DEFIBRILLATOR ANALYZER

QED-6

User's Guide

BIO-TEK®

QED-6 Defibrillator Analyzer

User's Guide

Bio-Tek® Instruments, Inc.
Part Number 3371002
Revision D
March 2002

Printed in the USA

Notices

Fluke Biomedical
6920 Seaway Blvd.
Everett, WA 98203
Sales & Customer Service:
775-883-3400 • 800-648-7952
http://www.flukebiomedical.com • sales@flukebiomedical.com

Service and Repair
Please call for RMA number before shipping
1420 75th Street SW
Everett, WA 98203
888-99FLUKE (888-993-5853) • 425-446-5560

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Revision Appendix

REVISION / DATE	SECTION	CHANGES
A July, 1992	--	First Issue
B 9/9/94	DOCUMENT	Text Changes
		Changed specifications.
		Removed schematics and Bill of Materials listings.
C February 1998	--	Updated **Notices**; revised European service address (Chapter 4); made editorial changes.
D March 2002	--	Made editorial changes throughout.
		Updated Notices.
		Revised Accessories table (page 1-12).
		Revised Figure 2.1 (page 2-4).
		Revised Figure 2.2.1 (page 2-5).
		Revised Figure 2.2.2 (page 2-6).
		Added description of waveforms now available in Energy Mode (page 2-8).
		Revised Bio-Tek RS-232 cable part number (page A-1).

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Introduction

Section 1

Regular testing of defibrillators and pacemakers is critical in order to ensure safe and effective operation. Bio-Tek's QED-6 Defibrillator Analyzer accurately verifies the output characteristics of all defibrillators and tests the parameters of non-invasive pacemakers. The QED-6 is battery operated and completely portable. Simple-to-use menu soft keys allow quick access to tests.

The QED-6 measures the delivered energy in Joules (watt-seconds) from a defibrillator by simulating the human body's resistance. The analyzer then measures the flow of current through that resistance. The standard resistance used by the QED-6 is 50 ohms. Defibrillator energy is measured in one of two ranges: 0-100 Joules, or 0-1000 Joules.

The defibrillator pulse waveform can be replayed via the ECG jacks or paddle plates for viewing on a recorder, or on an oscilloscope for greater detail.

Synchronization time in milliseconds is measured by timing the firing delay from either the Q-wave (base) or R-wave (peak) simulated by the QED-6. The simulated waveform is present at both the ECG jacks and the paddle plates. Peak voltage and peak current (amps) of the defibrillator pulse can be measured. Overshoot voltage and current measurements of the defibrillator pulse are calculated and displayed.

The QED-6 also measures the defibrillator's charge time (the time it takes for a defibrillator to reach its maximum charge setting).

Waveforms, including ECG, arrhythmias, and performance, help verify monitor and recorder accuracy, and also test the automatic defibrillator's ability to recognize and fire.

All waveforms are present at the ECG jacks, the paddle plates and scope output. Utilities allow the setting of Serial RS-232 communication parameters to download results to a printer or computer. Display contrast can be adjusted to obtain the best view of the LCD display.

Upgrading the QED-6

A number of pre-configured QED-6 models are available. In addition, older models may be upgraded by contacting Bio-Tek's Technical Assistance Center. The following QED-6 models are available:

- **QED-6:** Base unit. Features output energy, synchronization time, peak measurements, bi-directional RS-232.
- **QED-6M:** Features output energy, sync time, peak measurements, overshoot, bi-directional RS-232, waveforms, charge time measurements, 28 programmable autosequences.
- **QED-6H:** Output energy, sync time, peak measurements, overshoot, bi-directional RS-232, waveforms, charge time measurements, 28 programmable autosequences, pacer output measurements and pacer refractory period measurements.

Description

An isometric illustration of the QED-6 is provided in ***Figure 1.1*** below.

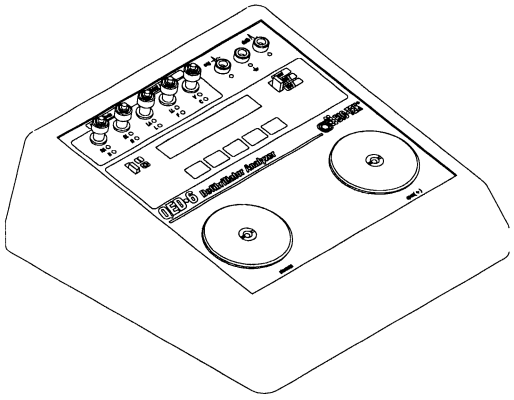


Figure 1.1*. QED-6 Isometric View*

Front Panel

The front panel of the QED-6 (***Figure 1.2***) includes the following operating features:

Universal ECG jacks that utilize AHA and International color coding, allowing for waveform output to monitor/recorder.

A "High Level ECG" Banana jack provides 1 Volt peak output of the selected waveform.

The "Common" Banana jack provides ground for the "High Level ECG" and "Defib Scope Out" jacks.

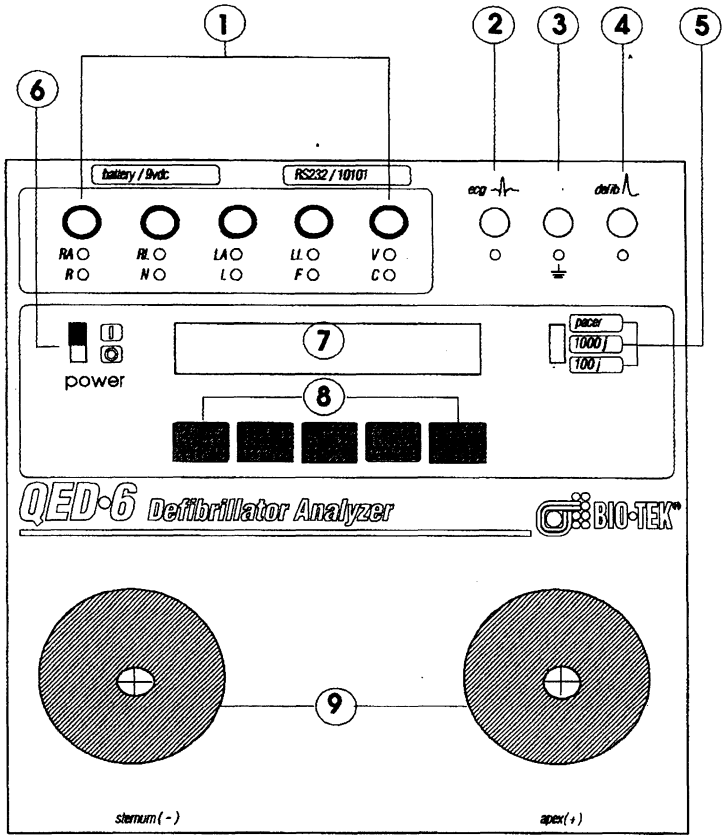


Figure 1.2. *QED-6 Front Panel Layout*

The "Defib Scope Out" Banana jack provides pulse output to an oscilloscope.

A range switch allows for defibrillator settings from 0 to **1000** Joules (high), for power below 0-**100** Joules (low) for increased accuracy, and a **PACER** range setting for pacer output measurements.

The **Power** switch enables the QED-6 (I = ON, O = OFF).

LCD display: 24 characters x 2 lines. The upper line of the LCD display provides messages and test results, while the bottom line displays menu choices.

Five "soft keys" can be used to select the desired function highlighted on the lower line of the display.

Two nickel-plated Defibrillator Paddle Plates are available for defibrillator paddle contact. All waveforms are present at the paddle plates simultaneously with the ECG jacks.

Back Panel

The Back Panel includes a battery holder that houses a 9-Volt alkaline battery, and a DC battery eliminator jack. An RS-232 D-9-pin Serial Port allows communications to a computer, serial printer or other Bio-Tek test equipment.

Specifications

OUTPUT POWER MEASUREMENT:

Load Resistance:	50 ohms ± 1% non-inductive 160 watts
Range:	1000 J: 0-1000.0 Joules 100 J: 0-100.0 Joules
Resolution:	0.1 Joule
Max. Voltage:	1000 J: 5500 Volts 100 J: 1750 Volts
Max. Current:	1000 J: 110 Amps 100 J: 35 Amps
Measurement Trip Levels:	1000 J: 66 ± 5 Volts 100 J: 20 ± 5 Volts
Pulse Width:	1-50 ms
Accuracy:	1000 J Range: ± 2% of reading 100-1000 J: ± 2 Joules 100 J Range: ± 2% of reading ± 0.1 Joule

SYNCHRONIZATION MEASUREMENTS:

Range:	0-199.9 ms
Measurement:	From peak of R-wave From base of R-wave
Accuracy:	1% of fullscale or ± 2 ms

ECG WAVEFORMS:

QRS complex:

Rates: 30, 60, 120, 180, 240 BPM

Rate Accuracy: ± 1% of setting

Amplitude: Fixed at 1 mV Lead II (RA-LL)
Fixed at 1.1 mV (Apex- Sternum)

Amplitude Accuracy: ± 2% (RA-LL)
± 10% (Apex-Sternum)

PERFORMANCE WAVEFORMS:

Pulse: 30, 60 BPM
pulse width -60 ms

Triangle Wave: 2 Hz

Square Wave: 0.125 Hz, 2 Hz, 50% duty cycle

Sine Waves: 10, 40, 50, 60, 100 Hz

Time Base Accuracy: ± 1% of setting

Amplitude: Fixed at 1 mV Lead II (RA-LL)
(Triangle wave 2 mV Lead II (RA-LL)
Fixed at 1.1 mV (Apex-Sternum)

Amplitude Accuracy: ± 2% (RA-LL)
± 10% (apex-sternum)

DEFIB WAVEFORM PLAYBACK

Time Base Expansion: 100:1 @ 25 mm/sec paper speed; each division equals 40 ms

Amplitude Scaling

Lead II (RA-LL):

1000 J Range: 1 mV = 3000 Volts

100 J Range: 1 mV = 900 Volts

ECG Output

1000 J Range: 0.5 V = 3000 Volts

100 J Range: 0.5 V = 900 Volts

ARRHYTHMIAS

Afib, Vfib, Atach, Vtach, Aflutter, RUN, PVC, R on T, Idioventricular

Rate Accuracy: ± 1%

Amplitude: Fixed at 1 mV Lead II (RA-LL)
Fixed at 1.1 mV (Apex-Sternum)

Amplitude Accuracy: ± 2 (RA-LL)
± 10% (Apex-Sternum)

SCOPE OUTPUTS:

ECG Hi-Level: Fixed at 1 Volt
Accuracy: ± 2%

Defib Output: Real Time

Pacer Range: 1V = 3.11 V

1000 J Range: 1V = 1450 V

100 J Range: 1V = 440 V

Amplitude Accuracy: ± 2% of scale

EXTERNAL NON-INVASIVE PACER MEASUREMENTS:

Load:	50 ohms ± 1% (Apex-Sternum)
R-wave Amplitude:	1.1 mV ± 10% (Apex-Sternum) 1 mV ± 2% Lead II (RA-LL)
Pulse Width:	1-50 ms
Peak Voltage:	0-12.5 Volts
Peak Current:	4-250 mA < 4 mA = 0.0 mA
Rate:	25-400 ppm < 25 ppm = 0 ppm
Refractory Period:	
Sensed:	110-500 ms < 110 ms = 110 ms
Pulsed:	70-500 ms < 70 ms = 70 ms
Accuracy:	± 2% of fullscale for pulse width, peak voltage current ± 1% of fullscale for rate and refractory period measurements

CALIBRATION SCREEN

Load:	50 ohms ± 1% (Apex-Sternum)
Amplitude scaling:	Apex (+) to Sternum (-)
Pacer Range:	318 counts/Volt
1000 J Range:	0.683 counts/Volt
100 J Range:	2.252 counts/Volt

Accuracy:	± 15 counts
Measurement Range:	Apex (+) to Sternum (-)
Pacer Range:	(0-12.86) = (0-4095)
1000 J Range:	(0-5995) = (0-4095)
100 J Range:	(0-1814) - (0-4095)
Zero Voltage Input:	0 ± 2 counts

PEAK / OVERSHOOT

Voltage Accuracy:	1000 J Range: ± 10 Volts 100 J Range: ± 25 Volts
Current Accuracy:	± 1 Amp

RS-232 OUTPUT / COMPUTER CONTROL:

Computer control allows the user to operate the QED-6 remotely via a serial RS-232 interface.

Requires a Bio-Tek RS-232 cable and a Bi-directional, D-9 connector.

Selectable Communications parameters:

Baud Rate: 300, 600, 1200, 2400, 9600
Parity: None, Even, Odd
Stop Bits: 1 or 2
Data Bits: 7 or 8

DISPLAY:

2-line x 24-character LCD
supertwist alphanumeric

POWER:

One 9-Volt Alkaline (Duracell MN1604 or equivalent);
12 hours continuous operation;
low battery indication;
120/240 Volts battery eliminator input.

WEIGHT:

4.54 lbs

DIMENSIONS:

26.67 x 24.13 x 10.16 cm

ENVIRONMENTAL OPERATING SPECS

Storage Temperature:	-25 to 50°C
Operating Temperature:	0 to 40°C
Maximum Humidity:	90% Relative Humidity

Accessories

DESCRIPTION	SUPPLIED	PART NUMBER
Carrying Case	Optional	3362013
QEDR Tags	100	93006
User's Guide	1	3371002
Warranty Card	1	
RS-232/Printer Cable, Serial	Optional	3360504
Printer (DPU 411-21)	Optional	97115
Printer Paper for DPU 411-21	Optional	97116
Converter Data, Serial-Parallel 110 V	Optional	61039
Power Supply for DPU-411-21 Printer (220 V)	Optional	61037
Internal Paddle Adapters	2	3360501
Automatic Paddle Adapters	Optional	
Hewlett Packard		3370506
Marquette		3370505
Laerdhal		3370500
Physio Control (Automatic Defibrillation)		3370502
Physio Control (Pacer)		3370503 3373000
Zoll Cable Assembly 9-VDC, 300-mA Adapter	Optional	61053

Installation and Operation

Section 2

Use the following checklist when unpacking the QED-6 to check the instrument for shipping damage.

Perform a visual inspection to ensure the front panel or case have not been damaged during shipping.

Check the LCD display to ensure that it is intact. If the QED-6 has been damaged, call your Bio-Tek representative immediately.

Place the QED-6 on a level surface and power up the instrument by turning the power switch to **I (ON).** Check the display. If the message, *Warning - Low Battery!!* appears, the instrument's battery requires replacement.

Operation Warnings

Before using the QED-6 with a defibrillator, the operator must be familiar with, and follow the safety precautions listed below:

- Inspect the defibrillator daily. Examine the paddles, lead wires, and power cord for cracks and frays.

- If the defibrillator is line powered, be sure that it is plugged into a grounded receptacle. Do not touch the electrical contact surfaces of the defibrillator paddles.

- Grip one paddle handle firmly in each hand. Apply to the QED-6 plates. Keep the paddles firmly depressed to prevent arcing that can cause injury to the operator and/or damage the QED-6 or defibrillator.

- Do not touch the contact plates on the QED-6 when the defibrillator paddles are being pressed onto the plates. Do not use any electrical paste or pads when testing a defibrillator with the QED-6.

Getting Acquainted

The QED-6 utilizes a 2-line x 24-character LCD display and "soft keys" to simplify operation (***Figure 2.1***).

The top line of the LCD display is used for test results and the bottom line provides menu choices. A menu selection is made by pressing the corresponding soft key. An audible "beep" verifies the selection.

Figure 2.2 provides an overview of the menus and functions that may be accessed from the QED-6 main menu.

For example, when the QED-6 is powered up, the following message appears briefly on the display, identifying the software version:

After a short delay, the display changes to the main menu:

Pressing the blue soft key corresponding to **ENERG**, **SYNC**, **PEAK** or **WAVE** prompts a submenu of specific functions to appear; pressing **esc** in any of the sub-menus returns the display to the previous menu, and ultimately to the main menu.

Pressing **more** from Main Menu 1 toggles the display to Main Menu 2; pressing **more** from Main Menu 2 returns you to Main Menu 1.

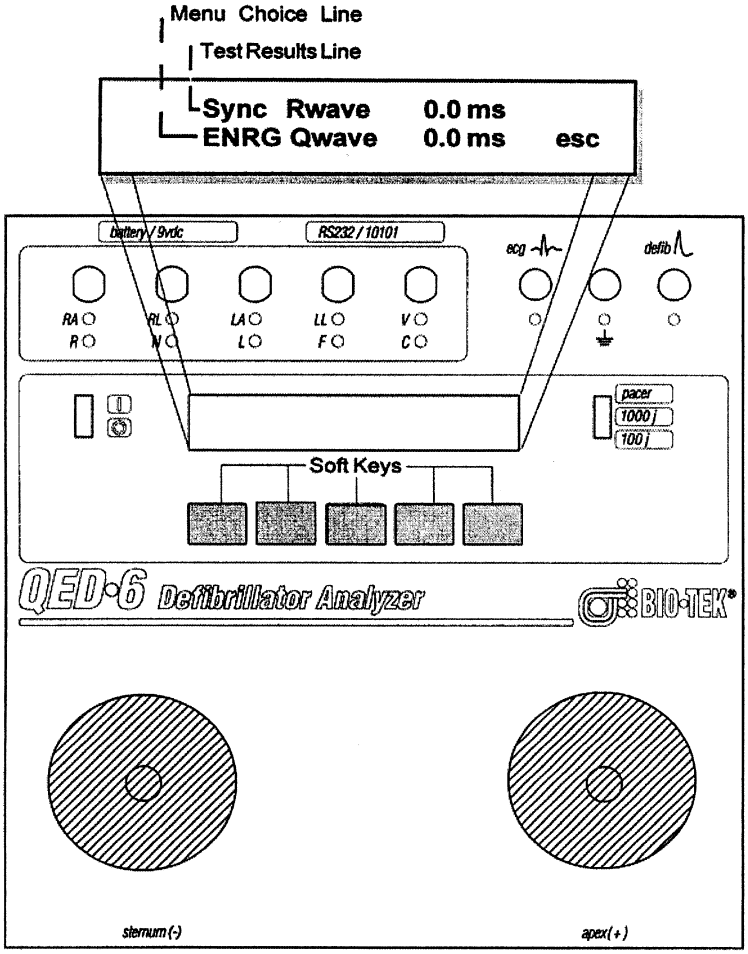


***Figure 2.1**. QED-6 Front Panel Display*

QED-6H Menu Structure / Main Menu 1

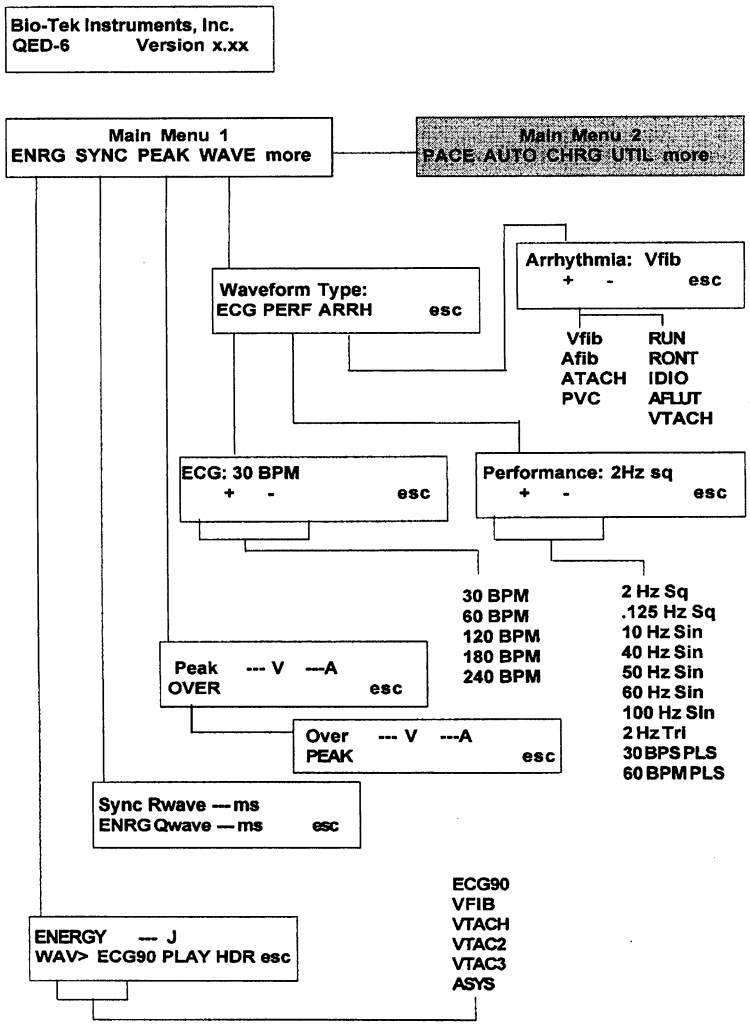


Figure 2.2.1. QED-6 Menu Structure (Main Menu 1)

QED-6H Menu Structure / Main Menu 2

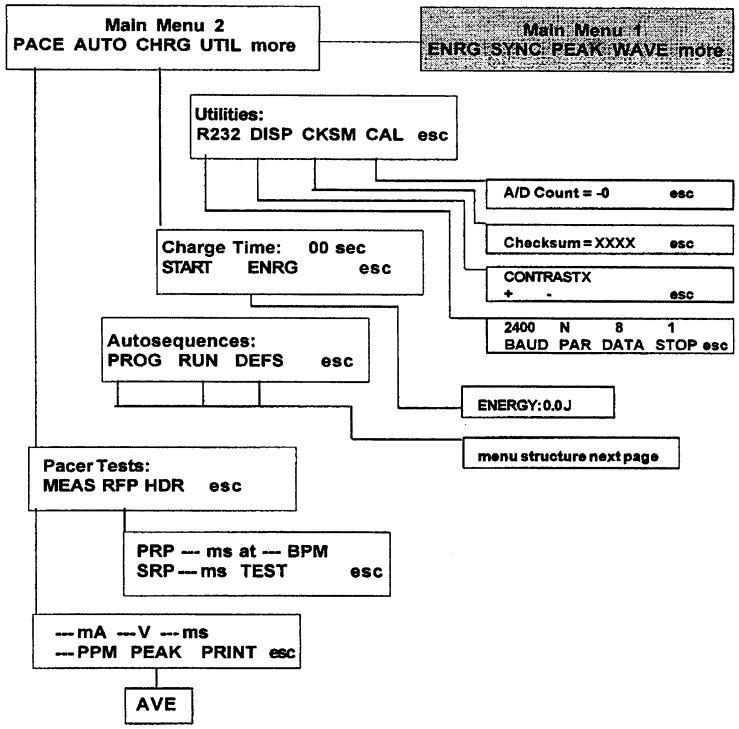


Figure 2.2.2. QED-6 Menu Structure (Main Menu 2)

Main Menu 2: Autosequence Menu Structure

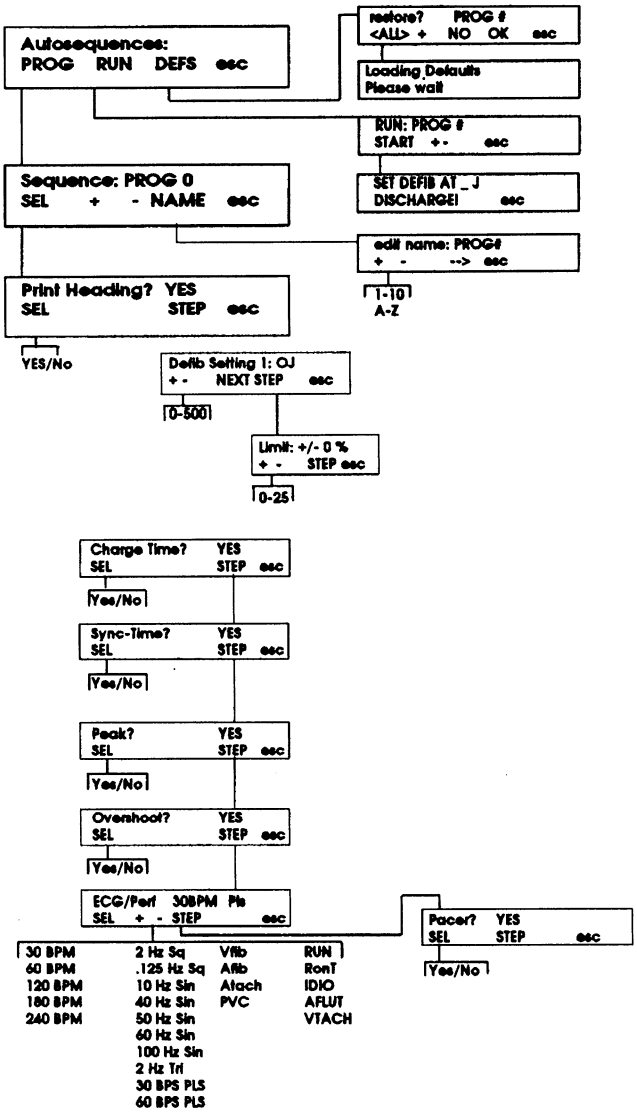


Figure 2.2.3. QED-6H Autosequence Menu Structure (Main Menu 2)

Measuring Defibrillator Energy

1) Power up the defibrillator to be tested, and select the energy output following the manufacturer's instructions.

2) Turn the QED-6 **ON**. Main Menu 1, as shown below, will appear on the display.

3) Press the soft key corresponding to **ENRG** to access the power menu shown below:

When **WAV☮** is selected, the QED-6 will increment through a list of available waveforms (**ECG90, VFIB, VTACH, VTAC2, VTAC3** and **ASYS**). The selected waveform will be displayed as the text for the second soft key. The waveform will appear through the ECG adapters and QED-6 front panel paddles and will be available to trigger an automatic defibrillator to discharge.

After the defibrillator discharges, the output will switch to a 90 BPM ECG waveform.

The following waveforms are available in Energy Mode:

ECG90	The default waveform; after a discharge, the ECG90 will resume.
VFIB	Ventricular Fibrillation
VTACH	125 BPM, VTACH
VTAC2	240 BPM, Monomorphic
VTAC3	300 BPM, Polymorphic
ASYS	Asystole

If the range switch is set to **Pacer**, the following message will appear momentarily:

ATTENTION Select DEFIB Range

4) Select the QED-6's 1000 Joule range (high) for defibrillator outputs over 100 Joules, or select the 100 Joule range (low) for outputs under 100 Joules. Select the high range for unknown defibrillator output power.

5) Simultaneously press the two defibrillator paddles onto the contact electrode plates on the front of the QED-6 (***Figure 2.3***).

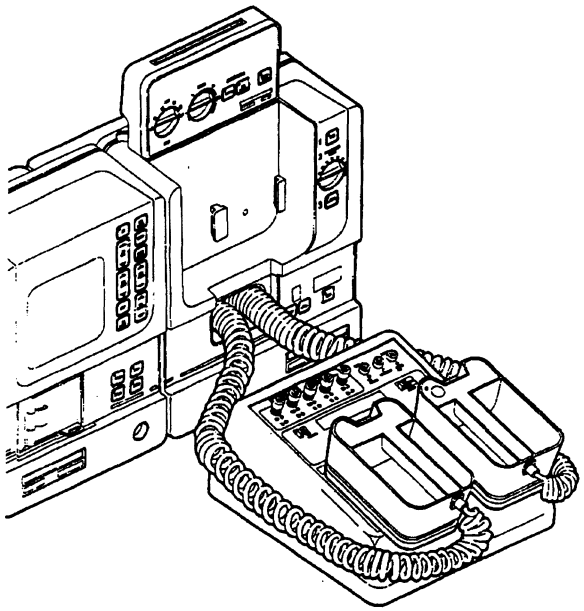
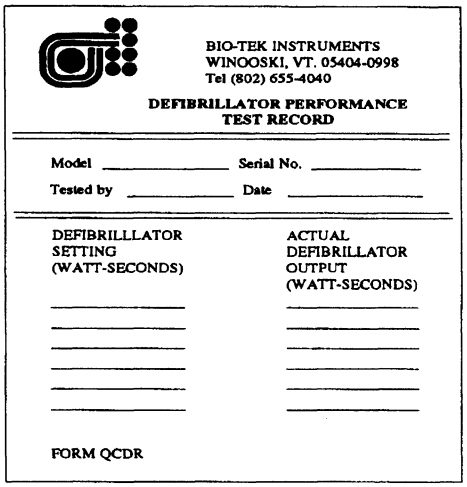


Figure 2.3*. Defibrillator Energy Testing*

6) Initiate a discharge from the defibrillator.

7) Observe the output settings and the actual readings displayed on the QED-6, and record them on the QEDR performance tag (***Figure 2.4***).

Note: **The QED-6 will continue to display the reading until the next defibrillator pulse is fired.**


BIO-TEK INSTRUMENTS
WINOOSKI, VT. 05404-0998
Tel (802) 655-4040

DEFIBRILLATOR PERFORMANCE TEST RECORD

Model _____ Serial No. _____

Tested by _____ Date _____

DEFIBRILLLATOR SETTING (WATT-SECONDS)	ACTUAL DEFIBRILLATOR OUTPUT (WATT-SECONDS)
_____	_____
_____	_____
_____	_____
_____	_____
_____	_____
_____	_____

FORM QCDR

Figure 2.4. *QEDR Performance Tag*

To test automatic defibrillators for their ability to recognize ventricular fibrillation and/or ventricular tachycardia, and automatically fire:

1) Attach the optional automatic defibrillator paddle adapters to the QED-6.

2) Connect the ECG patient leads to the QED-6 as shown in ***Figure 2.5***.

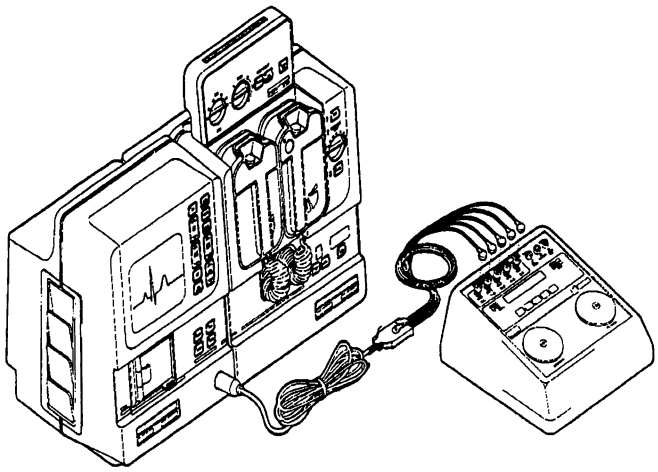


Figure 2.5. *ECG Lead Configuration*

3) Press the soft key corresponding to **VFIB** (refer to ***Figures 2.2.1*** and ***2.2.2*** for an overview of the menu functions). A ventricular fibrillation waveform will be simulated by the QED-6 through the ECG jacks and paddle plates. Once a discharge is complete, the QED-6 will output a 90 BPM Normal Sinus Rhythm.

4) Press the soft key corresponding to **VTACH**. A ventricular tachycardia will be simulated by the QED-6 through the ECG jacks and paddle plates. Once the discharge is complete, the QED-6 will output a 90 BPM Normal Sinus Rhythm.

Defib Pulse Playback

The QED-6 allows the user to play the defibrillator pulse waveform for the purpose of analysis. Playback is accomplished using a strip recorder or defibrillator monitor through the ECG jacks or scope output. The waveform can also be inspected on an oscilloscope through the high-level ECG outputs. To play back the defibrillator pulse:

1) Follow Steps 1-4 in the section titled *Measuring Defibrillator Energy.*

2) Connect the ECG patient leads to the QED-6 as shown in ***Figure 2.5***.

3) After the defibrillator discharge, press the soft key labeled **PLAY**. The last defibrillator pulse will be replayed each time **PLAY** is pressed. Refer to the specifications section for playback scaling on a chart recorder.

Oscilloscope Viewing of Output

The QED-6 provides 2 banana jacks for real-time oscilloscope viewing. An oscilloscope with storage capability should be used. To view the output on the oscilloscope:

1) Connect the oscilloscope to the QED-6 using a banana plug and a scope probe. Using a scope probe ensures signal integrity.

2) Attach the ground from the scope probe to the "common" black jack on the QED-6. Attach the scope probe's positive lead to the defib output.

3) Set the oscilloscope trigger on "external" and connect a lead between the input of the oscilloscope and the external trigger input.

4) Set the time scale on the oscilloscope to 1 ms/division and adjust to the desired expansion after observing the waveform output.

5) Set the gain on the oscilloscope to 0.2 V/division and adjust to the desired level after observing the waveform.

6) Activate the storage control on the oscilloscope.

7) For most applications, set the oscilloscope input coupling control to "AC" mode.

Note: If the defibrillator under test uses a discharge waveform with sizable DC components (trapezoidal or pulsatile discharge), improved output waveform fidelity can be obtained by placing the oscilloscope in the DC-coupling mode.

8) Follow steps 1-6 in the section titled *Measuring Defibrillator Energy*. The waveform is 1/1450 when in the 1000 Joule range, and 1/440 in the 100 Joule range of the input voltage through 50 ohms. The actual magnitude of the discharge voltage can be obtained by using the following equation:

$V_{discharge} = V_{scope}(1450)$ High range

$V_{discharge} = V_{scope}(440)$ Low range

9) Observe that the waveform appears on the oscilloscope. Repeatedly discharge the defibrillator while adjusting the time and the gain to the optimal scale for observing the waveform.

10) If the waveform does not appear on the oscilloscope, readjust the trigger levels on the oscilloscope and repeat steps 7, 8, and 9.

Measuring Synchronization

The QED-6 measures the synchronization time (cardioversion delay time) of synchronized defibrillators. A 90 BPM ECG waveform is output through the ECG jacks and the paddle plates. During normal operation, the defibrillator recognizes and responds to this trigger by discharging within a certain amount of time.

The QED-6 is capable of measuring up to 199.9 ms in delay time from either the peak or the base edge of the "R" wave. Typical acceptable delay times are within 60 ms from the peak of the "R" wave. To measure synchronization:

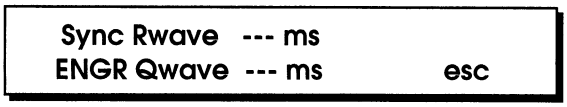
1) Turn the defibrillator to be tested to "ON" and select the desired energy output in accordance with the manufacturer's instructions.

2) Connect the ECG patient leads to the QED-6 as shown in ***Figure 2.5***.

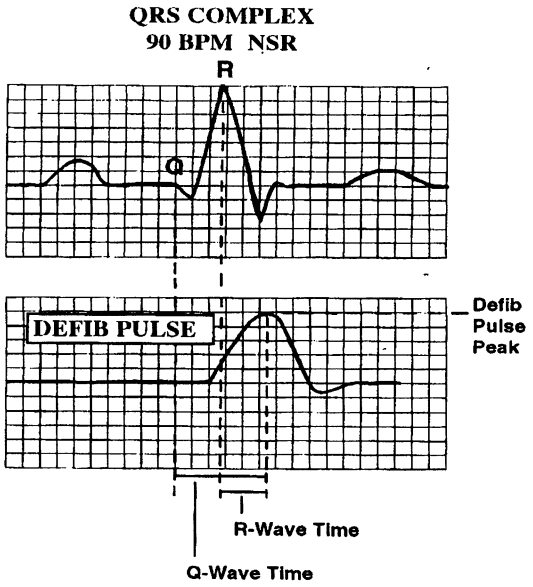
3) Power up the QED-6 by sliding the power switch to the **ON** position (forward).

4) The QED-6 will display Main Menu 1, as shown below:

5) Press the soft key corresponding to **SYNC** to enter the sync menu shown below:



Sync time measurements are performed as shown:



6) Select the 1000 Joules range on the QED-6 for defibrillator outputs over 100 Joules or select the 100 Joule range for outputs under 100 Joules. Select the 1000 Joule range for unknown defibrillator output power.

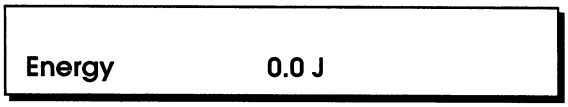
7) Place the defibrillator in synchronous mode.

8) Simultaneously press both defibrillator paddles to the contact plates of the QED-6.

9) Initiate a discharge from the defibrillator.

10) Press the soft key corresponding to **ENRG** to view the energy readings. The reading will appear as shown below.

Note: The LCD will display the reading for about 2 seconds.



Generating Waveforms

The QED-6 generates a series of waveforms designed to verify the accuracy of ECG machine/monitors. These waveforms, available for simulation via ECG jacks or paddle plates, are calibrated for lead II at 1 mV:

ECG	Performance	Arrhythmia
30 BPM	30 BPM Pulse	Atrial Fibrillation
60 BPM	60 BPM Pulse	Atrial Flutter
120 BPM	2 Hz Triangle (2 mV)	Atrial Tachy
180 BPM	0.125 Hz Square (50% d.c.)	Idioventricular
240 BPM	2.0 Hz Square (50% d.c.)	PVC
	10 Hz Sine	R on T
	40 Hz Sine	Run
	50 Hz Sine	Ventricular Fib.
	60 Hz Sine	Ventricular Tachy
	100 Hz Sine	

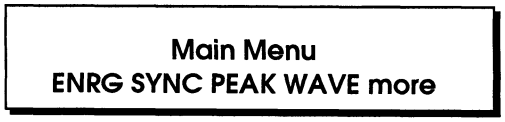
Procedure

1) Turn the defibrillator to be tested to **ON**.

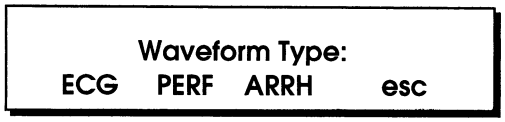
2) Connect the ECG patient leads to the QED-6 as shown in ***Figure 2.5***.

3) Power up the QED-6 by sliding the power switch to **ON** (forward).

4) Main Menu 1 will appear on the QED-6 display.

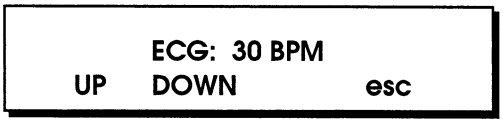


5) Press the soft key corresponding to **WAVE** to access the waveform menu:



6) Press the soft key corresponding to the desired wave simulation:

- **ECG** for ECG waveforms (menu shown below)
- **PERF** for performance waveforms
- **ARRH** for arrhythmia waveform



7) To select the next available waveform, press the soft key corresponding to + (up).

   To select the previous waveform, press the soft key corresponding to - (down).

8) Observe the waveform on the monitor under test.

Note: The waveform selected will continuously play until another is selected, or until the soft key corresponding to esc is pressed.

Testing High Level Out

All waveforms available through the ECG jacks are simultaneously output through the **High Level** jacks. This offers the user a 1-Volt peak signal for testing purposes.

To test **High Level** signal:

1) Using an oscilloscope and a scope probe, measure the output waveform on the high level output.

Note: Use a scope probe to guarantee signal integrity.

2) Refer to *Generating Waveforms*, page 2-17.

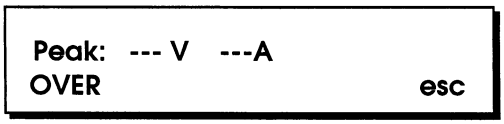
Measuring Peak Voltage, Current and Overshoot

To measure the peak voltage and current of the defibrillator pulse:

1) Power up the defibrillator to be tested, and select the energy output following manufacturer's instructions.

2) Power up the QED-6. Main Menu 1, as shown below, will appear on the display.

3) Press the soft key corresponding to PEAK to access the current and voltage menu:



Pressing the soft key that corresponds to **PEAK/OVER** toggles the measurement between Peak current and voltage, and Over current and voltage.

4) On the QED-6, select the 1000 Joule range for defibrillator outputs over 100 Joules, or select the low range (100J) for outputs under 100 Joules. Select the high range for unknown defibrillator output power.

5) Simultaneously press the two defibrillator paddles onto the contact electrode plates on the front of the QED-6.

6) Initiate a discharge from the defibrillator.

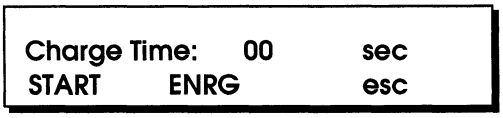
7) Observe the LCD on the QED-6 and record the defibrillator voltage and current.

Note: The LCD will continue to display the reading until the next defibrillator pulse is fired.

Charge Time (QED-6M, H)

1) From Main Menu 1, press **more** to access Main Menu 2. The following display will appear.

2) From Main Menu 2, press the soft key below CHRG. The following screen will appear.



3) Select the QED-6's 1000 Joule range (high) for defibrillator outputs over 100 Joules, or select the 100 Joule range (low) for outputs under 100 Joules. Select the high range for unknown defibrillator output power.

4) Press the two defibrillator paddles onto the contact electrode plates on the front of the QED-6.

5) Press the soft key corresponding to **START**, and initiate the defibrillator's charge cycle.

   As soon as the defibrillator reaches full charge, discharge it. Note the time (in seconds) on the display. The maximum for the QED-6 is 60 seconds. After 60 seconds is reached, the QED-6 displays **OVER**.

Pacer (Non-Invasive) Testing

1) From Main Menu 1, press **more** to access Main Menu 2. The following display will appear.

```
MAIN MENU 2
PACE AUTO CHRG UTIL more
```

2) Ensure that the front panel range switch is set to pacer. Otherwise the unit will beep and display the following message:

```
Attention!
Select PACER range
```

3) From Main Menu 2, press the softkey labeled **PACE**. The following display will appear:

```
PACER TESTS
MEAS RFP HEDR esc
```

4) Connect the output from the pacer to the QED-6 shown in ***Figure 2.6***.

Note: The Pacer can be in either demand or non-demand mode.

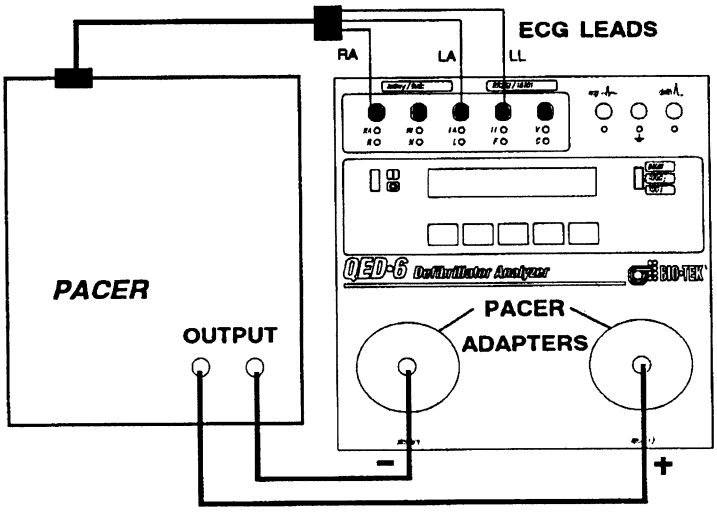


Figure 2.6. Connecting Pacer Output to QED-6

5) Select **MEAS** from the pacer tests menu. The following display will appear:

---MA	---V	---MS
---BPM		PRINT esc

--- indicates no pacer pulses received.

6) Set the pacer at various current and heart rate settings. The results will be displayed. Press **PRINT** for a hard copy.

Note: Pacer voltage and current are displayed as Average voltage and current. If a printer is connected to the QED-6, the printout will also document peak voltage and current. If computer control is being utilized, no peak values are available. All voltage measurements are referenced to the internal 50 ohms load.

Pacer Refractory Period Testing

1) Set Pacer in Demand Mode

2) From Main Menu 2, press the soft key corresponding to .**PACE**. to get to the Pacer Tests menu:

```
Pacer Test:
MEAS RFP HDR esc
```

3) Press .**RFP**. from the pacer tests menu to select refractory period testing. Refer to ***Figure 2.6*** for setup. The following menu appears.

```
PRP ---- ms at ---- PPM
SRP ---- ms  TEST  esc
```

----- indicates results received from pacer.

PRP Pulsed refractory period (refer to theory of operations for definition of PRP & SRP)

SRP sensed refractory period

BPM pacing rate at which the test was performed

4) Press .**TEST**. to start testing. The dashed lines will flash, indicating the test is in progress and pulses are detected. When the refractory period is determined, the results will be displayed.

Note: At slow rates it may take 1-3 minutes to determine the refractory tests. The test will be quicker at higher pacing rates. The results will automatically be output via the RS-232 port. Do not alter the pacing rate during refractory measurements or incorrect data may be recorded.

Autosequencing (QED-6H)

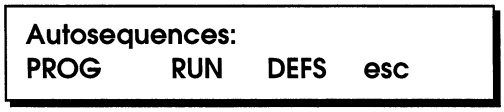
The QED-6H can store in memory up to 28 automatic sequences to fully test defibrillator performance according to protocol. Standard defaults for Programs 0-27 for the QED-6H are:

Print Heading:	Yes
Energy Measurements:	10 J 100 J 200 J 300 J 360 J
Energy Limits +/-	5%
Charge Time:	Yes
Sync Time:	Yes
Peak:	No
Overshoot:	No
ECG performance:	30 BPM 120 BPM 240 BPM 2 Hz Sq .125 Hz Sq 10 Hz Sin 40 Hz Sin 50 Hz Sin 60 Hz Sin 100 Hz Sin 2 Hz Tri 60 BPM PLS Vfib
Pacer:	No

Programming an Automatic Test Sequence

From Main Menu 2

1) Press the soft key corresponding to **AUTO** to access the Autosequences menu.

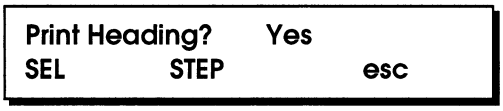


2) Press the **PROG** soft key to access the individual programs to be modified.

Select the program to be modified by pressing the + or - soft keys to increment/decrement program numbers. Available programs are 0-28. Pressing **NAME** allows the program name to be modified.

3) Press the **SEL** soft key to confirm the program selected for modification. You will be asked if you wish to attach a header to the data to be output after the test sequence has been run.

Press **SEL** to toggle between Yes and No.



4) Press STEP to advance to the next check item.

Press .+ .or. -. to increment or decrement the Defib setting.

Press **NEXT** for the next Defib setting.

5) Press STEP to advance to the next check item:

Press .+. or. -. to increment/decrement the accuracy limit.

6) Press .**STEP**. to advance to the next check item.

Press. **SEL**. to select .**Yes**. or .**No**..

7) Press .**STEP**. to advance to the next check item.

Press .**SEL**. to select .**Yes**. or .**No**..

8) Press .**STEP**. to advance to the next check item.

Press .**SEL**. to select .**Yes**. or .**No**.. Selecting .**Yes**. includes Peak Voltage and Peak Current measurements.

9) Press **STEP** to advance to the next check item.

Press **SEL** to select **Yes** or **No**.

10) Press STEP to advance to the next check item.

Press **SEL** to program/deprogram a waveform. An * indicates the item is programmed.

Press **+** or **-** to advance to the next waveform.

11) Press **STEP** to advance to the next check item.

Press **SEL** to select **Yes** or **No**.

12) Press **STEP** to return to the program menu.

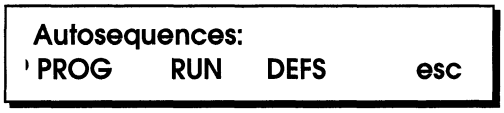
13) Press **esc** to save changes.

Note: The changes will be saved until the program is modified again, or the QED-6 is reset to factory defaults.

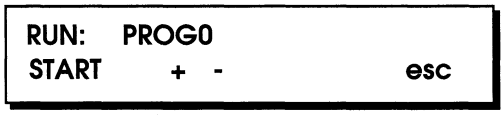
Running an Automatic Test Sequence

From Main Menu2:

1) Press the soft key corresponding to **AUTO** to access the autosequence programs.



2) Press the soft key corresponding to **RUN** to select an autosequence program, which are numbered 0-27.



3) Choose a Program number by pressing the soft key corresponding to + or - to increment/decrement the program numbers.

4) Press the **START** soft key to start the selected program.

Note: If the range switch is not already set to the appropriate range (100 J for settings under 100 Joules, or 1000 J for settings over 199 J) and Pacer for PACE tests, the QED-6 will sound an audible alarm and a warning message will appear until the condition is corrected.

The QED-6 will prompt the user through the complete autosequence program. Data output (if requested) to a printer or computer will occur after the test sequence has been run.

Resetting the QED-6 for Factory Defaults

From Main Menu 2:

1) Press the soft key corresponding to **AUTO** to enter the Autosequences Menu.

2) Press the **DEFS** (defaults) soft key to access the Restore menu.

3) Press **OK** to restore **PROG1** to factory defaults. Press **NO** or **esc** to back up one menu level. Press **(ALL)** to restore all 28 factory default programs.

Data Transfer and Utilities

Section 3

Serial Port

The QED-6 provides a Male D9 (9 pin) Serial Port, located on the back side of the unit, for the transfer of data to a computer or printer. The Data Computer Equipment (DCE) wiring configuration is shown below.

PIN	FUNCTION
1	Unused
2	RX
3	TX
4	DTR
5	Unused
6	Unused
7	Unused
8	Serial
9	232 Ground

Bio-Tek Serial Cable (optional accessory)

Use the Bio-Tek serial cable to transfer data from the QED-6 serial port to any IBM (or compatible) computer or printer. The Data Terminal Equipment (DTE) wiring configuration is:

PIN	FUNCTION
1	Unused
2	TX
3	RX
4	RTS
5	CTS
6	DSR
7	232 Ground
8 - 25	Unused

Printing the QED-6 Report Header

All test reports received by the QED-6 may be printed via the RS-232 port. A serial printer, or a serial-to-parallel converter and a parallel printer is required. You will also need Bio-Tek's serial cable and null modem device. For more information and/or part numbers for these items, refer to the *Accessories* list in **Section 1** of this manual.

- To print a Report header from the **ENRG** (Energy) menu:

  1) At Main Menu 1, press the **ENRG** soft key

  2) At the Energy Menu press the soft key corresponding to **HDR**. The header will be forwarded via the serial port to the target device (computer or serial printer).

- To print a Report Header from the **PACE** (Pacer) menu:

  1) At Main Menu 1, press the **more** soft key to access Main Menu 2.

2) At Main Menu 2, press the **PACE** soft key.

3) At the Pacer Menu, press the soft key corresponding to **HDR**. The header will be forwarded via the serial port to the target device (computer or serial printer). An example of the header is shown in ***Figure 3.1***.

- An example of a standard printout (manual operation) with a header is shown in ***Figure 3.1***. During manual operation, results are output to the printer (or computer) immediately after each test is performed.

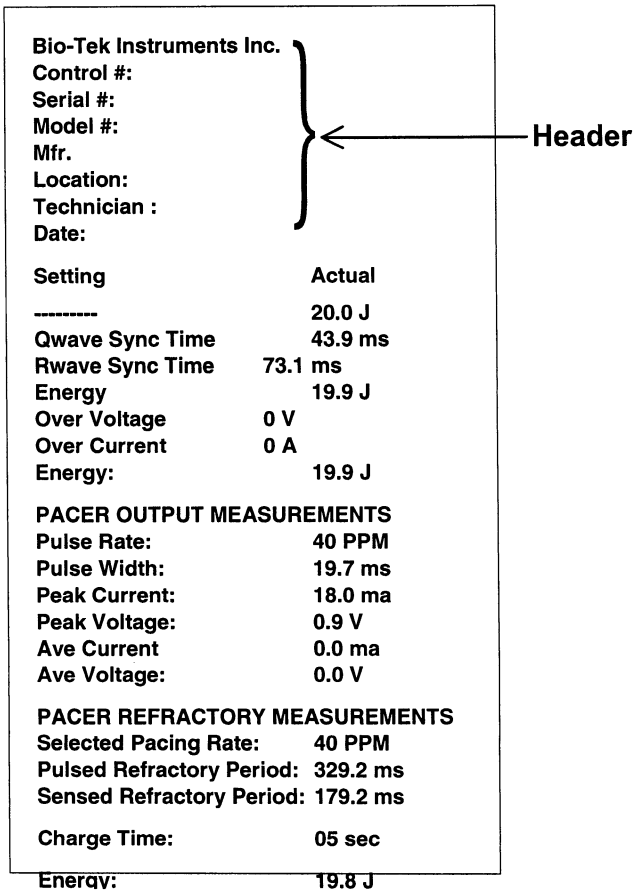
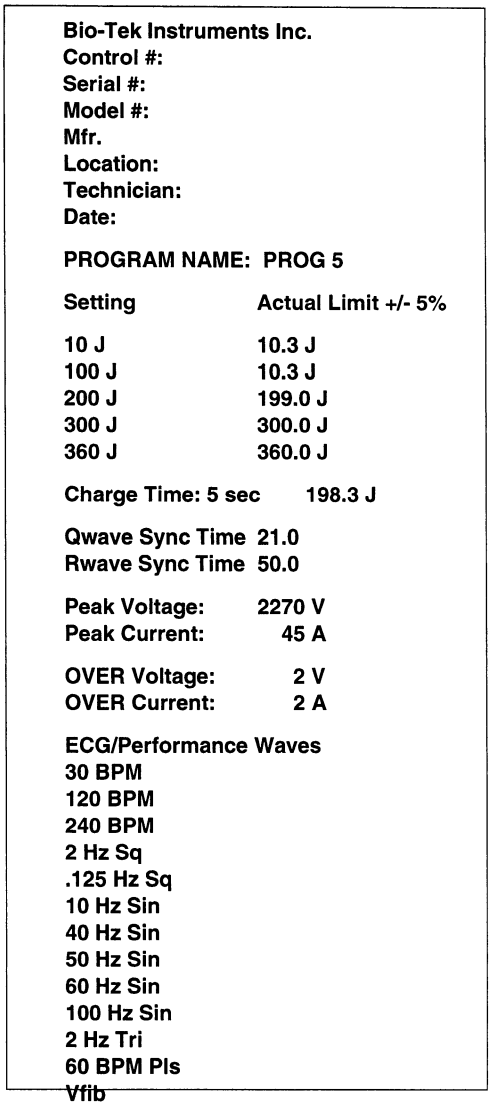


Figure 3.1. *Manual Output with Header*

- An example of a standard printout (automatic sequence) with a header is shown in ***Figure 3.2.*** In autosequencing mode, all results are output to the printer (or computer) after the sequence is complete.



Bio-Tek Instruments Inc.
Control #:
Serial #:
Model #:
Mfr.
Location:
Technician:
Date:

PROGRAM NAME: PROG 5

Setting	**Actual Limit +/- 5%**
10 J	**10.3 J**
100 J	**10.3 J**
200 J	**199.0 J**
300 J	**300.0 J**
360 J	**360.0 J**

Charge Time: 5 sec 198.3 J

Qwave Sync Time 21.0
Rwave Sync Time 50.0

Peak Voltage: 2270 V
Peak Current: 45 A

OVER Voltage: 2 V
OVER Current: 2 A

ECG/Performance Waves
30 BPM
120 BPM
240 BPM
2 Hz Sq
.125 Hz Sq
10 Hz Sin
40 Hz Sin
50 Hz Sin
60 Hz Sin
100 Hz Sin
2 Hz Tri
60 BPM Pls
Vfib

Figure 3.2. *Automatic Sequence Output with Header*

```
PACER OUTPUT MEASUREMENTS
Pulse Rate:                 40 PPM
Pulse Width:                0.0 ms
Peak Current:               0.0 ma
Peak Voltage:               0.0 V
Ave Current                 0.0 ma
Ave Voltage:                0.0 V

PACER REFRACTORY MEASUREMENTS
Selected Pacing Rate:       40 PPM
Pulsed Refractory Period:   329.2 ms
Sensed Refractory Period:   195.4 ms
```

Figure 3.2 (concluded): *Automatic Sequence Output with Header*

The Utilities Menu

The Utilities function provides control over serial data flow parameters and LCD display values.

To access the Utilities menu:

1) Power up the QED-6. Main Menu 1 will appear on the display:

2) Press the soft key corresponding to **more** to access Main Menu 2:

3) Press the soft key corresponding to **UTIL** to access the Utilities Menu:

Utilities:
R232 DISP CKSM CAL esc

Adjusting RS-232 Parameters

Parameters for RS-232 data transfer (baud rate, parity setting, data bit and stop setting) may be set within the RS-232 menu. To set RS-232 parameters:

1) Press the soft key corresponding to **R232** to enter the RS-232 menu:

XXXX X X X
BAUD PAR DATA STOP esc

2) Press the soft key that corresponds to the parameter to be changed. Repeated pressing of the soft key will cycle through the setting options.

   The following settings are recommended:

   BAUD rate: 300, 600, 1200, 2400, 9600
   PARity: N, E, O
   DATA Bits: 8, 7
   Stop Bits: 1,2

   The QED-6 factory default setting is 2400, N, 8, 1.

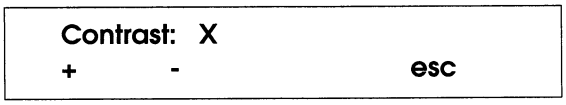
   1. When **esc** is pressed, the last displayed parameters are stored in memory and retained when power is off.

Adjusting Display Contrast

Display contrast on the QED-6 may be adjusted to optimize viewing of menus and test data. To set display contrast:

1) From Main Menu 2, press the soft key corresponding to **UTIL**.

2) At the Utilities menu, press the soft key corresponding to **DISP** to access the display contrast menu.



3) Press the **-** (down) soft key to lower the numerical value and **increase the contrast**.

   Press the **+** soft key (up) to increase the numerical value and **decrease the contrast.**

The default is **5**. When **esc** is pressed, the last display value is stored in memory while power is off.

Computer Control Commands

The QED-6's RS-232 bi-directional interface allows communications with a PC. The computer may be used to send the commands to the QED-6.

The test data that is being gathered by the QED-6 is automatically sent to the PC via the RS-232 port for inclusion in a test form (created by Bio-Tek's OTIS Test Integration Software). The information that is sent to the computer is identical to the data sent to the printer. *The null modem supplied with the Bio-Tek serial cable is not required when data is being transferred to a computer.*

During operation, the QED-6 senses if an RS-232 cable or printer is attached, and sends data to the appropriate device. If neither is attached, test data appears on the display.

Communications Protocol

Refer to *Adjusting RS-232 Parameters*, page 3-6, to prepare the QED-6 for serial communications with an attached computer.

The computer and QED-6 should share the same Baud Rate, Parity, Data and Stop Bits. For example, if the QED-6 has been set up for a baud rate of **2400**, **No** Parity, **8** Data bits and **1** Stop bit, the COM port on the computer should be set to operate at these settings.

Initializing Computer Control

- To initialize computer control of the QED-6, send an "[" (open bracket) command from the computer.
- To release the QED-6 from computer control, send a Quit Com session command **[Q]** from the computer.

Computer Control Commands

QED-6 Functions	Computer Control Commands ( )
Quit COM session	(Q)
Return last result	(R)
Version of QED-6	(VER)
ECG 30	(W01)
ECG 60	(W02)
ECG 120	(W03)
ECG 180	(W04)
ECG 240	(W05)
Pulse 30 BPM	(W06)
Pulse 60 BPM	(W07)
Square wave 0.125 Hz	(W08)
Square wave 2 Hz	(W09)
Sin 10	(W10)
Sin 40	(W11)
Sin 50	(W12)
Sin 60	(W13)
Sin 100	(W14)
Triangle 2 Hz	(W15)
AFIB	(W16)

Computer Control Commands

QED-6 Functions	Commands ( )
AFLUT	(W17)
ATACH	(W18)
PVC 1	(W19)
RUN	(W20)
R on T	(W21)
IDIO	(W22)
VTACH	(W23)
VFIB	(W24)
Stop Waveform Output	(WSP)
Energy with VFIB	(NRG)
Energy with VTACH	(EVT)
Print a Header	(HDR)
Sync-Time BASE	(STB)
Sync-Time PEAK	(STP)
Peak Current	(PVT)
OVER Voltage	(OVT)
OVER Current	(OCR)
PACER Beats/Minute	(BPM)
PACER Volts	(PAV)
PACER Current	(PAC)
PACER Pulse Width	(PAW)
PACER Pulsed Refractory	(PRP)
PACER Sensed Refractory	(SRP)
Charge Time	(CRG)

Troubleshooting and Service

Section 4

This section provides a brief troubleshooting guide to help you pinpoint potential problems with the QED-6, and if necessary, obtain service or technical assistance from Bio-Tek Instruments.

Warranty

Bio-Tek warrants the QED-6 to the original purchaser for a period of one year from the original purchase date. The warranty covers normal use and service, as well as defective material or workmanship. If the customer ships the QED-6 Defibrillator Analyzer to Bio-Tek, postage prepaid, and Bio-Tek determines the defect to be in materials or manufacturing, Bio-Tek shall opt to repair or replace the unit without cost to the customer.

This warranty is void if the QED-6 is visibly damaged by accident, misuse, or repaired or altered by persons not authorized by Bio-Tek, or its serial number defaced or removed.

Bio-Tek Instruments reserves the right to discontinue the QED-6 at any time, or change specifications, price or design without notice and without incurring any obligation. Bio-Tek guarantees

availability of service parts for 5 years after the manufacture of the unit has been discontinued.

Parts shall include materials, charts, instructions, diagrams, and accessories furnished with the unit. The purchaser assumes all liability for any damages or bodily injury which may result from the use or misuse of the unit by the purchaser, his employees, agents or customers.

Storage and Shipping

The QED-6 should be stored between 25°C and 40°C with a relative humidity of 50%. The optional carry case is recommended for storage. It is recommended that the storage environment be free from vibration.

Troubleshooting

The chart on the following page provides basic troubleshooting information for the QED-6. Problems other than those described in this section should be referred to the Bio-Tek Service Department at 800.242.4685.

Description	Cause	Action
"Warning - low battery!!" indication on display	Low battery	Replace battery
Two beeps/sec. on power up	Defective RAM or incorrectly inserted RAM	Call factory
Four beeps/sec. on power up	Incorrectly inserted EPROM, misprogrammed EPROM or defective EPROM	Call factory
Infrequent resets during operation	Hi EMI fields produced by defib units	Reset power on QED-6 and continue operation.

Returning the QED-6 for Service

If repairs are required, the QED-6 should be returned to the factory.

Before returning the instrument, contact Bio-Tek's Service Department to obtain a **Return Material Authorization Number**. Record the RMA number in a prominent place on the outside of the packing box, and refer to the number in any correspondence with Bio-Tek Service.

Pack the instrument carefully, using the original packing materials, and insure for full value. If the original packing materials have been discarded or are unusable, call Bio-Tek for replacement packing or instructions. Failure to pack the instrument properly could void your warranty.

Return the instrument to:

Service and Repair
1420 75th Street SW
Everett, WA 98203
888-99FLUKE (888-993-5853) • 425-446-5560
http://www.flukebiomedical.com • sales@flukebiomedical.com

Theory of Operation

Section 5

The QED-6 defibrillator analyzer utilizes a microprocessor-based design and sophisticated algorithms to control all system activities.

Upon power-up of the instrument, the microprocessor receives software instructions from the resident firmware. The hardware and software integration provides valuable information to the user. This information is presented on the 2-line by 24-character display and can be output on the QED-6's asynchronous serial port.

The Load Board Assembly

The load board assembly encompasses the following functional blocks:

1) **50-Ohm Load** - The input load consists of one 50-ohm, 160-watt resistor. This resistance simulates the impedance of the human thorax under high-voltage pulse conditions.

2) **Differential Input Amplifier/Scope Output** - The input amplifier performs a differential voltage measurement across the input load. The Pacer, 1000 Joule and 100 Joule range switch on the front panel configures the diff-amp. Logic level signals are sent back to the microprocessor to record the switch setting. With a 4.12 volt full-scale output, the maximum allowable input voltage is approximately 12.8 volts for the Pacer range, 6000 volts for the 1000 J range and 1800 volts for the 100 J range.

   At the output of the diff-amp, the scope out amplifier performs a x1 buffer on the signal. The scope output signal is therefore a buffered 1:1 representation of the diff-amp output.

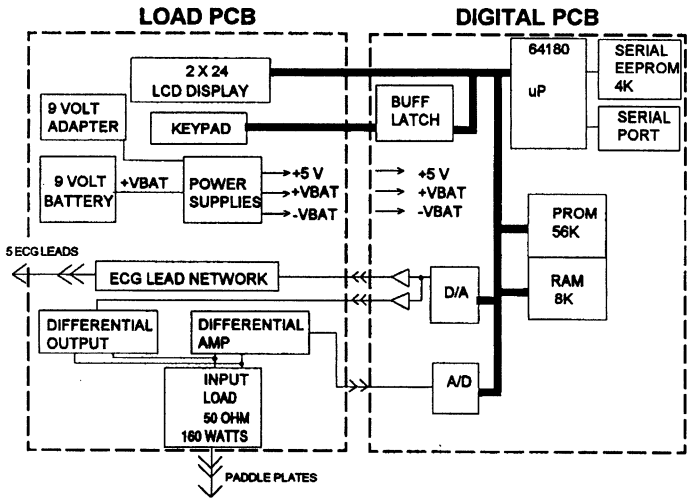


Figure 5.1. QED-6 Operational Block Diagram

3) **ECG Signal Paths** - The ECG signals are present at these locations: the paddles, ECG posts, and the high-level output. The single-ended ECG signal gets amplified differentially by a gain of x4 yielding an 8V differential output. This output is then presented across the 50-ohm input load after being scaled down by a factor of 1/7200 to give 1.11 mvolts on the paddles.

   This signal is sensed by automatic defibrillators to trigger the output pulse. The 1-Volt ECG signal is output at the high level output and input to the ECG lead divider network. The passive divider network scales the signal down by a factor of 1/1000 when differentially measuring the lead II configuration (LL)(RA), thus giving 1 mV.

4) **Power Supplies** - The QED-6 is powered by a 9-Volt alkaline battery. This source is converted into +5 Volts and -V battery with a linear regulator and a switched capacitor voltage converter. The +/- V battery supplies are used to power all the op amps while the +5V is used to power the digital electronics.

   Additionally, an external power jack is provided for use with a 9-VDC modular power source that plugs into the AC line. Plugging into this jack mechanically disconnects the battery.

5) **Key Pad** - The 5-position key pad is used to control the functions of the instrument. The microprocessor scans the keypad every 10 ms to check for key presses.

   Upon a key closure, a debounce algorithm is performed and if the key is valid then the soft key label on the display above the key is performed. Furthermore, when a key is pressed, a beep notifies the user that a successful key closure has occurred.

6) **Display** - The display is a 2-line by 24-character display which interfaces directly to the microprocessor bus.

   The display handshaking is handled by a digital logic block that satisfies all the display interfacing specifications. The

programmable contrast adjust is derived on the digital PC board and has a range of 0 - 0.4 volts.

The Digital Board Assembly

The Digital PC board assembly encompasses the microprocessor, memory, control and interface circuits, serial port, beeper, and the Digital-to-Analog and Analog-to-Digital functions.

1) **Microprocessor** - The 64180 microprocessor is a Z80-based microcontroller that contains 2 programmable timers, asynchronous and synchronous serial ports, DMA capability, Interrupts, and a low power sleep function.

   A 12.288 MHz crystal is divided by two in the processor to yield a 6.144 MHz system clock rate. The processor is configured by software to insert one wait state for all I/O instructions; this allows slow peripherals, such as the display, to function.

2) **Memory** - The memory consists of 56K of PROM, 8K of RAM, and 1024 bytes of EEPROM. The PROM contains the software necessary to control the QED-6 functions. Included is a checksum self check which verifies memory contents. If a checksum failure occurs a 4 Hz beep signals the user.

   The static RAM is used during program execution to hold data buffers and stack information. Upon power-up, a RAM test is performed to verify integrity of all locations. This is done by writing and reading 00h, 55h, and ffh to every location. Upon completion, the RAM is cleared with all zeros (00h). If a RAM test failure occurs, a 2 Hz beep signals the user.

   The serial EEPROM are two eight-pin devices that are electrically erasable/programmable. Each is configured for 512 bytes by grounding the (org) pins and are connected directly to the microprocessors high-speed synchronous

serial port to exchange information. The devices are used to store user-programmable information and setups, retaining this information while power is off. Since the devices require a specific stream of serial data to reprogram memory locations, the non-volatility of the information is extremely high.

3) **LCD Enable Circuit** - The LCD enable circuit provides the correct digital interface between the microprocessor and the LCD display. The display requires strict setup and hold times in order to function correctly, and this condition is satisfied by feeding a signal back to the WAIT input of the processor. The WAIT signal delays the processor's machine cycle long enough to allow the display's addressing criterion to be met.

4) **Serial Port -** The serial communications originates from the microprocessor's asynchronous serial port 0. The communications protocol is user-configurable, and the setup is performed by software internal to the processor.

   The logic level signal output from the processor's serial channel is converted to RS-232 levels (+/-5V to +/-15V) by a full duplex level translator (U2). The signals then flow through series resistors and are referenced to ground by transorbs to eliminate transients on peripheral equipment. Filter inductors are present in the serial cable, and placed at the connector near the peripheral device in order to filter EMI picked up by the cable. When the correct cable is connected to the serial port, a digital signal is pulled low to allow serial communications. If the incorrect cable is used then this signal remains high and serial communication is inhibited.

5) **Low Battery Detection** - The low battery detection circuit will output a low level digital signal when the battery voltage reaches 6.1 volts. This signal is polled along with the function keys every 10 ms and if a low battery condition occurs the display will indicate "WARNING - LOW BATTERY!!" In order to continue, replace the battery, or use an external power source.

6) **Contrast Adjustment** - The display contrast adjustment is performed by a 3-bit R2R ladder network, in conjunction with a summing op amp configuration. This configuration forms a basic 3-bit D/A function with 8 selectable levels. The total range is 0 - 0.4 volts, with a resolution of 50 mV. As the voltage decreases, the contrast becomes greater, making the display appear darker.

   The user interface is in the UTIL menu and one may select a contrast level from 0 - 7 with 7 providing the greatest contrast. Upon exiting from the contrast selection menu, the value selected is stored in the serial EEPROM memory and is retained until reprogrammed.

7) **Analog-to-Digital Conversion** -The defibrillator input signal from the LOAD PC board VDIFF flows through a 1 Kohm resistor with a corner frequency at 16 kHz. It then flows through a passive single pole filter network at the input to the A/D to bypass high-speed noise. The A/D is a bipolar 12-bit plus sign successive approximation type with a complete auto calibration feature. The CAL pin, when pulled low, performs a full-scale calibration for gain and linearity. With the AZ pin pulled low, an auto zero is performed on every conversion. With a 1.536 MHz clock frequency, the conversion rate is 20 microseconds. The reference voltage is nominally 4.12 volts which gives a 1.1 mV per-bit resolution for each of the 4095 bits.

8) **Digital to Analog Converter** - The D/A converter is an 8-bit type with a 1.235V reference yielding a 4.84 mV per-bit resolution. The converter is used to generate synthesized waveforms in order to verify ECG monitor integrity. The output flows through a x2 gain amp with a filter at 796 Hz. This signal is then offset and inverted to form a symmetrical signal with respect to ground. This signal flows to the load PC board and to the amplifier network that places the waveform on the paddles, then to the high-level network and the ECG lead network.

System Operation

1) **Energy Measurements** - Energy is mathematically defined as the integral over time of the power forcing function P(t). P(t) is defined as voltage as a function of time squared, divided by the load resistance. The unit of measure for energy of one Joule is equal to one Watt-Sec, and the energy delivered to a resistive load by a defibrillator is defined as follows:

$$\text{ENERGY} = \int P(t)\, dt$$

$$\text{Where, } P(t) = \frac{V(t)^2}{R}$$

Therefore,

$$\text{ENERGY} = \int \frac{V(t)^2}{R} dt$$

The QED-6 measures the energy output of a defibrillator by taking instantaneous voltage measurements every 104 microseconds across the 50-ohm load, 500 times giving a 52.08 ms measurement window. The QED-6 then extracts energy from these measurements by summing up the square of all the instantaneous voltages, multiplying by 104 microseconds, then dividing by the load resistance.

This computation is formally known as the RIEMANN SUM and is mathematically equivalent to the time integral for small dt. This relationship is shown on the following page.

$$\text{ENERGY} = \int \frac{V(2)^2}{R} dt = \left[\sum_{n=1}^{n=500} V(n)^2\right] \times \left[\frac{dt}{R}\right]$$

Where, $R = 50\ \Omega$

$dt = 104.166 \times 10^{-6}$ (sec)

Therefore,

$$\text{ENERGY} = \left[\sum_{n=1}^{n=500} V(n)^2\right] \times \left[\frac{104.166 \times 10^{-6}}{50}\right] \text{ Joules}$$

2) **Peak Measurements** - The peak voltage measurement is performed by scanning the 500 waveform samples after a pulse measurement is recorded and displaying the largest value. The peak current is then calculated by dividing this value by 50 ohms.

3) **Waveform Playback** - After an energy reading is taken, the 500 waveform samples reside in a RAM buffer. Upon request of playback, these values are scaled as output at the D/A converter. The waveform is played back with an expanded time base of 1 to 100 and can be recorded on an ECG monitor or strip chart.

4) **Sync Measurements** - The sync measurements are derived by counting the number of 104 microsecond interrupts that occur between the peak of the R-WAVE and the peak of the defibrillator pulse. This count is then displayed as the PEAK sync time. The base of the ECG signal occurs 29.2 ms before the peak, therefore the base time will be equal to (time peak + 29.2) ms. Both variables will overrange at 200 ms.

Pacer Output Measurements

Pacer output measurements consist of peak voltage, peak current, pulse width, and pulses per minute (PPM).

Since the waveform typically has a trapezoidal shape, the voltage and current measurements will be taken at the peak (***Figure 5.2***).

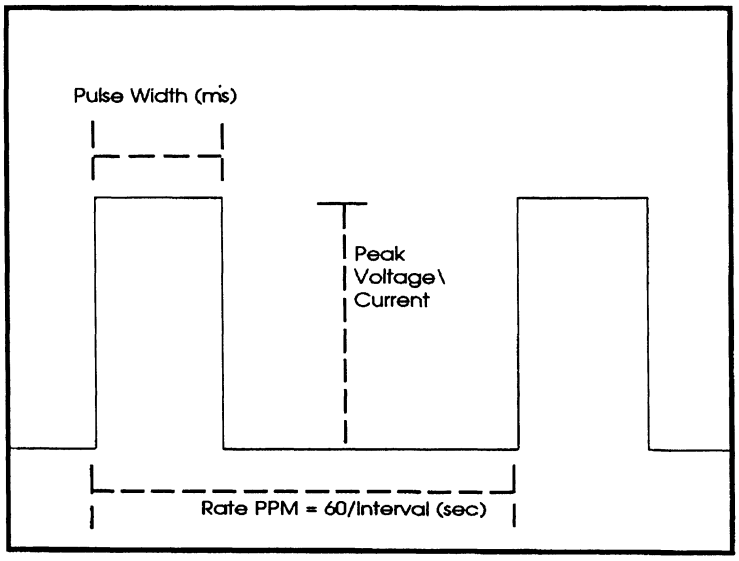


Figure 5.2*. Pacer Output Measurements*

Pulsed Refractory Period

The Pulsed Refractory Period is the time (typically 20-500 ms) after a pulse is delivered from the pacemaker, during which the pacemaker will not detect cardiac activity.

A. In ***Section A*** of ***Figure 5.3***, the QRS complex delivered from the QED-6 is within the refractory period of the pacemaker. The QRS from the QED-6 has no effect on the next pulse from the tested pacemaker.

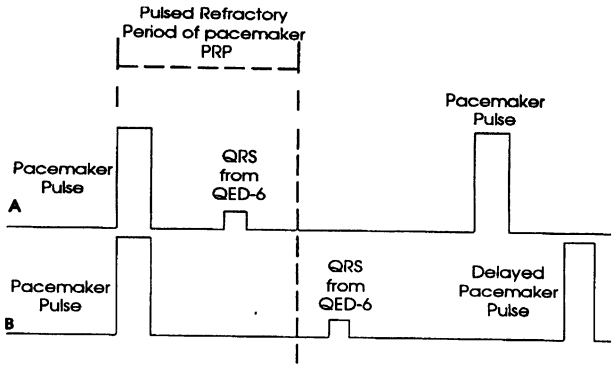


***Figure 5.3**. Pulsed Refractory Period*

B: In ***Section B*** of ***Figure 5.3***, the same pacemaker is being tested, but the QRS from the QED-6 is now on the opposite side of the line that indicates the pacemaker's Pulsed Refractory Period.

Notice that the next delivered pulse from the pacemaker has been delayed. The pacemaker has detected cardiac activity outside the pulsed refractory period of the pacemaker and has synchronized, starting at the peak of the R-Wave that exceeded the Refractory period. For example: if the pacer pulse rate is 60 PPM and an R-Wave exceeds the Pulsed Refractory period, then the next expected pacer pulse would occur 1 second following the peak of the R-Wave.

Note: The QRS complex delivered is a 1 mV, 40 ms triangle wave. All refractory measurements are determined from the peak of the R-wave.

QED-6 Operation

1. The QED-6 will determine the pulse rate of the pacemaker under test.

2. The QED-6 will output a single QRS complex with the

peak of the R-wave occurring 80 ms after the start of the pace pulse.

Note: The QRS complex for refractory period testing is output in the same fashion as ECG, performance or arrhythmias waveforms.

3. The QED-6 will keep incrementing or decrementing the delay from the start of the pacer pulse to the peak of the R-wave, until the Pulsed Refractory Period is determined to within a 1ms resolution. The delay at which the interval between pacer pulse changes will be displayed as the pulsed refractory period. The QED-6 should increment such that the Pulsed Refractory Period can be determined within 1 minute.

Sensed Refractory Period

Sensed Refractory Period (***Figure 5.4***) is the period after the pacemaker senses cardiac activity during which it will not detect further cardiac activity.

Note: All small amplitude pulses indicate simulated QRS from the QED-6. The first simulated R-wave is 25 ms beyond the Pulsed Refractory period.

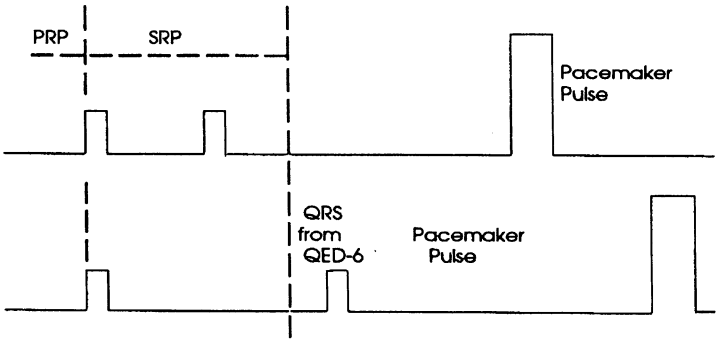


Figure 5.4*. Sensed Refractory Period*

A: The first simulated QRS is 25 ms after the predetermined Pulsed Refractory period of the pacemaker. The second QRS from the QED-6 is within the Sensed Refractory period of the pacemaker.

The first R-Wave causes the Pacer to re-synchronize its pulses staring from the peak of the R-Wave as described for Pulsed Refractory period. Since the second R-wave has not exceeded the Sensed Refractory period, then the next pacer pulse will occur synchronized to the first R-Wave. For example: If the pacer pulse rate is 60 BPM, then the next expected pacer pulse would occur 1 second following the peak of the first R-Wave.

B: The first simulated QRS is 25 ms after the predetermined Pulsed Refractory Period of the pacemaker. The second QRS from the QED-6 is outside the Sensed Refractory Period of the pacemaker. This condition causes the Pacer to synchronize its output to the Peak of the second R-Wave. (Example: If the pacer pulse rate is 60 BPM, then the next expected pacer pulse would occur 1 second after the peak of the second R-Wave.)

QED-6 Operation

1. The QED-6 will determine the Pulsed Refractory Period as described in the previous section. The QED-6 will then output the first R-wave 15 ms beyond the Pulsed Refractory Period point, followed by a second R-wave 100 ms beyond the Pulsed Refractory Period.

2. The QED-6 will continue incrementing or decrementing the delay between the first and second R-wave until the Sensed Refractory Period is determined within a 1 ms resolution. The delay is measured between the Pulsed Refractory Period and the peak of the second simulated R-wave, and is displayed as the sensed Refractory period.

Calibration Procedure

Section 6

Equipment Required

- DMM (DC voltage, DC current, resistance, and null function)

  Defib/Pacer (Physio-Control LIFEPAK® 9P or equivalent)

  DC Calibrator Station

  DC Variable Power Supply

  Serial Cable (3360500)

  Serial Printer (97115)

  Pulse Generator (Wavetek Model #75)

  External Power Source (61053)

  Pacer Plate Adapters (3370503) quantity (2)

Detailed Procedure

1) **Remove berg jumpers from BG1 on load board.**

Measure input load impedance using a DMM. Plug banana cables into plate screws. The load impedance should be 50.0 +/- .5 ohms. Record the load impedance on data sheet.

On the load board, measure differential input impedance using a DMM. Clip ball clip leads to TP9 and TP7. The differential impedance should be 3.01 M +/- 3 Kohms. Record on the data sheet. Clip ball clip leads to TP8 and TP6. The differential impedance should be 3.01 M +/- 3 Kohms. Record on the data sheet.

2) **Reinstall berg jumpers.**

Connect the variable power supply to the battery connector on QED-6 (pos to red wire and common to black wire). Adjust the supply to 8.5 VDC +/- .5 V. Set range switch to **100 Joules**. Turn QED-6 **ON.**

Check supply voltages.

Load Board:	
TP1 (common) to TP4	+5 VDC +/- .25V
TP1 (common) to TP2	-8 VDC +/- .4V
Digital Board:	
TP3 (common) to +5 A	+5 VDC +/- .25 V
TP3 (common) to -5 A	-5 VDC +/- .25 V

Check total current draw.

At the main menu, measure the current from the DC supply using the DMM. Current should be less than 40 mA.

Check low battery circuit.

Slowly decrease the voltage level from the DC supply until **WARNING-LOW BATTERY!** appears on the display. Measure the voltage on the analog board at TP3 (common) and TP4 (+VBATT). The voltage should be between 5.8 VDC and 6.2 VDC. Turn the QED-6 **OFF**. Disconnect the variable power supply.

Attach the external power source (61053) to the QED-6 at the external power jack.

Turn the QED-6 **ON**. On the load board, measure the voltage between TP3(+) and TP1(common) and verify that it is 8-12 volts DC. Record results.

Check the soft keys.

Each time a key is pressed, there should be a short beep. At Main Menu 1, press the soft key corresponding to **ENRG**. The display should change.

Press the **esc** key and repeat this procedure for the **SYNC**, **PEAK**, and **WAVE** keys. The menu structure is detailed in Section 2, ***Figure 2.2.1***.

Check the EEPROM storage.

At Main Menu 1, press the **more** key to access Main Menu 2. Press the key corresponding to **UTIL**, then press the **DISP** key. Set the contrast to **5**, using the **UP** and **DOWN** keys.

Press the **esc** key and turn the unit **OFF** and then **ON**. Move to Main Menu 2, and press the **UTIL** key, then **DISP**. The contrast setting should be at **5**.

Check the serial port operation.

Attach the serial cable to the QED-6 and the printer. Press the **esc** key and then the **R232** key. Press the soft key corresponding to each parameter to set up the display as follows: **BAUD** (2400), **PAR** (N), **DATA** (8), **STOP** (1).

Press the **esc** key, to return to Main Menu 2. Press the **more** key to move to Main Menu 1. Press the **ENRG** key then the **HEDR** key. The following header should be printed (***Figure 6.1***).

Bio-Tek Instruments Inc

Control#:_____
Serial#:_____
Model#:_____
Mfr:_____
Location:_____
Technician:_____
Date:_____

Figure 6.1. Serial Port Header

Disconnect the serial cable.

3) **On the load board, connect the positive output of the calibrator to TP6 and the negative output to TP7.**

At Main Menu 2, press the UTIL key, and then the CAL key.

Input 0.00 VDC from the calibrator. Select each range on the range switch and verify that the count is 0 +/- 2 for each position.

Switch to Pacer range.

Input +303 mVDC from the calibrator. Adjust RT1 on the Digital PCB until the A/D count on the display equals -3000 counts. Check off data sheet.

Input -303 mVDC from the calibrator. Verify that the count is +3000 +/- 15 counts. Record the results on the data sheet. Set the calibrator to STDBY. Lock trimpot RT1 on Digital PCB.

Select 1000 Joules range.

Input +57vdc from the calibrator. The display should read -1213 +/-15 counts. Record results on data sheet. Set calibrator to STDBY.

Select 100 Joules range.

Input +57 VDC from the calibrator. The display should read -4000 +/-15 counts. Record results on data sheet. Set the calibrator to STDBY.

Connect the DVM between the DEFIB output(+) and the ground jack(-) on the QED-6 front panel. Select 100 Joules range.

Input 57 VDC from the calibrator. The voltage read should be (3.96 - 4.12 VDC). Record the results on the data sheet. Set the calibrator to STDBY.

Press the **esc** key twice. Press the **more** key once, then press the **ENRG** key once.

Input +9.45 VDC from the calibrator. The reading displayed should be (87.2-92.8 Joules). Record the results on the data sheet. Set the calibrator to STDBY.

4) **Disconnect the output cable from the calibrator and connect it to the output of the pulse generator.**

Set the output of the pulse generator as follows:

Output amplitude	10 V
Pulse width	50 ms
Pulse delay	300 ms
Auto trigger continuously	
Sync off rising edge	

Connect TP1 (Trigger 1) on the digital board to the EXT Input on the pulse generator and reference to TP7.

Check sync operation.

Select the 100 J range. Press the **esc** key to return to Main Menu 1, then press the **SYNC** key. The **SYNC TIME PEAK** should be 80 +/-2 ms.

Record the results on the data sheet, and disconnect the pulse generator. Press the **esc** key to return to the Main Menu 1.

5) Use the following tests to verify differential output amplitudes at three locations for the ECG signals.

When performing these tests, null the DVM when the signal goes low, and record the voltage level when the signal goes high.

Verify amplitude at the ECG output banana jack.
Connect the (+) lead to the ECG banana jack and the (-) lead to the ground banana jack on the unit. Press the **WAVE** key, then the **PERF** key. Select the .125 Hz Sq performance wave using the **UP** key.

Using the DVM and the nulling procedure described in this section, verify that the voltage is toggling between (0 - 1 vdc) +/-.02vdc. Record on the data sheet.

Verify the amplitude at the ECG lead II output.
Connect the (+) lead to LL and the (-) lead to RA ECG posts.

Using the DVM and the nulling procedure described in this section, verify that the voltage is toggling between (0 - 1 mvdc) +/-.02 mvdc. Record on data sheet.

Verify the amplitude at the contact plates.
Connect the (+) lead to the APEX and the (-) lead to the STERNUM.

Using the DVM and the nulling procedure described in this section, verify that the voltage is toggling between (0 - 1.1 m VDC) +/- .11 m VDC. Record on the data sheet.

Disconnect all test leads. Turn unit **OFF**.

6) Install new battery (P/N 47002).

Place top shroud on the base without using screws (screws will be installed at the final inspection phase). Reconnect the serial cable to the QED-6.

Check energy measurements.

Turn the QED-6 on, and press the **ENRG** key.

Set the QED-6 range switch to **100 Joules.** Set defibrillator output to 50 watt-seconds. Place the paddles on the QED-6 contact plates and defibrillate. The QED-6 reading should be approximately 50.0 Joules.

Set the defib to 200 watt-seconds and defibrillate. **OVER** should be displayed.

Set the QED-6 range switch to **1000 Joules.** Set the defibrillator to 200 watt-seconds and defibrillate. The QED-6 reading should be approximately 200.

Set the defibrillator to 360 watt-seconds and defibrillate. The QED-6 reading should be approximately 360 Joules. Verify that the results are printed on the printer.

Check sync operation.

Attach the patient snap leads to the ECG posts on the QED-6.

Turn the defibrillator on and select lead II.

Press the **esc** key, and then the **SYNC** key on the QED-6.

Set the sync to **ON** and set to 50 watt-seconds. There should be an ECG waveform on the defibrillator monitor at this time. Place the paddles on the QED-6 plates, and press the buttons on the paddles.

The defibrillator will fire at the next R wave.

After the **PEAK** reading is displayed, press the **BASE** key and verify that both the PEAK and BASE times are printed on the printer.

Make a strip of 60 BPM Pulse on the recorder.
Press the **esc** key to return to Main Menu 1.

Press the **WAVE** key then the **PERF** key. Use the **UP** key to select **60 BPM Pls**. Verify that the defibrillator ECG monitor is still configured, and make a strip of the waveform. Attach the strip to the data sheet.

Check the pacer measurement operation.
Attach the patient snap leads from the defibrillator unit to the ECG posts on the QED-6.

Set the QED-6 range switch (on the front panel) to **Pacer**.

Move to Main Menu 2, and press the soft key that corresponds to **Pacer**. Press the **MEAS** key.

Turn the defibrillator unit on, and connect the pacer cable to the QED-6 using the pacer plate adapters.

Enable the pacing module on the defibrillator unit. Select 100 BPM and adjust the output current knob until the QED-6 display reads 100 +/- 10 mA.

Press the **PRINT** key and verify the results are printed on the printer. Attach the printout which includes **HEADING**, **ENERGY**, **SYNC**, and **PACER** to the data sheet.

7) Calibration is complete. Remove the serial cable and turn the QED-6 off.

Closed Box Test Procedure

Appendix A

The following procedure has been written to provide a closed box test to verify performance of QED-6 measurements and simulations.

Equipment Required:

- DMM (HP 34401A, Keithly 191, or equivalent)
- DC Power Supply (capable of 0-12 Volts DC 250 mA
- Function Generator (4 Hz 20% duty cycle, 50 ms pulse width, 4 Volts)
- Digital Oscilloscope (HP54502A or equivalent)
- Defibrillator
- Defibrillator Analyzer (Electronics Unlimited DT-650)
- Bio-Tek RS-232 cable (BTI# 3360504)
- IBM compatible computer
- Terminal Emulation Software such as QMODEM or PROCOMM

1. 50-Ohm Load

Using the DVM, measure the resistance between the Apex and Sternum. Resistance will be 50 +/- 0.5 Ohms.

Record results in Section 1.0 of the data sheet.

2. Amplitude Accuracy

Connect a DC Power Supply across the Apex(+) and Sternum.

Connect the DVM in parallel with DC Power Supply.

Set the range switch (on the front panel) to **Pacer**.

Turn the QED-6 **ON**.

From Main Menu 1, press the **more** key to access Main Menu 2.

At Main Menu 2, press **UTIL**.

Select the **CAL** option on the QED-6 **UTIL** menu.

Input the following voltage:
+/- 0.001 volts

Input Voltage	**Counts Displayed**	**+/-1% +/- 1 LSD**
2.000	- 637	7
6.000	-1910	20
10.000	-3184	32
12.000	-3820	39

Record results in Section 2.0 of the data sheet.

3. Time Base Accuracy

Attach the output of a Function Generator to the QED-6 Apex(+) and Sternum (-).

Attach an oscilloscope in parallel with the Function Generator.

Set the oscilloscope to x10.

Set the Function Generator for 4.00 Hz and 10% duty cycle (25 ms pulse width square wave).

Set the output amplitude for 4.000 volts +/- 0.025 Volts.

Note: Waveform should have 0.000 to -0.005 Volts DC Offset.

Select **PACE** from Main Menu 2 and **MEAS** from Pacer Tests.

Verify that the QED-6 is displaying 25 ms pulse width (+/- 1 ms) and 240 BPM (+/- 1 BPM)

Record results in Section 3.0 of the data sheet.

4. Output Energy Verification

Return to Main Menu 1

Press **ENRG** and make sure the range switch is set to 100 Joules.

Set the defibrillator to the following settings:

- First Discharge the defibrillator into a calibrated energy analyzer such as the Electronics Unlimited DT-650. Then, at the same setting, discharge the defibrillator into the QED-6. Compare the readings between the DT-650 and the QED-6.

- Repeat the above procedure at the following settings: 50, 200, 300 Joules

Note: for measurements above 100 Joules, switch the range switch to 1000 Joules.

Results are dependent on the Accuracy of the defibrillator plus the accuracy of the DT-650 plus the accuracy of the QED-6. Sections 2 and 3 ensure the accuracy of the QED-6.

Record results in Section 4.0 of the data sheet.

5. Waveforms

Attach an oscilloscope to the ECG High Level output jacks (scope impedance of 10 Mohm).

Set the oscilloscope to x10.

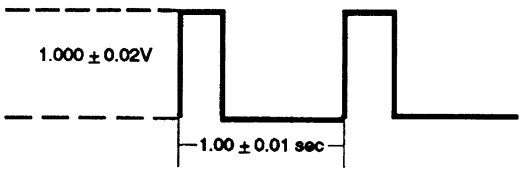
At Main Menu 1, press **Wave.** At **Waveform Type** press **PERF**. Select the 60 BPM PLS waveform.

Verify the amplitude and time base on the oscilloscope.

Amplitude: 1.000 Volt +/- 20 mV
Rate: 1.000 sec +/- .01 Sec

Note: Rate is measured from the start of each pulse.

Record results in Section 5.0 of the data sheet.



6. RS-232

From Main Menu 1, press the **more** key to access Main Menu 2.

From Main Menu 2, press the **UTIL** key. Select the **RS-232** option and set the parameters with the following values:

BAUD	PAR	Data	Stop
2400	N	8	1

Attach a 3360500 serial cable between the serial port of the QED-6 and the COM1 port of the computer.

Load a data communications program such as QMODEM or PROCOMM. Set the software in terminal emulation mode. Make sure the software **baud** rate agrees with the QED-6 (see settings above).

Return to Main Menu 1. Press **ENRG**. Press **HEDR**. The following header should appear on the computer screen:

```
Bio-Tek Instruments, Inc

Control #:_____________________
Serial  #:_____________________
Model #:_____________________
Mfr:_____________________
Location:_____________________
Technician:_____________________
Date:_____________________

Setting         Actual
```

Record **Pass** or **Fail** in section 6.0 of the data sheet.

This completes the test procedure for the QED-6 Closed Box Test.

QED-6 Closed Box Inspection Data Sheet

Serial #: _____

Date: _____

Tested By: _____

1. 50 ohm Test

_____ +/- .5 ohms

2. Amplitude Accuracy

Input Voltage	Actual counts	+/-	Limit
2.000	_____	637	7
6.000	_____	1910	20
10.000	_____	3184	32
12.000	_____	3820	39

3. Time Base Accuracy

4.0 volts +/- .1 volts
_____ Current 80.0 mA +/- 2 mA
_____ pulse width 25 ms +/- 1 ms
_____ rate 240 BPM +/- 1 BPM
_____

---

4. Output Energy

Setting	QED-6	DT-650
50	_____	_____
200	_____	_____
300	_____	_____

---

5. Waveforms

Amplitude _____ 1 Volt +/- 20 mV
Rate _____ 1.000 seconds
+/- .01 sec

---

6. RS-232 (check one)

Pass

Fail

QED-6