
Table of Contents

1	SPECIFICATIONS	1
1.1	Tests Performed	1
1.2	Performance Specifications	1
1.2.1	Energy Measurement, General	1
1.2.2	Defibrillator High Range Energy Test	2
1.2.3	Defibrillator Low Range Energy Test	2
1.2.4	Defibrillator Charge Time Test	3
1.2.5	Defibrillator Cardioversion Test	3
1.2.6	AED Performance Test	3
1.2.7	Pacemaker Pulse Test	3
1.2.8	Pacemaker Noise Immunity Test	4
1.2.9	Pacemaker Sensitivity Test	4
1.2.10	Pacemaker Refractory Period Test	4
1.3	ECG Simulator	5
1.3.1	Performance Test Waveforms	5
1.3.2	Normal Sinus Rhythm	5
1.3.3	Cardioversion, Shock Advisory and AED Test Waveforms	5
1.3.4	Arrhythmia Simulations	5
1.3.5	Pacemaker Test Waveforms	6
1.3.6	Performance Specifications	6
1.4	Non-Volatile Memory	6
1.4.1	Memory Type	6
1.4.2	Data Capacity	6
1.4.3	Test Record Content	6
1.4.4	Waveform Record Content	7
1.5	Interface	7
1.5.1	User Interface	7
1.5.2	Defibrillator Input	7
1.5.3	Pacemaker Input	7
1.5.4	ECG Simulator Outputs	7
1.5.5	Defibrillator/Pacer Waveform Output	7
1.5.6	High-Level ECG Output	7
1.5.7	USB Port	8
1.5.8	Serial (RS-232) Port	8
1.5.9	Keyboard Port	8
1.5.10	Power Supply	8
1.6	Environment	9
1.7	Dimensions	9
1.8	Accessories	9
1.8.1	Standard Accessories	9
1.8.2	Optional Accessories	9

Phase 3 OPERATING MANUAL

2	OVERVIEW	11
2.1	General Description	11
2.1.1	Test Capabilities	11
2.1.2	Data Log	12
2.1.3	Automated Testing	13
2.1.4	Connectivity	13
2.1.5	Viewing and Saving Defibrillator Waveforms	13
2.1.6	Principle of Operation	14
2.2	Controls and Interface Connections	15
3	SETUP	17
3.1	Connections	17
3.2	Optional Connections	21
3.2.1	High-Level ECG Output	21
3.2.2	Waveform Output	21
3.2.3	Serial (RS-232) Input/Output	22
3.2.4	Keyboard Port	24
3.2.5	USB Port	24
3.3	Setting Up a HyperTerminal Connection	26
4	OPERATION AND RELATED DISPLAYS	29
4.1	General Features of the User Interface	29
4.1.1	Keypad and Display Operation	29
4.1.2	Clip Record	30
4.1.3	CANCEL Key Operation	31
4.1.4	User Preference Settings	32
4.2	Powering Up	33
4.3	Main Menu	35
4.3.1	Test Pulse	36
4.3.2	Phase 3 ID	37
4.3.3	Set Clock	39
4.4	Manual Test Menu	40
4.4.1	DUT ID	41
4.4.2	Restarting Manual Tests	43
4.5	Defibrillator Test Menu	44
4.5.1	Defibrillator Energy Test	45
4.5.1.1	Selecting the Energy Test	45
4.5.1.2	Setting the ECG Simulator	47
4.5.1.3	Setting a Target and Tolerance	52
4.5.1.4	Performing the Energy Test	54
4.5.1.5	Viewing and Saving Defibrillator Waveforms	60
4.5.1.6	Capturing the Defibrillator Waveform in Real-Time	63
4.5.2	Defibrillator Charge Time Test	64
4.5.2.1	Selecting the Charge Time Test	64
4.5.2.2	Performing the Charge Time Test	65
4.5.3	Defibrillator Cardioversion Test	68

Phase 3 OPERATING MANUAL

4.5.3.1 Selecting the Cardioversion Test	68
4.5.3.2 Performing the Cardioversion Test	70
4.6 ECG Test Menu	73
4.6.1 Selecting the ECG Test	73
4.6.2 Performing the ECG Test	75
4.7 Pacemaker Test Menu	76
4.7.1 Pacemaker Load Selection	77
4.7.2 Pacemaker Pulse Test	79
4.7.2.1 Selecting the Pulse Test	79
4.7.2.2 Performing the Pulse Test	80
4.7.2.3 Capturing the Pacemaker Waveform	83
4.7.3 Pacemaker Refractory Period Test	84
4.7.3.1 Selecting the Refractory Period Test	84
4.7.3.2 Performing the Refractory Period Test	85
4.7.4 Pacemaker Noise Immunity Test	88
4.7.4.1 Selecting the Noise Immunity Test	88
4.7.4.2 Performing the Noise Immunity Test	89
4.7.5 Pacemaker Sensitivity Test	90
4.7.5.1 Selecting the Sensitivity Test	90
4.7.5.2 Performing the Sensitivity Test	91
4.8 AED Test Menu	94
4.8.1 Selecting the AED Test	94
4.8.2 Performing the AED Test	95
4.9 Data Log	98
4.9.1 Viewing and Storing the Clip Record	98
4.9.2 Recalling and Viewing Test Records	99
4.9.2.1 Selecting a Test Record	101
4.9.2.2 Printing a Test Record	101
4.10 Automated Testing	103
4.10.1 AutoSequence Overview	103
4.10.2 Selecting an AutoSequence	104
4.10.3 Running a Defib/Pacer AutoSequence	105
4.10.3.1 Automated Defibrillator Tests	105
4.10.3.2 Automated ECG Tests	108
4.10.3.3 Automated Pacemaker Tests	110
4.10.4 Running an AED AutoSequence	112
4.10.5 AutoSequence Conclusion	114
4.11 Self-Test Error Messages	115
4.11.1 Critical Self-Test Failures	115
4.11.2 Non-Critical Self-Test Failures	116

Phase 3 OPERATING MANUAL

5	REMOTE CONTROL	117
5.1	General Description	117
5.2	Remote Interface Mode	118
5.3	Command Set	118
5.3.1	ECG Configuration Command	120
5.3.2	Defib Energy Command	123
5.3.3	Defib Charge Time Command	125
5.3.4	Defib Sync (Cardioversion) Command	126
5.3.5	Pacer Load Select Command	127
5.3.6	Pacer Pulse Command	128
5.3.7	Pacer Refractory Command	129
5.3.8	Pacer Noise Immunity Command	130
5.3.9	Pacer Sensitivity Command	131
5.3.10	Phase 3 ID Command	132
5.3.11	Clear Last Test Command	132
5.3.12	Clear Wave Records Command	133
5.3.13	Clear Test Records Command	133
5.3.14	Acquire Waveform Data Command	134
5.3.15	Number of Test Records Command	135
5.3.16	Send Test Report Command	136
6	Phase3pc SOFTWARE	137
6.1	Installation	137
6.1.1	Installing Phase3pc	137
6.1.2	Installing USB Drivers	138
6.2	Phase 3 Remote Mode	139
6.3	AutoSequence Editor	140
6.3.1	Creating an AutoSequence	141
6.3.2	Editing an AutoSequence	141
6.3.3	Copying and Deleting AutoSequences	141
6.3.4	Uploading and Downloading AutoSequences	142
6.3.5	Printing AutoSequences	142
6.3.6	AutoSequence Editor	142
6.3.6.1	Editing the AutoSequence Title	143
6.3.6.2	Selecting the Device Under Test	144
6.3.6.3	Editing Defibrillator Energy Tests	144
6.3.6.4	Editing the Charge Time Test	144
6.3.6.5	Editing Cardioversion Tests	145
6.3.6.6	Editing ECG Performance Tests	145
6.3.6.7	Editing Pacer Tests	146
6.3.6.8	Editing the Pacer Load	146
6.3.6.9	Editing Pacer Pulse Tests	146
6.3.6.10	Editing the Noise Immunity Test	147
6.3.6.11	Editing Demand Sensitivity Tests	147
6.3.6.12	Editing Refractory Period Tests	148

Phase 3 OPERATING MANUAL

6.3.6.13 Editing Advanced Options	148
6.3.6.14 Editing AED Energy Tests	149
6.4 Test Report Generator	150
6.4.1 Downloading Test Reports	150
6.4.2 Viewing Test Reports	151
6.4.3 Saving Test Reports	152
6.4.3.1 Saving as a Text File	152
6.4.3.2 Saving as a CSV File	152
6.4.3.3 Saving as a MUP File	153
6.4.4 Searching for Test Reports	153
6.4.5 Opening Existing Test Reports	153
6.4.6 Printing Test Reports	153
6.5 Waveform Viewer	154
6.5.1 Downloading Wave Records	154
6.5.2 Viewing Wave Records	155
6.5.3 Capturing High-Resolution Waveforms	156
6.5.4 Opening Existing Waveforms	156
6.5.5 Using the Waveform Viewer	156
6.5.5.1 Zooming In and Out	156
6.5.5.2 Panning the Chart	157
6.5.5.3 Undo Zoom	157
6.5.5.4 Data Points On/Off	157
6.5.5.5 Setting the Chart Axes	157
6.5.5.6 Saving Waveform Data	158
6.5.5.7 Printing Waveforms	158
6.5.5.8 Editing the Device ID Field	159
6.5.5.9 Hot Key Summary	159
7 TROUBLESHOOTING AND MAINTENANCE	161
APPENDIX A. DEFAULT AUTOSEQUENCES	163
APPENDIX B. SAMPLE TEST REPORT	169

Phase 3 OPERATING MANUAL

Abbreviations, Definitions and Symbols

The following abbreviations, terms and acronyms are used throughout this manual:

AED	Automated External Defibrillator
AAMI	American Association of Medical Instrumentation
Arrhythmia	An abnormal rhythm of the cardiac muscle; an abnormal pattern or rate of heart beats.
AutoSequence	A series of measurements or test operations that are run automatically in a predefined order, with or without user involvement.
BPM	(ECG) Beats Per Minute
Biphasic	A type of defibrillator discharge waveform with one positive pulse and one negative pulse. The pulses may be of the form of a square wave, or an exponentially decaying square wave, or some variation thereof.
Cardioversion	A medical procedure in which an electrical discharge is applied to a patient to correct a cardiac arrhythmia, specifically tachycardia or atrial fibrillation. The procedure requires a defibrillator which can be set to synchronize its discharge to the electrocardiogram.
Clip Record	Temporary (volatile) memory where device information and test data is accumulated, until the data is saved as a Test Record.
Defib	A defibrillator; or, the act of defibrillating.
Demand Mode	In reference to pacemakers, a mode of operation in which the pacemaker is responsive to an ECG input signal. Also referred to as "synchronous mode". When operating in demand mode, the pacemaker generates pacing pulses in the absence of ECG activity.
DUT	Defibrillator Under Test, or Device Under Test
ECG	Electrocardiogram. Equivalent to EKG.
IEC	International Electrotechnical Commission

Phase 3 OPERATING MANUAL

Inter-phase Delay	The time duration between the first phase and the second phase of the defibrillator discharge, where the discharge current is nominally zero.
LA	Left arm ECG lead
LL	Left leg ECG lead
Monophasic	A type of defibrillator discharge waveform with only a single discharge pulse, as opposed to biphasic waveform.
Non-Demand Mode	In reference to pacemakers, a mode of operation in which the pacemaker is not responsive to an ECG input signal. Also referred to as "asynchronous mode". When operating in non-demand mode, the pacemaker generates pacing pulses regardless of whether there is ECG activity or not.
Paced Refractory Period	Immediately after generation of a pacing pulse, paced refractory period (PRP) is the time interval over which the pacemaker remains insensitive to the ECG. If a QRS occurs within the PRP following output of a pacing pulse, the pacemaker ignores this QRS.
Pacer	A transcutaneous pacemaker
PPM	(Pacemaker) Pulses Per Minute
Pulsed biphasic	Similar to the biphasic defibrillator discharge wave form, but modulated with a frequency of several kHz.
QRS complex	A specific segment of the electrocardiogram signal, comprising the Q, R and S waves, which corresponds to the heart systole.
RA	Right arm ECG lead
RL	Right leg ECG lead
Refractory Period	When a pacemaker is operating in synchronous or demand mode, the refractory period is the time interval during which the pacemaker is insensitive to an ECG input signal, and in particular, the QRS complex of the ECG.
Sensed Refractory Period	The time interval after a detected QRS during which a pacemaker remains insensitive to the ECG. If a QRS occurs within the refractory period following a detected QRS, the pacemaker then ignores this second QRS.

Phase 3 OPERATING MANUAL

Test Record	Test result data which has been saved to the non-volatile Data Log as a record of all tests performed on a particular defibrillator or pacemaker, as identified by I.D. or control number. A Test Record may be recalled from the Data Log for viewing on the LCD or printing. Test Records can be downloaded in bulk to a PC using Phase3pc software.
Transcutaneous Pacemaker	A pacemaker which stimulates cardiac muscle via electrodes applied to the outside of the body, usually the chest. Many defibrillators incorporate a transcutaneous pacemaker.
Tilt	The ratio of the voltage difference between the start voltage of the first phase of a defib discharge and the end voltage of the second phase, to the start voltage of the first phase. Expressed in percentage.
V1-V6	Precordial ECG leads

The following symbols appear on the labelling of *Phase 3*, and throughout this manual:



The operating manual provides valuable information on the proper use of *Phase 3*. It is highly recommended that the operator read the instructions thoroughly before operating the device. It is possible to damage the Device Under Test (DUT) and/or cause harm to the operator if *Phase 3* is used incorrectly



CAUTION: Electrical Shock Hazard, Refer servicing to qualified personnel
CAUTION: Consult Accompanying Documents

These warnings appear on the serial number label of *Phase 3*. *Phase 3* measures hazardous electrical voltages which MAY BE present when the covers are removed. The operator should read the Operating Manual to determine what actions to take in the event of failure of *Phase 3*. Refer to the Troubleshooting and Maintenance section of the Operating Manual.

In order to ensure ongoing performance accuracy, a TEST mode is provided on the Main Menu (refer to section 4.3.1). It is recommended that this feature be used on a routine basis, or any time a test result is in question.

Phase 3 OPERATING MANUAL









NOTE: Protection of the operator may be compromised if the instructions in this manual are not followed, or if *Phase 3* is used for a purpose not specified in this manual.



CAUTION: This device measures high voltage signals. For protection of the operator, inspect the Paddle Adapter and the interconnecting Paddle Adapter Cables on a regular basis for nicks, cracks or other damage that may compromise the insulating properties of the housing, wire or connectors. Replace any damaged or worn components immediately.

Typographic Conventions Used in this Manual

Style Example	Definition
CANCEL	Softkeys which appear on the <i>Phase 3</i> unit display
TEST RESULTS	Text which appear on the <i>Phase 3</i> unit display
Add Test	Text which appears on the PC screen when running <i>Phase3pc</i> software, or text which describes the action of an icon located on the PC screen.
{ }	Represents an actual key on a computer keyboard.
b+T	Represents the simultaneous pressing of the specified key combination on a computer keyboard.
 , 	Represents clickable icons which appear on the PC screen when running <i>Phase3pc</i> software
 ,  ,  ,  , ▲ , ▼ , ► , ◄	Represent special function keys located on the front panel of the <i>Phase 3</i> unit. Refer to section 4.1.1 for a detailed explanation of how these keys are used.

1 SPECIFICATIONS

1.1 Tests Performed

- Defibrillator Energy
- Defibrillator Charge Time
- Defibrillator Cardioversion
- Automated External Defibrillator (AED) Performance
- ECG Monitor Performance
- Pacer Pulse Characteristics
- Pacer Noise Immunity
- Pacer Sensitivity
- Pacer Refractory Periods

1.2 Performance Specifications

1.2.1 Energy Measurement, General

- | | |
|----------------------------------|--|
| • Load resistance: | 50 ohms $\pm 1\%$, non-inductive |
| • Signal sampling interval: | 11.4 microseconds |
| • Measurement time window: | 58.368 milliseconds |
| • ECG amplitude at defib pads: | 1 mV QRS |
| • WAVEFORM (oscilloscope) Output | |
| High Range: | 1000:1 amplitude attenuation |
| Low Range: | 200:1 amplitude attenuation |
| • Waveform Playback: | Captured discharge can be viewed via ECG outputs and paddles, with 200:1 time base expansion |
| • First Phase Pulse Width: | 0.1 - 58 msec |
| • Second Phase Pulse Width: | 0.1 - 58 msec |
| • Interphase Delay: | 0.1 - 58 msec |
| • Tilt: | 0 - 99.9 % |
| • Modulation Frequency: | 1000 - 8000 Hz |
| • Modulation Duty Cycle: | 0 - 99.9 % |

Phase 3 OPERATING MANUAL

1.2.2 Defibrillator High Range Energy Test

- Energy Measurement:
 - Range: 0.0 to 600.0 Joules
 - Accuracy: $\pm 1\%$ ± 2 LSD
- Voltage Measurement:
 - Range: 0 to 5000 Volts
 - Accuracy: $\pm 1\%$ ± 2 LSD
- Current Measurement:
 - Range: 0.0 to 100.0 Amps
 - Accuracy: $\pm 1\%$ ± 2 LSD
- Pulse Width Measurement:
 - Range: 0.10 to 58.36 milliseconds
 - Accuracy: $\pm 1\%$ ± 2 LSD
- Trigger Level: 80 Volts
- Playback Amplitude: 1 millivolt per 1000 volts on Lead II;
1 millivolt per 2000 volts at defib pads
- Test Pulse: 126 Joules $\pm 10\%$

1.2.3 Defibrillator Low Range Energy Test

- Energy Measurement:
 - Range: 0.0 to 50.0 Joules
 - Accuracy: $\pm 1\%$ ± 2 LSD
- Voltage Measurement:
 - Range: 0 to 1000 Volts
 - Accuracy: $\pm 1\%$ ± 2 LSD
- Current Measurement:
 - Range: 0.0 to 20.0 Amps
 - Accuracy: $\pm 1\%$ ± 2 LSD
- Pulse Width Measurement:
 - Range: 0.10 to 58.36 milliseconds
 - Accuracy: $\pm 1\%$ ± 2 LSD
- Trigger Level: 16 Volts
- Playback Amplitude: 1 millivolt per 200 volts on Lead II;
1 millivolt per 400 volts at defib paddles
- Test Pulse: 46 Joules $\pm 10\%$

Phase 3 OPERATING MANUAL

1.2.4 Defibrillator Charge Time Test

- Energy, Voltage, Current and Pulse Width specifications per 1.2.1.
- Charge Time Measurement:
 - Range: 0.0 to 99.9 seconds
 - Accuracy: ± 1 LSD

1.2.5 Defibrillator Cardioversion Test

- Energy, Voltage, Current and Pulse Width specifications per 1.2.1, 1.2.2.
- Sync Delay Measurement:
 - Range: -200 to +800 milliseconds
 - Accuracy: ± 1 LSD
- Delay Target: +20 to +65 msec window when enabled
- Sync Point: Selectable, peak of ECG Q or R wave

1.2.6 AED Performance Test

- Energy specifications per 1.2.1.
- Test Method: Verification of AED shock advisory report for specified ECG arrhythmia

1.2.7 Pacemaker Pulse Test

- Pulse Amplitude Measurement:
 - Range: 4 to 250 milliamps, all loads
 - Accuracy: $\pm 1\% \pm 1$ LSD
- Pulse Rate Measurement:
 - Range: 20 to 220 pulses per minute (PPM)
 - Accuracy: $\pm 1\% \pm 1$ LSD
- Pulse Width Measurement:
 - Range: 0.5 to 58.36 milliseconds
 - Accuracy: $\pm 1\% \pm 2$ LSD
- Pulse Energy Measurement:
 - Range: 1 μ J to 3000 mJ
 - Accuracy: $\pm 5\% \pm 1$ μ J
- Test Load Range: 50 to 1600 ohms, in 50 ohm steps
- WAVEFORM output: 50 milliamps per volt, all loads
- Measurement Methods: Average, leading edge, trailing edge, peak
- Test Pulse: 146 mA $\pm 10\%$

Phase 3 OPERATING MANUAL

1.2.8 Pacemaker Noise Immunity Test

- Test Waveform: 50Hz or 60Hz sine wave
- Noise Amplitude Range: 0.18 to 10.00 millivolts peak-to-peak
- Noise Amplitude Precision: 0.139 millivolts

1.2.9 Pacemaker Sensitivity Test

- Test Waveform: Square (SQRP), Triangle (TRIP) or Haversine (SSQP) pulse
- Waveform Width: 10, 25, 40, 100, or 200 milliseconds
- Amplitude Range: 0.00 to 3.00 millivolts peak

1.2.10 Pacemaker Refractory Period Test

- Paced Refractory Period (PRP):
 - Range: 50 to 750 milliseconds
 - Accuracy: ± 1 LSD
- Sensed Refractory Period (SRP):
 - Range: 50 to 750 milliseconds
 - Accuracy: ± 1 LSD

1.3 ECG Simulator

1.3.1 Performance Test Waveforms

- DC Pulse, 4 seconds
- Square Wave, 2 Hz
- Triangle Wave, 2 Hz
- Sine Wave @ 0.1, 0.5, 10, 20, 40, 50, 60, 70, or 100 Hz

1.3.2 Normal Sinus Rhythm

- 30, 60, 90, 120, 150, 180, 240 or 300 BPM

1.3.3 Cardioversion, Shock Advisory and AED Test Waveforms

- Atrial Fibrillation, Coarse (AFIB1)
- Atrial Fibrillation, Fine (AFIB2)
- Asystole (ASYS1) (random, low-frequency baseline fluctuation)
- Asystole - Flat (ASYS2) (flat line/zero volts)
- Supraventricular Tachycardia (SVTACH)
- Ventricular Tachycardia at 140 BPM (VTACH1)
- Ventricular Tachycardia at 160 BPM (VTACH2)
- Ventricular Tachycardia at 190 BPM (VTACH3)
- Torsades de Pointes at 200 BPM (PVTACH)
- Coarse Ventricular Fibrillation (VFIB1)
- Fine Ventricular Fibrillation (VFIB2)
- Square Pulse 1 ms at 60 BPM (SQRP1)

1.3.4 Arrhythmia Simulations

- Second Degree A-V Block
- Premature Atrial Contraction (PAC)
- Right Bundle Branch Block (RBBB)
- Premature Ventricular Contraction (PVC)
- R-on-T PVC
- Multifocal PVC
- Run of 5 PVC
- Bigeminy
- Trigeminy

Phase 3 OPERATING MANUAL

1.3.5 Pacemaker Test Waveforms

- SQRP (square) Pacer Trigger, width = 2, 25, 40, 100 or 200 msec
- TRIP (triangle) Pacer Trigger, width = 10, 25, 40, 100 or 200 msec
- SSQP (haversine) Pacer Trigger, width = 10, 25, 40, 100 or 200 msec

1.3.6 Performance Specifications

- Output Level: Selectable, 1 millivolt, 2 millivolt or 0.5 millivolt into ECG Lead II
- Impedance: 500 ohms
- Accuracy:
 - Rate: $\pm 0.2\%$
 - Amplitude: $\pm 2\%$

1.4 Non-Volatile Memory

1.4.1 Memory Type

- EEPROM

1.4.2 Data Capacity

- 50 Test Records
- 10 Defibrillator Waveform Records
- 32 Automated Test Sequences

1.4.3 Test Record Content

- Device ID (equipment control number)
- Time/date of test
- Test type (manual or AutoSequence test)
- Device type (standard defibrillator, or AED)
- Up to 10 defibrillator energy tests (or 32 AED energy tests)
- 1 defibrillator charge time test
- Up to 4 defibrillator cardioversion tests
- Up to 12 ECG performance tests
- Up to 10 pacer pulse tests
- 1 pacer noise immunity test
- Up to 2 pacer sensitivity tests
- Up to 2 pacer refractory period tests

Phase 3 OPERATING MANUAL

1.4.4 Waveform Record Content

- Device ID (equipment control number)
- Time/date of test
- Energy, voltage, current, and pulse width of captured discharge
- Discharge waveform data

1.5 Interface

1.5.1 User Interface

- LCD (5.2" x 1.5"; 40 characters x 8 lines text; 240 x 64 pixel graphics)
- 4 front panel soft-keys + 4 navigation keys
- Audio beeper
- LCD contrast adjustment (side panel)

1.5.2 Defibrillator Input

- Molex 42820-3212

1.5.3 Pacemaker Input

- 2 x safety-style banana jack (red (+)/black (-))

1.5.4 ECG Simulator Outputs

- 10 x safety-style banana jack (RA; RL; LA; LL; V1-V6)

1.5.5 Defibrillator/Pacer Waveform Output

- 1/8" monaural phono jack with signal on tip, sleeve ground

1.5.6 High-Level ECG Output

- 1/8" monaural phono jack with signal on tip, sleeve ground

Phase 3 OPERATING MANUAL

1.5.7 USB Port

- Connector: Type "B"
- Protocol: USB 1.1 or USB 2.0 compatible
- Data Transfer Rate: 64 bytes per millisecond

1.5.8 Serial (RS-232) Port

- Connector: DB9 Male
- Protocol: RS-232C; bidirectional; CTS handshaking;
9600 baud; 8 data bits; no parity bit;
1 stop bit

1.5.9 Keyboard Port

- Connector: PS/2 (6-pin miniDIN female)
- Protocol: Per PS/2 standard

1.5.10 Power Supply

- Battery: Internal 12V rechargeable
 - Battery Life: 24 hours of use between charges (nominal)
 - Battery Charger: See AC adapter, section 1.8.1
 - DC Voltage Input: 18VDC, 0.8A max
- * Note: The mains power supply voltage fluctuation is not to exceed +/- 10% of the specified nominal supply voltage or the specified input voltage range, whichever is applicable.

1.6 Environment

- 15°C to 40°C
- 15% to 90% RH
- Altitude: 2000m max.
- Indoor Use Only
- Category II
- Pollution Degree 2

1.7 Dimensions

- 9.5" (24cm) W x 8" (20cm) H x 5.5" (14cm) D
- Weight 3 lbs. (1.4 kg)

1.8 Accessories

1.8.1 Standard Accessories

- Adult Paddle Adapter
- Adult Paddle Adapter Cable
- USB Cable (A-B Male)
- *Phase3pc* Software on CDROM
- Operator's Manual on CDROM
- AC Adapter*, one of:
 - North America: 120VAC/60Hz to 15VDC/1A
 - UK: 240VAC/50Hz to 15VDC/0.8A
 - Europe/China: 220VAC/50Hz to 15VDC/0.8A
 - Japan: 120VAC/60Hz to 18VDC/1A

1.8.2 Optional Accessories

- ECG-to-Banana Adapter Set
- Internal Paddle Adapter Set
- Variable Load Module
- Unterminated Defibrillator Adapter Cable
- Unterminated Pacemaker Adapter Cable
- Terminated Defibrillator Adapter Cable - Banana Jacks
- Computer Interface Cable (RS-232 Null Modem), DB9F - DB9F
- Computer Interface Adapter (RS-232), DB9M - DB25F

Phase 3 OPERATING MANUAL

- Printer Interface Adapter, DB9M - DB25M
- Barcode Pen Reader, RS-232
- Barcode CCD Scanner c/w case, RS-232
- Barcode CCD Scanner c/w case, PS/2
- Soft Case, Phase3
- Soft Case, Large
- Paddle Adapter Interconnect Cable, 24"
- Serial Adapter Kit (RJ12 to DB9F), ES601 to Phase3

Accessories shown were current as of the date of release of this manual. For part numbers and a current, complete list of available accessories, visit www.datrend.com or contact Datrend Customer Service (see Chapter 7 for contact details)

Compliance With Standards

Phase 3 has been certified to meet the following safety standards:

CAN/CSA-C22.2 No. 61010-1-(2nd Edition) - Safety Requirements for Electrical Equipment for Measurement, Control, and Laboratory Use, Part 1: General Requirements

UL Std. No. 61010-1 (2nd Edition) - Safety Requirements for Electrical Equipment for Measurement, Control, and Laboratory Use - Part 1: General Requirements

IEC/EN 61010-1 (Ed.2.0) - Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 1: General requirement

Following manufacture, all units are subjected to, and have passed the requirements of the 'Routine Tests' defined in Annex F of the above Standard(s).

2 OVERVIEW

2.1 General Description

2.1.1 Test Capabilities

Phase 3 is a portable, automated system for verifying performance of defibrillators and transcutaneous pacemakers of all types, including defibrillators which produce monophasic, biphasic, and Multipulse Biowave® (pulsed biphasic) discharges. *Phase 3* provides menu-driven procedures which allow you to test:

<i>Delivered Energy</i>	Measure the output energy of a defibrillator when it is discharged into <i>Phase 3</i> . Along with energy in joules, also measures peak voltage, current and duration of the discharge pulse.
<i>Charge Time</i>	Measure the time required for a defibrillator to charge up to its maximum energy setting. After charging, measures the energy delivered when the defibrillator is discharged into <i>Phase 3</i> .
<i>Cardioversion</i>	Verify the ability of a defibrillator to correctly synchronize its discharge to the QRS complex of the electrocardiogram.
<i>Monitor Performance</i>	Check the ECG monitor and chart recorder of a defibrillator with performance waves, normal sinus rhythms, and a wide variety of arrhythmias provided by the full-featured ECG simulator of <i>Phase 3</i> .
<i>AED Performance</i>	Verify the ability of an Automated External Defibrillator (AED) to correctly recognize life-threatening arrhythmias and advise delivery of a shock at the appropriate energy.
<i>Pulse Characteristics</i>	Measure amplitude, rate and width of pulses generated by the transcutaneous pacemaker of a defibrillator.
<i>Noise Immunity</i>	Verify the ability of a transcutaneous pacemaker to reject line frequency interference in the electrocardiogram.

Phase 3 OPERATING MANUAL

<i>Sensitivity</i>	Determine the smallest QRS complex that a transcutaneous pacemaker will recognize as valid.
<i>Refractory Period</i>	Determine the paced refractory period (PRP) and sensed refractory period (SRP) of a transcutaneous pacemaker.

Phase 3 incorporates one fixed 50 ohm load for defibrillator testing, and a variable load for pacer testing that may be set from 50 to 1600 ohms in 50 ohm steps. To accommodate requirements of the IEC60601-2-4 standard for defibrillators, the ***Variable Load Module*** (VLM) may be added to *Phase 3* as an optional accessory, allowing the user to perform energy tests with an alternative defibrillator load ranging from 25 to 175 ohms in 25 ohm steps.

Phase 3 may be powered from its internal battery or from AC power using the accessory adapter provided with the unit. The rechargeable battery can provide up to 24 hours of continuous operation.

Phase 3 is small and light-weight, allowing you to easily carry the analyzer to institutional areas where defibrillators are located. As you perform each test, results can be saved to the non-volatile Data Log of *Phase 3*, for later review on the LCD, output to an attached printer, or download to a personal computer.

2.1.2 Data Log

Phase 3 incorporates a non-volatile memory or "data log" which is used to save test results or ***Test Records***. For each defibrillator tested, *Phase 3* can create a Test Record containing energy, charge time and cardioversion test results, which may be combined with results from ECG and transcutaneous pacemaker tests. The non-volatile memory of *Phase 3* provides storage for up to 50 such Test Records, each Record being identified by the control number of the defibrillator tested. The non-volatile memory can also be used to store up to 10 defibrillator discharge waveforms as ***Wave Records***. Test Records and Wave Records can be downloaded to a personal computer by means of *Phase3pc* software, included on CDROM with the analyzer.

Phase 3 OPERATING MANUAL

2.1.3 Automated Testing

For fully automated testing, *Phase 3* provides 32 *AutoSequences* which may be user-programmed by means of *Phase3pc* software. An AutoSequence test may include steps for measuring defibrillator energy, charge time, and synchronization delay; ECG performance; and pacemaker pulse characteristics, noise immunity, sensitivity, and refractory periods. *Phase 3* comes equipped with pre-programmed AutoSequences loaded into its non-volatile memory, which can be modified or supplemented as desired via *Phase3pc* software.

For each test or measurement performed in an AutoSequence, the expected value of the result or target is specified, so that *Phase 3* will automatically pass or fail the result depending on an acceptance range derived from the target and a selected tolerance. In manual tests, target and tolerance parameters may be optionally entered "on the fly", while measurements are being taken.

2.1.4 Connectivity

Phase 3 has two communication ports: Serial I/O and USB. The Serial I/O interface is an RS-232 Port that may be connected to a personal computer, accessory barcode reader, serial printer, or automated testing system such as the ES601Plus Automated Safety Analyzer. The USB Port is intended solely for rapid data transfer to a personal computer using the accessory *Phase3pc* software. To permit rapid data entry of equipment control numbers, *Phase 3* also provides a PS/2 Port which may be connected to a standard PS/2 keyboard, or to a PS/2 barcode reader.

2.1.5 Viewing and Saving Defibrillator Waveforms

In addition to providing an analog output suitable for connection to a conventional oscilloscope, *Phase 3* provides a number of unique features related to defibrillator waveform capture and examination, including:

Show Waveform

After discharging a defibrillator into *Phase 3*, view the captured waveform on the *Phase 3* graphical LCD. Three selections for both vertical and horizontal axes are provided, allowing you examine the waveform in greater detail.

Playback

Play back the captured defibrillator waveform into the ECG monitor or chart recorder of the defibrillator, with 200:1 timebase expansion. *Phase 3* may be configured to automatically playback the waveform following detection of a valid defibrillator discharge.

Phase 3 OPERATING MANUAL

Wave Records	Save the captured waveform as a Wave Record, for later download and graphical plotting by the accessory Phase3pc software (included). To allow a greater number of Wave Records to be stored, the signal data is compressed by Phase 3 before saving.
Real-Time Capture	Capture high-resolution signal data immediately after a defibrillator discharge, by rapid data transfer via USB to a personal computer running Phase3pc software. Real-time wave capture may also be performed via RS-232 when Phase 3 is operating in remote control mode.

Wave Records are meant to provide a qualitative "snap shot" of the defibrillator signal, but for some types of discharges, data resolution of the compressed waveform may be insufficient for detailed numerical analysis such as might be required in a laboratory investigation or research. As an alternative to Wave Records, **Phase 3** in conjunction with **Phase3pc** software can provide real-time waveform capture of a discharge. With real-time capture, **Phase3pc** can produce a graphic chart of the waveform data on the PC screen immediately after a discharge, accompanied by the analysis results such as energy, voltage, current and pulse duration. High-resolution waveform data can then be saved as a file on the PC for later recall, or for export to other data analysis programs such as a spreadsheet.

2.1.6 Principle of Operation

In principle, **Phase 3** is a waveform analyzer that determines the characteristics of an electrical discharge signal produced by a defibrillator and/or transcutaneous pacemaker. These characterizations include: signal energy, peak current, peak voltage, pulse width, pulse rate, and refractory intervals.

Measurements are accomplished by sampling the defibrillator signal from the defib pads or from the pacer terminals at a high speed. Sampling is triggered by either the rising or falling edge of the input signal, ensuring the waveform will be captured even if the operator connects the defib or pacer to **Phase 3** with reversed polarity.

Once **Phase 3** is triggered, the signal is digitized with 13 bits of precision and approximately 58 milliseconds of signal data having a sample interval of 11.4 microseconds are then stored. After acquiring the signal data, **Phase 3** calculates test results based on the samples. As each measurement result is derived (energy; voltage; current; and so on), the result is temporarily stored in the Clip Record which is located in volatile memory (RAM). Once all tests have been completed, the user can save the test results by entering an equipment control number for identification and then transferring the contents of the Clip Record to a Test Record in the non-volatile Data Log.

2.2 Controls and Interface Connections

Figure 1 illustrates the user controls and electrical interfaces of *Phase 3*. The electrical interfaces are described in Chapter 3 of this manual. Operation of *Phase 3* via the keypad and LCD is described in Chapter 4.

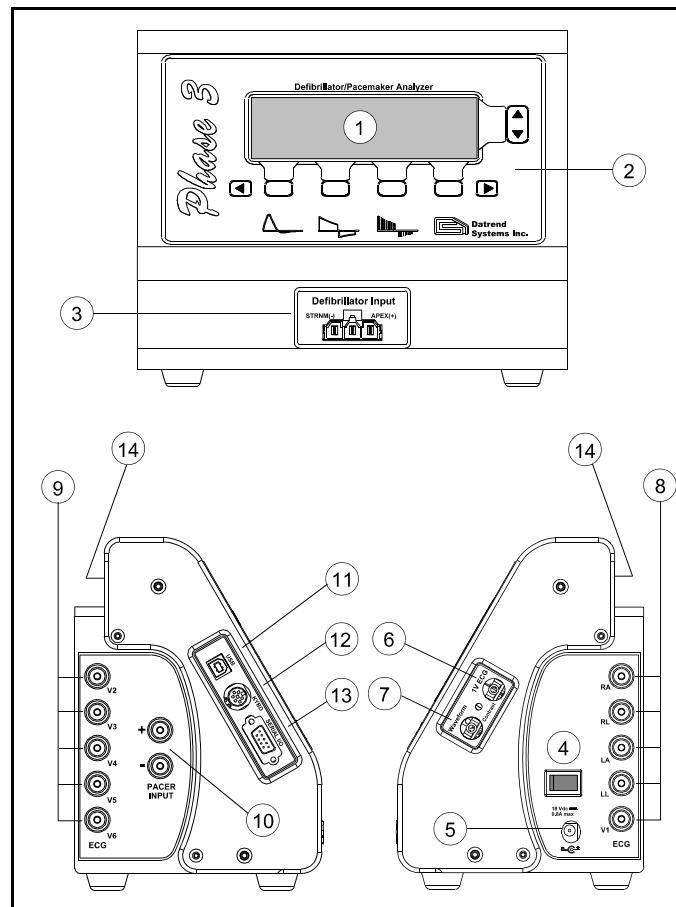


Figure 1: Controls and Interfaces

- | | | | |
|----|-----------------------------------|-----|----------------------------------|
| 1. | Liquid Crystal Display (LCD) | 8. | ECG Outputs (RA; RL; LA; LL; V1) |
| 2. | Keypad | 9. | ECG Outputs (V2; V3; V4; V5; V6) |
| 3. | Defibrillator Input | 10. | Pacemaker Input |
| 4. | Power ON/OFF Switch | 11. | USB Port |
| 5. | DC Power Input | 12. | PS/2 Keyboard Port |
| 6. | High-Level ECG Output (1V QRS) | 13. | Serial I/O Port (RS-232) |
| 7. | Waveform Output (to oscilloscope) | 14. | Carrying Handle |

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3 SETUP

3.1 Connections

- a. Place *Phase 3* on a stable surface and insert the plug of the provided AC adapter into the power input jack located on the right side panel (**Figure 1**). Plug the adapter into an AC outlet.



IMPORTANT:

YOUR *Phase 3* HAS BEEN PROVIDED WITH ONE OF THE FOLLOWING AC ADAPTERS:

North America: 120VAC/60Hz to 15VDC/1A; NEMA 5-15P plug

United Kingdom: 240VAC/50Hz to 15VDC/0.8A; BS 1363 plug

Europe/China: 220VAC/50Hz to 15VDC/0.8A; CEE 7/16 plug

Japan: 120VAC/60Hz to 18VDC/1A

USE ONLY THE AC ADAPTER PROVIDED WITH YOUR INSTRUMENT. SUBSTITUTION OR USE OF AN ALTERNATE AC ADAPTER MAY DAMAGE *Phase 3* AND VOID THE WARRANTY.

Phase 3 OPERATING MANUAL

- b. If you wish to test a defibrillator having external paddles, connect the Adult Paddle Adapter included with *Phase 3* to the Defibrillator Input using the Paddle Adapter Cable (**Figure 2**). At each end of the cable, depress the catch on the plug, fit the plug all the way into the mating receptacle, then release the catch to lock the cable securely in place.

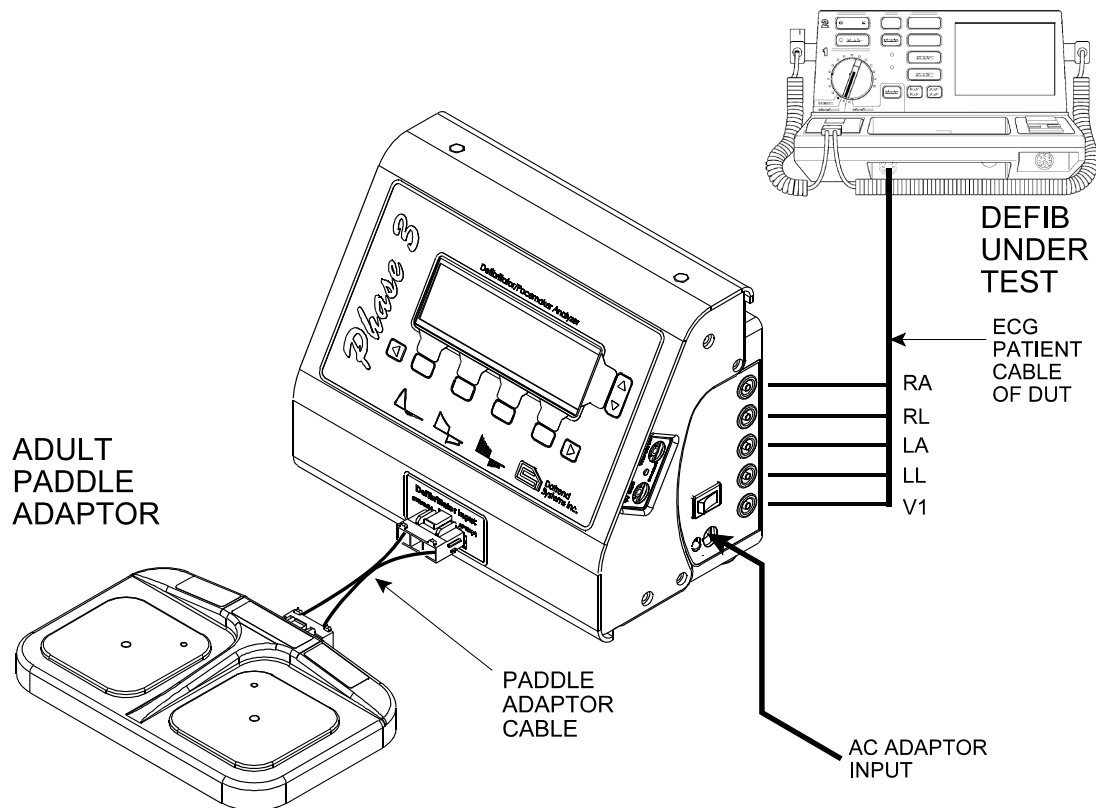


Figure 2 - Connection to defibrillator under test.

Alternatively, for hands-free testing, you may connect the output of the defibrillator directly to the Defibrillator Input of *Phase 3* by means of a suitable adapter cable. An unterminated defibrillator adapter cable is available as an optional accessory, or various manufacturer specific cables are available (contact Datrend or visit our website www.datrend.com).

Phase 3 OPERATING MANUAL



NOTE:

When using unterminated cable, you should observe polarity of the connection as indicated on the Defibrillator Input label [STERNUM(-); APEX(+)]. Reverse polarity connection cannot damage *Phase 3* or produce incorrect measurement results, however, the defibrillator waveform may appear inverted if viewed on the *Phase 3* LCD.

An adapter set for testing internal paddles is also available as an optional accessory. Refer to the information sheet supplied with the Internal Paddle Adapter Set for instructions on how to fit these adapters to the pads on the Adult Paddle Adapter.

- c. Connect ECG leads from the defibrillator under test (DUT) to the ECG simulator outputs located on left and right side panels of *Phase 3* (Figure 1). Connections for standard 3- or 5-wire ECG patient cables (RA; RL; LA; LL; V) are provided on the right side panel of *Phase 3*; optional chest connections (V2-V6) for diagnostic ECG are located on the left side panel. *Phase 3* accepts standard or safety-style banana plugs for the ECG connections. An Adapter Set which can interface *Phase 3* to snap-style ECG patient leads is available as an optional accessory.
- d. If testing of a transcutaneous pacemaker is required, connect the pacemaker output to the PACER INPUT terminals located on the left side panel of *Phase 3* (Figure 3). The PACER INPUT connections will accept standard or safety-style banana leads. An unterminated pacemaker adapter cable is available as an optional accessory.

You should avoid discharging a defibrillator into the Pacer Input of *Phase 3*. Repeated discharges at high energy levels may eventually result in degradation or damage to the pacer input, which is not covered by warranty (see page ii). Check connection of the defibrillator to *Phase 3* before you discharge.

Phase 3 OPERATING MANUAL

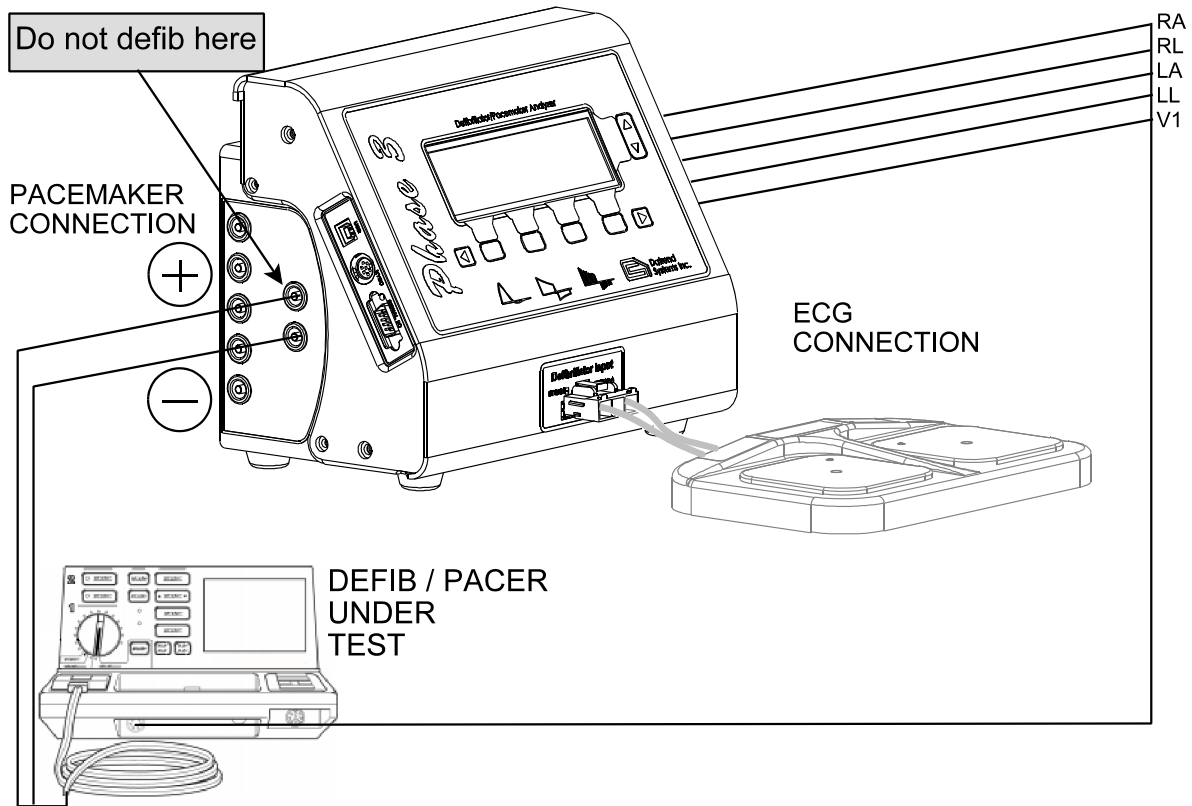


Figure 3 - Connection for pacemaker testing.

3.2 Optional Connections

Refer to **Figure 1** to locate the optional interface connections described in this section.

3.2.1 High-Level ECG Output

A high-level analog output signal from the *Phase 3* ECG simulator is available at the *1V ECG* jack located on the right side panel. This is a 1/8" monaural phono jack having the signal on the tip connection and ground on the sleeve. This output is capable of driving a load of 10k ohms or higher.

The signal amplitude observed at the *1V ECG* jack depends on the SCALE setting of the ECG simulator. At this jack, the QRS complex of the ECG will have 1 volt peak amplitude when the simulator is set to "x1 scale"; 2 volt amplitude on "x2 scale"; and 0.5 volt amplitude on "x0.5 scale".

3.2.2 Waveform Output

The WAVEFORM output is located on the right side panel of *Phase 3* and is intended for connection of an oscilloscope or similar instrument. The WAVEFORM output is a 1/8" monaural phono jack having the signal on the tip connection and ground on the sleeve.

When performing defibrillator tests, the WAVEFORM output will provide a scaled analog signal representative of the defibrillator discharge. When LOW RANGE energy measurement is selected, the WAVEFORM output provides **1 volt output per 200 volts** at the *Phase 3* Defibrillator Input (200:1 attenuation). When HIGH RANGE energy measurement is selected, the WAVEFORM output provides **1 volt output per 1000 volts** at the Defibrillator Input (1000:1 attenuation).

When performing pacemaker tests, the WAVEFORM output provides a scaled analog signal representative of the pacemaker pulse train. In this case, the WAVEFORM output provides **1 volt output per 50mA** at the *Phase 3* PACER INPUT. The WAVEFORM scale remains constant regardless of the pacemaker load selected for the test.

Phase 3 OPERATING MANUAL

3.2.3 Serial (RS-232) Input/Output

The Serial I/O Port of *Phase 3* can be used to interface to any one of the following RS-232 peripheral devices.

Personal Computer	<ul style="list-style-type: none">• Controls <i>Phase 3</i> remotely through a COM port using the remote command instruction set.• Downloads test result data (Test Records) stored in the <i>Phase 3</i> memory.
Serial Printer	<ul style="list-style-type: none">• Generates a hard copy printout of Test Records stored in non-volatile Data Log of <i>Phase 3</i>.
Barcode Reader or Scanner	<ul style="list-style-type: none">• Enables rapid entry of an equipment control number as scanned from a barcode label on the defibrillator under test.
Automated Test System	<ul style="list-style-type: none">• Controls <i>Phase 3</i> using the remote command instruction set.

The multifunction Serial Port is realized through a DB9 male connector whose pinout is shown in **Figure 4**. The protocol of the Serial Port is **9600** baud, **N, 8, 1**.

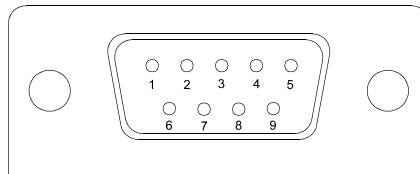


Figure 4: Serial I/O Port (front view)

Barcode readers which are compatible with the *Phase 3* RS-232 Port are available as optional accessories.

Phase 3 OPERATING MANUAL

Optional accessory cables are also available to connect other peripheral devices to *Phase 3*:

- Connection from *Phase 3* to a DB9 PC COM port is achieved using a DB9F to DB9F NULL MODEM cable.
- Connection from *Phase 3* to a DB25 COM port is achieved using a NULL MODEM cable, noted above, in combination with a DB9M to DB25F adapter.
- Connection from *Phase 3* to a serial printer is possible. Contact Datrend for details.

Alternatively, cables made to the specifications listed in **Table 3-1** may be used to connect *Phase 3* to a peripheral device. Connectors specified in the table are for the *cables*, and shaded cells in the table indicate no connection.

Table 3-1: RS-232 Interface Cable Specifications

Phase 3 (DB9F)	PC (DB9F)	PC/MedTester (DB25F)	Serial Printer (DB25M)
2 - RXD	3 - TXD	2 - TXD	
3 - TXD	2 - RXD	3 - RXD	3 - RXD
5 - GND	5 - GND	7 - GND	7 - GND
9 - VCCOUT			
6 - BUSY	4 - DTR	20 - DTR	20 - DTR



IMPORTANT:

Never connect a RS-232 Barcode Reader to *Phase 3* if the power is on. The Barcode Reader is powered from *Phase 3* and may be damaged if “hot-plugged”. Always turn *Phase 3* off BEFORE connecting a RS-232 Barcode Reader to the Serial I/O Port.

Phase 3 OPERATING MANUAL

3.2.4 Keyboard Port

The Keyboard Port of *Phase 3* is intended for optional connection of a PS/2 personal computer keyboard, or alternatively, a PS/2-compatible Barcode Scanner.

Connection of a PS/2 keyboard or barcode scanner to *Phase 3* is optional but simplifies entry of an ID, such as an equipment control number, for the defibrillator under test (DUT). Alternatively, the keypad of *Phase 3* may be used to enter a DUT ID if an external keyboard or barcode scanner is not available.



IMPORTANT:

Never connect a PS/2 device (Keyboard or Barcode Scanner) to *Phase 3* if the power is on. The PS/2 device is powered from *Phase 3* and may be damaged if "hot-plugged". Always turn *Phase 3* off before connecting a PS/2 device.

3.2.5 USB Port

The USB Port of *Phase 3* is intended to work specifically with *Phase3pc* software, supplied with *Phase 3* on CD ROM as a standard accessory. A USB cable is also provided with *Phase 3* as a standard accessory.

Phase 3 may be "hot-plugged" to the PC using the supplied USB cable at any time while the instrument is running. Once *Phase3pc* successfully detects *Phase 3*, data may be transferred to or from the PC via the high-speed USB connection.

With *Phase3pc* software, you can:

- Create, modify, save, and print automated sequences of defibrillator and pacemaker tests ("AutoSequences"). AutoSequences created with *Phase3pc* can be uploaded into the non-volatile memory of *Phase 3*. AutoSequences stored in *Phase 3* can be downloaded to *Phase3pc* for editing and re-uploading to *Phase 3*.
- Download Test Records stored in the non-volatile Data Log of *Phase 3*. *Phase3pc* generates Test Report documents from the Test Records, which you can then print, save to disk, or export to equipment management software.

Phase 3 OPERATING MANUAL

- Download Wave Records stored in the non-volatile memory of *Phase 3*. *Phase3pc* generates graphical plots of the waveform data which you can then print or save to disk.
- Acquire high-resolution samples of defibrillator discharge waveforms, using the real-time waveform capture mode.

Refer to Chapter 6 of this manual for more information on installing and using *Phase3pc* software.

3.3 Setting Up a HyperTerminal Connection

As described in Section 3.2.3, the Serial I/O Port of *Phase 3* may be connected to the serial communications port (COM port) of a personal computer. A terminal program (i.e., Windows 98/2000/XP HyperTerminal or equivalent) running on the PC may then be used to receive *Phase 3* Test Reports and save them to a text file. Follow the instructions below to set up HyperTerminal for use with *Phase 3*.

- a. Open HyperTerminal: In Windows XP, click **Start**, point to **All Programs**, point to **Accessories**, point to **Communications** and click on HyperTerminal.
- b. You will be prompted to enter a name for the HyperTerminal connection and select an icon associated with this new connection (**Figure 5**). Enter a suitable name, select the desired icon, and click on **OK**. Next time, click on this icon from Explorer or the **Start** menu to avoid having to set up a new connection every time you wish to use HyperTerminal.



Figure 5 - New connection for *Phase 3*.

- c. A dialogue box will appear asking which port to connect to. Select the appropriate COM port and click **OK**.
- d. Another dialogue box appears to configure the port settings. Configure the port settings as shown in **Figure 6** and click **OK**.

Phase 3 OPERATING MANUAL

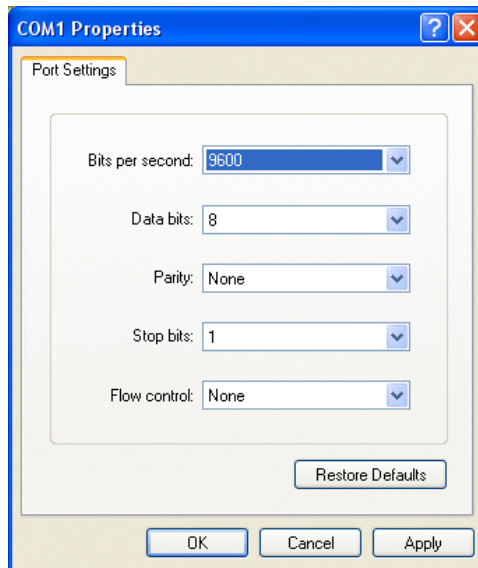


Figure 6 - HyperTerminal COM port

In the HyperTerminal program window, click on **Transfer** in the menu bar and click on **Capture Text** to save all Test Records to a file. In the **File** box, type a descriptive name for the file, and then click **Start**.

- e. HyperTerminal is now ready to receive data sent from *Phase 3* to the PC. Refer to Section 4.9.2.2 for instructions on how to initiate RS-232 transmission of Test Reports from *Phase 3*.
- f. Once all Test Reports have been transferred, stop capturing text. In the **Transfer** menu, point to **Capture Text** and click on **Stop**.

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4 OPERATION AND RELATED DISPLAYS

4.1 General Features of the User Interface

4.1.1 Keypad and Display Operation

The keypad and display of *Phase 3* are shown in **Figure 7**. The keypad comprises four general-purpose keys that have functions defined by the *Phase 3* software, as represented by labels which are shown on the display immediately above each key. In this manual, these keys are referred to as "softkeys". Four additional keys labelled with arrows take specific functions depending on the state of the display.

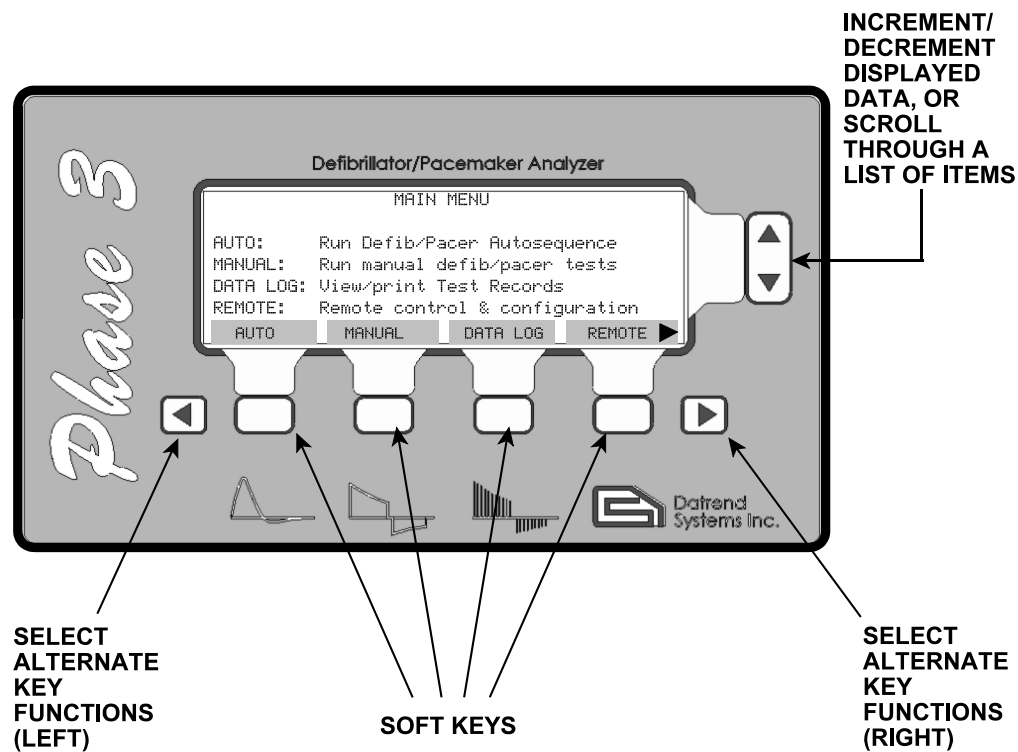


Figure 7 - *Phase 3* keypad functions.

Phase 3 OPERATING MANUAL



These keys are used to respectively increment or decrement displayed data. Alternatively, these keys may be used to scroll through a list of displayed items. These buttons will have a repeating action if pressed and held down. When these keys are active, ▲ ▼ symbols will appear on the LCD display at the far right. These keys will remain inactive until the ▲ ▼ symbols are displayed.



Press this button to access additional softkey functions "on the right". This button becomes active whenever a ► symbol appears on the display at the bottom righthand corner, for example, as shown in **Figure 7**.



Press this button to access additional softkey functions "on the left". This button becomes active whenever a ◀ symbol appears on the display at the bottom lefthand corner.

4.1.2 Clip Record

As defibrillator and pacemaker tests are performed with *Phase 3*, the individual test results are collected in a temporary area of memory which is designated the **Clip Record**. When testing is complete and results are to be saved, the contents of the Clip Record are then copied to a **Test Record**, which resides in non-volatile memory. When a Test Record is recalled from non-volatile memory for viewing or printing, the Record data is placed in the Clip Record.

The Clip Record is in volatile memory and any data stored in it will be lost if *Phase 3* power is interrupted before the Clip Record data is saved as a Test Record. Test Records saved in non-volatile memory are retained when the power to *Phase 3* is switched off.

As *Phase 3* is used to perform individual measurements and tests, the Clip Record will progressively accumulate the following data:

- Device ID (equipment control number)
- Date and Time of test
- Defibrillator test data (energies, charge time, cardioversion sync delays)
- ECG test data (waveform and test result)
- Pacemaker test data (test load, pulse characteristics, and results of immunity, sensitivity and refractory period tests)

Data accumulated in the Clip Record may be reviewed at any point during the manual testing process by pressing the **VIEW** button on the MANUAL TEST menu (see Section 4.4).

4.1.3 CANCEL Key Operation

CANCEL is a special softkey that is used throughout the operator interface of *Phase 3*. **CANCEL** allows the user to cancel a measurement in progress, or a series of previously-acquired measurements, and return the operator interface to a higher level menu from which various types of measurements are selected.

Pressing **CANCEL** can lead to erasure of selected test data in the Clip Record. The amount and type of data erased will depend on which user interface menu is being displayed when **CANCEL** is pressed. **CANCEL** has increasing impact on the Clip Record data as the level of the menu in the user interface increases.

At the lowest level, if **CANCEL** is pressed **immediately after** a measurement is taken, then the result of that single measurement is discarded without confirmation, and will not be copied to the Clip Record. For example, if you measure a defibrillator energy, you may press **CANCEL** immediately after the measurement is displayed to discard that single result. You may then repeat the energy measurement. If a softkey other than **CANCEL** is pressed following an energy measurement, then the energy result is copied to a designated location in the Clip Record.

If **CANCEL** is pressed **before** a measurement is taken, but **after** a number of measurements of the same type have been performed, then all measurements of that type will be deleted from the Clip Record, but only if you confirm the cancellation when prompted by *Phase 3* (see **Figure 8**).

CANCEL TESTING			
Cancel testing? (the current test will be deleted from the Clip Record).			
YES	NO		

Figure 8 - Confirmation prompt for CANCEL keypress.

For example, if you measure a series of defibrillator energies and then press **CANCEL** before completing the next energy measurement, then all energy measurement data accumulated in the Clip Record will be deleted if **YES** is pressed in response to the prompt of **Figure 8**.

Phase 3 OPERATING MANUAL

Various types of defibrillator tests, including energy, charge time and cardioversion, are selected via the DEFIBRILLATOR TEST menu which is described in Section 4.5 of this manual. If **CANCEL** is pressed on the DEFIBRILLATOR TEST menu, then all energy, charge time and cardioversion results being held in the Clip Record will be deleted, but only if you confirm the cancellation by pressing **YES** when prompted by *Phase 3* (Figure 8). However, only the defibrillator test data will be affected; ECG and pacemaker results that may also be present in the Clip Record are not disturbed if **CANCEL** on the DEFIBRILLATOR TEST menu is pressed and confirmed. The **CANCEL** softkey has similar deletion scope on the ECG and PACER TEST menus, as described later in this manual.

If **CANCEL** is pressed and confirmed at the highest level of menu in the user interface, for example the MANUAL TEST menu (Section 4.4), then all test data currently stored in the Clip Record will be deleted.

If **CANCEL** is pressed on a menu which is used for entering data or setting a test parameter, the effect of **CANCEL** is to discard any changes that may have been made to the parameter being edited. Examples include menus for the ECG simulator, data entry of target and tolerance, and ID (control number) entry. In these cases, pressing **CANCEL** has no effect on the contents of the Clip Record.

The deletion scope of the **CANCEL** softkey is explicitly specified in each Section of this manual which discusses a user interface screen having a cancel function. When in doubt, refer to the pertinent Section to determine exactly what potential effect **CANCEL** may have on the Clip Record.

4.1.4 User Preference Settings

Certain parameters or settings in the *Phase 3* are meant to be set to the operator's test preference. These parameters, once set, will remain at that setting until specifically changed by the operator. These parameters will retain their setting after the power is turned off, and will be in effect the next time power is applied. The parameters that exhibit this behaviour are:

- ECG Simulator MODE (refer to section 4.5.1.2)
- Playback length (refer to section 4.5.1.2)
- Pacer amplitude measurement METHOD (refer to section 4.7.2)
- Pacer Load (refer to section 4.7.1)
- Refractory Test ECG WAVE (refer to section 4.7.3)
- Refractory Test ECG scale (refer to section 4.7.3)
- Pacer Noise Immunity Frequency (refer to section 4.7.4.1)

4.2 Powering Up

- a. Set the power switch on the left side panel of *Phase 3* to the ON position. The *Phase 3* LCD will display a power-up screen while performing a number of internal self-tests (**Figure 9**). The firmware version of the instrument will be shown on this screen while the self-test is in progress.

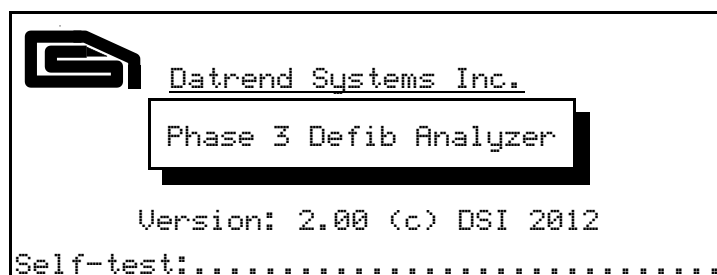


Figure 9 - Power-on screen during self-test.

- b. If required, adjust the LCD contrast control on the right side panel of *Phase 3* using a trimpot adjustment tool (see **Figure 1**).
- c. Upon completion of the self-test, the screen illustrated in **Figure 10** will appear, reporting the self-test results as follows:

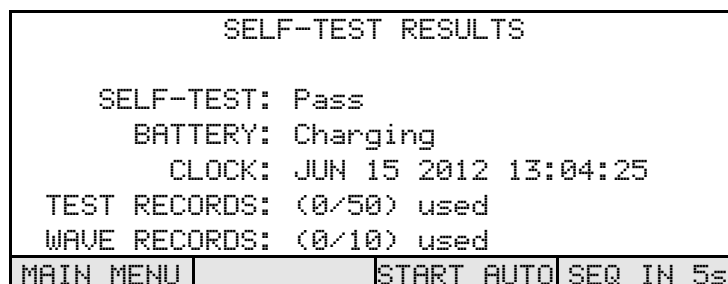


Figure 10 - Self-test results.

- d. *Phase 3* then starts count down 5 seconds, after which it will automatically enter the first autosequence test. During this 5 second, the operator may press the **MAIN MENU** to stop it from entering the autosequence and go directly to the **MAIN MENU** , or press the **START AUTO** soft key to enter the autosequence directly.

Phase 3 OPERATING MANUAL

- SELF-TEST: Pass
means all internal hardware checks have passed their respective tests. If there is a hardware failure, *Phase 3* will report the fault by means of an alarm tone and message on the display. Refer to Section 4.11 if this should happen.
 - BATTERY: Charging
means *Phase 3* is being powered by the AC adapter, and that the internal battery is being charged.
 - BATTERY: xx.x V
means *Phase 3* is being powered by its internal battery. The terminal voltage of the battery is indicated on the LCD as "xx.x" volts. The indication for a charged battery will range from 12.5 to 14.5 volts.
 - TEST RECORDS: (n/50)
USED
represents the number of Test Records "n" currently stored in the non-volatile Data Log of *Phase 3*. The maximum number of Test Records that *Phase 3* can hold is 50, as indicated.
 - WAVE RECORDS: (n/10)
USED
represents the number of Wave Records "n" currently stored in the non-volatile Data Log of *Phase 3*. The maximum number of Wave Records that *Phase 3* can hold is 10, as indicated.
- e. The label displayed on the LCD above each front panel key corresponds to the function of the key for the currently-viewed screen. In this manual, these keys are referred to as "softkeys".
- f. Upon successful conclusion of the self-test, press the **OK** softkey to proceed to the main operating menu of *Phase 3*.

4.3 Main Menu

Referring to **Figure 11**, functions available on the **MAIN MENU** of *Phase 3* are:

MAIN MENU			
AUTO:	Run Defib/Pacer Autosequence		
MANUAL:	Run manual defib/pacer tests		
DATA LOG:	View/print Test Records		
REMOTE:	Remote control & configuration		
AUTO	MANUAL	DATA LOG	REMOTE >

Figure 11 - Main menu of *Phase 3*.

- AUTO** Press to view a list of automated test sequences ("AutoSequences") stored in the non-volatile memory of *Phase 3*. See Section 4.10 for further information on automated testing.
- MANUAL** Press to enter the MANUAL TEST menu, from which manually-conducted defibrillator, ECG, or pacemaker tests may be selected. See Section 4.4 for further information on manual testing.
- DATA LOG** Press to view a list of Test Records currently stored in the Data Log. See Section 4.9 for information related to Test Record viewing and printing.
- REMOTE** Press to activate Remote Mode. In this mode, *Phase 3* may be controlled via RS-232 from a PC, or from a safety analyzer such as ES601Plus, to perform various types of measurements and acquire the data from such measurements. This mode is also used to configure AutoSequences, via a USB connection, with the assistance of *Phase3pc* software supplied with *Phase 3*. Refer to Chapter 5 for more information on Remote Mode, and Chapter 6 for information on installation and use of *Phase3pc*.
- Press to access additional softkey functions as shown in **Figure 12**, and as described below.

<	TEST	ID	SET CLK	
---	------	----	---------	--

Figure 12 - Alternate softkeys of Main Menu.

- TEST** Press to trigger a self-test of the data acquisition hardware. Refer to Section 4.3.1.

Phase 3 OPERATING MANUAL

- ID** Press to input an optional ID for *Phase 3*, such as a control number to identify *Phase 3* in an equipment management system. Refer to Section 4.3.2.
- SET CLK** Press to set local time and date. Refer to Section 4.3.3.
- ◀ Press to restore softkey functions as shown in **Figure 11**.

4.3.1 Test Pulse

When selected from the **MAIN MENU**, the **TEST PULSE** function automatically triggers a series of internal test pulses which are captured by the data acquisition system and are then analyzed, thereby simulating the measurement of a defibrillator or pacemaker discharge. This automated self-check procedure requires a few seconds to complete. While the procedure is in progress, the **CANCEL** softkey may be pressed to abort the test.

Once the test pulses have been analyzed, the results are displayed and compared to 'expected values' which are determined at the time of manufacture of your *Phase 3* unit (**Figure 13**).

TESTING COMPLETED			
	MEASURED	EXPECTED	RESULT
DEFIB HI:	126.1J	126.4J ±5%	PASS
DEFIB LO:	45.3J	45.5J ±5%	PASS
PACER:	144.1mA	144.6mA ±5%	PASS
OK			

Figure 13 - Test Pulse results.

A result within the acceptance range is indicated as "PASS" on the display of **Figure 13**. Any result outside the acceptance range is indicated as "FAIL". A "FAIL" result is suggestive of a corresponding hardware defect inside the instrument. In the event of a "FAIL", refer to Chapter 7 of this manual.

It is recommended that this test be performed on a regular basis, or any time a test result is in question. Press **OK** to continue with the use of the tester.

Phase 3 OPERATING MANUAL



NOTE:

The TEST PULSE function of *Phase 3* provides a functional check of the data acquisition hardware. A "PASS" **does not** indicate that *Phase 3* is within calibration.

Regardless of results obtained for the TEST PULSE, calibration is still required at the intervals specified in the **WARRANTY** section of this manual. When calibration is due, contact Datrend Customer Service to determine the authorized service facility nearest you. See Chapter 7 of this manual.

4.3.2 Phase 3 ID

Pressing **ID** on the MAIN MENU allows you to enter information, such as a control number, for uniquely identifying *Phase 3* within an equipment management system. After downloading Test Record data from *Phase 3* into *Phase3pc* software, this **ID** will then appear in Test Report documents that are automatically generated by the software.

Phase 3 ID			
Enter a unique ID / control number			
using the ▼ ▲ ◀ ▶, or by means of an ▲			
attached barcode reader or PS/2 kbd.			
Phase 3 ID: ----- ▼			
^			
CLEAR	<---	--->	CANCEL

Figure 14 - Entry of *Phase 3* ID.

Phase 3 OPERATING MANUAL

Referring to **Figure 14**, the softkeys operate as follows on the ID entry screen:

← → Move the ^ cursor left/right.

CLEAR Clear the displayed ID and show ----- . Changes to **ENTER** if any characters are input.

ENTER Save the displayed ID in the non-volatile memory of *Phase 3*.

CANCEL Do not save to memory of *Phase 3*; discard changes.

The ▲ ▼ keys to the right of the LCD display are used to increment/decrement the character shown above the ^ cursor.

If a RS-232 or PS/2 barcode reader (wand or scanner) is plugged into the appropriate port of *Phase 3*, then power will be applied to the reader when this menu is entered. A barcode may be scanned which will then appear on this display. Press **ENTER** to store the displayed information as the ID, See Sections 3.2.3 and 3.2.4 for barcode reader connection instructions.

In Manual Entry mode, the ID is input by placing the ^ character below a - using the ← → keys and scrolling through available characters using the ▲ ▼ keys. The ID displayed on the screen may be cleared by pressing **CLEAR**, accepted by pressing **ENTER**, or **CANCEL** to discard the data and return to the MAIN MENU.

If a barcode scanner is attached and is used to scan a barcode representing the ID, the screen of 4.1.2 will be displayed and the ID will be automatically accepted when the AUTO-ENTER timer reaches zero.

Phase 3 ID			
Enter a unique ID / control number			
using the ▼ ▲ ◀ ▶, or by means of an ▲			
attached barcode reader or PS/2 kbd.			
▼			
PHASE 3 ID : XCV16652-----			
AUTO-ENTER in 6 sec.			
ENTER			CANCEL

Figure 15 - *Phase 3* ID menu barcode entry.

Phase 3 OPERATING MANUAL

If the Phase 3 is attached to a PS/2 keyboard, the entire softkey row will be blanked after you start typing on the keyboard. When data entry is complete, press **ENTER** or **ESC** on the keyboard (replaces **ENTER** and **CANCEL** on the softkey row) to complete the action.

4.3.3 Set Clock

Pressing **SET CLK** on the MAIN MENU allows you to set the time and date of the real-time clock. The clock is maintained by a lithium backup battery when the *Phase 3* power is switched off.

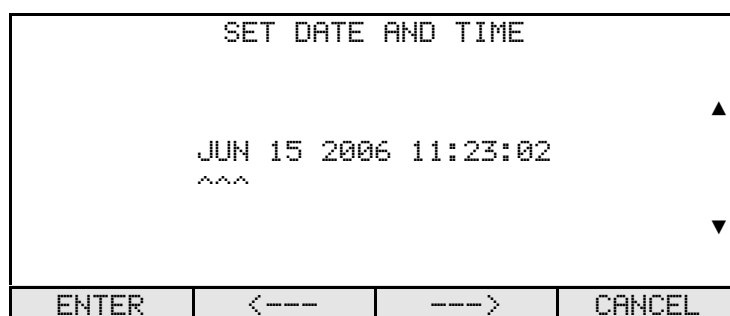


Figure 16 - Setting the real-time clock.

Referring to **Figure 16**, the softkeys operate as follows on the SET CLK screen:

← → Move the ^ cursor left/right.

ENTER Set the clock of *Phase 3* to the time and date shown on the display.

CANCEL Do not change the current setting of the clock, discard any changes.

The ▲ ▼ keys to the right of the LCD display are used to increment/decrement the item shown above the ^ cursor.

4.4 Manual Test Menu

Pressing the **MANUAL** softkey on the MAIN MENU causes *Phase 3* to display the MANUAL TEST menu (**Figure 17**). Functions available on the MANUAL TEST menu are:

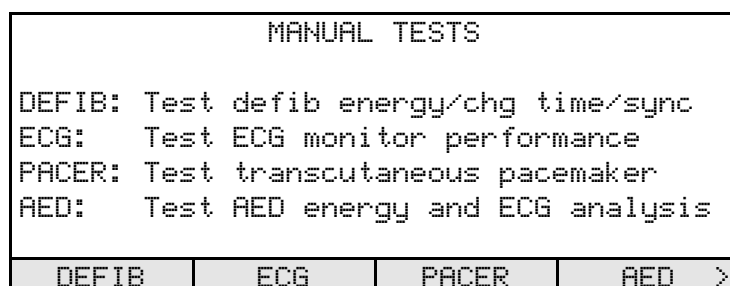


Figure 17 - Manual Test menu.

- DEFIB** Press to enter a menu for manually testing defibrillator energy output, charge time to maximum energy, and synchronization of the discharge to the ECG. Refer to Section 4.5.
- ECG** Press to enter a menu for manually controlling the ECG simulator, to allow the monitor of a defibrillator to be tested. Refer to Section 4.6.
- PACER** Press to enter a menu for manually testing a defibrillator's transcutaneous pacemaker, including measurement of pacer pulse characteristics and refractory intervals. Refer to Section 4.7.
- AED** Press to enter a menu for manually testing output energy and ECG pattern analysis of an Automated External Defibrillator (AED). Refer to Section 4.8.
- Press to access additional softkey functions as shown in **Figure 18**, and as described below.



Figure 18 - Alternate softkeys of Manual Test menu.

- VIEW** Press to view measurement data currently stored in the Clip Record. Refer to Section 4.9.

Phase 3 OPERATING MANUAL

- STORE** Press to copy the current contents of the Clip Record to a Test Record in the non-volatile memory. If an ID for the defibrillator under test has not been entered when **STORE** is pressed, you will be prompted to enter an ID per Section 4.4.1.
- I.D.** At any time during the manual test process, press **I.D.** to input identification information, such as a control number, for the defibrillator or pacemaker under test. Refer to Section 4.4.1.
- CANCEL** Cancel the manual test and return to the MAIN MENU. All measurement data in the Clip Record will be deleted if you press **YES** in response to the cancellation confirmation which will be displayed. For additional information on **CANCEL**, see Section 4.1.3.
- ◀ Press to restore softkey functions as shown in **Figure 17**.

4.4.1 DUT ID

Pressing **I.D.** on the MANUAL TEST menu allows you to enter information, such as a control number, for uniquely identifying the defibrillator under test (DUT). Test Records stored in the non-volatile Data Log of *Phase 3* are identified by DUT ID, as are the Test Report documents which are generated by *Phase3pc* software when the Test Record data is downloaded from *Phase 3* to the PC.

DEFIBRILLATOR ID			
Enter a device ID / control number			
using the ▼ ▲ ◀ ▶, or by means of an			
attached barcode reader or PS/2 kbd.			
DEFIB ID: _____			
^			
CLEAR	<---	--->	CANCEL

Figure 19 - Entry of DUT ID.

Phase 3 OPERATING MANUAL

Referring to **Figure 19**, **Figure 20**, the softkeys operate as follows on the ID entry screen:

← → Move the ^ cursor left/right.

CLEAR Clear the displayed ID and show ----- . Changes to **ENTER** if any characters are input.

ENTER Save the displayed ID in the Clip Record.

CANCEL Do not save to Clip Record; discard changes.

The ▲ ▼ keys to the right of the LCD display are used to increment/decrement the character shown above the ^ cursor.

In Manual Entry mode, the ID is input by placing the ^ character below a - using the ← → keys and scrolling through available characters using the ▲ ▼ keys. The ID displayed on the screen may be cleared by pressing **CLEAR**, accepted by pressing **ENTER**, or **CANCEL** to discard the data and return to the MAIN MENU.

If a barcode scanner is attached and is used to scan a barcode representing the ID, the screen of **Figure 20** will be displayed and the ID will be automatically accepted when the AUTO-ENTER timer reaches zero.

DEFIBRILLATOR ID			
Enter a device ID / control number			
using the ▼ ▲ ◀ ▶, or by means of an attached barcode reader or PS/2 kbd.			
DEFIB ID: XCV16652-----			
AUTO-ENTER in 6 sec.			
ENTER	<---	--->	CANCEL

Figure 20 - Phase3 ID menu barcode entry

If the Phase 3 is attached to a PS/2 keyboard, the entire softkey row will be blanked after you start typing on the keyboard. When data entry is complete, press **ENTER** or **ESC** on the keyboard (replaces **ENTER** and **CANCEL** on the softkey row) to complete the action.

4.4.2 Restarting Manual Tests

If you select **DEFIB**, **ECG**, **PACER** or **AED** from the MANUAL TEST menu, and the Clip Record already contains measurement data corresponding to that type of test, *Phase 3* will prompt you to confirm overwriting the existing test results with new results from the test you have selected (Figure 21).

OVERWRITE EXISTING TEST DATA			
Re-start this test? (All existing data for this test will be erased).			
YES	NO		

Figure 21 - Confirmation for restarting a test.

Press **YES** to proceed with the selected manual test, or **NO** to retain the current contents of the Clip Record and return to the MANUAL TEST menu.

Once you have started testing a defibrillator or pacemaker and have collected measurement data in the Clip Record for these types of DUT, you cannot then change to testing an Automated External Defibrillator (AED). This is because AED measurement data is incompatible with the measurement data obtained from testing a conventional defibrillator/pacemaker. If **AED** is selected from the MANUAL TEST menu, and the Clip Record already contains measurement data from defibrillator and/or pacemaker tests, then the error message of Figure 22 is displayed.

CANNOT PERFORM THIS TEST			
The Clip Record currently contains test results that are incompatible with the test you are trying to perform. Consult the operator's manual for more details.			
OK			

Figure 22 - Data Incompatibility Error.

The message of Figure 22 will also be displayed if you have collected AED measurement data in the Clip Record, and then try to initiate defibrillator or pacemaker tests by pressing **DEFIB** or **PACER** respectively.

Phase 3 OPERATING MANUAL

If the display of **Figure 22** appears, press **OK** to acknowledge the error and return to the MANUAL TEST menu. Save the current contents of the Clip Record by pressing **STORE**. Then, initiate a new test by pressing the desired softkey on the MANUAL TEST menu.

4.5 Defibrillator Test Menu

Press the **DEFIB** softkey on the MANUAL TEST menu to enter the DEFIBRILLATOR TEST menu (**Figure 23**). Functions available on this menu are:

DEFIBRILLATOR TESTS			
ENERGY:	Test defib output energy		
CHG TIME:	Test charge time to max energy		
SYNC:	Test defib synchronization (cardioversion test)		
DONE:	Return to Manual Test menu		
ENERGY	CHG TIME	SYNC	DONE >

Figure 23 - Defibrillator Test menu.

ENERGY Press to measure delivered energy, peak voltage and current, and discharge pulse width. Refer to Section 4.5.1.

CHG TIME Press to measure charge time at maximum output energy. Refer to Section 4.5.2.

SYNC Press to measure synchronization of the defibrillator discharge to either the R-wave or Q-wave of the simulated ECG. If the ECG simulation happens to be set to "atrial fibrillation", then the Sync Test may also be referred to as a cardioversion test. Refer to Section 4.5.3.

DONE Press to return to the MANUAL TEST menu. Defibrillator measurement data in the Clip Record *are retained*.

► Press to access additional softkey functions as shown in **Figure 24**, and as described below.

<			CANCEL
---	--	--	--------

Figure 24 - Alternate softkeys of Defibrillator Test menu.

Phase 3 OPERATING MANUAL

CANCEL Cancel the defibrillator test and return to the MAIN MENU. Defibrillator measurement data in the Clip Record will be deleted if you press **YES** in response to the cancellation confirmation which will be displayed. All other data in the Clip Record will be retained. For additional information on **CANCEL**, see Section 4.1.3.

◀ Press to restore softkey functions as shown in **Figure 23**.

4.5.1 Defibrillator Energy Test

4.5.1.1 Selecting the Energy Test

Press the **ENERGY** softkey on the DEFIBRILLATOR TEST menu to enter the DEFIB ENERGY test menu (**Figure 25**). Functions available on this menu are:

```
DEFIB ENERGY (HI RANGE)      TEST(01/10)
      WAITING FOR DISCHARGE
Target:      - - - . - JOULES
      ---.-
      ECG Wave: VFIB1 (x1 scale) > NSR 60
```

Figure 25 - Defibrillator Energy Test menu.

RANGE Press to toggle between *LOW* and *HIGH* range energy measurement. The range currently in use is indicated on the display as either (HI RANGE) or (LO RANGE) respectively. Select the range based on the energy setting of the defibrillator under test (DUT), as follows:

- LOW range: Select if measuring energy below 50 joules.
- HIGH range: Select if measuring energy of 50 joules or higher, up to 600 joules maximum input.

Phase 3 OPERATING MANUAL

ECG Press to enter a menu for setting up the ECG simulator. Note the waveform setting and the amplitude scale of the simulator are shown on the display, to the right of ECG Wave. According to **Figure 25**, the default setting of the simulator for energy tests is coarse ventricular fibrillation (VFIB1) with amplitude set to $\times 1$ scale (1mV QRS on ECG Lead II). There are several options available for the operation of the tester after an energy pulse has been measured. Refer to Section 4.5.1.2 for instructions describing operation of the ECG simulator and the settings available.

TARGET Press to enter optional energy target and tolerance settings which will allow *Phase 3* to *automatically* pass or fail the energy measured when the defibrillator is discharged. The current settings of the energy target (in joules) is shown on the display as TARGET and $xxx.x$. According to **Figure 25**, by default the target and tolerance are disabled until values are entered by the user, which then enables the automatic pass/fail feature of the ENERGY TEST menu. Refer to Section 4.5.1.3 for instructions on how to input a target and tolerance. The TARGET will flash as a reminder that there is a target set and to prompt the user to change it if appropriate.

DONE Press to return to the DEFIBRILLATOR TEST menu. Energy measurement data in the Clip Record *are retained*.

► Press to access additional softkey functions as shown in **Figure 26**, and as described below.



Figure 26 - Alternate softkeys of Defibrillator Energy Test menu.

CANCEL Cancel the energy test and return to the DEFIBRILLATOR TEST menu. **Energy** measurement data in the Clip Record will be deleted if you press **YES** in response to the cancellation confirmation which will be displayed. All other data in the Clip Record will be retained. For additional information on **CANCEL**, see Section 4.1.3.

◀ Press to restore softkey functions as shown in **Figure 25**.

4.5.1.2 Setting the ECG Simulator

Pressing the **ECG** softkey on the ENERGY TEST menu causes *Phase 3* to display a menu for setting up the ECG simulator (**Figure 27**, page 50). The ECG simulator provides a total of 55 Waveforms which are organised in seven Wave Banks. Depending on the test being performed, certain banks may be disabled as the waveforms contained within those banks are not applicable to the test.

The display of **Figure 27** shows the **WAVE BANK** and the full title of the **WAVEFORM** currently in effect, as well as an abbreviated waveform title which is shown on the display immediately below the full title. The abbreviated waveform title (e.g. VFIB1) may be used in place of the full title on some displays of the *Phase 3* operator interface. **Table 4-1** lists all of the available Banks and Waveforms, and whether or not the waveform is available on the ECG SETUP menu for specified defibrillator, pacemaker and AED tests.

Phase 3 OPERATING MANUAL

Table 4-1: ECG Simulator Banks and Waveforms

● indicates ECG waveform is selectable for test

Wave Bank	Waveform	Short Title	Defib Energy Test	Defib Chg Test	Defib Sync Test	ECG Test	AED Test	Pacer Sens.	Pacer Refr.
Off	Off	Off	●	●		●			
Shock Advisory/AED	Coarse AFIB	AFIB1	●	●	●	●	●		
	Fine AFIB	AFIB2	●	●	●	●	●		
	Asystole	ASYS1	●	●		●	●		
	Asystole - Flat	ASYS2	●	●		●	●		
	SupraVent Tachycardia	SVTACH	●	●		●	●		
	Ventricular Tachy 140 BPM	VTACH1	●	●		●	●		
	Ventricular Tachy 160 BPM	VTACH2	●	●		●	●		
	Ventricular Tachy 190 BPM	VTACH3	●	●		●	●		
	Torsades de Pointes 200 BPM	PVTACH	●	●		●	●		
	Coarse VFIB	VFIB1	●	●		●	●		
	Fine VFIB	VFIB2	●	●		●	●		
	Pulse, 1 msec	SQRP1	●	●		●	●		
Square Pacer Trigger	Pulse, 2 msec	SQRP2				●			●
	Pulse, 25 msec	SQRP25				●		●	●
	Pulse, 40 msec	SQRP40				●		●	●
	Pulse, 100 msec	SQRP100				●			●
	Pulse, 200 msec	SQRP200				●			●
Triangle Pacer Trigger	Pulse, 10 msec	TRIP10				●			●
	Pulse, 25 msec	TRIP25				●		●	●
	Pulse, 40 msec	TRIP40				●		●	●
	Pulse, 100 msec	TRIP100				●			●
	Pulse, 200 msec	TRIP200				●			●
Haversine Pacer Trigger	Pulse, 10 msec	SSQP10				●			●
	Pulse, 25 msec	SSQP25				●		●	●
	Pulse, 40 msec	SSQP40				●		●	●
	Pulse, 100 msec	SSQP100				●			●
	Pulse, 200 msec	SSQP200				●			●

Phase 3 OPERATING MANUAL

Wave Bank	Waveform	Short Title	Defib Energy Test	Defib Chg Test	Defib Sync Test	ECG Test	AED Test	Pacer Sens.	Pacer Refr.
Performance	DC Pulse, 4 sec	PULSE				•			
	Square Wave, 2 Hz	SQR2HZ				•			
	Triangle Wave, 2 Hz	TRI2HZ				•			
	Sinewave, 0.1 Hz	SIN01				•			
	Sinewave, 0.5 Hz	SIN05				•			
	Sinewave, 10 Hz	SIN10				•			
	Sinewave, 20 Hz	SIN20				•			
	Sinewave, 40 Hz	SIN40				•			
	Sinewave, 50 Hz	SIN50				•			
	Sinewave, 60 Hz	SIN60				•			
	Sinewave, 70 Hz	SIN70				•			
	Sinewave, 100 Hz	SIN100				•			
Sinus Rhythm	ECG 30 BPM	ECG30				•			
	ECG 60 BPM	ECG60			•	•			
	ECG 90 BPM	ECG90			•	•			
	ECG 120 BPM	ECG120			•	•			
	ECG 150 BPM	ECG150				•			
	ECG 180 BPM	ECG180				•			
	ECG 240 BPM	ECG240				•			
	ECG 300 BPM	ECG300				•			
Arrhythmia	2nd deg. AV Block	BLKII				•			
	Prem Atrial Contraction	PAC				•			
	Rt Bundle Br Block	RBBB				•			
	Prem Ventr Contraction	PVC				•			
	R-on-T PVC	RONT				•			
	Multifocal PVC	MFPVC				•			
	Run of 5 PVC	RUN5				•			
	Bigeminy	BIGEM				•			
	Trigeminy	TRGEM				•			



Figure 27 - Setup menu for the ECG simulator.

Referring to the ECG SETUP menu shown in **Figure 27**, functions available on the menu are:

- OK** Press to accept the ECG simulator settings as shown on the display and return to the previous menu. Note: The ECG waveform does not change until **OK** is pressed.
- BANK** Press to modify the Wave Bank of the ECG simulator. Refer to **Table 4-1** to determine which Wave Banks will be enabled for the type of test being performed.
- WAVEFORM** Press to modify the Waveform for the selected Bank. Refer to **Table 4-1** to determine which Waveforms will be enabled for the type of test being performed.
- SCALE** Press to set the simulator's amplitude scale to one of these choices:
 - x1 (corresponding to 1mV QRS amplitude on ECG Lead II)
 - x2 (corresponding to 2mV QRS amplitude on ECG Lead II)
 - x0.5 (corresponding to 0.5mV QRS amplitude on ECG Lead II)
- Press to access additional softkey functions as shown in **Figure 28**, and as described below.



Figure 28 - Alternate softkeys of ECG Setup menu.

Phase 3 OPERATING MANUAL

MODE

Press to select the response of the ECG simulator to a discharge from the defibrillator under test, as follows:

OFF After a defibrillation pulse is detected, Phase3 continues to output the selected waveform. When this option is selected, the LCD will display:

"DO NOT respond to defib discharge"

>NSR60 The instant that a defibrillation pulse is detected, Phase3 automatically changes to normal sinus rhythm at 60 BPM. This option is indicated on the LCD as:

"Revert to sinus rhythm at 60 BPM after shock detected"

This is the **default setting** of the SIMULATOR MODE.

PLAYBK After a defibrillation pulse is detected and the energy is displayed on the LCD, the ECG simulator then plays back the defibrillator waveform (either 1/3 of the waveform data, or the full waveform), after which the simulator returns to outputting the selected ECG waveform. The duration of the playback is governed by the PLAYBACK MODE, as described below. This option is indicated on the LCD as:

"Play back defib waveform after shock detected"

PB+NSR After a defibrillation pulse is detected and the energy is displayed on the LCD, the ECG simulator then plays back the defibrillator waveform (either 1/3 of the waveform data, or the full waveform), and then changes to normal sinus rhythm at 60 BPM after the playback is completed. The duration of the playback is governed by the PLAYBACK MODE, as described below. This option is indicated on the LCD as:

"Play back waveform after shock detected, then revert to NSR60"

See **Figure 29**

Phase 3 OPERATING MANUAL

PLAYBACK Press to toggle between the two available choices for simulator playback of an acquired defibrillator waveform:

- 1/3 waveform (4-second playback time). This is the **default setting**.
- Full waveform (12-second playback time)

See **Figure 29**

CANCEL Press to discard any changes made to ECG simulator settings and return to the previous menu.

◀ Press to restore softkey functions as shown in **Figure 27**.

Note: The **MODE** and **PLAYBACK** selections are User Preference Settings that will remain in effect until changed by the operator. When operating the *Phase 3* in manual test mode, the changes made here will apply to the defibrillator test currently in progress as well as to future tests, even if the *Phase 3* power is switched off and then back on.

ECG SIMULATOR SETUP			
SIMULATOR MODE:			
Revert to sinus rhythm at 60 BPM after shock detected.			
PLAYBACK MODE:			
1/3 waveform (4 sec play time)			
<	OK	MODE	PLAYBACK
			CANCEL

Figure 29 - Simulator Mode settings.

4.5.1.3 Setting a Target and Tolerance

Phase 3 allows you to optionally specify a target or expected value for a measurement to be made, and a tolerance or acceptance range which spans either side of the target. If a target and tolerance have been entered, *Phase 3* will automatically compare the measurement result to the target when the measurement is performed. If the difference between the measurement result and the target lies within the tolerance range, *Phase 3* will automatically assign a "PASS" to the result. If the difference lies outside the tolerance, *Phase 3* will automatically assign a "FAIL" to the result.

Phase 3 OPERATING MANUAL

Entering tolerances and targets for manual measurements is always *optional*. If you do not wish to enter a target and tolerance, you can simply "PASS" or "FAIL" any test result yourself, via corresponding softkeys provided on the *Phase 3* keypad, and thereby manually store the result with your pass/fail assessment in the Clip Record.

Press the **TARGET** softkey on the ENERGY TEST menu to display a menu for inputting an energy target and tolerance (**Figure 30**).

ENERGY TARGET AND TOLERANCE			
ENERGY RANGE: HIGH (MAX. 600J)			
TOLERANCE: $\pm 10\%$			
ENERGY TARGET: 150.0 Joules			
^			
USE $\leftarrow \rightarrow$ TO ADJUST ENERGY TARGET			
RANGE	TOL $\pm\%$	CANCEL	ENTER

Figure 30 - Entry of energy target and tolerance.

On this menu, the softkeys assume the following functions:

- $\leftarrow \rightarrow$ Move the ^ cursor left/right.
- $\uparrow \downarrow$ Increment/decrement the digit shown above the ^ cursor. *Phase 3* will not allow you to set the target value outside the permitted range which is shown closer to the bottom of the display.
- RANGE** Toggle between high and low energy range. The maximum value of the energy target will be affected if low range is selected.
- TOL $\pm\%$** Press to modify the displayed tolerance. Choices available are:
 - $\pm 5\%$
 - $\pm 10\%$
 - $\pm 15\%$
 - $\pm 20\%$
 - OFF (disables automatic pass/fail assessment)
- CANCEL** Press to discard any changes made to target and tolerance settings and return to the previous menu.
- ENTER** Save the displayed target value and tolerance.

4.5.1.4 Performing the Energy Test

The purpose of the energy test is to verify that a defibrillator accurately delivers the amount of energy which has been selected by the operator. In addition to delivered energy, the test reports other parameters of the defibrillator discharge, such as voltage, current and pulse width, so that conformance to manufacturer's specifications can be confirmed. Normally, a number of different energy settings will be tested, for example: 10, 20, 50, 100, 200, 300 and 360 joules.

To perform a defibrillator energy test:

- a. Connect the defibrillator under test (DUT) to **Phase 3** according to Section 3.1.
- b. *Optionally*, if you would like to capture high-resolution waveform data in real-time, connect the USB Port of **Phase 3** to a personal computer using the supplied USB cable, then run **Phase3pc** software on the PC (see Chapter 6 for more information on installing and using **Phase3pc** software).
- c. On the DEFIBRILLATOR TEST menu, press **ENERGY**. The display of **Figure 31** will appear.

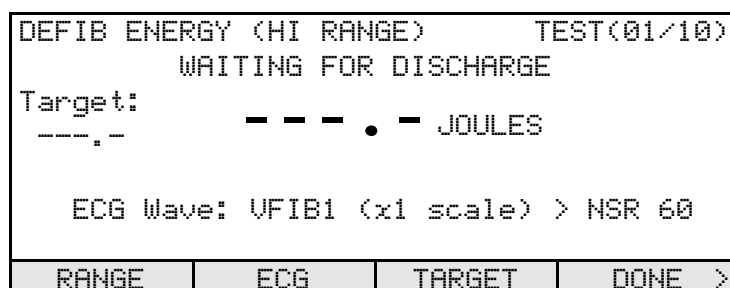


Figure 31 - Defibrillator Energy Test menu.

- d. Set the DUT to the desired energy level.
- e. On **Phase 3**, press **RANGE** to modify the energy measurement range as required. Select "LO" range if the DUT is set to less than 50 joules, otherwise, select "HI" range.
- f. *Optionally*, if you would like to change the waveform of the ECG simulator, press **ECG** to view the ECG setup menu. Refer to Section 4.5.1.2.

Phase 3 OPERATING MANUAL

- g. *Optionally*, if you would like to have **Phase 3** automatically pass or fail the measurement you are about to take, press **TARGET**, enter a target energy, and select a tolerance. Refer to Section 4.5.1.3.
- h. If using external or internal paddles, apply the paddles firmly to the **Phase 3** Paddle Adapter.
- i. Charge the DUT.
- j. Discharge the DUT into **Phase 3**. Peak current and voltage readings will appear on the display immediately after the discharge. **Phase 3** will calculate the energy and display the result in Joules. The energy calculation will require approximately four seconds to complete. Depending on the ECG MODE settings (see section 4.5.1.2), **Phase 3** may automatically play back the defibrillator pulse waveform to the ECG terminals and paddle plates, then change the ECG output to normal sinus rhythm ("NSR60").
- k. If the measurement is being performed on LOW range, and **Phase 3** detects distortion (clipping) in the acquired waveform data, **Phase 3** will produce an alarm message on the display (**Figure 32**). The measurement results are invalid if this alarm is displayed. Acknowledge the alarm by pressing the **OK** softkey, then repeat the measurement after selecting HIGH range on the menu of **Figure 32**.

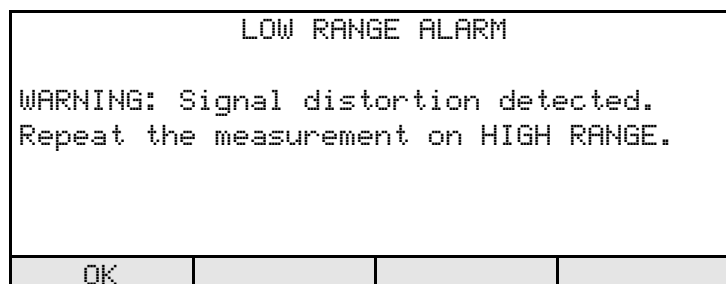


Figure 32 - Warning if signal distortion detected.

- l. If the measurement is being performed on HIGH range, and **Phase 3** detects distortion (clipping) in the acquired waveform data, **Phase 3** will produce an alarm message on the display. The alarm title will be "HIGH RANGE ALARM", and the warning message is:

"WARNING: Signal distortion detected. Signal exceeds maximum input level".

Phase 3 OPERATING MANUAL

- m. If the acquired signal data is valid, but a target has not been entered, *Phase 3* will display the results according to **Figure 33**.

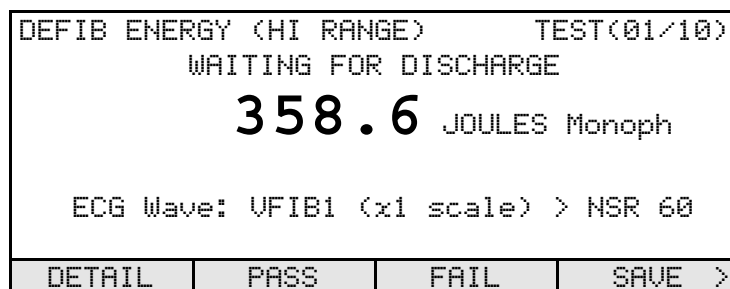


Figure 33 - Energy test results: no target specified.

Functions available on this display are:

DETAIL

Phase 3 automatically recognizes monophasic, biphasic and multiphasic discharge waveforms and shows the waveform type next to the energy measurement. Depending on the waveform type, press **DETAIL** will bring up a new screen showing detailed measurement data. See **Figure 34**, **Figure 35** and **Figure 36**. Press **BACK** to go back to the previous menu.

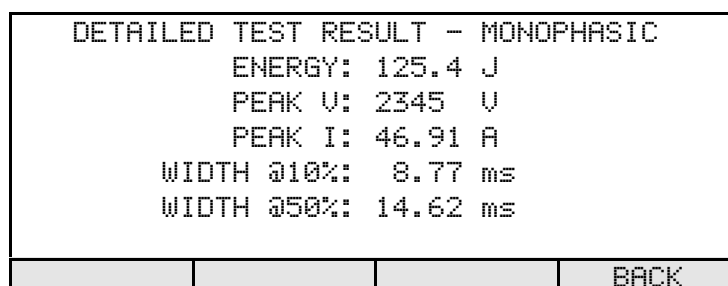


Figure 34 - Detailed energy test results: Monophasic.

Phase 3 OPERATING MANUAL

DETAILED TEST RESULT - BIPHASIC			
----- Phase 1 -----		----- Phase 2 -----	
Energy: 100.1 J		Energy: 25.3 J	
Va:1123V Ia: 22.46A		Va: 652V Ia: 13.04A	
Up:2345V Ip: 46.90A		Up:1433V Ip: 28.66A	
Width: 12.45 ms		Width: 10.65 ms	
Tilt: 43.1%		Delay: 1.92 ms	
			BACK

Figure 35 - Detailed energy test results: Biphasic.

DETAILED TEST RESULT - PULSED BIPHASIC			
----- Phase 1 -----		----- Phase 2 -----	
Energy: 100.1 J		Energy: 25.3 J	
Up:2345V Ip: 46.90A		Up:1433V Ip: 28.66A	
Width: 12.45 ms		Width: 10.65 ms	
Frequency: 7952 Hz		Tilt: 35.9%	
Duty Cyc.: 49.5%		Delay: 1.92 ms	
			BACK

Figure 36 - Detailed energy test results: Pulsed Biphasic.

- PASS** Save the displayed measurement data (energy, current, voltage, and pulse widths) to the Clip Record with a "PASS" assessment. The test counter shown at the top right corner of the display will increment, until a maximum of **10** energy tests have been accumulated in the Clip Record. If **PASS** is pressed after 10 energy results have been stored, then each new result will overwrite the Clip Record location reserved for energy test #10.
- FAIL** As described above for the **PASS** softkey, except that a "FAIL" assessment will be saved in the Clip Record with the data, rather than a "PASS".
- SAVE** Simply save the measurement results to the Clip Record, with neither a "PASS" nor a "FAIL". The test counter displayed at top right is incremented, as described above for **PASS**.
- Press to access additional softkey functions as shown in **Figure 37**, and as described below.

Phase 3 OPERATING MANUAL



Figure 37 - Alternate softkeys of Energy Test result, with no target.

- SHOW WAV** Press to view the captured defibrillator waveform on the LCD. Refer to Section 4.5.1.5.
- SAVE WAV** Press to save the captured defibrillator waveform as a **Wave Record**. Refer to Section 4.5.1.5.
- PLAYBACK** Press to play back the captured defibrillator waveform into the ECG monitor or chart recorder of the DUT, via the ECG simulator. Refer to Section 4.5.1.5. The play back time will be either 4 or 12 seconds, as set by the PLAYBACK MODE function (see section 4.5.1.2)
- CANCEL** Press to discard the measurement results shown on the display of **Figure 33**. The results on the display are not saved to the Clip Record and the test counter shown on the LCD is not incremented. The Clip Record is otherwise unaffected.
- ◀ Press to restore softkey functions as shown in **Figure 33**.

- n. If a target and tolerance have been entered per Section 4.5.1.3, **Phase 3** will display the results according to **Figure 38**.

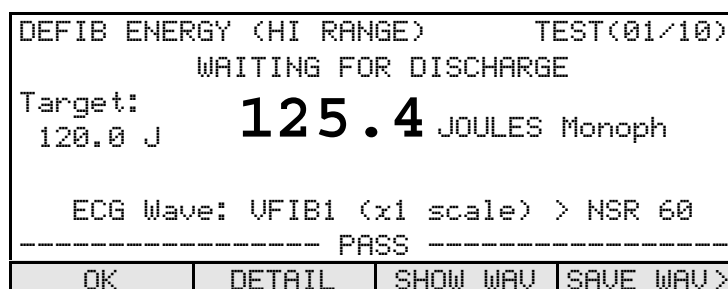


Figure 38 - Energy test results: target specified.

Functions available on this display are:

Phase 3 OPERATING MANUAL

OK Accept the pass/fail assessment as determined by *Phase 3* and save the assessment with the measurement results to the Clip Record. The test counter shown at the top right corner of the display will increment, until a maximum of **10** energy tests have been accumulated in the Clip Record. If **OK** is pressed after 10 energy results have been stored, then each new result will overwrite the Clip Record location reserved for energy test #10.

DETAIL These softkeys provide the same functions as described above for
SHOW WAV the case when no target has been specified.
SAVE WAV
PLAYBACK
CANCEL

- o. While showing the results of an energy discharge, *Phase 3* is ready to process another discharge without any further operator intervention. The display screen (**Figure 33** or **Figure 38**) will be indicating "WAITING FOR DISCHARGE". If the defibrillator is discharged at this time, without pressing a **PASS**, **FAIL**, **SAVE**, or **OK** softkey, *Phase 3* will automatically **SAVE** the measurement results currently being displayed, and will then proceed to process the new discharge. This allows a series of manual energy tests to be performed without the need to press any keys on *Phase 3*.
- p. Repeat steps (d) to (o) as required until the desired number of DUT energy levels have been tested, up to a maximum of **10** energies. More than 10 energy levels can be tested, however, if such results are saved to the Clip Record via **PASS**, **FAIL**, **SAVE**, or **OK** softkeys, then the Clip Record location reserved for energy test #10 will be overwritten with each new result.
- q. When all tests have been completed, press **DONE** (see **Figure 31**). Energy results accumulated in the Clip Record are retained and may be supplemented with data from other defibrillator, ECG and pacemaker tests.

Phase 3 OPERATING MANUAL

4.5.1.5 Viewing and Saving Defibrillator Waveforms

Phase 3 provides unique features for viewing and saving the waveform of a defibrillator discharge. These features are enabled after completion of each energy measurement, via the **PLAYBACK**, **SHOW WAV** and **SAVE WAV** softkeys described in the preceding Section.

PLAYBACK After an energy measurement, press this softkey to play back the captured defibrillator waveform into the ECG monitor or chart recorder of the DUT, via the ECG simulator of *Phase 3*. The display will appear as shown in **Figure 39** as the playback progresses. To stop a playback in progress, press the **CANCEL** softkey at any time.

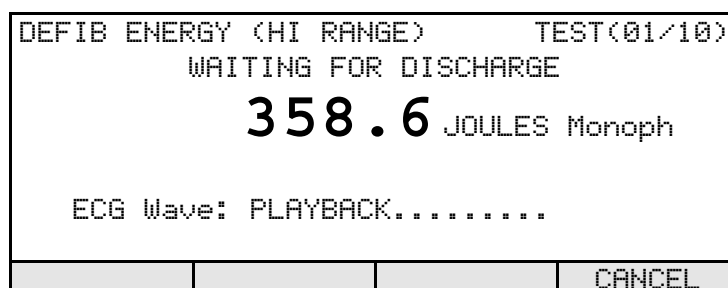


Figure 39 - Playback of captured waveform via ECG simulator.

If the energy measurement was performed on HIGH range, an ECG monitor set to Lead II will show 1mV for each 1000V of defibrillator signal, or 1mV for each 2000V if the signal is being observed at the contact pads of the *Phase 3* Paddle Adapter. If the measurement was performed on LOW range, an ECG monitor on Lead II will show 1mV per 200V of defib signal, or 1mV per 400V at the Paddle Adapter. Each second of signal shown on the ECG monitor or chart recorder will correspond to 5 milliseconds of the defibrillator waveform (200:1 timebase expansion).

The length of the play back will be determined by the PLAYBACK MODE setting (refer to section 4.1.5.2). Play back of the entire waveform requires approximately 12 seconds. The alternative PLAYBACK MODE will play back the first 1/3 of the waveform data, which will require approximately 4 seconds. In most cases, this will display the complete signal of interest.

Waveform playback may also be initiated automatically after a defibrillator discharge, by selecting the appropriate option for the SIMULATOR MODE of the ECG SETTINGS function (refer to section 4.1.5.2). In this mode, playback will occur immediately after the waveform parameters have been calculated and displayed on

Phase 3 OPERATING MANUAL

the LCD.

SHOW WAV After an energy measurement, press this softkey to view the captured defibrillator waveform on the *Phase 3* display (Figure 40).

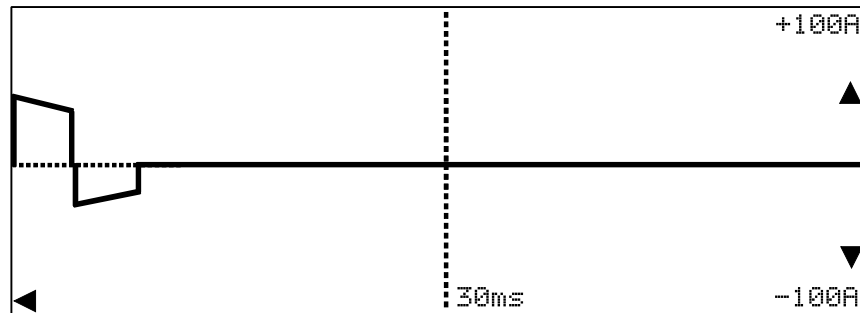


Figure 40 - Example of captured waveform display.

When viewing a defibrillator waveform with the **SHOW WAV** function, the *Phase 3* keypad operates as follows:

- ▼▲ Contract/expand the vertical scale. The available choices depend on the energy measurement range, as follows:

<u>HIGH range</u>	<u>LOW range</u>
• 0 to ± 25 Amps	• 0 to ± 5 Amps
• 0 to ± 50 Amps	• 0 to ± 10 Amps
• 0 to ± 100 Amps (default)	• 0 to ± 20 Amps (default)

- ◀▶ Contract/expand the horizontal scale. The available choices are:

- 0 to 20 milliseconds
- 0 to 40 milliseconds
- 0 to 60 milliseconds (default)

Press any key other than ▼▲◀▶ to return the display to the previous menu.

Phase 3 OPERATING MANUAL

SAVE WAV After an energy measurement, press this softkey to save the defibrillator waveform in the non-volatile memory as a **Wave Record**. If you have not yet entered an ID for the defibrillator under test (DUT) when **SAVE WAV** is pressed, you will be prompted to enter an ID (see Section 4.4.1). Once a DUT ID has been provided to *Phase 3*, the screen of **Figure 41** will be shown.

SAVE WAVEFORM		RECORD(05/10)	
DEFIB ID: CN3416			
DEFIB RANGE: HIGH			
RECORD LENGTH: 58.4msec at Ts=45.6usec			
DATE/TIME: JUN 15 2006 13:04:48			
LENGTH	DELETE	STORE	CANCEL

Figure 41 - Saving a Wave Record.

The functions provided by the SAVE WAVEFORM menu are:

- | | |
|---------------|--|
| LENGTH | This button changes the amount of data to be saved in the Wave Record, toggling between 14.692 msec of waveform data (with sample interval $T_s=11.4\mu\text{sec}$), or 58.368 msec of data ($T_s=45.6\mu\text{sec}$, or every 4 th data point). The default is 58.368 msec of data. |
| DELETE | Delete the last Wave Record that was saved to the non-volatile memory. A prompt requiring you to confirm the deletion will be displayed if this softkey is pressed. This function allows you to replace a previously-saved waveform with the current waveform. |
| STORE | Save the waveform data to the non-volatile memory as a Wave Record. The record counter shown at the top right corner of the display will be incremented by one. The maximum number of waveforms that can be saved is 10. This softkey will not appear on the display once there are ten Wave Records in memory. If the memory is full, use the DELETE softkey to remove unwanted Records to make space for new Records. |
| CANCEL | Return to the previous menu without saving the Wave Record. |



NOTE:

The defibrillator waveform data is always compressed when *Phase 3* creates a Wave Record, in order to conserve memory space. The compressed signal data adequately represents a defibrillator waveform for qualitative purposes, such as graphing a picture of the waveform. For detailed numerical analysis of the waveform data, such as might be done in a laboratory-based investigation or research, the real-time waveform capture mode should be used. Refer to Section 4.5.1.6.

Once Wave Records have been saved to the non-volatile memory, the Records may later be downloaded into *Phase3pc* software for graphical plotting and printing. Refer to Chapter 6 for details.

4.5.1.6 Capturing the Defibrillator Waveform in Real-Time

Phase 3 with *Phase3pc* software provides a feature for capturing high-resolution waveform data on a personal computer. The data can be acquired after each defibrillator energy measurement is completed, while the display is in the state shown in **Figure 33**, **Figure 34**, **Figure 35**, **Figure 36** or **Figure 38**.

Clicking the **Waveform Capture** icon in *Phase3pc* causes the detailed waveform data to be rapidly transferred to the PC via the USB connection. After a waveform graph is plotted, *Phase3pc* allows the user to print the graph or save the detailed data to a file for further numerical analysis. Refer to Section 6.5.3 for additional details.

Defibrillator waveform capture may also be performed via RS-232 when *Phase 3* is operating in remote control mode. Refer to Chapter 5 for details.

4.5.2 Defibrillator Charge Time Test

4.5.2.1 Selecting the Charge Time Test

Press the **CHG TIME** softkey on the DEFIBRILLATOR TEST menu to enter the CHARGE TIME menu (Figure 42). Functions available on this menu are:

CHARGE TIME (MAX 99.9s) Discharges: 0			
Charge to MAXIMUM ENERGY and Discharge, or, press START to measure charge time.			
ENERGY: - - - . - J		TIME: - - . - - s	
ECG Wave: VFIB1 (x1 scale) > NSR 60			
START	ECG	MAX TIME	TARGET>

Figure 42 - Defibrillator Charge Time menu.

The intent of this test is to determine if the battery of the defibrillator is in reasonable condition and will be able to charge the defibrillator, even when under some stress from clinical use. The defibrillator should first be unplugged from the AC power. Prior to beginning the actual charge time test, the defibrillator may now be discharged into *Phase 3* several times. The number of pre-test discharges will be tracked and reported in the upper right corner of the screen. These pre-test discharges are counted, but they are not analyzed. When the requisite number of pre-test discharges have been made, the actual charge time measurement can be initiated by pressing the **START** softkey. The number of pre-test discharges will be reported in the final test report.

- | | |
|-----------------|--|
| START | Press to start the measurement of the charge time. |
| ECG | Press to enter a menu for setting up the ECG simulator. Refer to Section 4.5.1.2 for instructions describing operation of the ECG simulator. |
| MAX TIME | Press to input an upper limit for the charge time determined by this test. Choices available are: 5, 10, 15, 20, 25, 30, 35, 40 and 99.9 seconds. If an upper limit less than 99.9 seconds is selected, the charge time obtained by the test will be compared to the limit and automatically passed or failed by <i>Phase 3</i> accordingly. |
| TARGET | Press to enter optional energy target and tolerance settings which will allow <i>Phase 3</i> to automatically pass or fail the energy measured when the defibrillator is discharged. Refer to Section 4.5.1.3 for instructions on how to input a target and tolerance. |

Phase 3 OPERATING MANUAL

- ▶ Press to access additional softkey functions as shown in **Figure 43**, and as described below.



Figure 43 - Alternate softkeys of Defibrillator Charge Time menu.

CANCEL Cancel the charge time test and return to the DEFIBRILLATOR TEST menu. Charge time data in the Clip Record will be deleted if you press **YES** in response to the cancellation confirmation which will be displayed. All other data in the Clip Record will be retained. For additional information on **CANCEL**, see Section 4.1.3.

- ◀ Press to restore softkey functions as shown in **Figure 42**.

4.5.2.2 Performing the Charge Time Test

The purpose of a charge time test is to determine the length of time a defibrillator requires to charge up to its maximum energy. To simulate a worst-case operating condition, the test is normally done with the defibrillator powered by its internal battery.

Note that real-time waveform capture via USB is inhibited in this test mode. Use the energy test described in Section 4.5.1 to capture defibrillator waveform data in real-time.

To perform a charge time test:

- a. Connect the defibrillator under test (DUT) to *Phase 3* according to Section 3.1.
- b. On the DEFIBRILLATOR TEST menu, press **CHG TIME**. The display of **Figure 42** will appear.
- c. Set the DUT to its MAXIMUM energy setting.
- d. Disconnect the DUT from the AC line so that the DUT is operating from its internal battery supply. This simulates a worst-case operating condition for the DUT.
- e. On *Phase 3*, optionally press **ECG** to modify the settings of the ECG Simulator as desired. Refer to Section 4.5.1.2.
- f. *Optionally*, if you would like to have *Phase 3* automatically pass or fail the measured charge time, press **MAX TIME** to select the desired upper limit.

Phase 3 OPERATING MANUAL

- g. *Optionally*, if you would like to have **Phase 3** automatically pass or fail the measured energy, press **TARGET**, enter a target value for the maximum energy, and select a tolerance. Refer to Section 4.5.1.3.
- h. *Optionally*, discharge the DUT several times into **Phase 3** before starting the actual charge time test to exercise the battery. The number of pre-test discharges performed will appear at the top right corner of the LCD display.
- i. Press the **START** softkey. A timer will be displayed which will start counting down from 5 seconds.
- j. Apply the paddles firmly to the **Phase 3** Paddle Adapter. You have 5 seconds to get ready.
- k. **Charge** the DUT when the countdown timer reaches zero and **Phase 3** emits a beep tone. **Phase 3** will also display: CHARGE THEN DISCHARGE as an additional prompt to you.
- l. **Discharge** the DUT as soon as it reaches full charge. The measured charge time will be displayed, after which **Phase 3** will calculate and display the energy delivered.
- m. If a **MAX TIME** has not been entered and an energy **TARGET** has not been entered, **Phase 3** will display the results according to **Figure 44**.

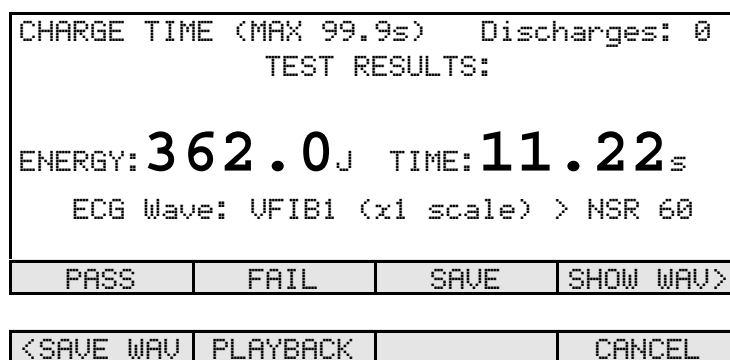


Figure 44 - Charge time results: no target or time limit specified.

- n. Refer to Section 4.5.1.4 for an explanation of the softkey functions appearing on this display.

Phase 3 OPERATING MANUAL

- o. If either a **MAX TIME** or an energy **TARGET** has been entered, *Phase 3* will display the results according to **Figure 45**. If both targets are specified, charge time and energy results must both lie within their respective acceptance ranges in order to obtain a "PASS", otherwise the overall result assigned by *Phase 3* will be a "FAIL".

CHARGE TIME (MAX 15.0s) Discharges: 0			
TEST RESULTS:			
ENERGY: 362.0 J TIME: 11.22 s			
ECG Wave: VFIB1 (x1 scale)			
----- PASS -----			
OK	SHOW WAV	SAVE WAV	PLAYBACK>

<			CANCEL
---	--	--	--------

Figure 45 - Charge time results: Target and MAX TIME specified.

- p. Refer to Section 4.5.1.4 for an explanation of the softkey functions appearing on the display of **Figure 45**.

4.5.3 Defibrillator Cardioversion Test

4.5.3.1 Selecting the Cardioversion Test

Press the **SYNC** softkey on the DEFIBRILLATOR TEST menu to enter the cardioversion or "SYNC TEST" menu (**Figure 46**).

SYNC TEST		TEST(01/04)	
WAITING FOR DISCHARGE			
ENERGY: - - - . - J DELAY: - - - - ms			
SYNC TO: R wave			
ECG Wave: VFIB1 (x1 scale) > NSR 60			
TARGET	ECG	SYNC TO	DONE>
<			CANCEL

Figure 46 - Defibrillator Cardioversion Test menu.

Functions available on this menu are:

TARGET Press to enter a menu (see **Figure 47**) for setting up optional energy target, tolerance settings and delay range which will allow *Phase 3* to automatically pass or fail the energy measured when the defibrillator is discharged. Press **ENERGY** to enter the energy target menu. Refer to Section 4.5.1.3. Press **DELAY** to enable or disable comparison of the measured sync delay to a predefined acceptance range of +20 to +65 milliseconds. This acceptance range is derived from specifications appearing in Section 104 of the **IEC60601-2-4** standard for defibrillators. If the delay target is enabled, *Phase 3* will automatically pass or fail the measured sync delay accordingly. Press **ENTER** to accept the target entered, or **CANCEL** to keep the previous setting.

Phase 3 OPERATING MANUAL

SYNC TEST TARGET AND TOLERANCE			
ENERGY RANGE: HIGH (MAX. 600J)			
TOLERANCE: $\pm 10\%$			
ENERGY TARGET: 100 Joules			
DELAY TARGET: +20 to +65 ms			
ENERGY	DELAY	CANCEL	ENTER

Figure 47 - Defibrillator Cardioversion Test Target Menu.

- ECG** Press to enter a menu for setting up the ECG simulator. Refer to Section 4.5.1.2 for instructions describing operation of the ECG simulator. According to **Figure 46**, note the default simulator settings for this test will cause the ECG to automatically switch from coarse atrial fibrillation to normal sinus rhythm at 60 BPM when *Phase 3* detects the defibrillator discharge.
- SYNC TO** Press to select the time reference with respect to which the defibrillator synchronization delay will be measured. Options available are:
- Q wave of simulated ECG (default)
 - R wave of simulated ECG
- DONE** Press to return to the DEFIBRILLATOR TEST menu. Cardioversion test results in the Clip Record **are retained**.
- Press to access additional softkey functions as shown in **Figure 46** , and as described below.
- CANCEL** Cancel the cardioversion test and return to the DEFIBRILLATOR TEST menu. Cardioversion test data in the Clip Record will be deleted if you press **YES** in response to the cancellation confirmation which will be displayed. All other data in the Clip Record will be retained. For additional information on **CANCEL**, see Section 4.1.3.
- ◀ Press to restore softkey functions as shown in **Figure 46**.

Phase 3 OPERATING MANUAL

4.5.3.2 Performing the Cardioversion Test

The purpose of a cardioversion test is to verify that a defibrillator can correctly synchronize its discharge to the electrocardiogram. *Phase 3* measures synchronization delay from a specified point on the ECG QRS complex to the beginning of the defibrillator discharge. *Phase 3* provides space in the Clip Record for up to four cardioversion tests, allowing you to record the results for different types of ECG waveform, or at various energy levels.

Note that real-time waveform capture via USB is inhibited in this test mode. Use the energy test described in Section 4.5.1 to capture defibrillator waveform data in real-time.

To perform a cardioversion test:

- a. Connect the defibrillator under test (DUT) to *Phase 3* according to Section 3.1.
- b. On the DEFIBRILLATOR TEST menu, press **SYNC**. The display of **Figure 46** will appear.
- c. Set the DUT to the desired energy level.
- d. Activate "**SYNC**" operation or the equivalent functional mode on the DUT. The ECG monitor of the DUT may now show indicator marks on the ECG trace, marking each detected QRS in the ECG.
- e. On *Phase 3*, press **RANGE** to modify the energy measurement range as required. Select "LO" range if the DUT is set to less than 50 joules, otherwise, select "HI" range.
- f. *Optionally*, if you would like to change the waveform or mode of the ECG simulator, press **ECG** to view the ECG setup menu. Refer to Section 4.5.1.2.
- g. Press **SYNC TO** if required to choose the timing reference on the simulated ECG for measurement of the delay time.
- h. *Optionally*, if you would like to have *Phase 3* automatically pass or fail the measured energy, press **TARGET ENERGY**, enter a target value for the energy, and select a tolerance. Refer to Section 4.5.1.3.
- i. *Optionally*, if you would like to have *Phase 3* automatically pass or fail the measured sync delay, press **TARGET DELAY** to enable the sync acceptance range.
- j. If using external or internal paddles, apply the paddles firmly to the *Phase 3* Paddle Adapter.

Phase 3 OPERATING MANUAL

- k. Charge the DUT.
- l. Discharge the DUT into *Phase 3*. The timing of the discharge with respect to the simulated QRS will be displayed immediately, and the ECG simulator will change automatically to a normal sinus rhythm at 60 BPM. *Phase 3* will then calculate the energy and display the result.
- m. If the measurement is being performed on LOW range, and *Phase 3* detects distortion (clipping) in the acquired waveform data, *Phase 3* will produce an alarm message on the display (**Figure 48**). The measurement results *are invalid* if this alarm is displayed. Acknowledge the alarm by pressing the **OK** softkey, then repeat the measurement after selecting HIGH range via the menu of **Figure 46**.

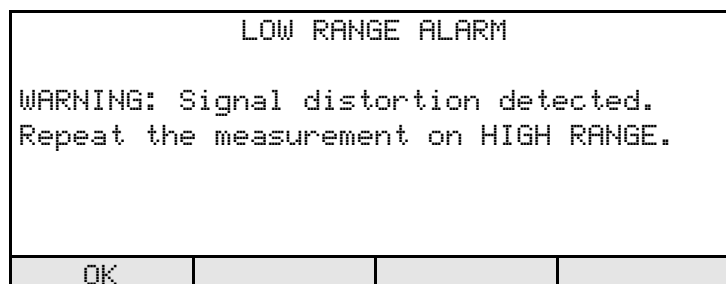


Figure 48 - Warning if signal distortion detected.

- n. If the delay target has not been enabled and an energy target has not been entered, *Phase 3* will display the results according to **Figure 49**. Refer to Section 4.5.1.4 for an explanation of the softkey functions appearing on this display.

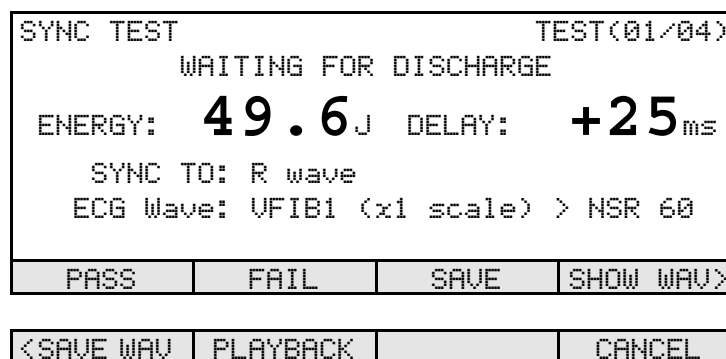


Figure 49 - Defibrillator Cardioversion Test result: no targets specified.

Phase 3 OPERATING MANUAL

- o. If either a delay target or an energy target has been entered, *Phase 3* will display the results according to **Figure 50**. If both targets are specified, sync delay and energy results must both lie within their respective acceptance ranges in order to obtain a "PASS", otherwise the overall result assigned by *Phase 3* will be a "FAIL". Refer to Section 4.5.1.4 for an explanation of the softkey functions appearing on the display of **Figure 50**.

SYNC TEST		TEST(01/04)	
WAITING FOR DISCHARGE			
ENERGY:	49.6J	DELAY:	+25ms
SYNC TO: R wave			
ECG Wave: VFIB1 (x1 scale) > NSR 60			
----- FAIL -----			
OK	SHOW WAV	SAVE WAV	PLAYBACK>
<			CANCEL

Figure 50 - Defibrillator Cardioversion Test result: delay target specified.

- p. Similarly to the ENERGY test, while showing the results of an SYNC energy discharge, *Phase 3* is ready to process another discharge without any further operator intervention. The display screen (**Figure 49** or **Figure 50**) will be indicating "WAITING FOR DISCHARGE". If the defibrillator is discharged at this time, without pressing a **PASS**, **FAIL**, **SAVE**, or **OK** softkey, *Phase 3* will automatically **SAVE** the measurement results currently being displayed, and will then proceed to process the new discharge. This allows a series of manual SYNC tests to be performed without the need to press any keys on *Phase 3*.
- q. Repeat steps (c) to (o) as required until the desired number of cardioversion tests have been performed, up to a maximum of 4. More than 4 tests can be done, however, if such results are saved to the Clip Record via **PASS**, **FAIL**, **SAVE**, or **OK** softkeys, then the Clip Record location reserved for cardioversion test #4 will be overwritten with each new result.
- r. When all tests have been completed, press **DONE** (see **Figure 46**). Cardioversion test results accumulated in the Clip Record are retained and may be supplemented with data from other defibrillator, ECG and pacemaker tests.

4.6 ECG Test Menu

4.6.1 Selecting the ECG Test

Press the **ECG** softkey on the MANUAL TEST menu to enter the ECG TEST menu (**Figure 51**). The ECG simulator provides a total of 55 Waveforms which are organised in seven Wave Banks. The display of **Figure 51** shows the WAVE BANK and the full title of the WAVEFORM currently in effect, as well as an abbreviated waveform title which is shown on the display immediately below the full title. Refer to **Table 4-1** of Section 4.5.1.2 for a listing of Banks and Waveforms provided by the ECG simulator of *Phase 3*.

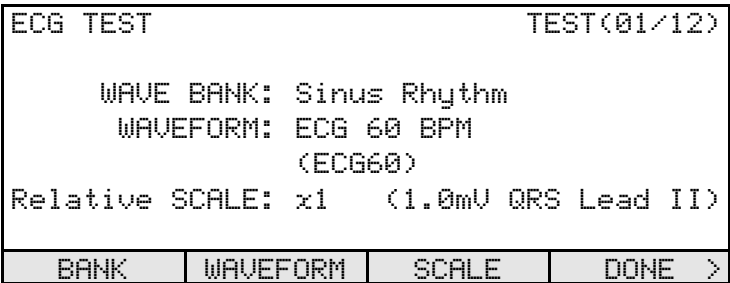


Figure 51 - ECG Test menu.

Functions available on the ECG TEST menu are:

- | | |
|-----------------|--|
| BANK | Press to modify the Wave Bank of the ECG simulator. Refer to Table 4-1 of Section 4.5.1.2. |
| WAVEFORM | Press to modify the Waveform for the selected Bank. Refer to Table 4-1 of Section 4.5.1.2. |
| SCALE | Press to set the simulator's amplitude scale to one of these choices: <ul style="list-style-type: none"> • x1 (corresponding to 1mV QRS amplitude on ECG Lead II) • x2 (corresponding to 2mV QRS amplitude on ECG Lead II) • x0.5 (corresponding to 0.5mV QRS amplitude on ECG Lead II) |
| DONE | Press to return to the MANUAL TEST menu. ECG test results in the Clip Record <i>are retained</i> . |
| ► | Press to access additional softkey functions as shown in Figure 52 , and as described below. |



Figure 52 - Alternate softkeys of ECG Test menu.

PASS

Save the ECG waveform to the Clip Record along with a "PASS" mark. The test counter shown at the top right corner of the display will increment, until a maximum of **12** ECG tests have been accumulated in the Clip Record. If **PASS** is pressed after 12 ECG results have been stored, then the new result will overwrite the Clip Record location reserved for ECG test #12.

FAIL

As described above for **PASS**, except save a "FAIL" mark to the Clip Record with the ECG waveform.

CANCEL

Cancel the ECG test and return to the MANUAL TEST menu. ECG results in the Clip Record will be deleted if you press **YES** in response to the cancellation confirmation which will be displayed. All other data in the Clip Record will be retained. For additional information on **CANCEL**, see Section 4.1.3.



Press to restore softkey functions as shown in **Figure 51**.

Phase 3 OPERATING MANUAL

4.6.2 Performing the ECG Test

The purpose of an ECG test is to verify that the ECG monitor and/or strip chart recorder of a defibrillator is functioning according to the manufacturer's performance specifications. Tests typically performed on a defibrillator ECG monitor could include those listed in **Table 4-2**:

Table 4-2: ECG Monitor Tests

Monitor/Chart Recorder Test	Test Waveform(s)
Low-frequency response	DC Pulse, 4 seconds (Performance Wave Bank)
Gain and damping	Square Wave, 2 Hz (Performance Wave Bank)
Linearity	Triangle Wave, 2 Hz (Performance Wave Bank)
R-wave detection	Triangle or Haversine Pulse, 10-200msec, 60BPM (Triangle/Haversine Trigger Pacemaker Bank)
Wideband frequency response	Sine Wave, 0.1 - 100 Hz (Performance Wave Bank)
Line frequency rejection	Sine Wave, 50 Hz or 60 Hz (Performance Wave Bank)
Rate accuracy and R-wave recognition	All waveforms of Sinus Rhythm Bank, 30-300 BPM
Arrhythmia detection and classification	All waveforms of Arrhythmia Bank
Shock advisory reporting	All waveforms of Shock Advisory/AED Bank

To perform an ECG test:

- Connect the defibrillator under test (DUT) to *Phase 3* according to Section 3.1.
- On the MANUAL TEST menu, press **ECG**. The display of **Figure 51** will appear.
- On the *Phase 3*, select the desired ECG Bank and Waveform.
- Observe the response of the monitor and/or chart recorder and press **PASS** or **FAIL** as appropriate to record the waveform tested and the test result.
- Repeat steps (c) and (d) as required until the desired number of ECG tests have been performed, up to a maximum of 12. More than 12 tests can be done, however, if such results are saved to the Clip Record via **PASS** or **FAIL** softkeys, then the Clip Record location reserved for ECG test #12 will be overwritten with each new result.
- When all tests have been completed, press **DONE**. ECG test results accumulated in the Clip Record are retained and may be supplemented with data from manual defibrillator and pacemaker tests.

4.7 Pacemaker Test Menu

Press the **PACER** softkey on the MANUAL TEST menu to enter the PACER TEST menu (Figure 53). Functions available on this menu are:

PACER TESTS	
LOAD:	Set Pacer Load Value
PULSE:	Pacer Pulse Measurement
REFRACT:	Sensed/Paced Refractory Period
DONE:	Return to Manual Test menu
LOAD	PULSE
REFRACT	DONE >

Figure 53 - Pacemaker Test menu.

- LOAD** Press to set the load resistor that will be used in all pacemaker tests. Refer to Section 4.7.1.
- PULSE** Press to measure pacemaker pulse characteristics, such as amplitude, rate and pulse width. Refer to Section 4.7.2.
- REFRACT** Press to measure the pacemaker's refractory periods. Refer to Section 4.7.3.
- DONE** Press to return to the MANUAL TEST menu. Pacemaker measurement data in the Clip Record **are retained**.
- Press to access additional softkey functions as shown in **Figure 54**, and as described below.

IMMUNITY	SENS		CANCEL
----------	------	--	--------

Figure 54 - Alternate softkeys of Pacemaker Test menu.

- IMMUNITY** Press to measure a pacemaker's immunity to line-frequency noise. Refer to Section 4.7.4.
- SENS** Press to measure sensitivity of the pacemaker to the ECG signal. Refer to Section 4.7.5.
- CANCEL** Cancel the pacemaker test and return to the MAIN MENU. Pacemaker measurement data in the Clip Record will be deleted if you press **YES** in response to the cancellation confirmation which will be displayed. All other data in the Clip Record will be retained. For additional information on **CANCEL**, see Section 4.1.3.

Phase 3 OPERATING MANUAL

◀ Press to restore softkey functions as shown in **Figure 53**.

4.7.1 Pacemaker Load Selection

Press the **LOAD** softkey on the PACER TEST menu to view or change the pacemaker test load (**Figure 55**). Functions available on this menu are:

SET PACER LOAD RESISTOR			
LOAD: 50 ohms			
LOAD RANGE: 50 - 1600 ohms			
SELECT	LOAD+50	LOAD-50	CANCEL >

Figure 55 - Selection of Pacemaker Test Load.

- SELECT** Press to set the load to the displayed resistance and return to the PACER TEST menu.
- LOAD+50** Press to increase the load by 50 ohms. Adjustment is limited to the range of 50 to 1600 ohms, as shown on the display.
- LOAD-50** Press to decrease the load by 50 ohms.
- CANCEL** Press to return to the PACER TEST menu without changing the load.

▶ Press to access additional softkey functions as shown in **Figure 56**, and as described below.

< SELECT	LOAD+200	LOAD-200	CANCEL
----------	----------	----------	--------

Figure 56 - Alternate softkeys of Pacemaker Test Load selection

Phase 3 OPERATING MANUAL

LOAD+200 Press to increase the load by 200 ohms.

LOAD-200 Press to decrease the load by 200 ohms.

◀ Press to restore softkey functions as shown in **Figure 55**.

Note: The pacer load selection is a User Preference Setting that will remain in effect until changed by the operator. When operating the *Phase 3* in manual test mode, the changes made here will apply to the pacer test currently in progress as well as to future tests, even if the *Phase 3* power is switched off and then back on.

NOTE:

All pacemaker tests must be performed with the *same* load resistor. Always choose the load *before* beginning a series of pacer tests.

If the Clip Record contains pacemaker test data when the **LOAD** softkey on the PACER TEST menu is pressed, *Phase 3* will warn you that changing the load will cause pacemaker results in the Clip Record to be erased (see **Figure 57**).

In this case, you may press the **NO** softkey to return to the PACER TEST menu without affecting data in the Clip Record. Or, you can press **YES** to erase the pacer results and then proceed to change the load resistor as required.

ERASE PACER MEASUREMENTS IN CLIP RECORD			
Warning: all pacer tests must be performed with the same pacer load. Changing the load at this point will invalidate all existing measurements in the Clip Record and they will be erased. Press YES to change load, NO to abort.			
YES	NO		

Figure 57 - Warning when changing load after acquiring test results.

4.7.2 Pacemaker Pulse Test

4.7.2.1 Selecting the Pulse Test

Press the **PULSE** softkey on the PACER TEST menu to enter a menu for determining the characteristics of the pacemaker pulse (**Figure 58**). The selected test load will appear on the top line of the display as shown in the figure. Functions available on the PACER PULSE menu are:

PACER PULSE				900 ohms TEST(01/10)			
Set up Pacer, then press START							
AMPL: - - - . - mA				RATE: - - - . - PPM			
WIDTH: --. -- ms				ENERGY: ---. - mJ			
METHOD: Peak Value							
START				METHOD		DONE >	
< AMPL		WIDTH		RATE		CANCEL	

Figure 58 - Pacemaker Pulse Test menu.

- START** Press to start the measurement. The pacemaker should be running in asynchronous or non-demand mode before this key is pressed.
- METHOD** Press to select the method to be applied in determining the pulse amplitude. The choices available are:
- Average - amplitude is averaged across the pulse's width
 - Leading edge - amplitude is taken from the pulse's rising edge
 - Trailing edge - amplitude is taken from the pulse's falling edge
 - Peak value - amplitude is the peak value seen during the pulse
- DONE** Press to return to the PACER TEST menu. Pulse test results in the Clip Record **are retained**.
- Press to access additional softkey functions as described below.
- AMPL** Press to enter optional target and tolerance settings for the pulse amplitude, which will allow *Phase 3* to automatically pass or fail the measured amplitude when the pacemaker pulse train is detected. Entering a pacer amplitude target is very similar to entering an energy target during a defibrillator test. Refer to Section 4.5.1.3 for instructions on how to input a target and tolerance.

Phase 3 OPERATING MANUAL

- WIDTH** Press to enter optional target and tolerance settings for the pulse width, which will allow *Phase 3* to automatically pass or fail the measured width when the pacemaker pulse train is detected. Entering a pacer width target is very similar to entering an energy target during a defibrillator test. Refer to Section 4.5.1.3 for instructions on how to input a target and tolerance.
- RATE** Press to enter optional target and tolerance settings for the pulse rate, which will allow *Phase 3* to automatically pass or fail the measured rate when the pacemaker pulse train is detected. Entering a pacer rate target is very similar to entering an energy target during a defibrillator test. Refer to Section 4.5.1.3 for instructions on how to input a target and tolerance.
- CANCEL** Cancel the pulse test and return to the PACER TEST menu. Pulse Test data in the Clip Record will be deleted if you press **YES** in response to the cancellation confirmation which will be displayed. All other data in the Clip Record will be retained. For additional information on **CANCEL**, see Section 4.1.3.
- ◀ Press to restore softkey functions as shown in **Figure 58**.

Note: The selection for amplitude **METHOD** is a User Preference Setting that will remain in effect until changed by the operator. When operating the *Phase 3* in manual test mode, the changes made here will apply to the pacer test currently in progress as well as to future tests, even if the *Phase 3* power is switched off and then back on.

4.7.2.2 Performing the Pulse Test

The purpose of a pacemaker pulse test is to verify that the pacemaker output signal is in conformance with manufacturer's specifications for a given load resistance. *Phase 3* provides space in the Clip Record for up to 10 pulse tests, allowing you to record the results for different settings of pacemaker output current and pulse rate.

To perform a pacemaker pulse test:

- a. Connect the output from the transcutaneous pacemaker of the defibrillator under test (DUT) to *Phase 3* according to Section 3.1.
- b. Select the pacemaker load (Section 4.7.1) according to testing requirements specified by the DUT manufacturer. Typically, the load corresponds to the largest resistance into which the pacemaker can deliver its maximum rated output current. Refer to the manufacturer's service manual for the DUT to determine the required load.

Phase 3 OPERATING MANUAL

- c. On the PACER TEST menu, press **PULSE**. The display of **Figure 58** will appear.
- d. Set the DUT to *asynchronous* or *non-demand* operating mode.
- e. Set the output current and pulse rate on the DUT to the desired values.
- f. *Optionally*, if you would like **Phase 3** to automatically pass or fail the measured pulse amplitude, press **AMPL** and enter a target value and tolerance.
- g. *Optionally*, if you would like **Phase 3** to automatically pass or fail the measured rate, press **RATE** and enter a target value and tolerance.
- h. *Optionally*, if you would like **Phase 3** to automatically pass or fail the measured pulse width, press **WIDTH** and enter a target value and tolerance.
- i. Select the amplitude measurement **METHOD**. The required method may be specified by the manufacturer in the DUT service manual. If the manufacturer does not specify a method, or if the DUT service manual is not available, choose "Average".
- j. Press **START** to measure the pacemaker pulse. The **START** softkey will be changed to a **STOP** softkey (**Figure 59**). The first measurement will be completed and the results displayed after two successive pacemaker pulses are detected. **Phase 3** will continue to acquire and analyze pacer pulses until the **STOP** softkey is pressed. Each time the results are displayed on the screen, **Phase 3** will emit an audible 'click'.

NOTE: the audible 'click' is *not* an indication of the pacer rate, only an indication that new data is on the display. Generally, the 'click' will occur every 2 to 3 pacer pulses, depending on the rate. For a given rate, the 'click' will be periodic and a missing 'click' may indicate **Phase 3** encountered a pulse that was difficult to analyze. Frequent missing 'clicks' may be an indication that the pacer pulses are of an abnormal shape or inconsistent rate.

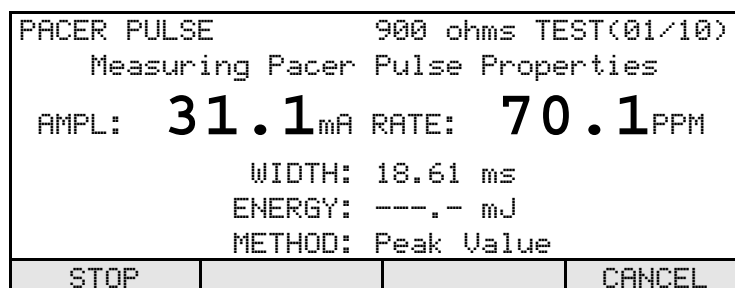


Figure 59 - Pacemaker Pulse Test in progress: no targets specified.

Phase 3 OPERATING MANUAL

- k. If no targets (amplitude, rate or width) have been entered when **STOP** is pressed, *Phase 3* will display the results for the last pacer pulse acquired according to **Figure 60**. The pacer pulse energy is also calculated at this time and is expressed in either mJ, when the energy is greater than 10 mJ, or in μ J otherwise. Refer to Section 4.5.1.4 for an explanation of the softkey functions appearing on this display.

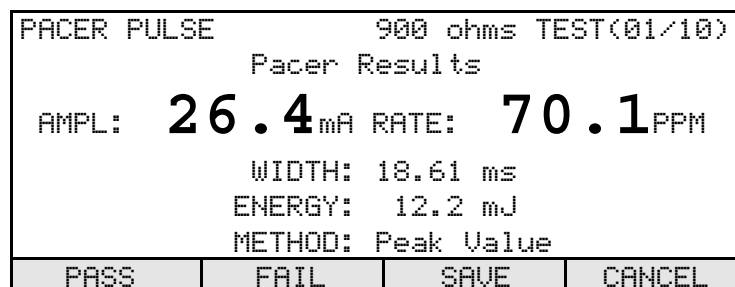


Figure 60 - Pacemaker Pulse Test result: no targets specified.

- l. If any of the three available targets has been entered (amplitude, rate or width), *Phase 3* will display the results according to **Figure 61**. If more than one target has been specified, then all corresponding results must lie within their respective acceptance ranges in order to obtain a "PASS", otherwise the overall result assigned by *Phase 3* will be a "FAIL". Refer to Section 4.5.1.4 for an explanation of the softkey functions appearing on the display of **Figure 61**.

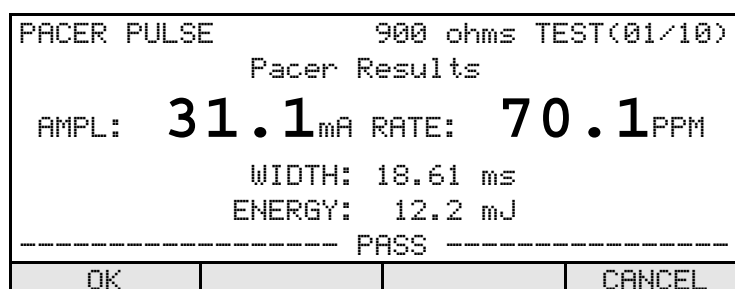


Figure 61 - Pacemaker Pulse Test results: amplitude & rate targets specified.

- m. Repeat steps (e) to (l) as required until the desired number of pulse tests have been performed, up to a maximum of **10**. More than 10 tests can be done, however, if such results are saved to the Clip Record via **PASS**, **FAIL**, **SAVE**, or **OK** softkeys, then the Clip Record location reserved for pacemaker pulse test #10 will be overwritten with each new result.
- n. When all tests have been completed, press **DONE** (see **Figure 58**). Pacemaker pulse

Phase 3 OPERATING MANUAL

test results accumulated in the Clip Record are retained and may be supplemented with data from other pacemaker, ECG and defibrillator tests.

4.7.2.3 Capturing the Pacemaker Waveform

Phase 3 with *Phase3pc* software provides a feature for capturing high-resolution waveform data on a personal computer. The data can be acquired after the **STOP** softkey has been pressed, while the display is in the state shown in **Figure 59** or **Figure 60**.

Clicking the **Waveform Capture** icon in *Phase3pc* causes the detailed waveform data to be rapidly transferred to the PC via the USB connection. After a waveform graph is plotted, *Phase3pc* allows the user to print the graph or save the detailed data to a file for further numerical analysis. Refer to Section 6.5.3 for additional details.

Pacemaker waveform capture may also be performed via RS-232 when *Phase 3* is operating in remote control mode. Refer to Chapter 5 for details.

4.7.3 Pacemaker Refractory Period Test

4.7.3.1 Selecting the Refractory Period Test

Press the **REFRACT** softkey on the PACER TEST menu to enter a menu for determining refractory intervals of a pacemaker (**Figure 62**). The selected test load will appear on the top line of the display as shown in the figure. Functions available on the PACER REFRACTORY menu are:

PACER REFRACTORY 50 ohms TEST(01/02)			
Start Pacer, then press START			
REFRACTORY MIN: --- msec		MAX: --- msec	
REFRACTORY PRP: --- msec		SRP: --- msec	
ECG WAVE: TRIP40 (x2 Scale)			
PACER RATE: --- PPM			
START	ECG		DONE >

Figure 62 - Pacemaker Refractory Test menu.

- START** Press to start the test. The pacemaker should be running in synchronous or demand mode before this key is pressed.
- ECG** Press to enter a menu for setting up the ECG simulator. Refer to Section 4.5.1.2 for instructions describing operation of the ECG simulator.
- DONE** Press to return to the PACER TEST menu. Refractory measurement data in the Clip Record *are retained*.
- Press to access additional softkey functions as shown in **Figure 63**, and as described below.

< START	MIN	MAX	CANCEL
---------	-----	-----	--------

Figure 63 - Alternate softkeys of Pacer Refractory Test menu.

- MIN** Press to enter an optional minimum permitted value for the refractory periods, which will allow *Phase 3* to automatically pass or fail the measured periods at the end of the test. Both the paced and sensed refractory periods will be compared to this minimum limit if a limit is entered. Entering a minimum limit is very similar to entering an energy target during a defibrillator test. Refer to Section 4.5.1.3 for instructions on how to input a target. The **MIN** limit range is 50 - 750 msec.

Phase 3 OPERATING MANUAL

MAX Press to enter an optional maximum permitted value for the refractory periods, which will allow *Phase 3* to automatically pass or fail the measured periods at the end of the test. Both the paced and sensed refractory periods will be compared to this maximum limit if a limit is entered. Entering a maximum limit is very similar to entering an energy target during a defibrillator test. Refer to Section 4.5.1.3 for instructions on how to input a target. The **MAX** limit range is 50 - 750 msec.

CANCEL Cancel the refractory period test and return to the PACER TEST menu. Refractory period data in the Clip Record will be deleted if you press **YES** in response to the cancellation confirmation which will be displayed. All other data in the Clip Record will be retained. For additional information on **CANCEL**, see Section 4.1.3.

◀ Press to restore softkey functions as shown in **Figure 62**.

Note: The "ECG WAVE" and "Scale" for the refractory test, set by means of the **ECG** menu, are User Preference Settings that will remain in effect until changed by the operator. When operating the *Phase 3* in manual test mode, the changes made here will apply to the refractory test currently in progress as well as to future tests, even if the *Phase 3* power is switched off and then back on.

4.7.3.2 Performing the Refractory Period Test

The purpose of a pacemaker refractory period test is to verify that paced and sensed refractory periods are per manufacturer's specifications for the DUT. These intervals are defined as follows:

- **Refractory Period:** When a pacemaker is operating in synchronous or demand mode, the "refractory period" is the time interval during which the pacemaker is insensitive to an ECG input signal, and in particular, the QRS complex of the ECG.
- **Paced Refractory Period (PRP):** Immediately after generation of a pacing pulse, PRP is the time interval over which the pacemaker remains insensitive to the ECG. If a QRS occurs within the PRP following output of a pacing pulse, the pacemaker ignores this QRS.
- **Sensed Refractory Period (SRP):** SRP is the time interval after a detected QRS during which the pacemaker remains insensitive to the ECG. If a QRS occurs within the SRP following a detected QRS, the pacemaker then ignores this second QRS.

Phase 3 OPERATING MANUAL

Phase 3 provides space in the Clip Record for up to 2 refractory period tests, allowing you to record results for different rate settings on the pacemaker, or for different trigger waveforms on the *Phase 3* ECG simulator.

To perform a refractory period test:

- a. Connect the output from the transcutaneous pacemaker of the defibrillator under test (DUT) to *Phase 3* according to Section 3.1.
- b. If no pacemaker tests have yet been performed, select the pacemaker load (Section 4.7.1) according to testing requirements specified by the DUT manufacturer. Do not change the load if the Clip Record contains data from previous pacemaker tests.
- c. On the PACER TEST menu, press **REFRACT**. The display of **Figure 62** will appear.
- d. Set the DUT to *synchronous* or *demand* operating mode.
- e. Set the output current and pulse rate on the DUT. The output current should be set to approximately mid-range. A pacer rate ranging from 60 to 120 PPM is recommended. Rates in excess of 120 PPM should be avoided.
- f. On *Phase 3*, optionally press **ECG** to modify the settings of the ECG simulator as desired. Refer to Section 4.5.1.2.
- g. *Optionally*, if you would like *Phase 3* to automatically pass or fail the measured refractory intervals, press **MIN** and enter a minimum allowed refractory period, then press **MAX** and enter the maximum allowed period.
- h. Press **START** to start the test. The test proceeds as a number of successive pacemaker pulses are acquired. First, *Phase 3* determines the pacemaker's pulse rate, which is displayed on the LCD as PACER RATE. Then, *Phase 3* will determine the PRP by outputting ECG trigger pulses after each pacing pulse is detected. Following determination and display of PRP, *Phase 3* then proceeds to determine the SRP. During the test, *Phase 3* will display a progress indicator just above the softkey row. At a pacer rate of 90 PPM, the entire test will require about 30 seconds to complete.
- i. If neither a minimum limit nor a maximum limit has been entered, *Phase 3* will display the results according to **Figure 64**. Refer to Section 4.5.1.4 for an explanation of the softkey functions appearing on this display.

Phase 3 OPERATING MANUAL

PACER REFRACTORY		50 ohms TEST(01/02)	
REFRACTORY MIN: --- msec MAX: --- msec			
REFRACTORY PRP: 284 msec SRP: 262 msec			
ECG WAVE: TRIP40 (x2 Scale)			
PACER RATE: 90 PPM			
PASS	FAIL	SAVE	CANCEL

Figure 64 - Pacemaker Refractory Test results: no limits specified.

- j. If either limit has been entered, *Phase 3* will display the results according to **Figure 65**. If limits have been specified, then both refractory periods must lie within the limits in order to obtain a "PASS", otherwise the overall result assigned by *Phase 3* will be a "FAIL". Refer to Section 4.5.1.4 for an explanation of the softkey functions appearing on the display of **Figure 65**.

PACER REFRACTORY		50 ohms TEST(01/02)	
REFRACTORY MIN: 200 msec MAX: 300 msec			
REFRACTORY PRP: 284 msec SRP: 262 msec			
ECG WAVE: TRIP40 (x2 Scale)			
PACER RATE: 90 PPM			
----- PASS -----			
OK			CANCEL

Figure 65 - Pacemaker Refractory Test results: min/max limits specified.

- k. Repeat steps (e) to (j) if desired. More than two tests can be done, however, if such results are saved to the Clip Record via **PASS**, **FAIL**, **SAVE**, or **OK** softkeys, then the Clip Record location reserved for pacemaker refractory test #2 will be overwritten with each new result.
- l. When all tests have been completed, press **DONE** (see **Figure 62**). Refractory period results accumulated in the Clip Record are retained and may be supplemented with data from other pacemaker, ECG and defibrillator tests.

4.7.4 Pacemaker Noise Immunity Test

4.7.4.1 Selecting the Noise Immunity Test

Press the **IMMUNITY** softkey on the PACER TEST menu to enter a menu for determining immunity of a pacemaker to line-frequency noise (**Figure 66**). The selected test load will appear on the top line of the display as shown in the figure. Functions available on the PACER NOISE IMMUNITY menu are:

PACER NOISE IMMUNITY 50 ohms			
Set Pacer to DEMAND MODE and press START			
to begin test...			
NOISE FREQUENCY: 60Hz			
NOISE AMPLITUDE: -.--mV			
START	NOISE		CANCEL

Figure 66 - Pacemaker Immunity Test menu.

- START** Press to start the test. The pacemaker should be running in synchronous or demand mode before this key is pressed.
- NOISE** Press to toggle the noise frequency between 50 Hz and 60 Hz.
- CANCEL** Cancel the noise test and return to the PACER TEST menu. Noise Test data in the Clip Record will be deleted if you press **YES** in response to the cancellation confirmation which will be displayed. All other data in the Clip Record will be retained. For additional information on **CANCEL**, see Section 4.1.3.

Note: The **NOISE** frequency is a User Preference Setting that will remain in effect until changed by the operator. When operating the *Phase 3* in manual test mode, the changes made here will apply to the immunity test currently in progress as well as to future tests, even if the *Phase 3* power is switched off and then back on.

Phase 3 OPERATING MANUAL

4.7.4.2 Performing the Noise Immunity Test

The purpose of the noise immunity test is to verify that a pacemaker operating in demand mode does not respond to line frequency noise at its ECG input.

In this test, **Phase 3** outputs a line frequency sine wave via the ECG simulator and observes the effect on the pacemaker. The test automatically passes if the pacemaker continues to pace at its set rate when the output of the ECG simulator is set to maximum (10 millivolts peak-to-peak). The test automatically fails if the pacemaker ceases pacing for a sine wave amplitude less than 10 millivolts.

To perform the noise immunity test:

- a. Connect the output from the transcutaneous pacemaker of the defibrillator under test (DUT) to **Phase 3** according to Section 3.1.
- b. If no pacemaker tests have yet been performed, select the pacemaker load (Section 4.7.1) according to testing requirements specified by the DUT manufacturer. Do not change the load if the Clip Record contains data from previous pacemaker tests.
- c. On the PACER TEST menu, press **IMMUNITY**. The display of **Figure 66** will appear.
- d. Set the DUT to *synchronous* or *demand* operating mode.
- e. Set the output current and pulse rate on the DUT. The output current should be set to approximately mid-range. A pacer rate ranging from 60 to 120 PPM is recommended. Rates in excess of 120 PPM should be avoided.
- f. On **Phase 3**, set the noise frequency to either 50 or 60 Hz as required.
- g. Press **START** to start the test. The test proceeds as a number of successive pacemaker pulses are acquired. First, **Phase 3** determines the pacemaker's pulse rate. After measuring the rate, **Phase 3** will then begin to output a sine wave to the pacemaker via the ECG simulator.
- h. As each pacer pulse is detected, **Phase 3** introduces an audible 'click' and increases the noise signal amplitude by 0.139 mV. The test will pass if the pacemaker does not react to a 10 millivolt sine wave (**Figure 67**). If there is no activity from the pacer for 4 seconds for any noise level less than 10 mV, the test will fail. At 90PPM, the test will require about 50 seconds to complete if the pacemaker passes, or less if it fails.
- i. Press **OK** to save the immunity result in the Clip Record, or **CANCEL** to discard the result.

Phase 3 OPERATING MANUAL

PACER NOISE IMMUNITY 50 ohms			
Test Results			
NOISE FREQUENCY: 60Hz			
NOISE AMPLITUDE: 10.00mV			
----- PASS -----			
OK			CANCEL

Figure 67 - Pacemaker Immunity Test result.

4.7.5 Pacemaker Sensitivity Test

4.7.5.1 Selecting the Sensitivity Test

Press the **SENS** softkey on the PACER TEST menu to enter a menu for determining sensitivity of a pacemaker to the ECG amplitude (**Figure 68**). The selected test load will appear on the top line of the display as shown in the figure. Functions available on the PACER SENSITIVITY menu are:

PACER SENSITIVITY 50 ohms TEST(01/02)			
Start Pacer, then press START			
AMPL: --.--mV SENSITIVITY LIMIT: --.--mV			
ECG WAVE: TRIP40			
PACER RATE: --- PPM			
START	LIMIT	ECG	DONE >

Figure 68 - Pacemaker Sensitivity Test menu.

- START** Press to start the test. The pacemaker should be running in synchronous or demand mode before this key is pressed.
- LIMIT** Press to enter an optional maximum permitted value for the sensitivity, which will allow *Phase 3* to automatically pass the AMPL result at the end of the test, provided the AMPL result is less than the limit. Entering this limit is very similar to entering an energy target during a defibrillator test. Refer to Section 4.5.1.3 for instructions on how to input a target.
- ECG** Press to enter a menu for setting up the ECG simulator. Refer to Section 4.5.1.2 for instructions describing operation of the ECG simulator.

Phase 3 OPERATING MANUAL

DONE Press to return to the PACER TEST menu. Sensitivity measurement data in the Clip Record are retained.

- Press to access additional softkey functions as shown in **Figure 69**, and as described below.



Figure 69 - Alternate softkeys of Pacer Sensitivity Test menu.

CANCEL Cancel the sensitivity test and return to the PACER TEST menu. Sensitivity Test data in the Clip Record will be deleted if you press **YES** in response to the cancellation confirmation which will be displayed. All other data in the Clip Record will be retained. For additional information on **CANCEL**, see Section 4.1.3.

- ◄ Press to restore softkey functions as shown in **Figure 68**.

4.7.5.2 Performing the Sensitivity Test

The purpose of the sensitivity test is to determine the smallest ECG signal that will reliably trigger a pacemaker, and to verify this signal level is in accordance with manufacturer's specifications. *Phase 3* provides space in the Clip Record for up to 2 sensitivity tests, allowing you to record results for different trigger waveforms on the *Phase 3* ECG simulator.

To perform the sensitivity test:

- Connect the output from the transcutaneous pacemaker of the defibrillator under test (DUT) to *Phase 3* according to Section 3.1.
- If no pacemaker tests have yet been performed, select the pacemaker load (Section 4.7.1) according to testing requirements specified by the DUT manufacturer. Do not change the load if the Clip Record contains data from previous pacemaker tests.
- On the PACER TEST menu, press **SENS**. The display of **Figure 68** will appear.
- Set the DUT to *synchronous* or *demand* operating mode.
- Set the output current and pulse rate on the DUT. The output current should be set to approximately mid-range. A pacer rate ranging from 60 to 120 PPM is recommended. Rates in excess of 120 PPM should be avoided.

Phase 3 OPERATING MANUAL

- f. On *Phase 3*, optionally press **ECG** to modify the settings of the ECG simulator as desired. Refer to Section 4.5.1.2.
- g. *Optionally*, if you would like *Phase 3* to automatically pass or fail the measured sensitivity, press **LIMIT** and enter a maximum permitted value for the test result.
- h. Press **START** to start the test. The test proceeds as a number of successive pacemaker pulses are acquired. First, *Phase 3* determines the pacemaker's pulse rate, which is displayed on the LCD as PACER RATE. Then, *Phase 3* will determine the sensitivity by outputting ECG trigger pulses of variable amplitude after each pacing pulse is detected. During the test, *Phase 3* will display a progress indicator (a rotating line) just above the softkey row.
- i. As each pacer pulse is detected, *Phase 3* will emit an audible 'click'. For each detected pacer pulse, *Phase 3* will increase the ECG signal level in steps of 0.045mV until the pacer is inhibited. After the pacer is inhibited, the ECG level is reduced and then increased in steps of 0.015mV until the pacer is again inhibited. The test will stop when the pacer is inhibited by the ECG signal, or a maximum ECG level of 3 mV is reached. For a pacer having a sensitivity of nominally 1 mV, and at a rate of 90PPM, the sensitivity test will require about 20 seconds.
- j. If a sensitivity limit has not been entered, *Phase 3* will display the results according to **Figure 70**. Refer to Section 4.5.1.4 for an explanation of the softkey functions appearing on this display.

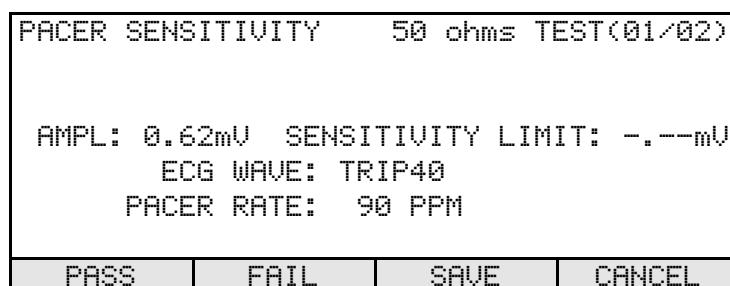


Figure 70 - Pacemaker Sensitivity Test result: no sensitivity limit.

- k. If a sensitivity limit has been entered, *Phase 3* will display the results according to **Figure 71**. Refer to Section 4.5.1.4 for an explanation of the softkey functions appearing on this display.

Phase 3 OPERATING MANUAL

PACER SENSITIVITY 50 ohms TEST(01/02)			
AMPL: 0.42mV SENSITIVITY LIMIT: 0.75mV			
ECG WAVE: TRIP40			
PACER RATE: 90 PPM			
----- PASS -----			
OK			CANCEL

Figure 71 - Pacemaker Sensitivity Test result: limit specified.

- l. Repeat steps (e) to (j) if desired. More than two tests can be done, however, if such results are saved to the Clip Record via **PASS**, **FAIL**, **SAVE**, or **OK** softkeys, then the Clip Record location reserved for sensitivity test #2 will be overwritten with each new result.
- m. When all tests have been completed, press **DONE** (see **Figure 68**). Sensitivity results accumulated in the Clip Record are retained and may be supplemented with data from other pacemaker, ECG and defibrillator tests.

4.8 AED Test Menu

4.8.1 Selecting the AED Test

Press the **AED** softkey on the MANUAL TEST menu to enter a menu for testing Automated External Defibrillators or "AEDs" (**Figure 72**). Functions available on this menu are:

AED PERFORMANCE		TEST(01/32)	
Trigger Shock or press NO SHOCK to conclude each test.			
ENERGY: ---.-J			
ECG WAVE: AFIB1 (x1 Scale)			
ECG TYPE: UNSHOCKABLE			
NO SHOCK	ECG	AUTO-NSR	DONE >

Figure 72 - AED Test menu.

- NO SHOCK** Press this softkey if the AED audibly and/or visually advises the user that the AED cannot or should not be discharged.
- ECG** Press to enter a menu for setting up the ECG simulator. Refer to Section 4.5.1.2 for instructions describing operation of the ECG simulator.
- AUTO-NSR** Press this softkey to enable or disable automatic response of the ECG simulator to a defibrillator discharge. If AUTO-NSR is enabled, "> NSR60" will appear on the LCD to the right of the ECG WAVE, in which case a defibrillator discharge will cause the simulator to automatically change to a normal sinus rhythm at 60BPM. Once triggered by a discharge, the NSR60 simulation will remain in effect for subsequent tests, until changed via the **ECG** softkey described above.
- DONE** Press to return to the MANUAL TEST menu. AED measurement data in the Clip Record are retained.
- Press to access additional softkey functions as shown in **Figure 73**, and as described below.

<			CANCEL
---	--	--	--------

Figure 73 - Alternate softkeys of AED Test menu.

Phase 3 OPERATING MANUAL

CANCEL Cancel the AED test and return to the MANUAL TEST menu. AED Test data in the Clip Record will be deleted if you press **YES** in response to the cancellation confirmation which will be displayed. All other data in the Clip Record will be retained. For additional information on **CANCEL**, see Section 4.1.3.

◀ Press to restore softkey functions as shown in **Figure 72**.

4.8.2 Performing the AED Test

The primary purpose of the AED test is to determine whether an AED can analyze and correctly classify an input ECG signal as shockable or not shockable. A second purpose of the test is to record the energy of the discharge when the AED advises the user to administer a shock, and a shock is then triggered. *Phase 3* provides space in the Clip Record for up to 32 AED test measurements, allowing you to record results for different ECG waveforms, AED shock series, and AED energy levels.

In an AED test, the *Phase 3* ECG simulator is limited to the waveforms listed in **Table 4-1** of Section 4.5.1.2. These ECG waveforms are classified according to AAMI guidelines¹ as follows:

<i>Phase 3</i> ECG Waveform	Waveform Classification
AFIB1 Coarse Atrial Fibrillation	Not shockable
AFIB2 Fine Atrial Fibrillation	Not shockable
ASYS1 Asystole (baseline > 0.1 mV)	Not shockable
ASYS2 Asystole - Flat	Not shockable
SVTACH Supraventricular Tachycardia	Not shockable
VTACH1 Ventricular Tachycardia @ 140BPM	Not shockable
VTACH2 Ventricular Tachycardia @ 160BPM	Shockable (depends on AED)
VTACH3 Ventricular Tachycardia @ 190BPM	Shockable (depends on AED)
PVTACH Torsades de Pointes @ 200BPM	Shockable (depends on AED)
VFIB1 Coarse Ventricular Fibrillation	Shockable
VFIB2 Fine Ventricular Fibrillation	Report only; do not classify as shockable or not shockable
SQRP1 Square Pulse 1 ms @ 60 BPM	Not shockable

1. *Circulation* 1997; V.95:1677-1682 AAMI

Phase 3 OPERATING MANUAL

According the preceding table, an AED which operates according to AAMI guidelines¹ for sensitivity and specificity should advise a shock only if the ECG clearly indicates ventricular fibrillation ($> 100 \mu\text{V}$), or a wide complex ventricular tachycardia in excess of 150 BPM.

To perform the AED test:

- a. Connect the AED to *Phase 3* according to Section 3.1.
- b. On the MANUAL TEST menu, press **AED**. The display of **Figure 72** will appear.
- c. *Optionally*, if you would like to change the ECG waveform, press **ECG** to modify the settings of the ECG simulator. Refer to Section 4.5.1.2.
- d. If necessary, press the "ANALYZE" or equivalent button on the AED, or set the AED to automatically analyze and report on the ECG waveform.
- e. If the AED analyzes the waveform and advises you *not to shock*, press the **NO SHOCK** softkey on *Phase 3*. If this is the correct AED response given the type of ECG waveform being simulated, *Phase 3* will automatically assign a "PASS" to the test result (**Figure 74**). The result of the test will be displayed for 3 seconds, a zero energy result will be saved in the Clip Rec ord, and then the *Phase 3* will go back to the screen of **Figure 72** . If the AED' s response is not correct for the selected ECG waveform, *Phase 3* will automatically assign a "FAIL" to the result.

AED PERFORMANCE		TEST(01/32)	
Test Results			
ENERGY: ---.-J			
ECG WAVE: AFIB1 (x1 Scale)			
ECG TYPE: UNSHOCKABLE			
----- PASS -----			

Figure 74 - AED test result: correctly recognized unshockable ECG wave.

- f. If the AED advises you 'to shock', discharge the AED into *Phase 3*. If this is the correct response for the type of ECG waveform being simulated, *Phase 3* will assign a "PASS" to the test result (**Figure 75**). If AUTO-NSR is enabled, the ECG simulator will output a normal sinus rhythm at 60BPM. The results of the test will be displayed for 5 seconds, the energy result will be saved in the Clip Record, and then the system will go back to the screen of **Figure 72**. If the AED' s response is not correct for the selected ECG waveform, *Phase 3* will assign a "FAIL" to the result.

Phase 3 OPERATING MANUAL

```
AED PERFORMANCE TEST(02/32)
Test Results

ENERGY: 150.8J
ECG WAVE: VFIB1 (x1 Scale)
ECG TYPE: SHOCKABLE
----- PASS -----
```

Figure 75 - AED test result: correctly recognized shockable ECG wave.

- g. If the AED advises a shock, but this conflicts with the ECG TYPE displayed on *Phase 3*, discharge the AED into *Phase 3* regardless. *Phase 3* will automatically assign a "FAIL" to this type of test result (**Figure 76**).

```
AED PERFORMANCE TEST(03/32)
Test Results

ENERGY: 149.6J
ECG WAVE: VTACH1 (x2 Scale)
ECG TYPE: UNSHOCKABLE
----- FAIL -----
```

Figure 76 - AED test result: incorrectly recognized unshockable ECG.

- h. Repeat steps (c) to (g) as required until the desired number of AED tests have been performed, up to a maximum of **32**.
- i. When all tests have been completed, press **DONE** (see **Figure 72**). AED test results accumulated in the Clip Record are retained and may be supplemented with data from additional ECG tests. However, additional defibrillator and pacemaker tests *cannot* be done since the Clip Record now contains AED results (see Section 4.4.2). The Clip Record contents must be saved to the non-volatile memory before new defibrillator and/or pacemaker tests can be initiated.

4.9 Data Log

4.9.1 Viewing and Storing the Clip Record

As defibrillator, ECG and pacemaker tests are executed from the MANUAL TEST menu (see Section 4.4), measurement data produced by these tests are accumulated in the Clip Record. The alternate softkey set of the MANUAL TEST menu (**Figure 77**) provides means for viewing the current contents of the Clip Record, or saving the Clip Record to a Test Record in the non-volatile Data Log.

MANUAL TESTS			
VIEW:	View Clip Record Contents		
STORE:	Save Clip Record		
I.D.:	Enter defib ID / control number		
CANCEL:	Return to Main Menu		
< VIEW	STORE	I.D.	CANCEL

Figure 77 - Manual Test menu: alternate softkey set.

The softkey functions provided on the menu of **Figure 77** are:

VIEW Press to view measurement data currently stored in the Clip Record. *Phase 3* will format the measurement data into a viewable TEST REPORT document, and will place the TEST REPORT on the display. The display will then appear similar to the example shown in **Figure 78**.

Phase 3 Defibrillator Analyzer	
Datrend Systems Inc.	
TEST REPORT	
DATE: June 15 2006	TIME: 13:45:13
DEFIB ID: CN1234	

Figure 78 - Viewing the contents of the Clip Record.

Press the ▼ ▲ keys to scroll down/up through the TEST REPORT which is shown on the display. Press any other key to exit the Clip Record viewer and return to the MANUAL TEST menu.

Phase 3 OPERATING MANUAL

- STORE** Press to copy the current contents of the Clip Record to a Test Record in the non-volatile memory. If an ID for the defibrillator under test has not been entered when **STORE** is pressed, you will be prompted to enter an ID per Section 4.4.1.
- I.D.** At any time during the manual test process, press I.D. to input identification information, such as a control number, for the defibrillator or pacemaker under test. Refer to Section 4.4.1.
- CANCEL** Cancel the manual test and return to the MAIN MENU. All measurement data in the Clip Record will be deleted if you press **YES** in response to the cancellation confirmation which will be displayed. For additional information on **CANCEL**, see Section 4.1.3.

4.9.2 Recalling and Viewing Test Records

The non-volatile Data Log is accessed from the MAIN MENU of *Phase 3* (see Section 4.3). The display will appear as shown in **Figure 79** when **DATA LOG** on the MAIN MENU is pressed. As shown in the figure, the number of Test Records currently stored in the Data Log is indicated at the top right corner. The **VIEW** and **PRINT** softkeys will not be visible unless a Clip Record has been loaded into memory.

DATA LOG		USED(07/50)	
LOAD: Clip Record from storage memory			
VIEW: Clip Record			
PRINT: Clip Record			
DELETE: Clip Record in storage memory			
LOAD	VIEW	PRINT	DELETE >

Figure 79 - Data Log menu.

Phase 3 OPERATING MANUAL

The softkey functions provided by the Data Log menu are:

- LOAD** Press to select a Test Record from the Data Log, and then load the Test Record into the Clip Record for viewing or printing. Refer to Section 4.9.2.1.
- VIEW** Press to view the current contents of the Clip Record. This softkey will not be visible until a Test Record has been loaded from the Data Log. *Phase 3* will format the measurement data into a TEST REPORT document, and will place the TEST REPORT on the display. The display will then appear similar to the example shown in **Figure 78**. Press the ▼ ▲ keys to scroll down/up through the TEST REPORT which is shown on the display. Press any other key to exit the Clip Record viewer and return to the MANUAL TEST menu.
- PRINT** Press to print a TEST REPORT document via the Serial I/O Port of *Phase 3*. Refer to Section 4.9.2.2. This softkey will not be visible until a Test Record has been loaded from the Data Log.
- DELETE** Press to delete a selected Test Record that was saved to the Data Log. The Test Record is selected in the same way as described in Section 4.9.2.1. A prompt requiring you to confirm the deletion will be displayed after you have selected a Test Record.
- Press to access additional softkey functions as shown in **Figure 80**, and as described below:



Figure 80 - Alternate softkeys of Data Log menu.

- DEL WAV** Press to delete all Waveform Records in the Data Log. A prompt requiring you to confirm the deletion will be displayed if you press the **DEL WAV** key.
- DEL ALL** Press to delete all Test Records and Wave Records currently stored in the Data Log. A prompt requiring you to confirm the deletion will be displayed if you press the **DEL ALL** key.
- CANCEL** Press to return to the MAIN MENU.
- ◀ Press to restore softkey functions as shown in **Figure 79**.

Phase 3 OPERATING MANUAL

4.9.2.1 Selecting a Test Record

Press the **LOAD** softkey on the DATA LOG menu to enter a menu for selecting a Test Record for viewing, deleting or printing (**Figure 81**). Press the ▼ ▲ keys to scroll down/up through the list of Test Records one record at a time. The Test Records are displayed on the screen with the most recent test first. Other softkey functions provided on this menu are:

DATA LOG				USED(07/50)
Select Test Record From List				
No.	DATE	TIME	DEFIB ID	▲
007	Jun 12	14:55	CN3412	
006	Jun 12	14:02	CN3418	
005	Jun 10	11:38	CN0115	▼
004	Jun 08	08:47	CN4437	
PAGE DN		PAGE UP		SELECT CANCEL

Figure 81 - Selecting a Test Record from the Data Log.

- PAGE DN** Press to move the displayed list down by four Test Records.
- PAGE UP** Press to move the displayed list up by four Test Records.
- SELECT** Press to select the Test Record highlighted at the top of the list. The Test Record will be loaded into the Clip Record, and can then be viewed or printed respectively via **VIEW** or **PRINT** softkeys on the DATA LOG menu.
- CANCEL** Do not select a Test Record; return to the DATA LOG menu.

4.9.2.2 Printing a Test Record

Phase 3 can transmit a TEST REPORT document from its DB9 Serial I/O Port to receiving devices having a RS-232 serial port, such as a serial printer or a personal computer. Before attempting to print, connect the receiving device to the Serial I/O Port of *Phase 3* according to the instructions in Section 3.2.3. Note the serial protocol of *Phase 3* is 9600 baud, No parity, 8 data bits, 1 stop bit (9600, N, 8, 1).

Phase 3 OPERATING MANUAL

After loading a Test Record from the Data Log, press the **PRINT** softkey on the DATA LOG menu to print the TEST REPORT document. The TEST REPORT is 40 characters wide and will comprise a variable number of lines, depending on what tests were performed. While the document is being printed, the *Phase 3* display will appear as shown in **Figure 82**.

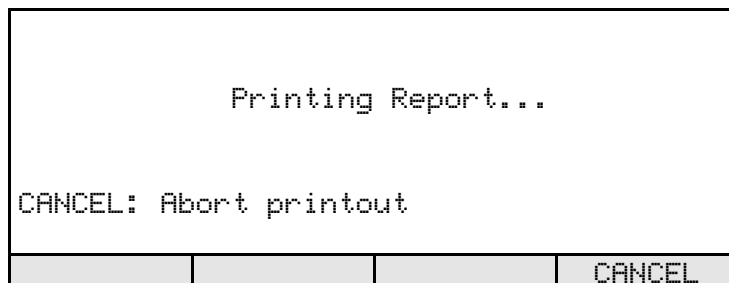


Figure 82 - Test Report printout in progress.

CANCEL may be pressed to abort the printout in progress. When the printout is completed, the display will automatically return to the DATA LOG menu.

If *Phase 3* detects that the receiving device is off-line, an alarm message will be shown (**Figure 83**). Correct the problem with the receiving device, then press **OK**. The display will return to the DATA LOG menu, from which a new printout can be initiated via the **PRINT** softkey.

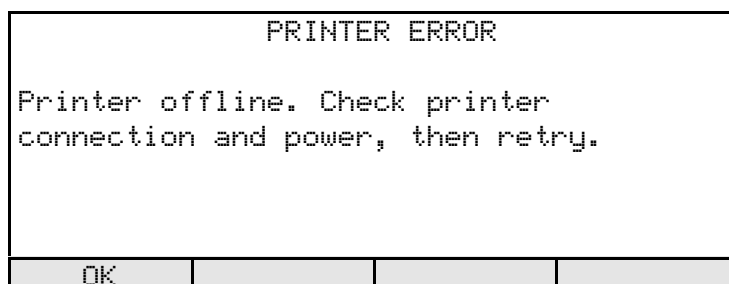


Figure 83 - Off-line error during printout.

4.10 Automated Testing

4.10.1 AutoSequence Overview

For fully automated testing, *Phase 3* provides 32 *AutoSequences* which may be user-programmed by means of the accessory *Phase3pc* software (included on the CD ROM supplied with your *Phase 3*). An AutoSequence test may include steps for measuring defibrillator energy, charge time, and synchronization delay; ECG performance; and pacemaker pulse characteristics, noise immunity, sensitivity, and refractory periods. *Phase 3* comes equipped with pre-programmed AutoSequences loaded into its non-volatile memory, which are provided as examples, and should be modified or supplemented to meet the users needs via *Phase3pc* software.

For each test or measurement performed in an AutoSequence, the expected value of the result or *target* is specified, so that *Phase 3* will automatically pass or fail the result depending on an acceptance range derived from the target and a selected *tolerance*.

There are two basic types of AutoSequence provided by *Phase 3*: Defib/Pacer and AED. In a Defib/Pacer AutoSequence, the order of test execution is:

- Defib Energy
- Defib Charge Time
- Defib Cardioversion (Sync)
- ECG Tests
- Pacer Pulse
- Pacer Noise Immunity
- Pacer Sensitivity
- Pacer Refractory

In an AED AutoSequence, the only type of test that can be performed is the "shock/no shock" energy test (see Section 4.8). Charge time, cardioversion, and pacemaker tests cannot be performed if the "DUT Type" of the AutoSequence has been set, via *Phase3pc* software, to "AED".

When an AutoSequence is selected from the AutoSequence menu of *Phase 3*, the Clip Record is erased. As each step of the AutoSequence is completed, the measurement data is accumulated in the Clip Record. At the end of the AutoSequence, you will be prompted to enter an ID for the defibrillator under test (DUT), after which a Test Record containing the results will then be saved to the non-volatile Data Log.

Phase 3 OPERATING MANUAL

4.10.2 Selecting an AutoSequence

Press the **AUTO** softkey on the *Phase 3* MAIN MENU (Section 4.3) to enter a menu for selecting an AutoSequence (**Figure 84**). Press the ▼ ▲ keys to scroll down/up through the list of AutoSequences one sequence at a time.

AUTOSEQUENCE TESTS			
----- SELECT TEST -----			
Test#	Title		
>001	HP CODEMASTER		▲
002	LAERDAL 2000		
003	MARQUETTE 1500		▼
004	PHYSIO LP9		
PAGE DN		PAGE UP	SELECT CANCEL

Figure 84 - Selecting an AutoSequence.

Other softkey functions provided on this menu are:

- PAGE DN** Press to move the displayed list down by four AutoSequences.
- PAGE UP** Press to move the displayed list up by four AutoSequences.
- SELECT** Press to select the AutoSequence indicated by the > cursor. The Clip Record will be erased, then the AutoSequence will begin execution.
- CANCEL** Do not select an AutoSequence; return to the MAIN MENU.



NOTE:

If the Test Record portion of the Data Log is full when the **AUTO** softkey on the MAIN MENU is pressed, an error message is displayed (**Figure 85**).

The Data Log must not be full when attempting to run an AutoSequence. Pressing **OK** on the display of **Figure 85** will return *Phase 3* to the MAIN MENU. The Data Log contents may then be downloaded and saved via *Phase3pc* software (see Chapter 6). After downloading, the Data Log may be partially or completely erased via the DATA LOG menu (see Section 4.9).

Phase 3 OPERATING MANUAL

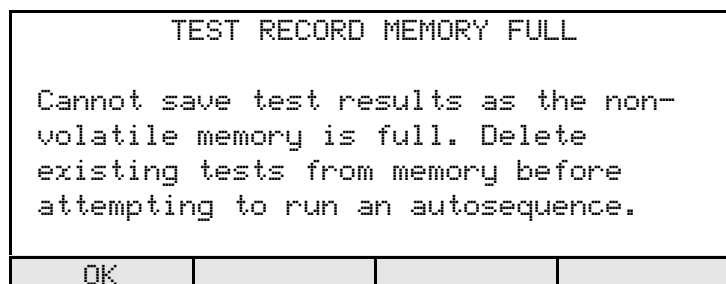


Figure 85 - AutoSequence execution prevented due to full Data Log.

4.10.3 Running a Defib/Pacer AutoSequence

4.10.3.1 Automated Defibrillator Tests

When running an AutoSequence for a defib/pacer, *Phase 3* will display test setup instructions for each step of the sequence, similar to the example of **Figure 86** for a defibrillator energy test. The type of test being performed at any step in the sequence is indicated at the top left of the display (DEFIB ENERGY in the example of **Figure 86**). The test count (01) and number of tests to be performed in the sequence (in this example, 07) are shown at top right.

Any *Phase 3* Autosequence can be programmed by the user to have an automatic timeout/advance feature. At each test step, the *Auto-Test Timer* of *Phase 3* will move the sequence forward from the user prompt to the measurement automatically, provided there is no operator input before a user-set delay time expires. After each measurement is completed, the Auto-Test Timer causes the user prompt for the next step of the sequence to be displayed. The Auto-Test Timer of a Autosequence may be set to "OFF", or it may be programmed for a 3, 5 or 9-second delay by means of the *Phase3pc* software. For example, **Figure 86** shows the first energy test of an Autosequence for which the Auto-Test Timer has been enabled with a delay of 5 seconds. The operator may press **TEST** to run the indicated test, or the user can wait for the Auto-Test Timer to count down to zero at which point the energy measurement screen, **Figure 87**, will be displayed automatically.

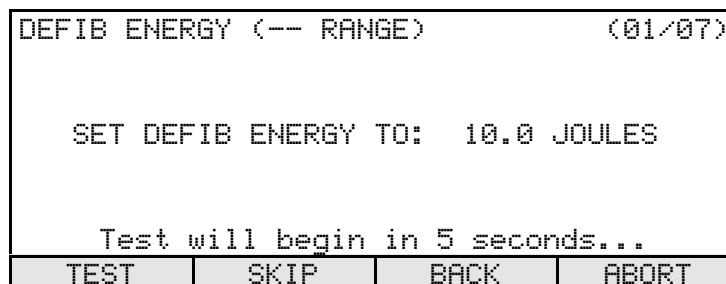


Figure 86 - AutoSequence example: first defib energy test of seven.

During AutoSequence execution, the softkeys provide these functions:

- If **TEST** of **Figure 86** is pressed, *Phase 3* will then display a screen corresponding to the type of measurement which is to be performed. For the case of a defib energy test, the display will appear similar to the example of **Figure 87**. On this display, the **BACK** softkey may be pressed to restore the instruction screen shown in **Figure 86**.



If the Auto-Test Timer is disabled, *Phase 3* will then provide the softkeys shown in **Figure 88**. Press **OK** to save the displayed result to the Clip Record and advance the sequence to the next step. Refer to Section 4.5.1.4 for a description of the other softkey functions appearing on the display of **Figure 88**.

Phase 3 OPERATING MANUAL

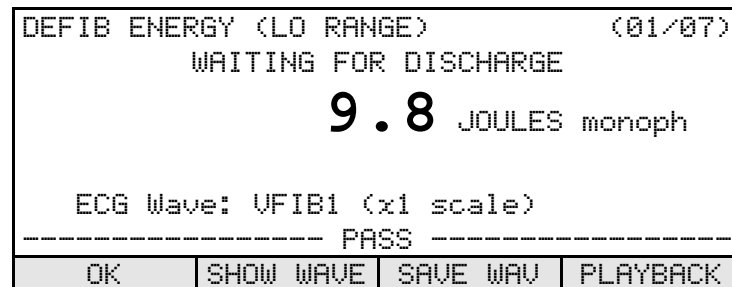


Figure 88 - Defib energy result during an AutoSequence.

For charge time and cardioversion tests, instructions similar to **Figure 86** are shown immediately prior to each test step. The appearance of the display following acknowledgement of the instructions will then be similar to the displays shown for manual charge time and cardioversion tests (see Sections 4.5.2 and 4.5.3 respectively). After the defibrillator discharge, the results are displayed and the softkeys will appear as shown in **Figure 88**.

Charge Time and Cardioversion (SYNC) tests operate in a similar manner, subject to the descriptions in sections 4.5.2 and 4.5.3 respectively.

4.10.3.2 Automated ECG Tests

If the AutoSequence includes ECG tests, then this part of the sequence will be preceded by the instruction display shown in **Figure 89**. If the Auto-Test Timer has been enabled, the delay countdown will appear on the LCD per **Figure 89**.

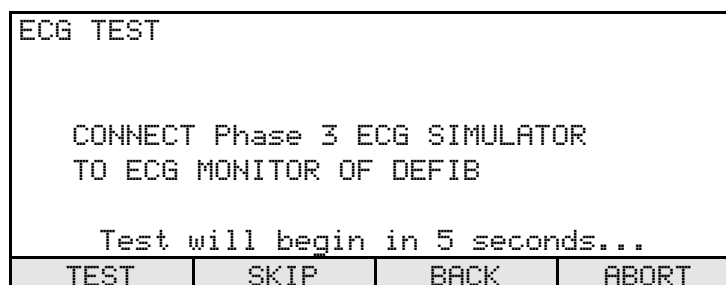


Figure 89 - AutoSequence incorporating ECG tests.

The softkey functions provided by this menu are:

- TEST** Press this softkey to proceed with the ECG tests.
- SKIP** Press this softkey to skip over **ALL** ECG tests that have been specified in the AutoSequence. If pacemaker tests have been enabled, the next display that will be shown will be instructions for the pacer tests.
- BACK** Press this softkey to decrement the sequencer to the immediately previous defib test (cardioversion, charge time, or energy - depending on what has been enabled in the AutoSequence) and show the instruction screen appropriate for that measurement.
- ABORT** Press to abort the sequence in progress. A prompt will be displayed asking you to confirm the abort. Pressing **YES** in response to this prompt will abort the sequence and return **Phase 3** to the MAIN MENU.

If **TEST** of **Figure 89** is pressed, **Phase 3** will then set the ECG simulator to the first waveform which has been specified in the sequence (**Figure 90**). The operator must press one of the softkeys to proceed, the auto-timer has no effect in this screen. The softkeys shown in the figure will then operate as follows:

Phase 3 OPERATING MANUAL

ECG TEST		TEST(01/08)	
WAVE BANK: Performance			
WAVEFORM: DC Pulse, 4 sec			
(PULSE)			
Relative SCALE: x1 (1.0mV QRS Lead II)			
	PASS	FAIL	BACK

Figure 90 - AutoSequence ECG test.

- PASS** Record a "PASS" in the Clip Record as the result for the displayed waveform, and increment the sequence to the next ECG waveform, or alternatively to the first of the pacer measurements if the current ECG waveform is the last waveform in the sequence.
- FAIL** Record a "FAIL" in the Clip Record as the result, and increment the sequence to the next ECG waveform.
- BACK** Return the sequence to the screen of **Figure 89**. Current contents of the Clip Record are not affected.

4.10.3.3 Automated Pacemaker Tests

If the AutoSequence includes pacemaker pulse tests, then this part of the sequence will be preceded by an instruction display which will be similar to the example shown in **Figure 91**. As indicated in the figure, the pacer test load which has been specified in the AutoSequence setup is indicated on the top line of the display. Softkeys appearing on the display of **Figure 91** provide the same functions as described previously for defibrillator energy tests (see Section 4.10.3.1). The Auto-Test Timer, if enabled, will not appear on the display of **Figure 91**, but the timer will cause the sequence to automatically advance to the next measurement after a 4-second delay once the pacer pulse test has been stopped.

PACER PULSE		1000 ohms (01/06)	
SET PACING MODE TO: ASYNCHRONOUS			
SET PACER OUTPUT TO: 200 mA			
SET PACER RATE TO: 60 PPM			
Activate Pacer and press "TEST"			
TEST	SKIP	BACK	ABORT

Figure 91 - AutoSequence example: first pacer pulse test of six.

Press **TEST** after the pacemaker has been set up as instructed on the display of **Figure 91**. The display will then appear as shown in **Figure 92** below. The test will begin immediately after the **TEST** key is pressed. Press **CANCEL** to review the instructions of **Figure 91**, or alternatively press **STOP** to halt the measurement.

PACER PULSE		1000 ohms TEST(01/06)	
Measuring Pacer Pulse Properties			
AMPL: 190.1 mA		RATE: 60.1 PPM	
WIDTH: 18.61 ms			
ENERGY: ---.- mJ			
METHOD: Peak Value			
STOP			CANCEL

Figure 92 - Start of pacer pulse test during an AutoSequence.

Phase 3 OPERATING MANUAL

When **STOP** is pressed, the measurement will be halted and the results displayed in a manner similar to the example shown in **Figure 93**. If the Auto-Test Timer is enabled, wait approximately 4 seconds for *Phase 3* to automatically save the results and advance to the next test step. The softkeys will all be blanked if the Auto-Test Timer is enabled. If the Auto-Test Timer is disabled, press the **OK** softkey to save the data to the Clip Record and advance *Phase 3* to the next step of the sequence.

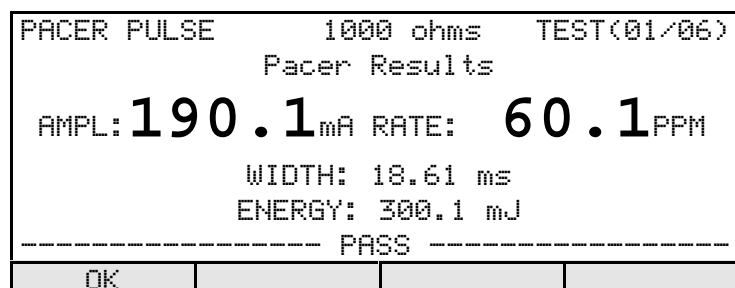


Figure 93 - Pacemaker pulse result during an AutoSequence.

Instructional displays for pacer noise immunity, sensitivity and refractory tests will appear similar to the screen of **Figure 94**. The softkeys on this display operate as previously described for the pacer pulse test.

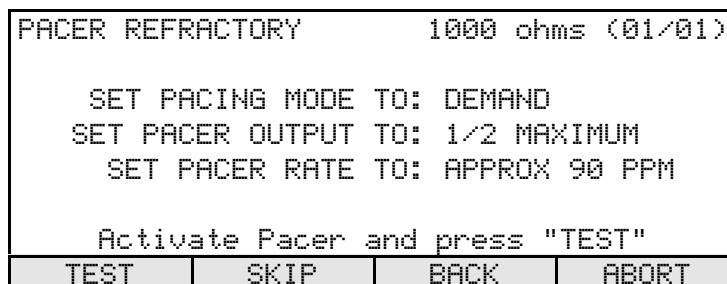


Figure 94 - AutoSequence example: pacer refractory test.

The pacer test procedure will be performed and the results displayed in a manner similar to the case of a manual test performed with targets (see **Figure 95**). Note that noise immunity, sensitivity, and refractory tests will each require some time to complete, ranging from about 10 seconds to 60 seconds, depending on the test and the rate setting of the pacemaker. When the test is complete and the result is displayed, press the **OK** softkey to save the data to the Clip Record and advance *Phase 3* to the next step of the sequence, or wait for an automatic save if the Auto-Test Timer is enabled. If the Auto-Test Timer is enabled, the softkeys will be blanked when the measurement is completed.

Phase 3 OPERATING MANUAL

```
PACER REFRACTORY    1000 ohms TEST(01/01)

REFRACTORY MIN:    100msec MAX:    250msec
REFRACTORY PRP:    231msec SRP:    115msec
ECG WAVE: TRIP40 (x1 Scale)
PACER RATE:    90 PPM
----- PASS -----
OK
```

Figure 95 - Pacemaker refractory result during an AutoSequence.

4.10.4 Running an AED AutoSequence

When running an AutoSequence for an AED, *Phase 3* will operate similarly as described in Section 4.8 for a manual AED test. The primary difference between a manual AED test and an AutoSequence AED test is that the ECG waveforms are defined in the setup of an AED AutoSequence. The Auto-Test Timer cannot be enabled in AED AutoSequences.

As in the manual mode, the ECG waveform may be set to revert to NSR60 after a discharge has been detected. This setting may be toggled using the **AUTO-NSR** key. After the test result has been accepted with the **OK** key, the ECG waveform will change to the setting dictated by the next step in the AutoSequence.

Upon selecting an AED AutoSequence, the display of *Phase 3* will appear as shown in Figure 96. The softkeys will then assume the following functions:

```
AED PERFORMANCE (01/09)
Trigger Shock or press NO SHOCK to
conclude each test.
ENERGY: ---.-J
ECG WAVE: UTACH2 (x1 Scale)
ECG TYPE: SHOCKABLE
NO SHOCK AUTO-NSR BACK ABORT
```

Figure 96 - AutoSequence AED test.

Phase 3 OPERATING MANUAL

- NO SHOCK** Press this softkey if the AED audibly and/or visually advises the user that the AED cannot or should not be discharged. For further details, see Section 4.8.
- AUTO-NSR** Press this softkey to toggle between changing to NSR60 after a discharge is detected, and, retaining the current ECG WAVE after a discharge is detected. The ECG WAVE will change to the next waveform in the sequence when the results are accepted with the **OK** key.
- BACK** Press this softkey to decrement the sequencer to the immediately previous AED test step.
- ABORT** Press to abort the sequence in progress. A prompt will be displayed asking you to confirm the abort. Pressing **YES** in response to this prompt will abort the sequence and return *Phase 3* to the MAIN MENU.

If the AED has been configured to automatically execute a "shock series", you should enable the **AUTO-NSR** feature of *Phase 3* before activating the "ANALYZE" function on the AED. This feature should inhibit the AED's "shock series" after the first discharge, which ensures that shocks are only delivered when *Phase 3* is ready to proceed.

If **NO SHOCK** is pressed, or if a discharge is detected, *Phase 3* will automatically assess the result as shown in the example display of **Figure 97**. The result of the test will be displayed for several seconds, the measurement result will be saved in the Clip Record, and then the *Phase 3* will advance to the next step of the sequence.

AED PERFORMANCE		(01/09)	
Test Results			
ENERGY: 150.8J			
ECG WAVE: UTACH2 (x1 Scale)			
ECG TYPE: SHOCKABLE			
----- PASS -----			

Figure 97 - AED test result during an AutoSequence.

4.10.5 AutoSequence Conclusion

After all measurements in the AutoSequence have been completed, the operator will be prompted to save the results to a Test Record via the menus of **Figure 98**, **Figure 99**.

SAVE RECORD			
SAVE TEST RECORD, OR PRESS 'BACK' TO RETURN TO TESTING			
NOTE: 'SAVE' will require you to enter an I.D. for the DUT.			
SAVE	BACK		ABORT

Figure 98 - Prompt displayed at end of AutoSequence.

Softkeys on this menu provide the following functions:

- SAVE** Press to save the measurement data acquired during the AutoSequence to a Test Record in the non-volatile Data Log. You will be prompted to enter an ID (e.g. control number) for the defibrillator under test. Refer to Section 4.4.1 for instructions regarding ID entry.
- BACK** Press this softkey to return *Phase 3* to the last test performed in the AutoSequence.
- ABORT** Press to abort the sequence and discard all data acquired. A prompt will be displayed asking you to confirm the abort. Pressing **YES** in response to this prompt will abort the sequence and return *Phase 3* to the MAIN MENU.

After the results have been saved, the screen of **Figure 99** will be displayed. Press **OK** to exit the AutoSequence.

AUTOSEQUENCE TEST RESULTS SAVED			
Test results have been saved into non- volatile memory at: Record xx/50			
Press OK to continue.			
OK			

Figure 99 - Prompt displayed at end of AutoSequence.

4.11 Self-Test Error Messages

When *Phase 3* is powered up, it will conduct a self-test as described in Section 4.2. Normally the self-test will pass, allowing the user to access the MAIN MENU of *Phase 3*.

Failures encountered during the self-test are reported via the display, accompanied by an alarm tone. Critical failures will prevent further operation of the instrument. For non-critical self-test failures, *Phase 3* will report the fault but will remain operable after the alarm is acknowledged by the user.

4.11.1 Critical Self-Test Failures

CALIBRATION ERROR

The factory calibration parameters stored in the instrument's non-volatile memory (EEPROM) have been corrupted. The instrument should be returned to an authorized service facility for re-calibration. Refer to Chapter 7 of this manual.

HARDWARE FAILURE

The internal analog-to-digital converter has failed its auto-zero calibration cycle. The instrument should be returned to an authorized service facility for repairs. Refer to Chapter 7 of this manual.

BATTERY DISCHARGED

Phase 3 is being operated from the internal battery, but the battery is close to full discharge. In this case, the instrument will automatically shut itself off if left on for more than a few seconds. Switch off the power to *Phase 3* immediately, connect the AC adapter, and then power up. *Phase 3* may be operated while the battery is being recharged.

Phase 3 OPERATING MANUAL

4.11.2 Non-Critical Self-Test Failures

BATTERY LOW WARNING

Phase 3 is being operated from the internal battery, but the battery has less than 20 minutes of usage remaining, before *Phase 3* will automatically shut itself off. The AC adapter should be connected to *Phase 3* as soon as possible. *Phase 3* may be operated while the battery is being recharged.

CLOCK WARNING

The time/date setting of the internal real-time clock was found to be invalid. After this alarm is acknowledged, the user will be prompted to set the clock. This self-test alarm may indicate the lithium battery which powers the clock should be replaced. The clock backup battery is not a user-serviceable item. Refer to Chapter 7 of this manual.

5 REMOTE CONTROL

5.1 General Description

The Serial I/O Port provides a RS-232 interface for controlling *Phase 3* remotely using an external device such as a personal computer or automated test system. *Phase 3* will recognize a predefined set of commands issued to its Serial I/O Port allowing the external device to start a test, stop a test, or retrieve test results automatically.

Remote commands allow the creation of simple programs on a personal computer that will automatically perform and document a defibrillator and/or pacemaker test according to a desired protocol. The command set is also compatible with automated test instrumentation, such as the ES601Plus Automated Safety Analyzer. Refer to the Operating Manual for your automated test instrument, especially with regard to port settings, cable wiring, data transmission format and data packet length. Note the serial protocol of *Phase 3* is 9600 Baud, 8 Data Bits, No Parity, 1 Stop Bit (9600, N, 8, 1).

The following sections present the remote control command set of *Phase 3*. When using these commands, it is assumed the user has connected the DUT to *Phase 3* prior to enabling the controlling device, and the controlling device is connected to *Phase 3* using the appropriate interface cable as described in Section 3.2.3. If using a program on a personal computer to command *Phase 3*, allow a delay of at least 100 milliseconds between consecutive remote commands to provide enough time for *Phase 3* to process and respond to each received command.

5.2 Remote Interface Mode

In order for *Phase 3* to respond to remote control commands, it must first be placed in *Remote Mode*. *Phase 3* will ignore all commands sent unless the instrument is running the Remote Mode interface.

To enter Remote Mode, press the **REMOTE** softkey on the MAIN MENU of *Phase 3*. The display will then appear as shown in **Figure 100**. Commands received via the Serial I/O Port are displayed on the LCD, as are the data which are returned in response to the commands. *Phase 3* also displays a counter which increments each time a valid command is received and processed. Between commands, **CANCEL** may be pressed to exit Remote Mode to the MAIN MENU of *Phase 3*.

REMOTE MODE MENU			
STATUS: Waiting		PORT: RS232	
COMMAND:		COUNT: 1	
			CANCEL

Figure 100 - Remote Mode menu.

5.3 Command Set

There are 16 commands in the remote control command set of *Phase 3*, summarized in the table below. Each command consists of a string of upper-case ASCII characters and numerals, terminated by a carriage return character (<CR> or \r).

If *Phase 3* receives a valid RS-232 command, it will execute the command, and return either an asterisk character followed by a carriage return (*<CR>) or a packet of data back to the controlling device depending on the type of command issued. With many of the measurement-related commands, a substantial amount of time may elapse before any data, for example energy test results, are returned to the controlling device.

If a command is syntactically incorrect, or is not recognized by *Phase 3*, a question mark character followed by a carriage return (?<CR>) is transmitted back to the controlling device.

Phase 3 OPERATING MANUAL

Summary of Phase 3 Remote Control Commands

Command	Description	Return
ECG	Set up ECG wave generator	
DE	Run Defib energy test	Data
DCH	Run Defib charge time test	Data
DS	Run Defib cardioversion test	Data
PLD	Set pacer load	
PP	Run pacer pulse test	Data
PRF	Run pacer refractory test	Data
PN	Run pacer immunity test	Data
PSN	Run pacer sensitivity test	Data
WAV	Acquire waveform data	Data
IDENT	Get identification string	Data
MEM	Get memory usage	Data
STR	Dump selected test record	Data
CLT	Clear last test record	
CTR	Clear all test records	
CWV	Clear all wave records	

Phase 3 OPERATING MANUAL

5.3.1 ECG Configuration Command

Description: The ECG configuration command sets the waveform, amplitude scale and discharge response mode of the ECG simulator. Typically, this command would be sent prior to other commands which invoke defibrillator or pacemaker measurements.

Syntax: ECG<code><scale><mode><CR>

where: <code> is a two letter code designating the Wave Bank and Waveform of the simulator. See table below for the Bank and Waveform letter codes.

<scale> is: 0 - for ECG simulator OFF
1 - for x1 amplitude scale
2 - for x2 amplitude scale
3 - for x0.5 amplitude scale

<mode> is: 0 - to disable response to defib discharge
1 - revert to NSR60 on detection of defib discharge
2 - play back the discharge waveform at the set playback time (4 or 12 sec), but do not change ECG waveform
3 - play back the discharge waveform at the set playback time (4 or 12 sec) and then revert to NSR60

Example: "ECGDJ10\r" Select Coarse VFIB simulation, x1 scale (waveform code DJ is from the table below)

Returns: (1) "*" \r" Acknowledge; ECG simulator has been set
(2) "?" \r" Syntax error/invalid command

Notes: To stop the simulation corresponding to waveform codes AF-AL, press the **STOP** softkey which will be displayed once the simulation has been started, or alternatively transmit an ASCII <Escape> character (0x1B) to *Phase 3* via the communications connection to abort the simulation and permit *Phase 3* to receive and process subsequent commands.

Phase 3 OPERATING MANUAL

Wave Bank	Waveform	ECG Wave Code
	DC Pulse, 4sec	AA
	Square Wave, 2 Hz	AB
	Triangle, 2 Hz	AC
	Sinewave, 0.1 Hz	AD
	Sinewave, 0.5 Hz	AE
	Sinewave, 10 Hz	AF
	Sinewave, 20 Hz	AG
	Sinewave, 40 Hz	AH
	Sinewave, 50 Hz	AI
	Sinewave, 60 Hz	AJ
	Sinewave, 70 Hz	AK
	Sinewave, 100 Hz	AL
Sinus Rhythm	ECG NSR, 30 BPM	BA
	ECG NSR, 60 BPM	BB
	ECG NSR, 90 BPM	BC
	ECG NSR, 120 BPM	BD
	ECG NSR, 150 BPM	BE
	ECG NSR, 180 BPM	BF
	ECG NSR, 240 BPM	BG
	ECG NSR, 300 BPM	BH
Arrhythmia	2 nd deg. AV-Block	CA
	Premature Atrial Contraction	CB
	Right Bundle Branch Block	CC
	Premature Ventricular Contraction	CD
	R-on-T PVC	CE
	Multifocal PVC	CF
	Run of 5 PVC	CG
	Bigeminy	CH
	Trigeminy	CI

Phase 3 OPERATING MANUAL

Wave Bank	Waveform	ECG Wave Code
Shock Advisory/AED	Coarse Atrial Fibrillation	DA
	Fine Atrial Fibrillation	DB
	Asystole (noise)	DC
	Asystole (flatline)	DD
	SupraVent. Tachycardia	DE
	Ventricular Tachycardia, 140BPM	DF
	Ventricular Tachycardia, 160BPM	DG
	Ventricular Tachycardia, 190BPM	DH
	Torsades de Pointes, 200BPM	DI
	Coarse VFIB	DJ
	Fine VFIB	DK
	Square Pulse 1msec / 60BPM	DL
Square Pacer Trigger	2 msec / 60BPM	EA
	25msec / 60BPM	EB
	40msec / 60BPM	EC
	100msec / 60BPM	ED
	200msec / 60BPM	EE
Triangle Pacer Trigger	10msec / 60BPM	FA
	25msec / 60BPM	FB
	40msec / 60BPM	FC
	100msec / 60BPM	FD
	200msec / 60BPM	FE
Haversine Pacer Trig.	10msec / 60BPM	GA
	25msec / 60BPM	GB
	40msec / 60BPM	GC
	100msec / 60BPM	GD
	200msec / 60BPM	GE
OFF	Turn ECG waveform OFF (0 VDC)	AX

Phase 3 OPERATING MANUAL

5.3.2 Defib Energy Command

Description: The defib energy command configures *Phase 3* to perform an energy test. *Phase 3* will return data in one of two possible formats *after* a discharge is acquired. See Section 4.5.1 for further information on the defib energy test.

Syntax: DE<range><return_data_format><CR>

where: <range> is: H - for High Range
L - for Low Range

<return_data_format> is:
C - for comma-separated variables (CSV) format
T - for "text" format

Example: "DEHT\r"

Run defib energy test; high range; return data in text format.

Returns: (1) For CSV formatted data:
"<energy>,<energy1>,<peak_volts1>,<peak_amps1>,<avg_volts1>,<avg_amps1>,<width1_10>,<width_50>,<peak_volts2>,<peak_amps2>,<avg_volts2>,<avg_amps2>,<width2_10>,<phase_delay>,<tilt>,<freq>,<duty>\r"

where: <energy> is delivered total energy, format "xxx.y J"
<energy1> is the delivered energy in phase 1, format "xxx.y J"
<peak_volts1> is peak voltage in phase 1, format "xxxx V"
<peak_amps1> is peak current in phase 1, format "xx.yy A"
<avg_volts1> is average voltage in phase 1, format "xxxx V"
<avg_amps1> is average current in phase 1, format "xx.yy A"
<width1_10> is 10% pulse width in phase 1, format "xx.yy ms"
<width_50> is 50% pulse width in phase 1, format "xx.yy ms"
<peak_volts2> is peak voltage in phase 2, format "xxxx V"
<peak_amps2> is peak current in phase 2, format "xx.yy A"
<avg_volts2> is average voltage in phase 2, format "xxxx V"
<avg_amps2> is average current in phase 2, format "xx.yy A"
<width2_10> is 10% pulse width in phase 2, format "xx.yy ms"
<phase_delay> is the time duration where the discharge energy is zero between phase 1 and phase 2, format "xx.yy ms"
<tilt> is the ratio of the voltage difference between the start voltage of the first phase of a defib discharge and the end voltage of the second phase, to the start voltage of the first phase, format "xx.y %"

Phase 3 OPERATING MANUAL

<freq> is the modulation frequency of a pulsed biphasic phasic discharge, format "xxxx Hz"

<duty> is the duty cycle of the modulation frequency of a pulsed biphasic discharge, format "xx.y %".

- (2) For "text" format data:
"ENERGY=<energy>\r"

where: <energy> is delivered total energy, format "xxx.yJ"

- (3) "?\r" Syntax error/invalid command
- (4) "TEST CANCELLED\r" if operator presses CANCEL key on *Phase 3* after this command is received but before a defibrillator discharge is measured.

Notes:

Energy value will be returned as "XXX. XJ" if the measurement is performed on LOW range, and signal distortion (clipping) is detected in the acquired waveform data. Repeat test using HIGH range. See Section 4.5.1.4.

Phase 3 OPERATING MANUAL

5.3.3 Defib Charge Time Command

Description: The defib charge time command configures *Phase 3* to perform a charge time test. Receipt of this command will initiate the 5-second countdown timer shown on the display. *Phase 3* will return data in one two possible formats, *after* a discharge is acquired. See Section 4.5.2 for further information on the defib charge time test.

Syntax: DCH<return_data_format><CR>

where: <return_data_format> is:
C - for comma-separated variables (CSV) format
T - for "text" format

Example: "DCHC\r"

Run defib charge time test; return data in CSV format.

Returns: (1) For CSV formatted data:
"<energy>,<charge_time>\r"

where: <energy> is delivered energy, format "xxx.y J"
<charge_time> is the charge time, format "xx.yy s" (or xx.y s for remote control via RS-232)

(2) For "text" format data:
"ENERGY=<energy> CHARGE=<charge_time>\r"

where: <energy> is delivered energy, format "xxx.y J"
<charge_time> is the charge time, format "xx.yy s" (or xx.y s for remote control via RS-232)

(3) "?\r" Syntax error/invalid command

(4) "TEST CANCELLED\r" if operator presses CANCEL key on *Phase 3* after this command is received but before a charge time is measured.

Notes: Charge Time measurements are normally preceded by one or more discharges of the defibrillator with the AC power disconnected. This portion of the test must be simulated in the remote mode by performing regular energy discharges. The programmer must keep track of the number of pre-test discharges performed.

Phase 3 OPERATING MANUAL

Phase 3 OPERATING MANUAL

5.3.4 Defib Sync (Cardioversion) Command

Description: The defib sync command configures *Phase 3* to perform a discharge sync/ cardioversion test. *Phase 3* will return data in one of two possible formats *after* a discharge is acquired. See Section 4.5.3 for further information on the defib cardioversion test. If the current ECG WAVE setting is not appropriate for this test, the ECG WAVE will be set to AFIB x1 automatically.

Syntax: DS<range><sync><return_data_format><CR>

where: <range> is: H - for High Range
L - for Low Range

<sync> is: Q - for Q-wave sync timing reference
R - for R-wave sync timing reference

<return_data_format> is:
C - for comma-separated variables (CSV) format
T - for "text" format

Example: "DSHQT\r"

Run defib sync test; high range; Q-wave sync; return data in "text" format

- Returns:
- (1) For CSV formatted data:
"<energy>,<delay_time>\r"

where: <energy> is delivered energy, format "xxx.y J"
<delay_time> is the sync delay time, format "xxxx ms"
 - (2) For "text" format data:
"ENERGY=<energy> CHARGE=<charge_time>\r"

where: <energy> is delivered energy, format "xxx.y J"
<delay_time> is the sync delay time, format "xxxx ms"
 - (3) "?\r" Syntax error/invalid command
 - (4) "TEST CANCELLED\r" if operator presses CANCEL key on *Phase 3* after this command is received but before a defibrillator discharge is measured.

Phase 3 OPERATING MANUAL

Notes: Energy will be returned as "XXX. XJ" if the measurement is performed on LOW range, and signal distortion (clipping) is detected in the acquired waveform data. Repeat test using HIGH range. See Section 4.5.1.4.

5.3.5 Pacer Load Select Command

Description: The pacer load select command sets the load resistor for pacemaker tests. Typically, this command would be sent prior to other commands which invoke pacemaker measurements.

Syntax: PLD<code><CR>

where: <code> is a single-letter code designating the load resistor. See table below for the resistor letter codes.

Example: "PLDd\r"

Select 1500 ohm pacer load

Returns: (1) "*" \r" Acknowledge; pacer load has been set
(2) "?" \r" Syntax error/invalid command

Pacer Load	Letter Code	Pacer Load	Letter Code	Pacer Load	Letter Code	Pacer Load	Letter Code
50Ω	A	450Ω	I	850Ω	Q	1250Ω	Y
100Ω	B	500Ω	J	900Ω	R	1300Ω	Z
150Ω	C	550Ω	K	950Ω	S	1350Ω	a
200Ω	D	600Ω	L	1000Ω	T	1400Ω	b
250Ω	E	650Ω	M	1050Ω	U	1450Ω	c
300Ω	F	700Ω	N	1100Ω	V	1500Ω	d
350Ω	G	750Ω	O	1150Ω	W	1550Ω	e
400Ω	H	800Ω	P	1200Ω	X	1600Ω	f

Phase 3 OPERATING MANUAL

5.3.6 Pacer Pulse Command

Description: The pacer pulse command configures *Phase 3* to perform a pacer pulse test. *Phase 3* will return data in one of two possible formats *after* at least two consecutive pacer pulses have been acquired. See Section 4.7.2 for further information on the pacer pulse test.

Syntax: PP<method><return_data_format><CR>

where: <method> is: A - for average
L - for leading edge
T - for trailing edge
P - for peak value

<return_data_format> is:
C - for comma-separated variables (CSV) format
T - for "text" format

Example: "PPLC\r" Run pacer pulse test; leading edge method; return data in CSV format.

- Returns:
- (1) For CSV formatted data:
"<current>,<width>,<rate>,<energy>\r"

where: <current> is pacer pulse current, format "xxx.y mA"
<width> is pacer pulse width, format "xx.yy ms"
<rate> is pacer pulse rate, format "xxx.y PPM"
<energy> is the pulse energy, format "xxxx.y mJ" or "xxxx μ J"
 - (2) For "text" format data:
"PULSE=<current> RATE=<rate>\r"

where: <current> is pacer pulse current, format "xxx.y mA"
<rate> is pacer pulse rate, format "xxx.y PPM"
 - (3) "?\r" Syntax error/invalid command
 - (4) "TEST CANCELLED\r" if operator presses CANCEL key on *Phase 3* after this command is received but before a pacer pulse is measured.
 - (5) "PACE TIMEOUT\r" if a pacer pulse is not detected within 3 seconds of receiving the command.

Phase 3 OPERATING MANUAL

5.3.7 Pacer Refractory Command

Description: The pacer refractory command configures *Phase 3* to determine both paced and sensed refractory intervals (PRP and SRP). *Phase 3* will return data in one of two possible formats, *after* both the PRP and SRP have been measured; this will require about 40 seconds at a pacer rate of 90 PPM. See Section 4.7.3 for further information on the pacer refractory test. If the current ECG WAVE setting is not appropriate for this test, the ECG WAVE will be set to TRIP40 x2 automatically.

Syntax: PRF<return_data_format><CR>

where: <return_data_format> is:

C - for comma-separated variables (CSV) format
T - for "text" format

Example: "PRFT\r" Run pacer refractory test; return data in text format.

Returns: (1) For CSV formatted data:
"<rate>,<prp>,<srp>\r"

where: <rate> is pacer pulse rate, format "xxx,y PPM"
<prp> is paced refractory period, format "xxx ms"
<srp> is sensed refractory period, format "xxx ms"

(2) For "text" format data:
"RATE=<rate> PRP=<prp> SRP=<prp>\r"

where: <rate> is pacer pulse rate, format "xxx,y PPM"
<prp> is paced refractory period, format "±xxxx ms"
<srp> is sensed refractory period, format "±xxxx ms"

(3) "?\r" Syntax error/invalid command

(4) "TEST CANCELLED\r" if operator presses CANCEL key on *Phase 3* after this command is received but before PRP and SRP are measured.

(5) "PACE TIMEOUT\r" if a pacer pulse is not detected within 3 seconds of receiving the command.

Phase 3 OPERATING MANUAL

5.3.8 Pacer Noise Immunity Command

Description: The pacer noise immunity command configures *Phase 3* to perform a noise immunity test. *Phase 3* will return data in one of two possible formats *after* the test is completed; if the test passes, this will require about 60 seconds at a pacer rate of 90 PPM. See Section 4.7.4 for further information on the pacer noise immunity test.

Syntax: PN<freq><return_data_format><CR>

where: <freq> is: A - for 60 Hz noise
 B - for 50 Hz noise

<return_data_format> is:
 C - for comma-separated variables (CSV) format
 T - for "text" format

Example: "PNAT\r"

Run pacer noise immunity test; noise frequency = 60 Hz; return data in text format.

Returns: (1) For CSV formatted data:
 "<freq>,<threshold>\r"

where: <freq> is the noise frequency, format "60Hz" or "50Hz"
 <threshold> is noise threshold amplitude, format "x.yy mV"

(2) For "text" format data:
 "FREQ=<freq> NOISE=<threshold>\r"

where: <freq> is the noise frequency, format "60Hz" or "50Hz"
 <threshold> is noise threshold amplitude, format "x.yy mV"

(3) "?\r" Syntax error/invalid command

(4) "TEST CANCELLED\r" if operator presses CANCEL key on *Phase 3* after this command is received but before the noise immunity has been measured.

Phase 3 OPERATING MANUAL

5.3.9 Pacer Sensitivity Command

Description: The pacer sensitivity command configures *Phase 3* to perform a pacer sensitivity test. *Phase 3* will return data in one two possible formats, *after* the test is completed; this will require about 20 seconds at a pacer rate of 90 PPM. See Section 4.7.5 for further information on the pacer sensitivity test.. If the current ECG WAVE setting is not appropriate for this test, the ECG WAVE will be set to TRIP40 automatically (scale not required).

Syntax: PSN<return_data_format><CR>

where: <return_data_format> is:
C - for comma-separated variables (CSV) format
T - for "text" format

Example: "PSNT\r"

Run pacer sensitivity test; return data in text format.

- Returns:
- (1) For CSV formatted data:
"<rate>,<sens>\r"

where: <rate> is pacer pulse rate, format "xxx.y PPM"
<sens> is ECG amplitude for sensitivity, format "x.yy mV"
 - (2) For "text" format data:
"RATE=<rate> SENS=<sens>\r"

where: <rate> is pacer pulse rate, format "xxx.y PPM"
<sens> is ECG amplitude for sensitivity, format "x.yy mV"
 - (3) "?\r" Syntax error/invalid command
 - (4) "TEST CANCELLED\r" if operator presses CANCEL key on *Phase 3* after this command is received but before the sensitivity has been measured.
 - (5) "PACE TIMEOUT\r" if a pacer pulse is not detected within 3 seconds of receiving the command.

Phase 3 OPERATING MANUAL

5.3.10 Phase 3 ID Command

Description: The ID command causes *Phase 3* to return its name to the controlling device. This command can be used to check for connection of *Phase 3* to the controlling device, and to verify that *Phase 3* is operating in Remote Mode.

Syntax: IDENT<CR>

Example: "IDENT\r"

Get ID of test instrument.

Returns:

(1)	"Phase 3\r"	Command received and understood.
(2)	"?\r"	Syntax error/invalid command

5.3.11 Clear Last Test Command

Description: The CLT command causes *Phase 3* to delete the last test record stored in EEPROM.

Syntax: CLT<CR>

Example: "CLT\r"

Deletes last test record.

Returns:

(1)	"*\r"	Command received and understood.
(2)	"?\r"	Syntax error/invalid command

Phase 3 OPERATING MANUAL

5.3.12 Clear Wave Records Command

Description: The CWV command causes *Phase 3* to delete all Wave Records stored in EEPROM.

Syntax: CWV<CR>

Example: "CWV\r"

Delete Wave Records from memory.

Returns:

(1)	"*\r"	Command received and understood.
(2)	"?\r"	Syntax error/invalid command

5.3.13 Clear Test Records Command

Description: The CTR command causes *Phase 3* to delete **ALL** Test and Wave Records stored in EEPROM.

Syntax: CTR<CR>

Example: "CTR\r"

Delete all Test and Wave Records from memory.

Returns:

(1)	"*"	Command received and understood.
(2)	"?\r"	Syntax error/invalid command

Phase 3 OPERATING MANUAL

5.3.14 Acquire Waveform Data Command

Description: The WAV command causes *Phase 3* to return the waveform data currently held in the data acquisition buffer via the RS-232 port.

This command works **ONLY** after completion of a successful “DE” (defib energy test) or “PP” (pacer pulse test) command. The data returned in response to “WAV” will represent a defibrillator discharge waveform after a “DE” command, or a single pacer pulse after a “PP” command.

Syntax: WAV<length><sample_rate><format><CR>

where:

- <length> is:
 - ‘1’ to ‘6’ - corresponding to 10 to 60 msec of waveform data
- <sample_rate> is:
 - L - low - corresponding to 45.6usec sample interval
 - M - medium - corresponding to 22.8 usec sample interval
 - H - high - corresponding to 11.4 usec sample interval
- <format> is:
 - A - for ASCII format
 - B - for binary format

Example: "WAV3HA\r"

Return 30 msec of waveform data at a sampling interval of 11.4 usec, in ASCII format.

Returns: The returned signal sample data are signed values. For a defib waveform, the data correspond to current in units of amperes x 100 (e.g. a value of -1579 corresponds to a signal sample equal to -15.79 amperes). For a pacer waveform, the data correspond to current in units of milliamps x 10 (e.g. a value of +453 corresponds to +45.3 milliamps).

- (1) For ASCII return format, each signal sample is represented as a string of ASCII digits, preceded by a ‘+’ or ‘-’ character to convey the sign as appropriate, and terminated with a carriage return character (‘\r’). After all requested signal data have been returned, a form feed character (‘\f’) is then sent and can be used to detect conclusion of the waveform download in ASCII mode.

Phase 3 OPERATING MANUAL

- (2) For binary return format, each data value is sent as a signed short (16-bit) integer, sent in low byte/high byte order. The requesting host can detect end-of-download via a timeout mechanism, or by waiting for the expected number of data values to be received. The number of data points conveyed in the download depends on the command parameters and is listed in the following table.

<length>	<sample_rate>		
	<u>'L'</u>	<u>'M'</u>	<u>'H'</u>
'1'	220	440	880
'2'	440	880	1760
'3'	660	1320	2640
'4'	880	1760	3520
'5'	1100	2200	4400
'6'	1320	2640	5280

- (3) "?\r" Syntax error/invalid command

5.3.15 Number of Test Records Command

Description: The MEM command causes *Phase 3* to return the number of Test Records currently stored in the EEPROM memory.

Syntax: MEM<CR>

Example: "MEM\r"

Send the number of Test Records currently in memory.

Returns: (1) "nnn\r" where nnn is " 0" to " 50" (note leading whitespace).
(2) "?\r" Syntax error/invalid command

Phase 3 OPERATING MANUAL

5.3.16 Send Test Report Command

Description: The STR command causes *Phase 3* to return the Test Record requested, in the format of a printed Test Report (see section 4.9.2.2).

Syntax: STR <record_number><CR>

Example: "STR16\r"

Get Test Report 16 from memory and send to PC in print format.

Returns:

(1)	"ASCII printed report"	There is no 'end-of-file ' marker. User must monitor for a specific text string (such as Date:), or time out to end the transmission.
(2)	"e\r"	Record does not exist.
(3)	"?\r"	Syntax error/invalid command

5.3.17 Escape Command

Description: The ESC command causes *Phase 3* to abort a test measurement initiated in remote mode.

Syntax: <ESC>

Example: "\x1B"

Aborts test measurement in progress.

Returns:

(1)	"TEST CANCELLED\r"	Command received and understood.
(2)	"?\r"	Syntax error/no test in progress

6 *Phase3pc* SOFTWARE

Datrend *Phase3pc* software provides a communication utility for *Phase 3* which allows the user to configure AutoSequences, download Test Records and Wave Records, and capture waveform data in real-time. *Phase3pc* is a self-contained Windows® application which is supplied as a standard accessory on CD ROM.

6.1 Installation

6.1.1 Installing *Phase3pc*

To install *Phase3pc* to your computer, place the *Phase3pc* CDROM into your computer's CDROM drive and close the drive. The installation application will begin automatically (Figure 101), unless your computer is set to ignore autorun applications.

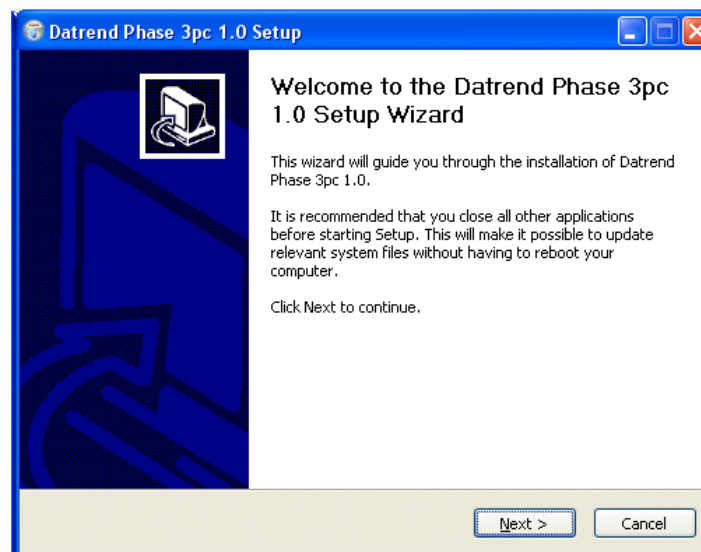


Figure 101 - Installation of *Phase3pc*.

Phase 3 OPERATING MANUAL

In the event the installation program does not start automatically, use the file explorer utility on your computer to locate the CDROM drive. Browse this drive to locate the file called **Phase3pcNNSetup.exe**. Double-click or otherwise execute this file and the installer will guide you through the installation process. We recommend that all default installation locations be left intact so future upgrades and enhancements will run smoothly.

At the end of the short installation process, you will be presented with a notification that the software has been installed, at which time you may either select or deselect the checkbox which asks if you would like to run **Phase3pc** upon closing the dialogue box. The computer does not have to be restarted before running **Phase3pc**.

6.1.2 Installing USB Drivers

When installation of **Phase3pc** is complete, connect **Phase 3** to your PC using the USB cable provided with your instrument. When **Phase 3** is connected to the PC for the first time, Windows should detect the connection and then automatically launch the New Hardware Wizard which will prompt you for the USB driver (**Figure 102**).

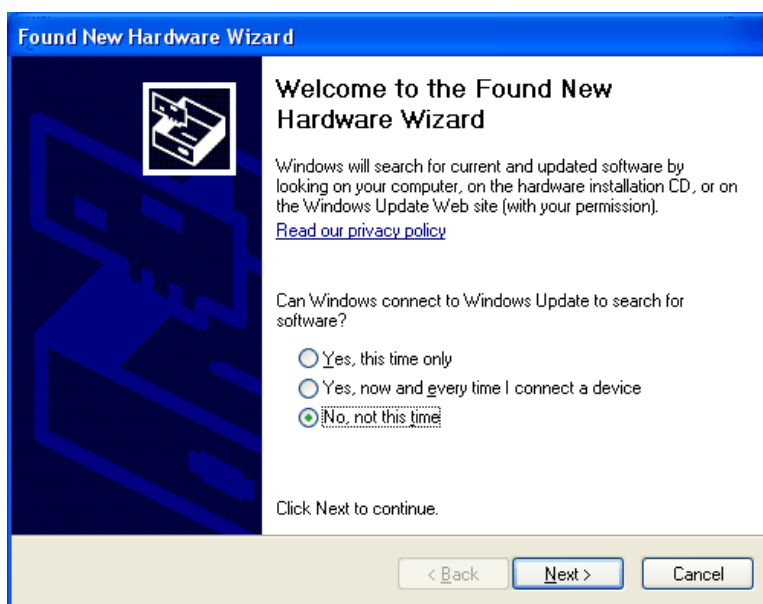


Figure 102 - New Hardware Wizard

The USB drivers for **Phase 3** are provided with **Phase3pc** software. When the Hardware Wizard asks for the files, direct the Hardware Wizard to your CD drive, or to the location where the files were downloaded. The Wizard should then find and install the required driver files.

Phase 3 OPERATING MANUAL

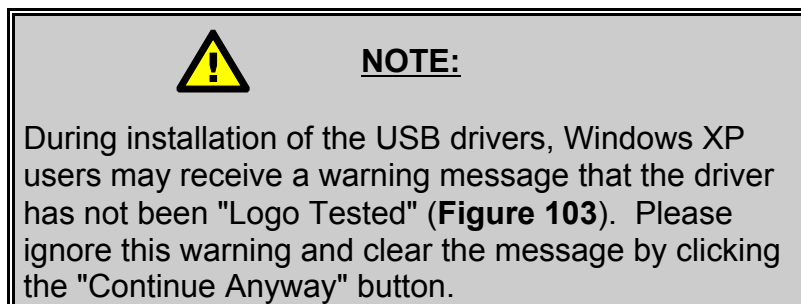


Figure 103 - Click "continue anyway".

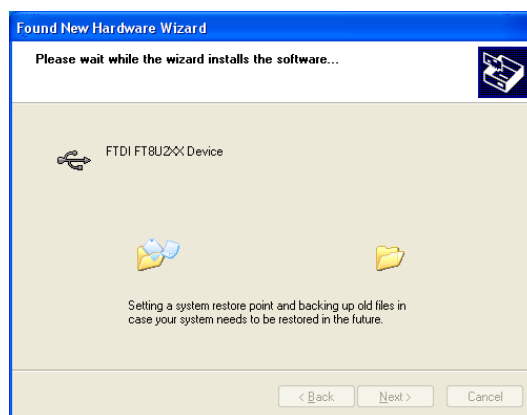


Figure 104 - Driver installation in progress.

6.2 Phase 3 Remote Mode

In order for *Phase 3* to work with *Phase3pc*, it must first be placed in *Remote Mode*. To enter Remote Mode, press the **REMOTE** softkey on the MAIN MENU of *Phase 3*. The display will then appear as shown in **Figure 105**. **CANCEL** may be pressed at any time to exit Remote Mode to the MAIN MENU of *Phase 3*.

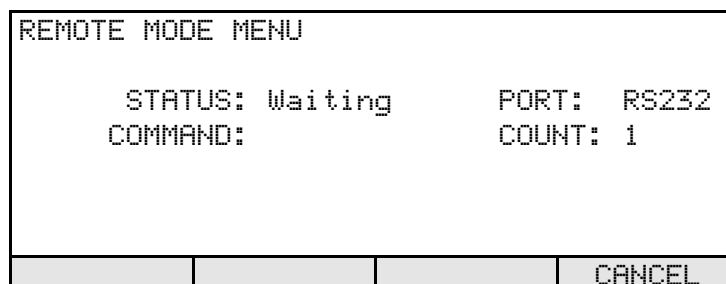
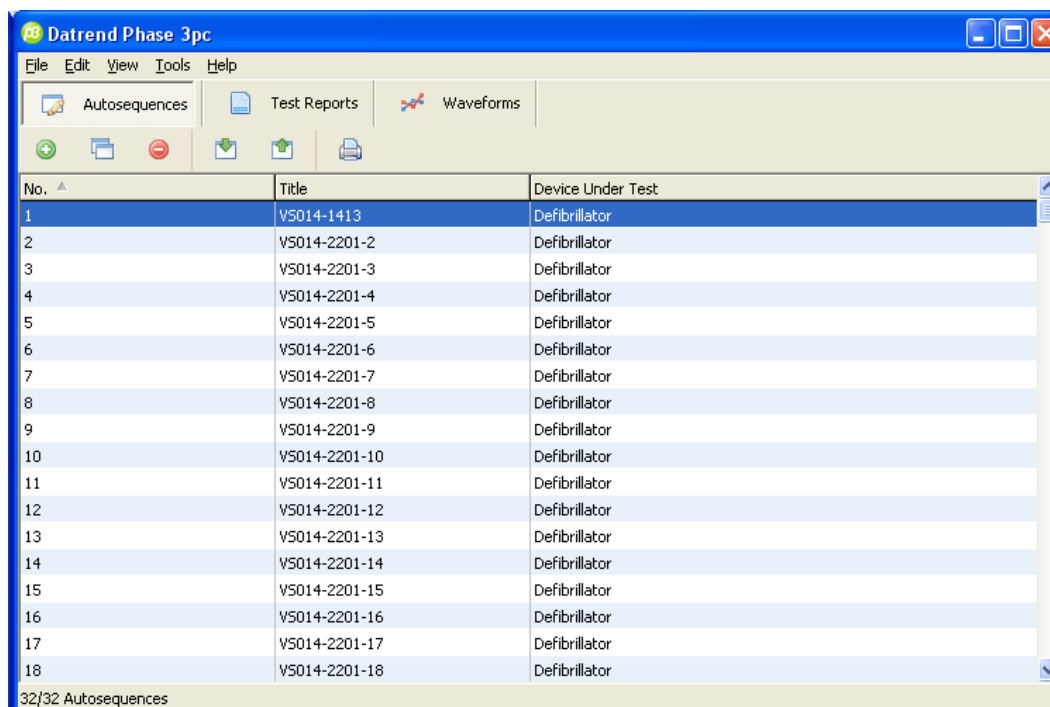


Figure 105 - Remote Mode menu of *Phase 3*.

6.3 AutoSequence Editor

When *Phase3pc* is run for the first time, the program starts up by displaying a library of AutoSequences which are stored locally on the computer (**Figure 106**). Each row in the grid represents one AutoSequence, as identified by a title and the type of device to be tested (defibrillator/pacer, or AED).



No.	Title	Device Under Test
1	V5014-1413	Defibrillator
2	V5014-2201-2	Defibrillator
3	V5014-2201-3	Defibrillator
4	V5014-2201-4	Defibrillator
5	V5014-2201-5	Defibrillator
6	V5014-2201-6	Defibrillator
7	V5014-2201-7	Defibrillator
8	V5014-2201-8	Defibrillator
9	V5014-2201-9	Defibrillator
10	V5014-2201-10	Defibrillator
11	V5014-2201-11	Defibrillator
12	V5014-2201-12	Defibrillator
13	V5014-2201-13	Defibrillator
14	V5014-2201-14	Defibrillator
15	V5014-2201-15	Defibrillator
16	V5014-2201-16	Defibrillator
17	V5014-2201-17	Defibrillator
18	V5014-2201-18	Defibrillator

Figure 106 - Phase3pc AutoSequence listing.

An AutoSequence is a sequence of steps which automates the testing of a defibrillator or pacemaker (see Section 4.10 for further details). *Phase3pc* can easily create, edit, and organize up to **32** AutoSequences. AutoSequences can then be uploaded from the software to *Phase 3* for storage in the non-volatile memory. Alternatively, AutoSequences stored in *Phase 3* can be downloaded into the software for editing, and then re-uploaded to the instrument. The AutoSequence toolbar of *Phase3pc* is shown in **Figure 107**.

Phase 3 OPERATING MANUAL

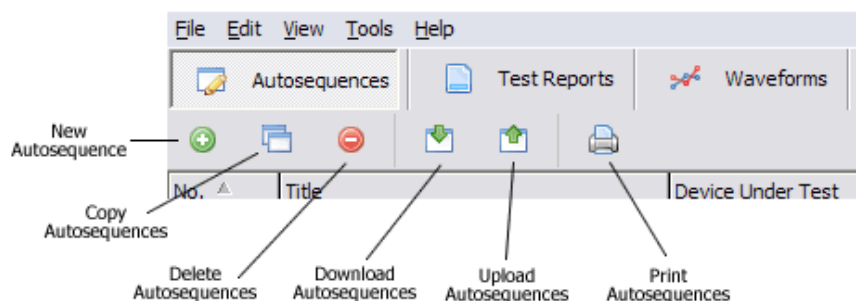


Figure 107 - AutoSequence Editor toolbar.

6.3.1 Creating an AutoSequence

Create a new AutoSequence by clicking **New Autosequence** on the AutoSequence toolbar, or by pressing **b+N** on the keyboard. A new AutoSequence will appear at the bottom of the AutoSequence grid. This new AutoSequence will be blank, that is, none of the tests provided by the AutoSequence will be enabled.

6.3.2 Editing an AutoSequence

Edit an AutoSequence by double-clicking an entry in the AutoSequence grid. The AutoSequence Editor will appear. See Section 6.3.6 for more information.

6.3.3 Copying and Deleting AutoSequences

To copy AutoSequences, select any number of AutoSequences in the grid by dragging the mouse over them. Then, click **Copy AutoSequences**, or press **b+C** on the keyboard. If the resulting number of AutoSequences is 32 or less, the copied AutoSequences will appear at the bottom of the grid.

To delete AutoSequences, select any number of AutoSequences in the grid by dragging the mouse over them. Then, click **Delete Autosequences**, or press **c** on the keyboard. A warning will appear requiring you to confirm the action. Click **Yes** to delete the AutoSequences.

6.3.4 Uploading and Downloading AutoSequences

AutoSequences can be transferred to *Phase 3* via a USB connection. Before attempting to upload or download, make sure *Phase 3* is connected to the PC and that *Phase 3* is running in *Remote Mode* (see Section 6.2).

To upload AutoSequences into *Phase 3*, click the **Upload Autosequences** button, or press b+U on the keyboard. To download AutoSequences stored in *Phase 3* to the PC, click the **Download Autosequences** button, or press b+D on the keyboard. In both instances, a communications progress window will appear. When the transfer has completed, click “OK”.

6.3.5 Printing AutoSequences



Phase3pc allows you to print all the AutoSequences, or a selected number of AutoSequences. To print one AutoSequence, highlight it in the grid. To print a range of AutoSequences, select the desired sequences by dragging the mouse over them.

Click **Print Autosequences**, or press b+P on the keyboard. The Print window will appear. Choose to print either the selected AutoSequence(s) or all of the AutoSequences, via the radio buttons which are provided on the Print dialog.

6.3.6 AutoSequence Editor

AutoSequences are comprised of different types of test, including:

- defibrillator energy, charge time, and synchronization delay;
- ECG monitor/chart recorder performance;
- pacemaker pulse, refractory, immunity and sensitivity; and
- AED performance.

Some test types, such as defibrillator energy, can be repeated a number of times with different configurations for each test. The AutoSequence Editor provides each test type with its own tab. If the test is a repeatable type, a list box will appear on the left-hand side of the Editor window, with **Add**  and **Delete**  buttons located below the list (**Figure 108**). The test options will appear on the right-hand side of the Editor window.

Phase 3 OPERATING MANUAL

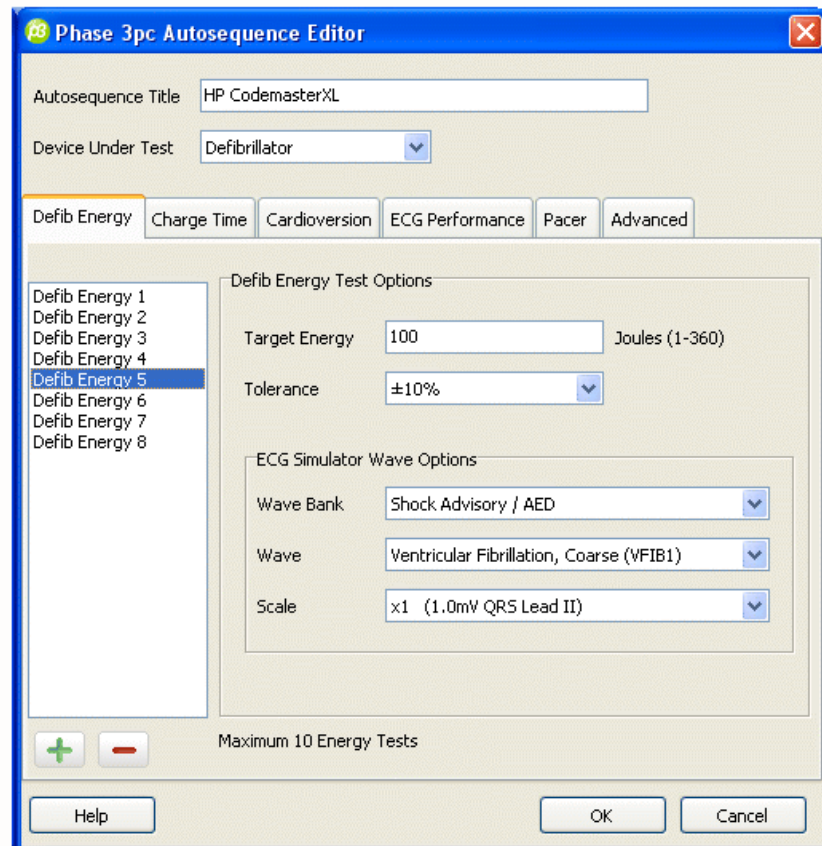




Figure 108 - Editing defib energy test#5.

To add a new test to the list, press the **Add test**  button below the list box. Select a test in the list box by clicking on it. The parameters of the selected test will then appear in the text boxes on the right. Delete a test from the list by selecting the test in the list box and clicking the **Delete test**  button, or pressing c on the keyboard.

6.3.6.1 Editing the AutoSequence Title

Edit the title of the AutoSequence in the Autosequence Title text field on the top of the Autosequence Editor. Normally, you would choose a title that represents the make and model of the

Phase 3 OPERATING MANUAL

defibrillator. The title can be a maximum of 16 characters.


Phase 3 OPERATING MANUAL

6.3.6.2 Selecting the Device Under Test

To test either a defibrillator and/or transcutaneous pacemaker, select **Defibrillator** in the **Device Under Test** combo box. To test an automated external defibrillator (AED), select **AED** in the **Device Under Test** combo box.

6.3.6.3 Editing Defibrillator Energy Tests

A defibrillator energy test measures the energy delivered by a defibrillator when it is discharged. The test is normally repeated several times, with the defibrillator set to different energy levels for each test. In an AutoSequence, each measured energy is compared a target value corresponding to the energy setting on the defibrillator. The tolerance of the test defines a range of acceptance for the measured energy. If the measured energy falls within the acceptance range defined by the AutoSequence settings for target and tolerance, *Phase 3* automatically passes the measured energy.

To begin editing defibrillator tests, select the **Defib Energy** tab (**Figure 108**). The maximum number of energy tests than can be performed in an AutoSequence is 10. Add tests if required, via the  button as previously described. Select a test from the list on the left. Enter the **Target Energy** for this test (i.e., the energy setting on the defibrillator), and choose a **Tolerance**. Set up the *Phase 3* ECG simulator for this test by first choosing the simulator **Wave Bank**, and then selecting the **Wave** (waveform). The amplitude scale of the Wave can also be changed by selecting a value in the **Scale** combo box.

6.3.6.4 Editing the Charge Time Test

A charge time test measures the time required for a defibrillator to charge up to a specified energy level, which is typically the maximum energy provided by the device.


To begin editing the charge time test, select the **Charge Time** tab on the AutoSequence Editor. An AutoSequence provides only one charge time test. To enable this test, click the **Enable Charge Time Test** checkbox. Enter the **Target Energy** for this test (i.e., the maximum energy setting on the defibrillator), and choose a **Tolerance**. Enter an upper limit for the measured charge time in the **Measured Charge Time** box. Set up the *Phase 3* ECG simulator for this test by first choosing the simulator **Wave Bank**, and then selecting the **Wave** (waveform). The amplitude scale of the Wave can also be changed by selecting a value in the **Scale** combo box.

Phase 3 OPERATING MANUAL

6.3.6.5 Editing Cardioversion Tests

A cardioversion test verifies the ability of a defibrillator to synchronize its discharge to the QRS complex of the ECG.

To begin editing cardioversion tests, click the **Cardioversion** tab of the AutoSequence Editor. When the first cardioversion test is enabled, the ECG simulator will be configured so that it reverts to normal sinus rhythm when a discharge is detected. If desired, disable this option under the **Advanced** tab of the AutoSequence Editor.

The maximum number of cardioversion tests that can be performed in an AutoSequence is 4. Add tests if required, via the  button as previously described. Select a test from the list on the left. Click the **Enable Delay Target** checkbox if you want *Phase 3* to pass or fail the measured sync delay. Enter the **Target Energy** for this test (i.e., the energy setting on the defibrillator), and choose a **Tolerance**. Set up the *Phase 3* ECG simulator for this test by first choosing the simulator **Wave Bank**, and then selecting the **Wave** (waveform). The amplitude scale of the Wave can also be changed by selecting a value in the **Scale** combo box. In the **Sync To** combo box, select the timing reference that will be used to measure the synchronization delay (Q or R wave).

6.3.6.6 Editing ECG Performance Tests

An ECG test verifies operation and performance of the monitor and/or chart recorder of a defibrillator. To begin editing ECG performance tests, click the **ECG Performance** tab of the AutoSequence Editor (**Figure 109**).

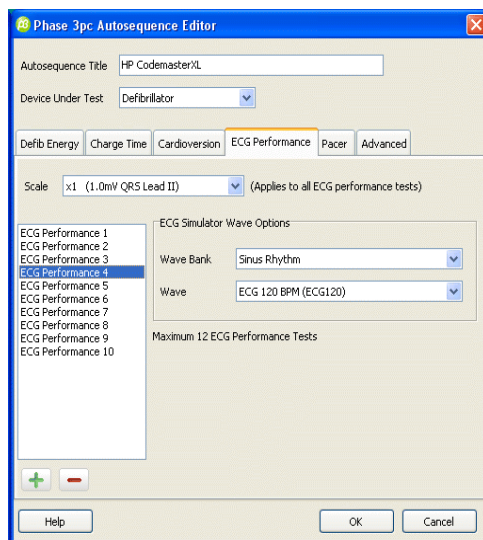


Figure 109 - Editing an ECG test.

Phase 3 OPERATING MANUAL

The maximum number of ECG tests that can be performed in an AutoSequence is 12. Select the ECG signal amplitude via the **Scale** combo box; the same amplitude will be used for all waveforms in the ECG sequence. Set the ECG simulator for each step of the sequence by first choosing the simulator **Wave Bank**, and then selecting the **Wave** (waveform).

6.3.6.7 Editing Pacer Tests

To begin editing pacer tests, click the **Pacer** tab of the AutoSequence Editor. The pacer sub menu will appear below the main tab menu (**Figure 110**). Click on the buttons of the pacer sub menu to navigate the various pacer tests described in the following sections.

6.3.6.8 Editing the Pacer Load

The pacer load is the load value which will be used by *Phase 3* in all pacer tests of an AutoSequence. Click the up or down arrow to respectively increase or decrease the resistance in 50 ohm increments.

6.3.6.9 Editing Pacer Pulse Tests

A pacer pulse test measures amplitude, rate and width of the pulses generated by a pacemaker (**Figure 110**). The maximum number of pulse tests that can be performed in an AutoSequence is 10.

To edit pacer pulse tests, click the "Pacer" tab and then click the "Pulse" button on the pacer sub menu. Select a test in the list on the left by clicking on it. For the selected test, enter a "Target Current" and **Pulse Rate** in the text fields provided on the right. A target for pulse width is optional, and can be enabled by clicking the checkbox next to the **Target Pulse Width** text field. Select the measuring method for pulse amplitude via the **Measuring Method** combo box. For more information on amplitude measuring methods, see Section 4.7.2.

Phase 3 OPERATING MANUAL

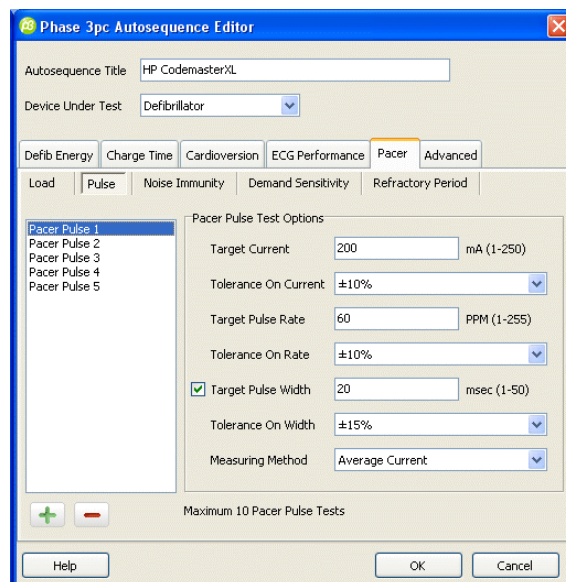


Figure 110 - Editing pacer tests (pulse test).

6.3.6.10 Editing the Noise Immunity Test

A noise immunity test verifies that a pacer will not respond to line frequency noise injected into its ECG input. An AutoSequence can include only one noise immunity test.

To edit the noise immunity test, click the **Pacer** tab and then click the **Noise Immunity** button on the pacer sub menu. To enable the test, click the **Enable Noise Immunity** checkbox. Select the frequency of the noise signal via the **Test Type** combo box.

6.3.6.11 Editing Demand Sensitivity Tests

A demand sensitivity test determines the smallest ECG signal that will reliably trigger a pacer when the pacer is operating in demand mode. The maximum number of sensitivity tests that can be performed in an AutoSequence is two.

To edit the sensitivity test, click the **Pacer** tab and then click the **Demand Sensitivity** button on the pacer sub menu. Select a test in the list on the left by clicking on it. For the selected test, enter a **Sensitivity Limit** in the text field provided on the right. This limit is the largest ECG signal that can be accepted to result in a passing test. Set up the *Phase 3* ECG simulator for this test by first choosing the simulator **Wave Bank**, and then selecting the **Wave** (waveform).

6.3.6.12 Editing Refractory Period Tests

A refractory period test determines the two refractory periods of the pacemaker under test. The paced refractory period (PRP) is the time interval following a pacer pulse during which ECG QRS complexes are ignored. The sensed refractory period (SRP) is the time interval following a detected QRS where a subsequent QRS is ignored. The maximum number of refractory tests that can be performed in an AutoSequence is two.

To edit the refractory test, click the **Pacer** tab and then click the **Refractory Period** button on the pacer sub menu. Select a test in the list on the left by clicking on it. For the selected test, enter maximum and minimum limits for both PRP and SRP in the text fields provided. Set up the *Phase 3* ECG simulator for this test by first choosing the simulator **Wave Bank**, and then selecting the **Wave** (waveform).

6.3.6.13 Editing Advanced Options

The **ECG Trigger Mode** listbox allows selection of one of four possible responses of the ECG simulator to a defibrillator discharge. *Phase 3* may automatically change its waveform to normal sinus rhythm when a discharge is detected from the defibrillator under test. Alternatively or in addition, *Phase 3* can play back the discharge waveform into the paddles or ECG leads of the defibrillator. See section 4.5.1.2 for more details on the MODE settings.

The **Auto-Test Timer** listbox allows selection of the length of time *Phase 3* will wait before proceeding to the next step in an AutoSequence, where appropriate. The Auto-Test Timer allows the operator time to read or respond to data or messages on the display screen, and may be turned OFF if full manual control of the AutoSequence is desired. See section (ref 4.10.3.1) for more details on the Auto-Test Timer.

Phase 3 OPERATING MANUAL

6.3.6.14 Editing AED Energy Tests

If the device under test is an AED, select "AED" in the **Device Under Test** combo box at the top of the AutoSequence Editor. The AED Energy test options will appear, while defibrillator and pacer test options will be hidden (**Figure 111**).

The maximum number of energy measurements that can be performed in an AED AutoSequence is 32. Select a test in the list on the left by clicking on it. Set up the *Phase 3* ECG simulator for this test by first choosing the simulator **Wave Bank**, and then selecting the **Wave** (waveform). The amplitude scale of the Wave can also be changed by selecting a value in the **Scale** combo box. The **Shockable** field displays the expected outcome of the test according to AAMI guidelines (see Section 4.8).

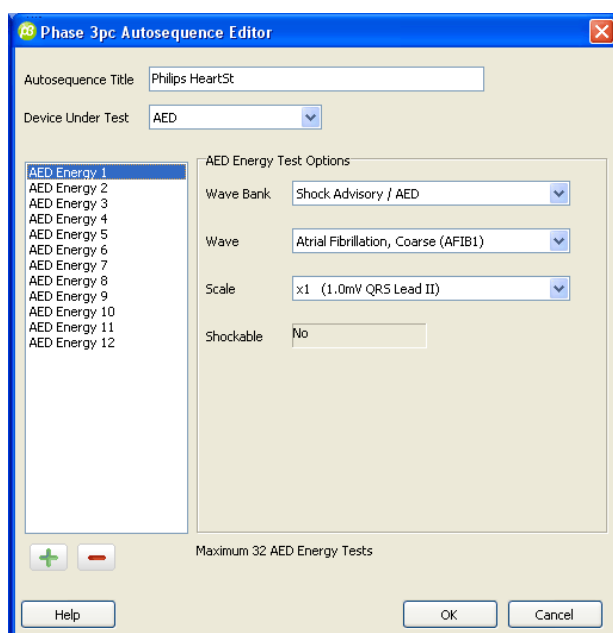


Figure 111 - Editing an AED sequence.

6.4 Test Report Generator

After a test is completed with *Phase 3*, results of the test can be stored as a Test Record in the non-volatile Data Log. Later, the test data can be downloaded into *Phase3pc* and viewed as Test Report documents. Test Reports can be saved in text, CSV, and Sentinel32 MUP formats.

Start working with test reports by clicking the **Test Reports** button on the main menu of *Phase3pc*. This will activate the Test Report toolbar (**Figure 112**).

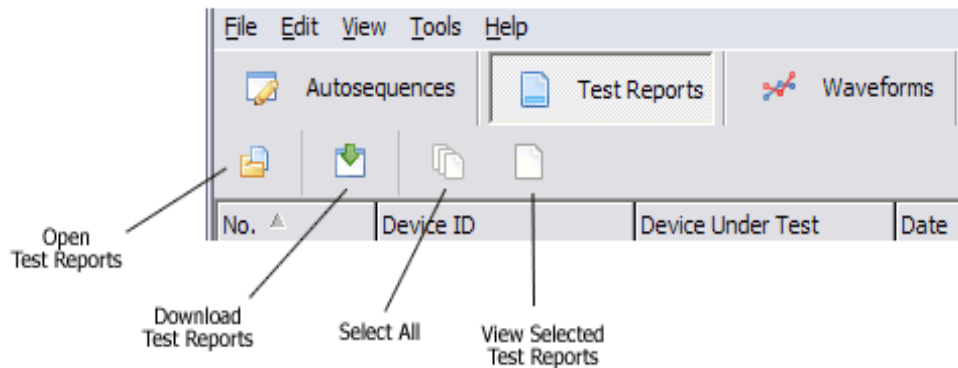
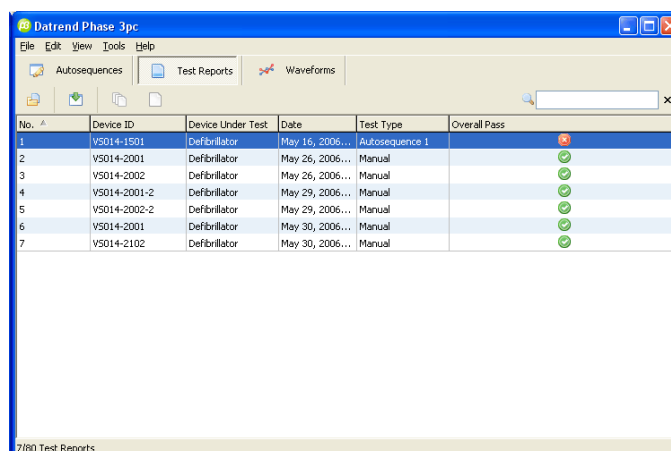


Figure 112 - Test Report toolbar.

6.4.1 Downloading Test Reports

Test Report data can be transferred from *Phase 3* via a USB connection. Before attempting to download, make sure *Phase 3* is connected to the PC and that *Phase 3* is running in *Remote Mode* (see Section 6.2). To download Test Reports, click the **Download Test Reports** button, or press b+D on the keyboard. A communications progress window will appear. When the transfer has completed, click "OK". The downloaded Reports will appear in a grid display below the Test Report toolbar (**Figure 113**).

Phase 3 OPERATING MANUAL



The screenshot shows the 'Datrend Phase 3pc' application window. It has a menu bar (File, Edit, View, Tools, Help) and a toolbar with icons for Autosequences, Test Reports, and Waveforms. Below the toolbar is a grid of test reports. The grid has columns for No., Device ID, Device Under Test, Date, Test Type, and Overall Pass. The data is as follows:

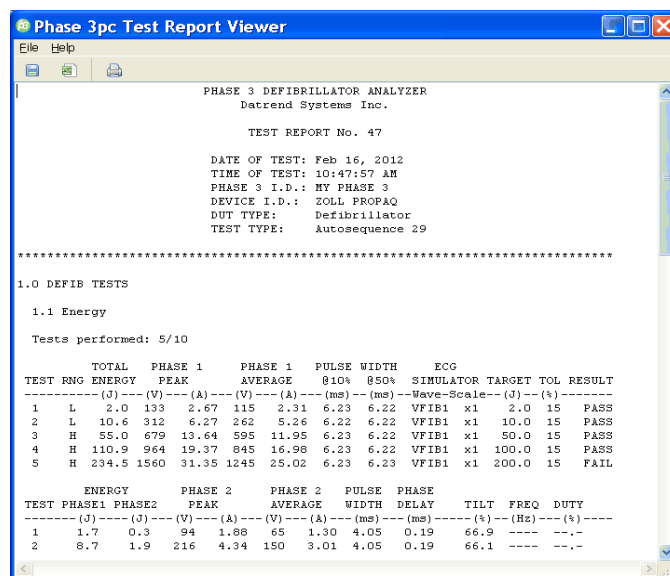
No.	Device ID	Device Under Test	Date	Test Type	Overall Pass
1	V5014-1501	Defibrillator	May 16, 2006...	Autosequence 1	✗
2	V5014-2001	Defibrillator	May 26, 2006...	Manual	✓
3	V5014-2002	Defibrillator	May 26, 2006...	Manual	✓
4	V5014-2001-2	Defibrillator	May 29, 2006...	Manual	✓
5	V5014-2002-2	Defibrillator	May 29, 2006...	Manual	✓
6	V5014-2001	Defibrillator	May 30, 2006...	Manual	✓
7	V5014-2102	Defibrillator	May 30, 2006...	Manual	✓

At the bottom of the window, it says '7/80 Test Reports'.

Figure 113 - Test Report listing following a download.

6.4.2 Viewing Test Reports

To view one or more Test Reports, simply select the desired Test Reports in the main Test Report grid (Figure 113) by dragging the mouse over them. Click the **View Test Reports** button. The Test Report Viewer will appear showing the test data from the selected Test Reports. Double-clicking on a single Test Report will also open the Test Report Viewer, which will then show only the selected Report (Figure 114).



The screenshot shows the 'Phase 3pc Test Report Viewer' window. It displays a detailed test report for 'PHASE 3 DEFIBRILLATOR ANALYZER' by 'Datrend Systems Inc.'. The report includes test parameters, test results, and a summary of tests performed.

TEST REPORT No. 47

DATE OF TEST: Feb 16, 2012
TIME OF TEST: 10:47:57 AM
PHASE 3 I.D.: MY PHASE 3
DEVICE I.D.: ZOLL PROPAQ
DUT TYPE: Defibrillator
TEST TYPE: Autosequence 29

1.0 DEFIB TESTS

1.1 Energy

Tests performed: 5/10

TEST	RNG	ENERGY	PEAK	PHASE 1 AVERAGE	PHASE 1 PULSE WIDTH	PHASE 1 PULSE	PHASE 1 DELAY	PHASE 1 TILT	PHASE 1 FREQ	PHASE 1 DUTY	ECG	SIMULATOR	TARGET	TOL	RESULT
1	L	2.0	133	2.67	115	2.31	6.23	6.22	VFIB1	x1	2.0	15	PASS		
2	L	10.6	312	6.27	262	5.26	6.22	6.22	VFIB1	x1	10.0	15	PASS		
3	H	55.0	679	13.64	595	11.95	6.23	6.22	VFIB1	x1	50.0	15	PASS		
4	H	110.9	964	19.37	845	16.98	6.23	6.22	VFIB1	x1	100.0	15	PASS		
5	H	234.5	1560	31.35	1245	25.02	6.23	6.23	VFIB1	x1	200.0	15	FAIL		

TEST	PHASE1	PHASE2	PHASE1 PEAK	PHASE2 PEAK	PHASE1 AVERAGE	PHASE2 AVERAGE	PHASE1 PULSE WIDTH	PHASE2 PULSE WIDTH	PHASE1 DELAY	PHASE2 DELAY	PHASE1 TILT	PHASE2 TILT	PHASE1 FREQ	PHASE2 FREQ	PHASE1 DUTY	PHASE2 DUTY
1	1.7	0.3	94	1.88	65	1.30	4.05	0.19	66.9	---	---	---	---	---	---	---
2	8.7	1.9	216	4.34	150	3.01	4.05	0.19	66.1	---	---	---	---	---	---	---

Figure 114 - Viewing a Test Report.

6.4.3 Saving Test Reports

6.4.3.1 Saving as a Text File

In the Test Report Viewer, Test Reports can be saved in both TXT (Text) and CSV (Comma Separated Values) formats. To save the viewed Test Report(s) in text format, click the "Save To Text" button of the Test Report Viewer. A directory browser will appear. Select the directory where the Test Reports should be saved. A file for each individual Test Report in the Viewer will now be created, where each file will be automatically assigned a filename according to:

DeviceID.YYYY_MM_DD.hh_mm_ss.txt

Above, **DeviceID** is the defibrillator ID (equipment control number or other ID), **YYYY** is the year, **MM** is the month, **DD** is the day, **hh** is the hour, **mm** is the minute, and **ss** is the second in which the Test Report file was created on the PC.

6.4.3.2 Saving as a CSV File

Saving Test Reports in CSV format produces the same result as saving to text format, except a CSV file is also created listing each device and a path to the Test Report text file for that device. Each line of the CSV file thus consists of:

"Device ID", "Test Date and Time", "Test Type", "Device Under Test", "Overall Pass",
"Filename and Path of Test Report"

Before creating the CSV file, a save file dialog will appear. Select the desired directory and specify a name for the CSV file. The CSV file and all corresponding Test Report text files will be saved in the chosen directory.

Phase 3 OPERATING MANUAL

6.4.3.3 Saving as a MUP File

To save the viewed Test Reports in Sentinel32 MUP format, select the **Save To MUP** option under the File menu of the Test Report Viewer. Select a location and either accept the default filename which is generated automatically, or enter an alternative filename on the Save dialog. By default, *Phase3pc* automatically generates a "medTester-style" filename which is intended to facilitate direct import into Sentinel32 through the medTester Communication dialog of that program. The format of the default MUP filename is:

MMDDhhmm.mup

where **MM** is the month, **DD** is the day, **hh** is the hour and **mm** is the minute in which the MUP file was created on the PC.

6.4.4 Searching for Test Reports

In the main Test Report window of *Phase3pc*, there is a search text box in the upper right hand corner (**Figure 115**). Use this to filter the downloaded Test Reports by Device ID, Device Under Test, Date, and Test Type. The search is real-time, so the results will display as the characters are typed into the search box. To cancel a search, click the **Cancel Search** button to the right of the search box, or press the | key on the keyboard.

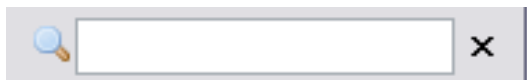


Figure 115 - Search box for Reports.

Tip: Quickly focus the cursor on the search box by pressing **b+F** on the keyboard.

6.4.5 Opening Existing Test Reports

To open a previously-saved Test Report for viewing, click the **Open Test Report** Button, or press **b+O** on the keyboard. Browse for the Test Report file to view.

6.4.6 Printing Test Reports

When viewing Test Report(s) in the Test Report Viewer, click the "Print" button to show the print dialog. Select the printer and click "OK" to print all Test Reports currently being shown in the Viewer. Clicking "Cancel" will close the print dialogue without printing.

6.5 Waveform Viewer

Wave Records can be saved by *Phase 3* while testing a defibrillator (for more information on Wave Records, see Section 4.5.1.5). A total of 10 low-resolution waveforms can be stored as individual Wave Records in the non-volatile Data Log of *Phase 3*. Later, these waveforms can be downloaded to *Phase3pc* for plotting as graphs.

High-resolution waveforms can also be captured in real-time by *Phase3pc*, immediately following a Defibrillator Energy measurement, or a Pacer Pulse measurement. Low-resolution and high-resolution waveforms can be viewed, saved, and printed.

Start working with waveforms by clicking the **Waveforms** button on the main menu of *Phase3pc*. This will activate the Waveform toolbar (**Figure 116**).

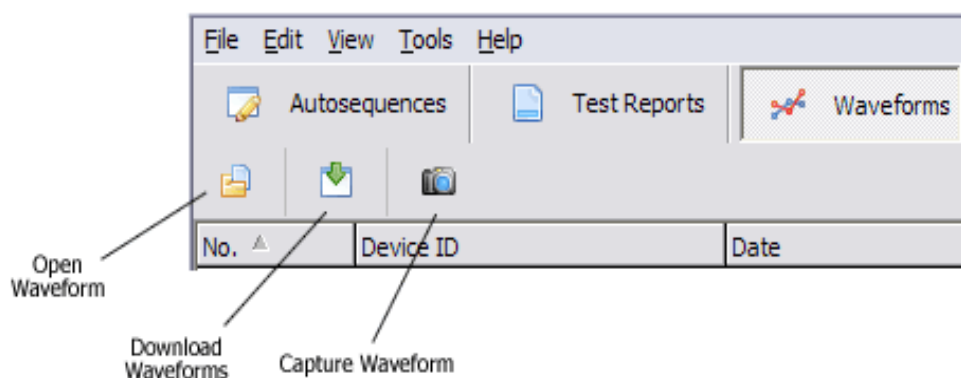
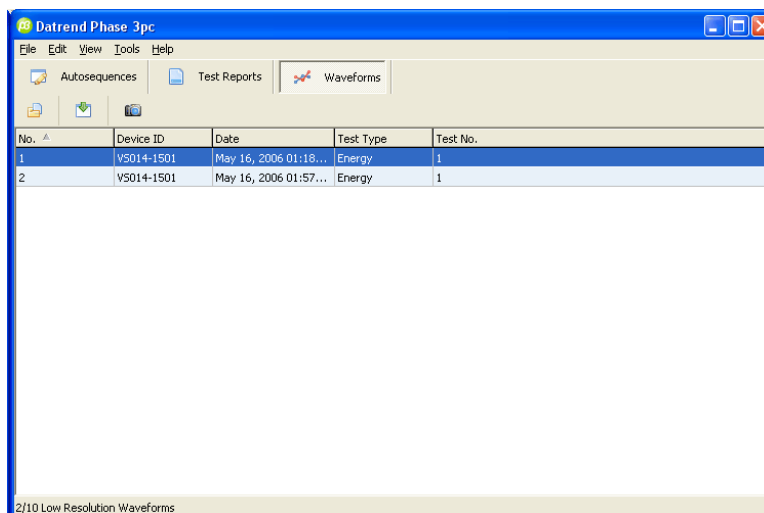


Figure 116 - Waveform toolbar.

6.5.1 Downloading Wave Records

Wave Record data can be transferred from *Phase 3* via a USB connection. Before attempting to download, make sure *Phase 3* is connected to the PC and that *Phase 3* is running in *Remote Mode* (see Section 6.2). To download Wave Records, click the **Download Test Reports** button, or press b+D on the keyboard. A communications progress window will appear. When the transfer has completed, click "OK". The downloaded Wave Records will appear in a grid display below the Waveform toolbar (**Figure 117**).

Phase 3 OPERATING MANUAL



The screenshot shows the 'Datrend Phase 3pc' application window. It has a menu bar (File, Edit, View, Tools, Help) and a toolbar with icons for Autosequences, Test Reports, and Waveforms. Below the toolbar is a table with the following data:

No.	Device ID	Date	Test Type	Test No.
1	V5014-1501	May 16, 2006 01:18...	Energy	1
2	V5014-1501	May 16, 2006 01:57...	Energy	1

At the bottom of the window, it says '2/10 Low Resolution Waveforms'.

Figure 117 - Wave Record listing following a download.

6.5.2 Viewing Wave Records

To view a Wave Record, double-click on an entry in the main waveform grid. The Waveform Viewer will then appear (Figure 118). See **Using The Waveform Viewer** (Section 6.5.5) for more information.

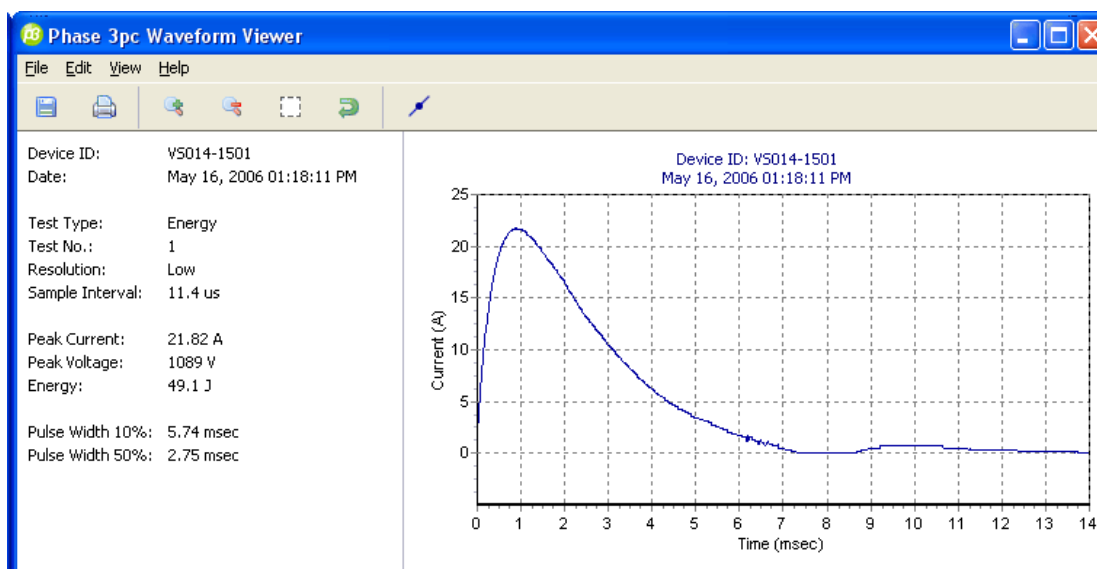


Figure 118 - Waveform Viewer.

6.5.3 Capturing High-Resolution Waveforms

After making a Defibrillator Energy measurement or Pacer Pulse measurement with *Phase 3* according to Section 4.5.1.4, the waveform from the test can then be captured by *Phase3pc*.

Phase 3 does not need to be running in Remote Mode for this to work. Simply make sure *Phase 3* is connected to the PC via USB, then click the **Capture Waveform** button, or press b+W on the keyboard.

Note: be sure to use a high quality, shielded USB 2.0 type cable connected to a USB port on the computer which is *not* on an extension cable from the main board. Defibrillator discharges may cause a disconnection of the USB device driver if the shield and grounding are not adequate. If disconnection occurs, Exit the program, unplug and re-plug the USB cable and re-start *Phase3pc*.

After the data transfer is complete, the Waveform Viewer will appear immediately with the resulting defibrillator discharge or pacer pulse waveform. Based on the content of the data received by *Phase3pc*, the display will format the results and graph to match a defibrillator energy discharge or a pacer pulse. See **Using The Waveform Viewer** (Section 6.5.5) for more information on manipulating the graph characteristics.

6.5.4 Opening Existing Waveforms

To open a previously saved waveform for viewing, click the **Open Waveform** Button, or press b+O on the keyboard. Browse for the waveform file to view.

6.5.5 Using the Waveform Viewer

Opening a Wave Record or waveform data file, or capturing a high-resolution waveform, activates the Waveform Viewer toolbar of *Phase3pc* (Figure 119). Waveform viewing and printing features are described in this section.

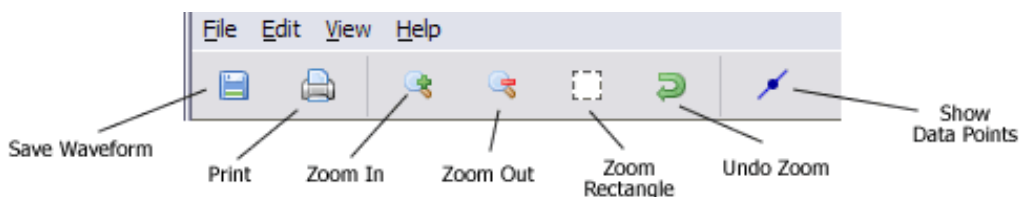


Figure 119 - Waveform Viewer toolbar.

Phase 3 OPERATING MANUAL

6.5.5.1 Zooming In and Out

Zoom in by clicking the **Zoom In** button, or by pressing $b+=$ on the keyboard. Zoom out by clicking the **Zoom Out** button, or by pressing $b+-$ on the keyboard. Zoom into a particular region of the chart by clicking the **Zoom Rectangle** button. The mouse cursor will change into a cross symbol. Select a zoom area by holding the left mouse button down and dragging, creating a rectangular area on the chart. Then, release the mouse button to see the changes. Note: The zoom area rectangle must not go left of the Y-Axis Zero Position.

6.5.5.2 Panning the Chart

Following a zoom-in or zoom-out, the chart may be panned in any direction.

Click the **Zoom Rectangle** button if this button is not already depressed. Pan the chart by holding down the left mouse button and dragging inside the chart area. The **Zoom Rectangle** button must be depressed to enable the drag-panning feature.

6.5.5.3 Undo Zoom

Click the **Undo Zoom** button, or press $b+Z$ on the keyboard to restore the chart to its original view.

6.5.5.4 Data Points On/Off

Click the **Show Data Points** button, or press $b+T$ on the keyboard to activate or de-activate markers on the individual data points which form the waveform trace.

6.5.5.5 Setting the Chart Axes

To explicitly set one or both chart axes, select **Set Chart Axis** from the **Edit** pull-down menu above the toolbar, or press $b+H$ on the keyboard. Alternatively, you can right-click the chart and then select **Set Chart Axis**. This will activate the Set Chart Axis form (**Figure 120**). Type minimum and maximum values for the time axis and the current axis in the text boxes provided, then click "OK". The chart will be re-drawn with the axes you have selected.

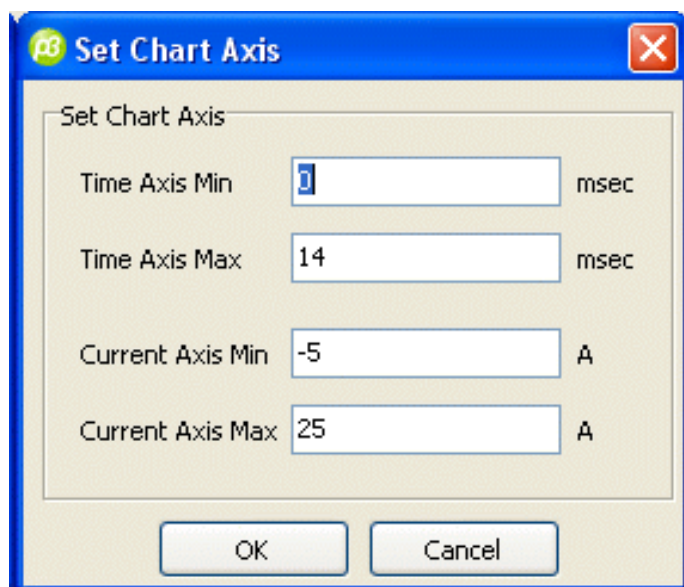


Figure 120 - Setting the chart axes.

6.5.5.6 Saving Waveform Data

A waveform being viewed can be saved in CSV format by clicking the **Save** button on the Waveform Viewer toolbar, or by pressing **b+S** on the keyboard. A Save Dialog will appear. Select the directory, enter a filename and click "OK". Each data point in the CSV file will be represented on its own line, in the following format:

[time], [current]

6.5.5.7 Printing Waveforms

A waveform being viewed can be printed. To print the waveform, click the **Print** button on the Viewer toolbar, or press **b+P** on the keyboard. A print dialog will appear. Select the printer and click "OK". The waveform will be printed as it appears in the chart, i.e., with the existing zoom/axis settings.

The waveform can be printed either with or without the test data shown at left in the **Wave Information Panel** of the Viewer. To toggle the information panel on or off, click **Show Wave Info** on the **View** pull-down menu above the toolbar, or press **b+I** on the keyboard.

Phase 3 OPERATING MANUAL

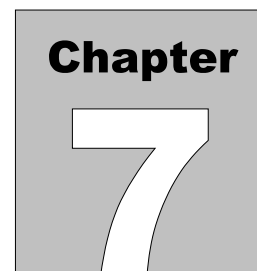
6.5.5.8 Editing the Device ID Field

After capturing a high-resolution waveform, you may wish to input a device ID to identify the device which produced the waveform. To edit the device ID, select the **Device ID** item under the **Edit** pull-down menu above the toolbar. Alternatively, click on the Device ID field in the Wave Information Panel. The Device ID field will become an editable field. Type the new device ID into the field, then press **e** on the keyboard.

6.5.5.9 Hot Key Summary

b+C	Copy
b+D	Download
b+F	Search / Find
b+H	Edit Chart Axes
b+I	Toggle Information On/Off
b+N	New
b+O	Open
b+P	Print
b+S	Save
b+T	Toggle Data Points On/Off
b+U	Upload
b+W	Capture Waveform
b+Z	Undo Zoom
b+=	Zoom In
b+-	Zoom Out
c	Delete
	Cancel Search

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7 TROUBLESHOOTING AND MAINTENANCE

Calibration of *Phase 3* by a Datrend Authorized Service facility is recommended on an *annual* basis, and is *required* to extend the product warranty. The basic one (1) year warranty can be extended to a maximum of five (5) years provided that calibration is performed by a Datrend Authorized Service Center on an *annual* basis.

In the event of battery discharge, connect *Phase 3* to the AC adapter/charger supplied with your instrument. Refer to Section 3.1 for further information on the AC adapter/charger. A fully depleted battery will require a minimum of 14 hours to recharge. *Phase 3* may be operated from the AC adapter while the battery is being charged.

The TEST PULSE feature of *Phase 3* should be used on a periodic basis to verify proper functioning of the instrument's data acquisition system, particularly if a questionable test result is obtained. Refer to section 4.3.1 for instructions regarding the TEST PULSE feature.

The *Phase 3* TEST PULSE does not verify tolerance of internal loads used for defibrillator or pacer testing. These loads can be verified externally using a calibrated and traceable ohmmeter, preferably an instrument which provides 4-wire measurement. To verify the defibrillator test load, probe with the ohmmeter across the Paddle Adaptor (see **Figure 2**, page 18). The result should be 49.5 to 50.5 ohms. To verify the pacemaker test load, select a value of resistance via the pacer LOAD menu (see sections 4.7 and 4.7.1). Measure with the ohmmeter connected at the pacer input jacks (see **Figure 3**, page 20). The measured result should be within one per-cent of the resistance selected on the LOAD menu.

Phase 3 should be cleaned with a soft, lint-free, damp cloth using a mild detergent. Use of other cleaning agents is prohibited.

Phase 3 OPERATING MANUAL



Phase 3 contains no user-serviceable parts. Opening the case of *Phase 3* for any reason will void the warranty and may compromise user safety. Refer servicing to qualified personnel.

NOTE:



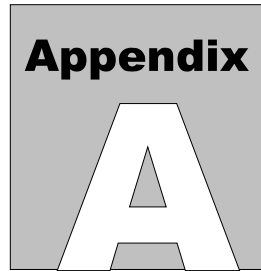
Protection of the operator may be compromised if the instructions in this manual are not followed, or if *Phase 3* is used for a purpose not specified in this manual.

For service assistance or calibration, contact Datrend Systems for a Return Materials Authorization (RMA) number and the location of the nearest Service Facility.

Datrend Systems Inc.
130 - 4020 Viking Way
Richmond, BC • CANADA • V6V 2L4
Tel: 800-667-6557 (North America Only) or
604-291-7747 • Fax 604-294-2355
e-mail: customerservice@datrend.com
www.datrend.com



CAUTION: This device measures high voltage signals. For protection of the operator, inspect the Paddle Adapter and the interconnecting Paddle Adapter Cables on a regular basis for nicks, cracks or other damage that may compromise the insulating properties of the housing, wire or connectors. Replace any damaged or worn components immediately.



APPENDIX A. DEFAULT AUTOSEQUENCES

Phase 3 comes equipped with AutoSequences stored in its non-volatile memory to provide *examples* of various test parameters configured by an AutoSequence. Default AutoSequences are installed with *Phase3pc* when the application is installed. *Phase3pc* permits the default AutoSequences to be modified or supplemented as desired; refer to Chapter 6 for instructions. The following AutoSequences are *examples* only to highlight some of the possible settings, and may not match those installed in your *Phase 3*. They may be modified at any time by Datrend in future releases of *Phase 3* or *Phase3pc*.

Note: These AutoSequences should be reviewed by the end user to determine if they are suitable for their purposes. Datrend takes no responsibility for the inappropriate use of these examples.

Autosequence Title: Generic Defib
Device Under Test: Defibrillator

ECG Trigger Mode: Change to NSR60 after shock
Auto-Test Timer: 5 seconds

Defib Energy Test 1
Target Energy: 20 J
Tolerance: +/-15%
Waveform: Ventricular Fibrillation, Coarse (VFIB1) - x1
Defib Energy Test 2
Target Energy: 50 J
Tolerance: +/-15%
Waveform: Ventricular Fibrillation, Coarse (VFIB1) - x1
Defib Energy Test 3
Target Energy: 100 J
Tolerance: +/-15%
Waveform: Ventricular Fibrillation, Coarse (VFIB1) - x1
Defib Energy Test 4
Target Energy: 200 J
Tolerance: +/-15%
Waveform: Ventricular Fibrillation, Coarse (VFIB1) - x1
Defib Energy Test 5
Target Energy: 300 J
Tolerance: +/-15%
Waveform: Ventricular Fibrillation, Coarse (VFIB1) - x1

Phase 3 OPERATING MANUAL

Charge Time Test

Target Energy: 360 J
Tolerance: +/-15%
Max Charge: 15 sec
Waveform: Ventricular Fibrillation, Coarse (VFIB1) - x1

Autosequence Title: HeartStream AED

Device Under Test: AED

AED Energy Test 1

Waveform: Atrial Fibrillation, Coarse (AFIB1) - x1
Shock Type: Not Shockable

AED Energy Test 2

Waveform: Atrial Fibrillation, Fine (AFIB2) - x1
Shock Type: Not Shockable

AED Energy Test 3

Waveform: Asystole, Random baseline (ASYS1) - x1
Shock Type: Not Shockable

AED Energy Test 4

Waveform: Asystole - Flat line (ASYS2) - x1
Shock Type: Not Shockable

AED Energy Test 5

Waveform: Supraventricular Tachycardia (SVTACH) - x1
Shock Type: Not Shockable

AED Energy Test 6

Waveform: Ventricular Tachycardia 140 BPM (VTACH1) - x1
Shock Type: Not Shockable

AED Energy Test 7

Waveform: Ventricular Tachycardia 140 BPM (VTACH1) - x1
Shock Type: Not Shockable

AED Energy Test 8

Waveform: Ventricular Fibrillation, Coarse (VFIB1) - x1
Shock Type: Shockable

AED Energy Test 9

Waveform: Ventricular Fibrillation, Coarse (VFIB1) - x1
Shock Type: Shockable

AED Energy Test 10

Waveform: Ventricular Fibrillation, Coarse (VFIB1) - x1
Shock Type: Shockable

AED Energy Test 11

Waveform: Asystole, Random baseline (ASYS1) - x1
Shock Type: Not Shockable

AED Energy Test 12

Waveform: Ventricular Tachycardia 160 BPM (VTACH2) - x1
Shock Type: Shockable

AED Energy Test 13

Waveform: Ventricular Tachycardia 160 BPM (VTACH2) - x1
Shock Type: Shockable

AED Energy Test 14

Waveform: Ventricular Tachycardia 160 BPM (VTACH2) - x1
Shock Type: Shockable

AED Energy Test 15

Waveform: Supraventricular Tachycardia (SVTACH) - x1
Shock Type: Not Shockable

Phase 3 OPERATING MANUAL

Autosequence Title: Lifepak12 w/Pace
Device Under Test: Defibrillator

ECG Trigger Mode: Change to NSR60 after shock
Auto-Test Timer: 5 seconds

Defib Energy Test 1
Target Energy: 2 J
Tolerance: +/-15%
Waveform: Ventricular Fibrillation, Coarse (VFIB1) - x1

Defib Energy Test 2
Target Energy: 5 J
Tolerance: +/-15%
Waveform: Ventricular Fibrillation, Coarse (VFIB1) - x1

Defib Energy Test 3
Target Energy: 10 J
Tolerance: +/-15%
Waveform: Ventricular Fibrillation, Coarse (VFIB1) - x1

Defib Energy Test 4
Target Energy: 20 J
Tolerance: +/-15%
Waveform: Ventricular Fibrillation, Coarse (VFIB1) - x1

Defib Energy Test 5
Target Energy: 50 J
Tolerance: +/-15%
Waveform: Ventricular Fibrillation, Coarse (VFIB1) - x1

Defib Energy Test 6
Target Energy: 100 J
Tolerance: +/-15%
Waveform: Ventricular Fibrillation, Coarse (VFIB1) - x1

Defib Energy Test 7
Target Energy: 200 J
Tolerance: +/-15%
Waveform: Ventricular Fibrillation, Coarse (VFIB1) - x1

Defib Energy Test 8
Target Energy: 300 J
Tolerance: +/-15%
Waveform: Ventricular Fibrillation, Coarse (VFIB1) - x1

Defib Energy Test 9
Target Energy: 360 J
Tolerance: +/-15%
Waveform: Ventricular Fibrillation, Coarse (VFIB1) - x1

Charge Time Test
Target Energy: 360 J
Tolerance: +/-15%
Max Charge: 15 sec
Waveform: Ventricular Fibrillation, Coarse (VFIB1) - x1

Cardioversion Test 1
Target Energy: 30 J
Tolerance: +/-15%
Waveform: ECG 120 BPM (ECG120) - x1
Sync Method: ECG R Wave

Phase 3 OPERATING MANUAL

Cardioversion Test 2

Target Energy: 100 J
Tolerance: $\pm 15\%$
Waveform: Atrial Fibrillation, Coarse (AFIB1) - x1
Sync Method: ECG R Wave

ECG Test

1. Square Wave, 2 Hz (SQR2HZ) - x1
2. DC Pulse, 4 sec (PULSE) - x1
3. Triangle Wave, 2 Hz (TRI2HZ) - x1
4. Sinewave, 10 Hz (SIN10) - x1
5. Sinewave, 40 Hz (SIN40) - x1
6. Sinewave, 60 Hz (SIN60) - x1
7. Sinewave, 100 Hz (SIN100) - x1
8. ECG 60 BPM (ECG60) - x1
9. ECG 30 BPM (ECG30) - x1
10. ECG 120 BPM (ECG120) - x1
11. ECG 180 BPM (ECG180) - x1
12. ECG 240 BPM (ECG240) - x1

Pacer Pulse Test 1

Target Current: 55 mA
Tolerance On Current: $\pm 10\%$
Target Pulse Rate: 40 PPM
Tolerance On Rate: $\pm 10\%$
Measuring Method: Peak Current

Pacer Pulse Test 2

Target Current: 55 mA
Tolerance On Current: $\pm 10\%$
Target Pulse Rate: 60 PPM
Tolerance On Rate: $\pm 10\%$
Measuring Method: Peak Current

Pacer Pulse Test 3

Target Current: 55 mA
Tolerance On Current: $\pm 10\%$
Target Pulse Rate: 100 PPM
Tolerance On Rate: $\pm 10\%$
Measuring Method: Peak Current

Pacer Pulse Test 4

Target Current: 55 mA
Tolerance On Current: $\pm 10\%$
Target Pulse Rate: 140 PPM
Tolerance On Rate: $\pm 10\%$
Measuring Method: Peak Current

Pacer Pulse Test 5

Target Current: 55 mA
Tolerance On Current: $\pm 10\%$
Target Pulse Rate: 170 PPM
Tolerance On Rate: $\pm 10\%$
Measuring Method: Peak Current

Pacer Pulse Test 6

Target Current: 100 mA
Tolerance On Current: $\pm 10\%$
Target Pulse Rate: 80 PPM
Tolerance On Rate: $\pm 10\%$
Target Pulse Width: 20 msec
Tolerance On Width: $\pm 10\%$
Measuring Method: Peak Current

Phase 3 OPERATING MANUAL

Pacer Pulse Test 7

Target Current: 130 mA
Tolerance On Current: +/-10%
Target Pulse Rate: 80 PPM
Tolerance On Rate: +/-10%
Target Pulse Width: 20 msec
Tolerance On Width: +/-10%
Measuring Method: Peak Current

Pacer Pulse Test 8

Target Current: 150 mA
Tolerance On Current: +/-15%
Target Pulse Rate: 80 PPM
Tolerance On Rate: +/-10%
Target Pulse Width: 20 msec
Tolerance On Width: +/-10%
Measuring Method: Peak Current

Pacer Pulse Test 9

Target Current: 200 mA
Tolerance On Current: +/-15%
Target Pulse Rate: 80 PPM
Tolerance On Rate: +/-10%
Target Pulse Width: 20 msec
Tolerance On Width: +/-10%
Measuring Method: Peak Current

Noise Immunity: 60 Hz

Pacer Sensitivity Test 1

Sensitivity Limit: 1 mV
Trigger Waveform: Pulse, 40 msec (TRIP40)

Pacer Refractory Test 1

Minimum Refractory: 100 msec
Maximum Refractory: 350 msec
Trigger Waveform: Pulse, 25 msec (SQR25)

Pacer Load: 200 ohms

Phase 3 OPERATING MANUAL

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B

APPENDIX B. SAMPLE TEST REPORT

Below is an example of a Test Report document created by *Phase3pc. Phase 3* itself has the capability of generating a simplified report document containing similar information, which can be transmitted via the Serial I/O Port to a serial printer or personal computer. Refer to Section 4.9.2.2 for instructions on how to output a Test Report via the Serial I/O Port of *Phase 3*.

The results in the Report shown below were obtained from an AutoSequence performed on a 'Test' Biphasic defibrillator. The Report incorporates results from defibrillator energy, charge time, and cardioversion tests, as well as pacemaker pulse, noise immunity and refractory tests.

PHASE 3 DEFIBRILLATOR ANALYZER
Datrend Systems Inc.

TEST REPORT No. 50

DATE OF TEST: Feb 16, 2012
TIME OF TEST: 10:47:57 AM
PHASE 3 I.D.: MY PHASE 3
DEVICE I.D.: Test Defibrillator
DUT TYPE: Biphasic Defibrillator
TEST TYPE: Autosequence 29

1.0 DEFIB TESTS

1.1 Energy

Tests performed: 5/10

TEST	RNG	TOTAL ENERGY (J)	PHASE 1 PEAK (V)	PHASE 1 AVERAGE (A)	PHASE 1 AVERAGE (V)	PULSE @10% (ms)	WIDTH @50% (ms)	ECG SIMULATOR	WAVE-SCALE	TARGET (J)	TOL (%)	RESULT
1	L	2.0	133	2.67	115	2.31	6.23	6.22	VFIB1 x1	2.0	15	PASS
2	L	10.6	312	6.27	262	5.26	6.22	6.22	VFIB1 x1	10.0	15	PASS
3	H	55.0	679	13.64	595	11.95	6.23	6.22	VFIB1 x1	50.0	15	PASS
4	H	110.9	964	19.37	845	16.98	6.23	6.22	VFIB1 x1	100.0	15	PASS
5	H	234.5	1560	31.35	1245	25.02	6.23	6.23	VFIB1 x1	200.0	15	FAIL

TEST	PHASE1	ENERGY PHASE2 (J)	PHASE 2 PEAK (V)	PHASE 2 AVERAGE (A)	PHASE 2 AVERAGE (V)	PULSE WIDTH (ms)	PHASE DELAY (ms)	TILT (%)	FREQ (Hz)	DUTY (%)
1	1.7	0.3	-94	-1.88	-65	-1.30	4.05	0.19	66.9	---
2	8.7	1.9	-216	-4.34	-150	-3.01	4.05	0.19	66.1	---
3	44.9	10.1	-493	-9.90	-340	-6.83	4.05	0.19	66.0	---
4	90.4	20.5	-703	-14.13	-485	-9.74	4.05	0.19	65.8	---
5	197.5	37.0	-946	-19.01	-654	-13.14	4.04	0.20	71.0	---

Phase 3 OPERATING MANUAL

1.2 Charge Time

Pre-test Discharges: 0

RNG	CHARGE TIME (sec)	MAXIMUM CHARGE TIME (sec)	ECG SIMULATOR Wave	Scale	ENERGY (J)	TARGET (J)	TOL (%)	RESULT
H	6.2	15.0	VFIB1	x1	234.2	200.0	15	FAIL

1.3 Cardioversion (Sync)

Tests performed: 1/4

TEST	RNG	SYNC TO:	SYNC DELAY (msec)	SYNC LIMITS (msec)	ECG SIMULATOR Wave	Scale	ENERGY (J)	TARGET (J)	TOL (%)	RESULT
1	H	Q-Wave	+46	+20/+65	AFIB1	x1	111.2	100.0	10	FAIL

2.0 TRANSCUTANEOUS PACEMAKER TESTS

LOAD RESISTANCE: 400 ohms

2.1 Pacer Pulse Measurements

Tests performed: 4/10

TEST	TEST METHOD	PULSE AMPL. (mA)	TARGET AMPL. (mA)	AMP TOL (%)	PULSE WIDTH (ms)	TARGET WIDTH (ms)	WIDTH TOL (%)	PULSE RATE (PPM)	TARGET RATE (PPM)	RATE TOL (%)	ENERGY (mJ)	RESULT
1	AVG.	19.4	20	10	39.99	----	--	59.9	60	10	6.135	PASS
2	AVG.	96.8	100	10	40.09	----	--	59.9	60	10	151.1	PASS
3	AVG.	48.5	50	10	40.05	----	--	120.0	120	10	37.9	PASS
4	AVG.	48.5	50	10	40.05	----	--	180.1	180	10	37.8	PASS

2.2 Noise Immunity

FREQUENCY (Hz)	AMPLITUDE (mV p-p)	RESULT
60	10.00	PASS

2.3 Paced/Sensed Refractory Period

Tests performed: 1/2

TEST	TRIGGER WAVEFORM	PACED REFR PERIOD (msec)	SENSED REFR PERIOD (msec)	MINIMUM REFR PERIOD (msec)	MAXIMUM REFR PERIOD (msec)	RESULT
1	TRIP25	272	278	50	750	PASS

Technician: _____ Date: _____