and then **Select (F4)**. Press **CANCEL (F5)** to cancel the selection. After selection the main menu will reappear.

- Select the desired waveform by pressing **UP (F2)** or **DOWN (F3)** and then **SELECT (F4)**. Press **CANCEL (F5)** to cancel the selection. After selection the main menu will reappear.



- For Immunity Testing Only.** The immunity test determines the pacemaker's susceptibility to 50/60 Hz interference signals. If you desire to test immunity simultaneously with other testing, press **SELECT NOISE (F2)**. The following load options will appear:



Select the desired noise form by pressing **UP (F2)** or **DOWN (F3)** and then **SELECT (F4)**. Press **CANCEL (F5)** to cancel the selection. After selection the main menu will reappear.

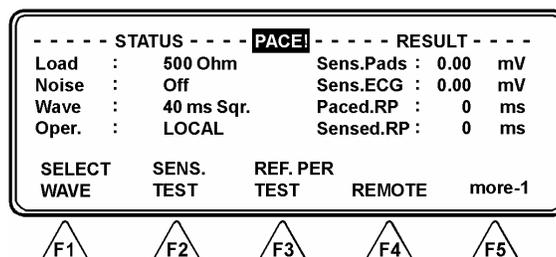
7.3 Demand Sensitivity Test

- General.** Sensitivity is the minimum QRS amplitude (mV) required to cause the pacemaker to operate in the demand mode. During sensitivity measurement three different waveforms are selectable with widths varying in steps from 10 to 200 ms. This waveform is delayed from the pacer pulse so that it is outside the pacing refractory period. DA-2003P then checks whether this wave is sensed or not by the pacemaker.

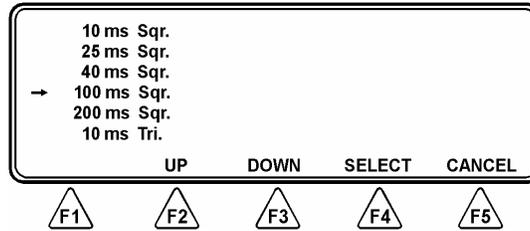
If it is not sensed, a message 'exceeded' is displayed which means that the pacemaker needs an amplitude more than 100 mV for sensing at that setting. If the wave is sensed, DA-2003P then reduces the amplitude in steps until it reaches the lowest value required for the pacemaker to sense it. (The internal algorithm used converges to the lowest value in the least number of cycles.) This lowest value is the sensitivity.

2. Procedure

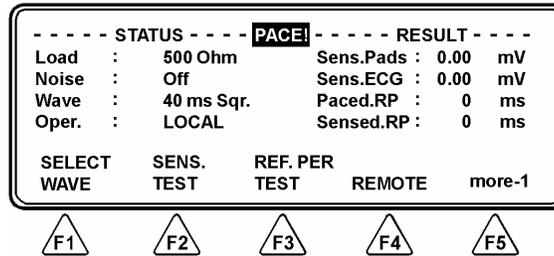
- From the main menu press **more-2**, then **SELECT WAVE (F1)**.



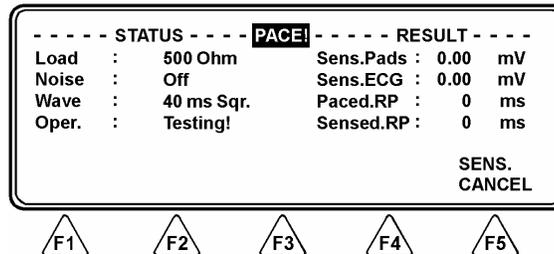
b. The following menu will be displayed:



c. Select the desired waveform by pressing **UP (F2)** or **DOWN (F3)** and then **Select (F4)**. Press **CANCEL (F5)** to cancel the selection. After selection the main menu will reappear.



d. Select **SENS. TEST (F2)**. The following display will appear:



e. Upon completion of testing the results will be displayed under RESULT. Press **SENS. TEST. CANCEL (F5)** to cancel the test.

7.4 Refractory Period Test

1. **General.** This test is used to test the time interval in milliseconds (ms) during which the pacemaker is insensitive to any external inputs. DA-2003P does this by measuring the maximum time interval after the generation of a pacer pulse, and maximum time interval after a QRS wave.

- a. **Refractory Period.** A time interval in milliseconds, during which a pacemaker is insensitive to any external inputs. If a QRS is detected during this period, the pacemaker ignores it. On the other hand, if a QRS is detected outside the refractory interval, then the pacemaker resets its internal timer and the next pacer pulse is generated after a delay of one time period from this QRS wave.
- b. **Paced Refractory Period.** The maximum time interval after the generation of a pacer pulse during which time the presence of a QRS wave is ignored.

The measurement of paced refractory period takes a few cycles of the pacemaker output. First, DA-2003P measures the pacer-to-pacer interval T. Then, it puts out a

square wave 40 milliseconds wide, delayed by delay time D, which is more than the pacing refractory period, from the last pacer pulse. The pacemaker senses this square wave. The delay time D is gradually decremented in subsequent cycles until the square waveform is not sensed by the pacemaker. The maximum value of the delay time D, for which the pace maker does not sense the square wave, is the paced refractory period.

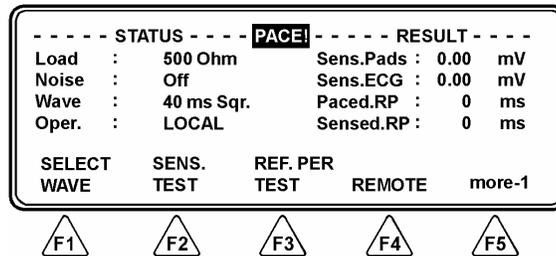
- c. **Sensed Refractory Period.** The maximum time interval after a QRS wave is sensed by the pacemaker during which time the presence of a second QRS wave is ignored.

The sensed refractory period is measured in a similar manner, except that DA-2003P now generates two square waves instead of one. The first square wave is generated at a fixed time delay from a pacer pulse, which is greater than the paced refractory period. The pacemaker always senses this square wave.

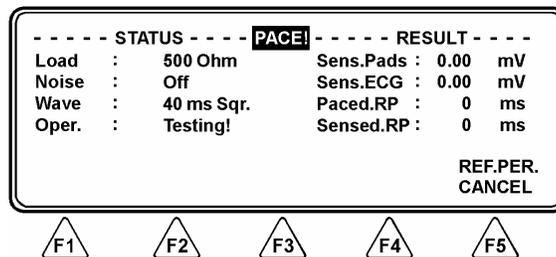
The second square wave is generated at a delay D from the first square wave. The initial value of D is selected to be greater than the sensed refractory period. Therefore the first time the pacemaker is on it also senses the second square wave. In subsequent cycles, the delay 'D' is gradually reduced until the pacemaker is unable to sense the second square wave. The maximum value of D, for which the pacemaker does not sense the second square wave, is the sensed refractory period.

2. Procedure

- a. From the main menu press **more-2**. Press **REF. PER. TEST (F3)**.



- b. The following display will appear while testing:



- c. Upon completion of testing the results will be displayed under RESULT. Press **REF. PER. CANCEL (F5)** to cancel the test.

VIII. WARRANTY

BC Group warrants that the DA-2003P Defibrillator Analyzer will substantially conform to published specifications and to the documentation, provided that it is used for the purpose for which it was designed. BC Group will, for a period of twelve (12) months from date of purchase, replace or repair any defective analyzer, if the fault is due to a manufacturing defect. In no event will BC Group or its local representatives be liable for direct, indirect, special, incidental, or consequential damages arising out of the use of or inability to use the DA-2003P Defibrillator Analyzer, even if advised of the possibility of such damages. BC Group or its local representatives are not responsible for any costs, loss of profits, loss of data, or claims by third parties due to use of, or inability to use the DA-2003P Defibrillator Analyzer. Neither BC Group nor its local representatives will accept, nor be bound by any other form of guarantee concerning the DA-2003P Defibrillator Analyzer other than this guarantee. Some jurisdictions do not allow disclaimers of expressed or implied warranties in certain transactions; therefore, this statement may not apply to you.

IX. TECHNICAL SUPPORT

BC Biomedical's DA-2003P Defibrillator Analyzer is backed by a superior support staff. If the DA-2003P ever fails to work perfectly, please contact the Technical Support Staff.

Written Communications

You may write a letter with your comments and send it to:

BC Biomedical
BC Group International, Inc.

3081 Elm Point Industrial Dr
St. Charles, MO USA 63301
OR

E-mail: sales@bcgroupintl.com

Phone Support

You can telephone the Technical Assistance Center at 314-638-3800 or 1-800-242-8428 between 8:00 AM and 4:30 PM Central Standard Time (CST) Monday through Friday, except holidays.

Whichever method of contact you choose, please provide the following information:

- Product name and serial number
- Revision level of your software
- The specific steps which reproduce your problem
- Any error codes displayed on screen
- A daytime phone number, fax number, and/or email address (if available)
- Your name / company