FLUKE®
Biomedical

Impulse 6000D

Defibrillator Analyzer

Impulse 7000DP

Defibrillator/Transcutaneous Pacer Analyzer

Users Manual

August 2007, Rev. 1, 1/08

Warranty and Product Support

Fluke Biomedical warrants this instrument against defects in materials and workmanship for one year from the date of original purchase OR two years if at the end of your first year you send the instrument to a Fluke Biomedical service center for calibration. You will be charged our customary fee for such calibration. During the warranty period, we will repair or at our option replace, at no charge, a product that proves to be defective, provided you return the product, shipping prepaid, to Fluke Biomedical. This warranty covers the original purchaser only and is not transferable. The warranty does not apply if the product has been damaged by accident or misuse or has been serviced or modified by anyone other than an authorized Fluke Biomedical service facility. NO OTHER WARRANTIES, SUCH AS FITNESS FOR A PARTICULAR PURPOSE, ARE EXPRESSED OR IMPLIED. FLUKE SHALL NOT BE LIABLE FOR ANY SPECIAL, INDIRECT, INCIDENTAL OR CONSEQUENTIAL DAMAGES OR LOSSES, INCLUDING LOSS OF DATA, ARISING FROM ANY CAUSE OR THEORY.

This warranty covers only serialized products and their accessory items that bear a distinct serial number tag. Recalibration of instruments is not covered under the warranty.

This warranty gives you specific legal rights and you may also have other rights that vary in different jurisdictions. Since some jurisdictions do not allow the exclusion or limitation of an implied warranty or of incidental or consequential damages, this limitation of liability may not apply to you. If any provision of this warranty is held invalid or unenforceable by a court or other decision-maker of competent jurisdiction, such holding will not affect the validity or enforceability of any other provision.

7/07

Notices

All Rights Reserved

Copyright Release

Fluke Biomedical agrees to a limited copyright release that allows you to reproduce manuals and other printed materials for use in service training programs and other technical publications. If you would like other reproductions or distributions, submit a written request to Fluke Biomedical.

Unpacking and Inspection

Follow standard receiving practices upon receipt of the instrument. Check the shipping carton for damage. If damage is found, stop unpacking the instrument. Notify the carrier and ask for an agent to be present while the instrument is unpacked. There are no special unpacking instructions, but be careful not to damage the instrument when unpacking it. Inspect the instrument for physical damage such as bent or broken parts, dents, or scratches.

Technical Support

For application support or answers to technical questions, either email techservices@flukebiomedical.com or call 1-800- 648-7942 or 1-425-446-6945.

Claims

Our routine method of shipment is via common carrier, FOB origin. Upon delivery, if physical damage is found, retain all packing materials in their original condition and contact the carrier immediately to file a claim. If the instrument is delivered in good physical condition but does not operate within specifications, or if there are any other problems not caused by shipping damage, please contact Fluke Biomedical or your local sales representative.

Standard Terms and Conditions

Refunds and Credits

Please note that only serialized products and their accessory items (i.e., products and items bearing a distinct serial number tag) are eligible for partial refund and/or credit. Nonserialized parts and accessory items (e.g., cables, carrying cases, auxiliary modules, etc.) are not eligible for return or refund. Only products returned within 90 days from the date of original purchase are eligible for refund/credit. In order to receive a partial refund/credit of a product purchase price on a serialized product, the product must not have been damaged by the customer or by the carrier chosen by the customer to return the goods, and the product must be returned complete (meaning with all manuals, cables, accessories, etc.) and in "as new" and resalable condition. Products not returned within 90 days of purchase, or products which are not in "as new" and resalable condition, are not eligible for credit return and will be returned to the customer. The Return Procedure (see below) must be followed to assure prompt refund/credit.

Restocking Charges

Products returned within 30 days of original purchase are subject to a minimum restocking fee of 15 %. Products returned in excess of 30 days after purchase, but prior to 90 days, are subject to a minimum restocking fee of 20 %. Additional charges for damage and/or missing parts and accessories will be applied to all returns.

Return Procedure

All items being returned (including all warranty-claim shipments) must be sent freight-prepaid to our factory location. When you return an instrument to Fluke Biomedical, we recommend using United Parcel Service, Federal Express, or Air Parcel Post. We also recommend that you insure your shipment for its actual replacement cost. Fluke Biomedical will not be responsible for lost shipments or instruments that are received in damaged condition due to improper packaging or handling.

Use the original carton and packaging material for shipment. If they are not available, we recommend the following guide for repackaging:

- Use a double–walled carton of sufficient strength for the weight being shipped.
- Use heavy paper or cardboard to protect all instrument surfaces. Use nonabrasive material around all projecting parts.
- Use at least four inches of tightly packed, industry-approved, shock-absorbent material around the instrument.

Returns for partial refund/credit:

Every product returned for refund/credit must be accompanied by a Return Material Authorization (RMA) number, obtained from our Order Entry Group at 1-800-648-7952 or 1-425-446-6945.

Repair and calibration:

To find the nearest service center, go to www.flukebiomedical.com/service or

In the U.S.A.:
Cleveland Calibration Lab
Tel: 1-800-850-4606
Email: globalcal@flukebiomedical.com

Everett Calibration Lab
Tel: 1-888-99 FLUKE (1-888-993-5853)
Email: service.status@fluke.com

In Europe, Middle East, and Africa:
Eindhoven Calibration Lab
Tel: +31-402-675300
Email: ServiceDesk@fluke.com

In Asia:
Everett Calibration Lab
Tel: +425-446-6945
Email: service.international@fluke.com

Certification

This instrument was thoroughly tested and inspected. It was found to meet Fluke Biomedical's manufacturing specifications when it was shipped from the factory. Calibration measurements are traceable to the National Institute of Standards and Technology (NIST). Devices for which there are no NIST calibration standards are measured against in-house performance standards using accepted test procedures.

WARNING

Unauthorized user modifications or application beyond the published specifications may result in electrical shock hazards or improper operation. Fluke Biomedical will not be responsible for any injuries sustained due to unauthorized equipment modifications.

Restrictions and Liabilities

Information in this document is subject to change and does not represent a commitment by Fluke Biomedical. Changes made to the information in this document will be incorporated in new editions of the publication. No responsibility is assumed by Fluke Biomedical for the use or reliability of software or equipment that is not supplied by Fluke Biomedical, or by its affiliated dealers.

Manufacturing Location

The Impulse 6000D and 7000DP Defibrillator/Transcutaneous Analyzers are manufactured at Fluke Biomedical, 6920 Seaway Blvd., Everett, WA, U.S.A.

Table of Contents

Title **Page**

List of Tables

List of Figures

Defibrillator Analyzer

Introduction

The Impulse 6000D and 7000DP (hereafter the Analyzer) are portable, battery-powered precision instruments for testing external defibrillators. The 7000DP has the added capability of testing trancutaneous pacemakers. Where the additional pacemaker testing capability is applicable, this manual qualifies the description with “7000DP only.” The model 7000DP appears in all product illustrations.

Intended Use

The Analyzer is used to determine that defibrillators and transcutaneous pacemakers are performing within their performance specifications through measurement of energy output.

Unpacking the Analyzer

Carefully unpack all items from the box and check that you have the following items:

- Impulse 6000D or 7000DP
- Battery charger
- Getting Started Manual
- Users Manual CD
- Defib paddle contact plates
- Impulse 6000D 7000DP Ansur Software CD (demo)

Table 1. Symbols

Symbol	Description
	Important information; refer to manual.
	Do not dispose of this product as unsorted municipal waste. Go to Fluke's website for recycling information.
	Conforms to relevant Australian EMC requirements
	Conforms to relevant Canadian and US standards
	Hazardous voltage
	Conforms to European Union directives
CAT I	IEC Measurement Category I – CAT I equipment designed to protect against transients in equipment on circuits not directly connected to MAINS. Under no circumstances should the terminals of the Analyzer be connected to any MAINS voltage.

Safety Information

In this manual, a **Warning** identifies hazardous conditions and actions that could cause bodily harm or death. A **Caution** identifies conditions and actions that could damage the Analyzer, the equipment under test, or cause permanent loss of data.

⚠⚠ Warning

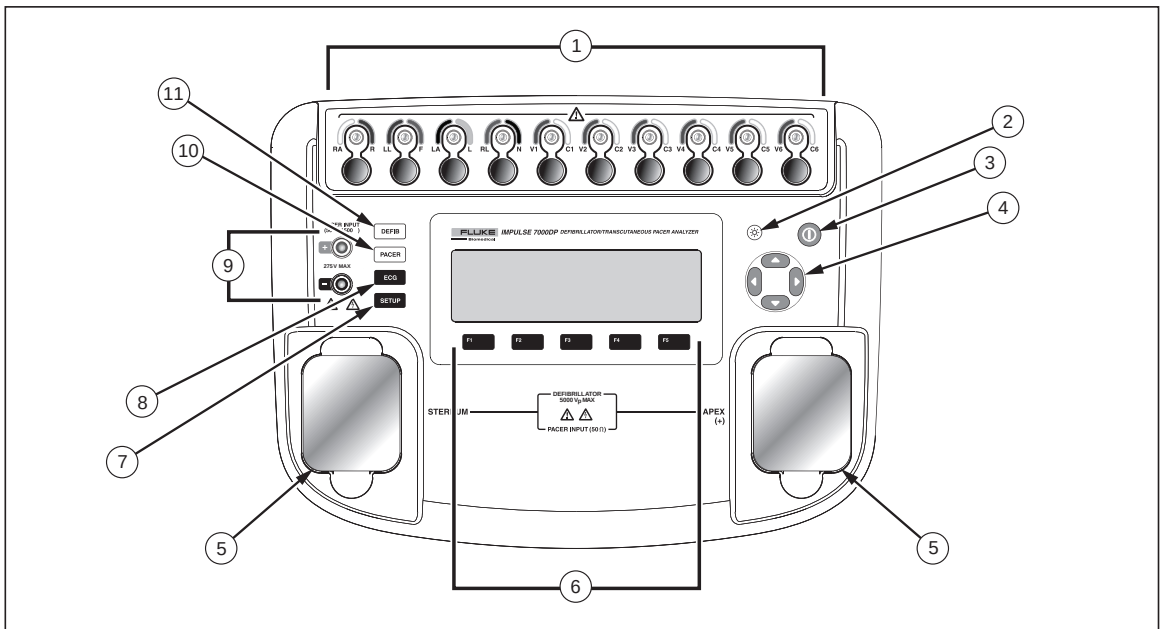
To avoid possible electrical shock or personal injury, follow these guidelines:

- **Use this Analyzer only in the manner specified by the manufacturer or the protection provided may be impaired.**
- **Read the Users Manual before operating the Analyzer.**
- **Do not use the product if it operates abnormally.**
- **Do not use the product in wet locations, around explosive gases or dust.**

- **Do not operate the Analyzer with the battery eliminator connected, unless connected directly to mains power. During battery operation, completely remove the battery eliminator/charger from both the Analyzer and wall socket.**
- **Do not connect the Analyzer to a patient or equipment connected to a patient. The Analyzer is intended for equipment evaluation only and should never be used in diagnostics, treatment or in any other capacity where the Analyzer would come in contact with a patient.**
- **Observe all precautions noted by the Device Under Test (DUT) equipment manufacturer when analyzing the DUT.**
- **Use extreme caution when working with voltages above 30 volts.**
- **Use the proper terminals, functions and ranges for the test being performed.**

Instrument Familiarization

Figure 1 and Table 2 describes the top-panel controls and connections of the Analyzer.



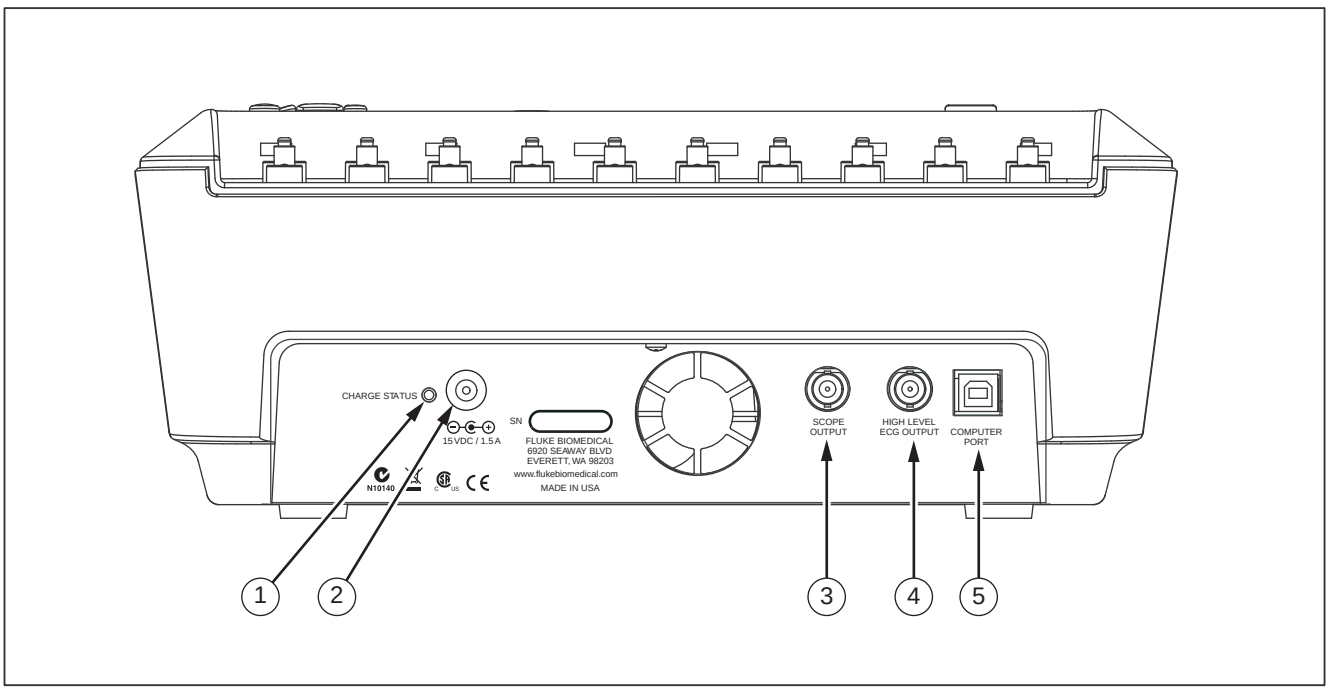
fak07.eps

Figure 1. Top-Panel Controls and Connections

Table 2. Top-Panel Controls and Connections

Item	Name	Description
1	ECG lead connectors	Outputs of low-level ECG signals (RA/R, LL/F, LA/L, RL/N, V1/C1, V2/C2, V3/C3, V4/C4, V5/C5, and V6/C6).
2	Backlight button	Turns the LCD display backlight on and off.
3	Power button	Turns the Analyzer on and off.
4	Navigation buttons	Cursor control buttons for navigating menus and lists.
5	Defib connectors	Defibrillator connections (Shown with removable defib paddle contact plates installed).
6	Function softkeys	Keys F1 through F5 are used to select from a number of selections that appear in the LCD display above each function softkey.
7	Setup button	Opens the setup menu.
8	ECG button	Opens the main menu for ECG test functions.
9	Pacemaker inputs	Input for low-level Pacer signal (7000DP only).
10	Pacer button	Opens the main menu for pacer test functions (7000DP only).
11	Defibrillator button	Opens the main menu for defibrillator test functions.

Figure 2 and Table 3 describes the rear-panel connections of the Analyzer.



fak08.eps

Figure 2. Rear-Panel Connections

Table 3. Rear-Panel Connections

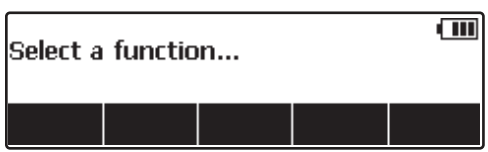
Item	Name	Description
1	Charge Status LED	Indicates RED while battery is charging. Indicates GREEN when the battery is fully charged and the charger is still connected.
2	Battery Charger connector	Input connector for attaching the battery charger to the Analyzer.
3	Scope output	Output signal jack for displaying the defib playback wave on an oscilloscope.
4	Hi-level ECG output	High-level ECG signal output jack for oscilloscope viewing.
5	Computer Port	Device Port (B-style USB) for controlling the Analyzer from a PC or instrument controller.

Turning the Analyzer On and Off

Note

Before using the Analyzer for the first time, plug the battery charger into the Analyzer and a power outlet and charge the Analyzer for at least 4 hours.

Press the power button (⏻) on the top panel to turn the Analyzer on. After a short self-test period, the Analyzer will display the screen shown in Figure 3 to indicate it is ready for operation.



fak01.eps

Figure 3. Analyzer Ready Display

Battery condition is displayed in the upper right-hand corner of the display (🔋) when a top-level menu is displayed. When a low battery is indicated, attach the battery charger to the Analyzer and plug it into a power outlet.

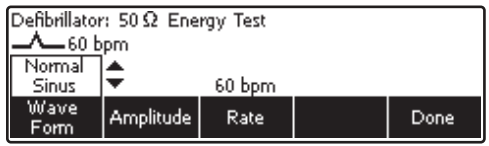
Accessing the Analyzer Tests

The Analyzer uses a series of menus to access various Analyzer functions and setup variables. As shown in Figure 4, the Analyzer indicates three different defibrillator tests (Energy, Sync, and Charge Time) along the bottom of the display. An Exit selection is also indicated as a way of backing out of the defibrillator tests. Pressing a softkey (F1 through F5) under a specific test will cause that test to be selected.

fak02.eps

Figure 4. Defibrillator Menu

Some menu selections reveal a list of selectable items by displaying ⬍ to the right of the presently selected item. See Figure 5. To change the selection, press either ⌃ or ⌄ to scroll through the possible selections. Once the desired selection appears, press the function softkey and ⬍ disappears from the display.



fak03.eps

Figure 5. Cursor Navigation Example

Analyzing Defibrillators

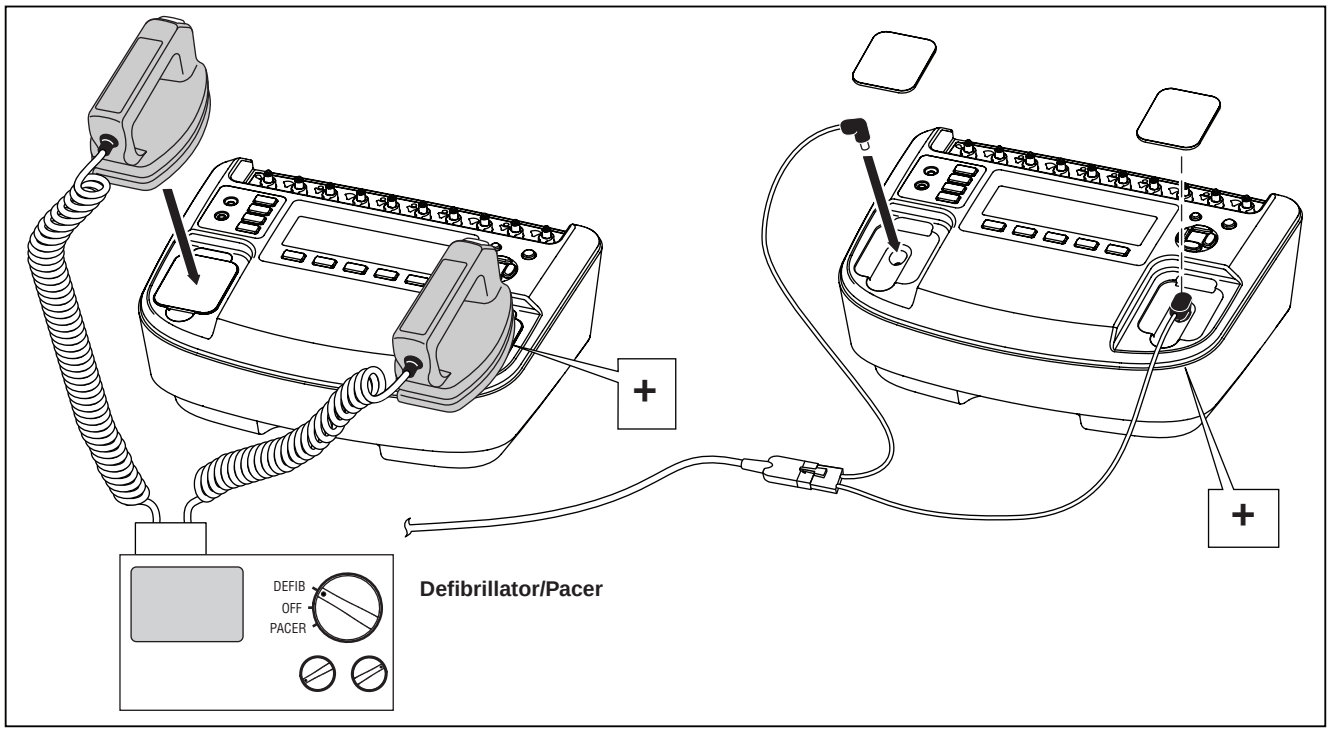
There are three main defibrillator test functions to evaluate a defibrillator's performance: Energy, Synchronization, and Charge Time. To set the Analyzer for defibrillator testing, press DEFIB.

The Analyzer's defibrillator input connectors are designed to be used with test leads or adapter plates when testing defibrillators using external paddles.

Connect the defibrillator to the Analyzer as shown in Figure 6.

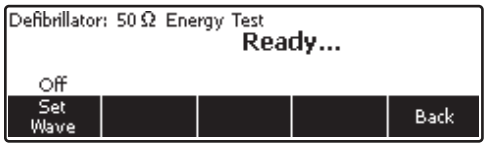
Testing Energy Levels

Press the softkey labeled **Energy** to enter the energy test procedure. As shown in Figure 7, the Analyzer has a waveform selection already set. Either the waveform characteristic is off or it was the last one setup from a previous defibrillator test.



fak11.eps

Figure 6. Defibrillator Test Connections



fak04.eps

Figure 7. Defibrillator Energy Test

If the waveform characteristics are correct, then charge the defibrillator using one of the energy settings, and with the defib paddles on the Analyzer's input, press the discharge button. The Analyzer senses the discharge and the energy delivered appears in the display in Joules.

Changing Waveform Characteristics

If the waveform characteristics are not the desired ones, press the softkey labeled **Set Wave**. The waveform, its amplitude, and frequency are new softkey selections. Press the softkey under the signal attribute you want to change. Use ▲ or ▼ to scroll through all the values. Once the desired value is set, press the softkey under the adjusted characteristic. This same process applies to Amplitude and Rate selections as well. With the three parameters set, press the softkey labeled **Done** to return to the discharge ready state.

The softkey labeled **Summary** provides additional information about the current discharge waveform depending on the defibrillator type tested. For dc Monophasic: peak voltage, peak current and pulse width. For dc bi-phasic: peak and average voltage, peak and average current, pulse width, interphase delay, and overall tilt. For ac bi-phasic: all dc bi-phasic data and ac carrier base frequency and duty cycle.

Note

AC Pulsed Bi-Phasic waveform has not been approved in the United States.

Testing Defibrillator Synchronization

From the Defibrillator main menu, press the softkey labeled **Sync**. As shown in Figure 8, the waveform selection is already set.

fak05.eps

Figure 8. Defibrillator Synchronization Test

The test measures the response of the defibrillator in its synchronous (sync) mode. Place the defibrillator in this mode. The defibrillator will now synchronize its discharge pulse with the ECG heart rate. The sync time measured is

the time from the ECG heart beat ‘R’ wave to the onset of the defibrillator pulse.

If the waveform characteristics are not correct, then change the characteristics as explained in the “Changing Waveform Characteristics” section earlier in this manual.

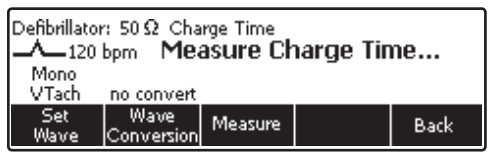
With the waveform set to the desired characteristics, charge the defibrillator and discharge it into the Analyzer’s defibrillator inputs. The Analyzer senses the discharge and the measured delay appears in the display.

The Analyzer can automatically identify the correct defibrillator waveforms delivered by the defibrillator under test. The softkey labeled **Summary** provides information about the current discharge waveform depending on the defibrillator type tested. For dc monophasic: peak voltage, peak current and pulse width. For dc bi-phasic: peak and average voltage, peak and average current, pulse width, interphase delay, and overall tilt. For ac bi-phasic: all dc bi-phasic data and ac carrier base frequency and duty cycle.

Testing Defibrillator Charge Time

Before starting the charge time test, ensure the defibrillator is not charged. This test measures the amount of time it takes the defibrillator to go from a full discharge to charge at the desired charge level (typically maximum setting) and then discharge into the Analyzer’s test load.

From the Defibrillator main menu, press the softkey labeled **Charge Time**. As shown in Figure 9, the waveform selection is already set and **Measure Charge Time…** is displayed.



fak06.eps

Figure 9. Defibrillator Charge Time Test

In a few seconds after pressing the softkey labeled **Measure**, a **Charge Defib in:** countdown begins. When the countdown reaches zero and sounds the beeper, press the charge button on the defibrillator. The Analyzer begins a Charge Time count up. When the defibrillator reaches full charge, discharge the defibrillator into the Analyzer.

Note

For this test the Analyzer is timing operator actions. The measurement depends on the user accurately starting the defibrillator as soon as it is charged. Any operator time delay is included in the measurement result. The user should repeat any tests that have not been timed accurately.

The Analyzer senses the discharge and the charge time appears in the display. Press the softkey labeled Measure to perform another charge time test.

The softkey labeled **Summary** provides additional information about the current discharge waveform depending on the defibrillator type tested. For dc monophasic: peak voltage, peak current and pulse width. For dc bi-phasic: peak and average voltage, peak and average current, pulse width, interphase delay, and overall tilt. For ac bi-phasic: all dc bi-phasic data and ac carrier base frequency and duty cycle.

Analyzing Pacemakers (7000DP only)

The Analyzer is designed to work with a variety of pacemaker brands. See the specifications section later in this manual for a list of pacemaker brands. The Analyzer measures and displays pacemaker pulse amplitude, rate, and width. It also performs demand sensitivity tests, measures and displays refractory periods, and tests the pacemaker's susceptibility to 50/60 Hz interference.

Setting Up the Analyzer for Pacer Testing

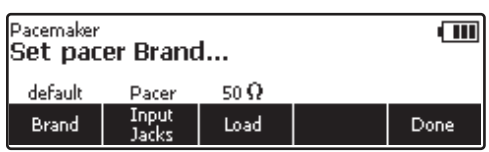
⚠ Caution

To avoid damage to the Analyzer or defibrillator, do not apply defibrillator pulses to the pacer inputs.

Connect the pacemaker to be tested to the Analyzer through either the pacer input jacks or defibrillator jacks as shown in Figure 11.

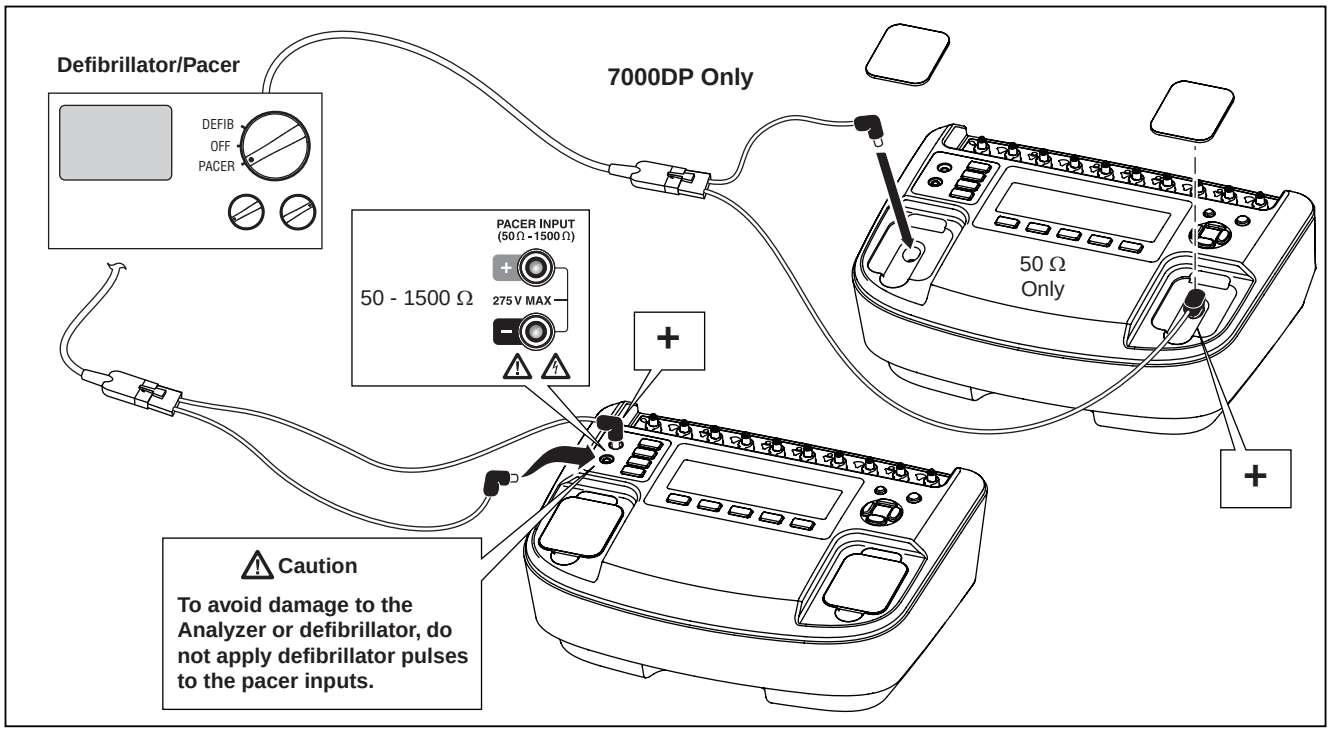
For tests where the pacemaker interacts with the simulated heart beat (Async, Demand, Sensitivity, and Refractory Period tests), the pacemaker senses the heart beat on its ECG leads. Connect the ECG leads to the Analyzer ECG posts as shown in Figure 20.

In preparation for testing a pacemaker, the Analyzer will have to be set to the specific brand of the pacemaker under test. Press PACER to enter the top-level pacer menu shown in Figure 10.



fak12.eps

Figure 10. Pacemaker Brand Selection



fak10.eps

Figure 11. Connecting a Pacemaker to the Analyzer

Press the softkey labeled **Brand** to activate the brand list and scroll through the list using ⏶ or ⏷. When the correct brand is displayed, enter the selection in one of three ways. Press the softkey labeled **Brand**, press one of the other two setup function softkeys (**Load** or **Input Jacks**) or press the softkey labeled **Done**.

The load the pacer is working into through the Analyzer's pacer inputs is set through the Load softkey. If the load value needs to be changed, press the softkey labeled **Load** and then use ⏶ or ⏷ to select a value between 50 and 1500 Ω in 50 Ω steps. Set the load value by pressing the Load softkey again, press one of the other two pacer variable softkeys, or press the softkey labeled **Done**.

Note

The load value is only selectable when the pacer input selection is set to input jacks. Only a 50 Ω load is available when the input selection is set to Defib.

The third pacer variable is the selection of the jacks where the pacemaker has been attached to the Analyzer. The input jacks softkey toggles between two settings: **Input Jacks** or **Defib**. The Input Jacks selection monitors the jack just to the left of the function and setup buttons. When Defib is selected, the Analyzer monitors the pacemaker through the defibrillator jacks.

When all three pacer setup variables are set to their desired values, press the softkey labeled **Done**. The Analyzer begins to monitor the pacer signal through the selected input jacks. When the pacer signal is detected the display indicates the pacemakers pulse rate, pulse width, energy, and amplitude. In addition, pacer test function labels appear above the softkeys indicating the Analyzer is ready to perform one of the pacer tests. See Figure 12.

fak13.eps

Figure 12. Displayed Pacer Parameters

Performing a Pacer Asynchronous Test

This qualitative test verifies the continuous (or non-demand) mode pacemaker's ability to interact with a simulated ECG signal. The Analyzer first measures the pacemaker's applied pulse rate then computes "underdrive" and "overdrive" rates for the simulated ECG signal. Initially, the "underdrive" rate is 85 % of the applied pacemaker rate and the "overdrive" rate is 115 % of the applied pacemaker rate.

When testing the attached pacemaker, operating in the continuous (or non-demand) mode, output should be active (ON) when either the “underdrive” ECG signal or “overdrive” ECG signal is selected. The rates of these “underdrive” and overdrive” ECG signals are user adjustable across a wide physiological range.

To perform an Async test, set the pacer for asynchronous operation and connect the pacer to the Analyzer’s pacer input jacks and appropriate ECG posts. Set the ECG signal for the Pacer Demand test. See the “Setting the ECG Signal for a Pacer Async Test” section later in this manual. Next, press the softkey labeled **Async**. Pressing the softkey labeled **Overdrive** causes the Analyzer’s ECG signal to output the rate shown above the Overdrive softkey label. See Figure 13. To change the overdrive rate, press ▲ or ▼.

fak14.eps

Figure 13. Pacer Async Overdrive Mode

Similarly, pressing the softkey labeled **Underdrive** causes the Analyzer’s ECG signal to jump to the rate shown above the Underdrive softkey label. To change the underdrive rate, press ▲ or ▼.

The Summary softkey appears after changing the output rate and when the softkey is pressed, displays a summary of the test which can also be uploaded to a PC.

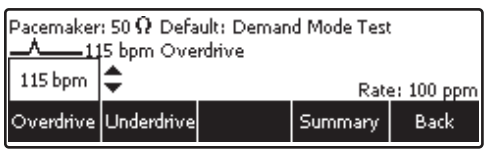
Performing a Pacer Demand Test

This qualitative test verifies the demand mode pacemaker’s ability to interact with a simulated ECG signal. The Analyzer first measures the pacemaker’s applied pulse rate then computes “underdrive” and “overdrive” rates for the simulated ECG signal. Initially, the “underdrive” rate is 85 % of the applied pacemaker rate and the “overdrive” rate is 115 % of the applied pacemaker rate.

When testing the pacemaker, operating in the demand mode, output should be active (ON) with the “underdrive” ECG signal and then inhibited (OFF) when the “overdrive” ECG signal is selected. The rates of these “underdrive” and overdrive” ECG signals can be adjusted across a wide physiological range using the Analyzer top panel controls.

To perform a Demand test, set the pacer into demand mode and connect the pacer to the Analyzer’s pacer input jacks and appropriate ECG posts. Set the ECG signal for the Pacer Demand test. See the “Setting the ECG Signal for a Pacer Demand Test” section later in this manual.

Next, press the softkey labeled **Demand**. Pressing the softkey labeled **Overdrive** causes the Analyzer's ECG signal to jump to the rate shown above the Overdrive softkey label. See Figure 14. To change the overdrive rate, press ▲ or ▼.



fak15.eps

Figure 14. Pacer Demand Overdrive Test

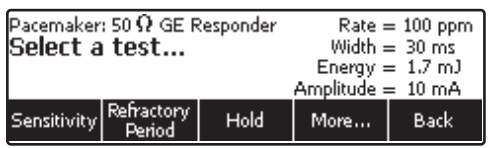
Similarly, pressing the softkey labeled **Underdrive** causes the Analyzer's ECG signal to jump to the rate shown above the Underdrive softkey label. To change the underdrive rate, press ▲ or ▼.

The summary softkey label appears when the test is complete. Pressing the Summary softkey displays the test results which can also be uploaded to a PC.

Performing a Pacer Sensitivity Test

This quantitative test determines the amplitude of the simulated ECG signal required by the demand mode pacemaker. The amplitude of the simulated ECG signal is increased in very small steps until the pacemaker senses it and inhibits the output pulse.

To perform a Pacer Sensitivity test, press the softkey labeled **More** from the Pacer Main menu to reveal the menu shown in Figure 15. Next press the softkey labeled **Sensitivity**.



fak16.eps

Figure 15. Pacer Sensitivity Test Display

Before starting the test, it may be necessary to change the parameters of the signal feeding the pacer. To change the signal, press the softkey labeled **Set Wave**. The shape of the waveform, the wave width, the wave's polarity, and its amplitude are all adjustable at this point. The Wave Form, Wave Width, and Amplitude softkeys open selections you can scroll through using ▲ and ▼. The Polarity softkey simply toggles between + and –. With all the parameters set, press the softkey labeled **Done**.

At this point, a sensitivity test is started by pressing the softkey labeled **Start Test**. When the test is complete, the sensitivity amplitude is displayed. Pressing the softkey

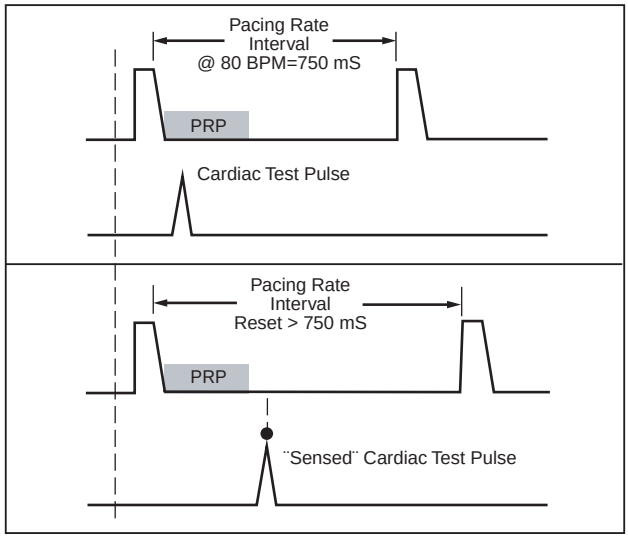
labeled **Summary** displays a summary of the test which can be uploaded to a PC.

Performing a Pacer Refractory Period Test

This test is composed of two related quantifiable tests that determine the demand mode pacemaker's ability to sense ECG activity immediately following either a paced event (PRP) or sensed ECG event (SRP).

Paced Refractory Period (PRP)

The Analyzer first measures the pacemaker's applied pulse rate, and then generates a simulated ECG signal within the expected PRP interval. See Figure 16. This coupling interval is slowly extended until the simulated ECG signal falls outside the PRP. The signal is then sensed by the pacemaker, causing the escape interval to reset. The result is a longer pacing pulse interval.



eyr003.eps

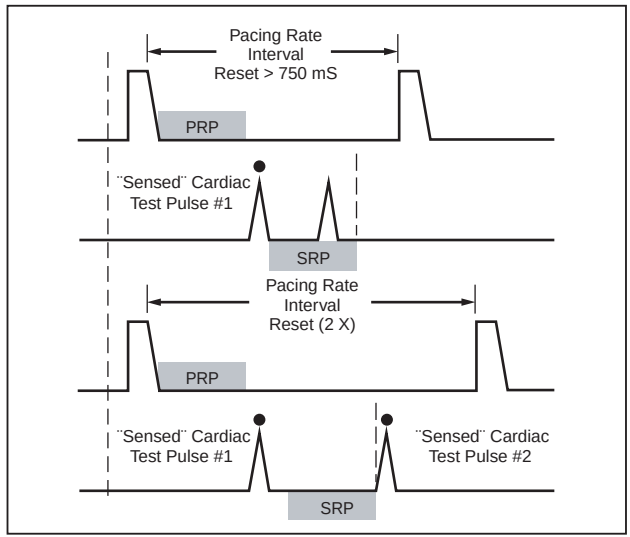
Figure 16. Paced Refractory Period (PRP)

Sensed Refractory Period (SRP)

The Analyzer next generates a second simulated ECG signal immediately trailing the first simulated ECG signal used to determine the PRP. See Figure 17. This coupling interval is slowly extended until the simulated ECG signal falls outside the PRP. The signal is then sensed by the pacemaker, causing the escape interval to reset. The result is a longer pacing pulse interval.

To perform a refractory period test, press the softkey labeled More from the Pacer Main menu to reveal the menu shown in Figure 15. Next press the softkey labeled **Refractory Period**. When the test is completed the PRP and SRP values are displayed. If at any time the test needs to be stopped, press the softkey labeled **Abort**.

When the test is completed, **Summary** appears over one of the softkeys and will display a summary of the test which can be uploaded to a PC.



eyr004.eps

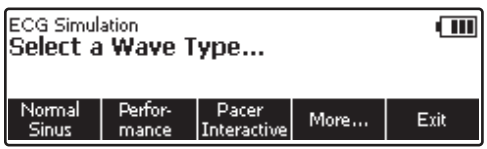
Figure 17. Sensed Refractory Period (SRP)

Simulating ECG Signals

The Analyzer simulates a wide range of ECG signals to test pacemaker operation. The ECG signals are categorized under menu selections found at the ECG main menu. To set the Analyzer's ECG output, press **ECG** to open the ECG menu. The ECG menu is shown in Figure 18.

Note

If noise is present in the ECG with the battery charger plugged in, unplug it from the charger to correct the problem.



fak18.eps

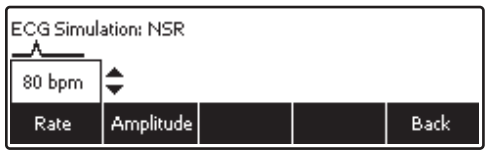
Figure 18. ECG Main Menu

Connecting to the ECG Terminals

Figure 20 shows the proper way of connecting a pacer or ECG monitor to the Analyzer's ECG posts.

Setting a Normal Sinus Rhythm ECG Signal

From the ECG main menu, press the softkey labeled **NSR**. The ECG signal is present on the ECG posts immediately with the previous rate and amplitude settings. Rate and amplitude are the two user-settable variables for an NSR ECG signal. See Figure 19.



fak19.eps

Figure 19. Normal Sinus Rhythm Rate Selection

To set the amplitude of the ECG signal, press the softkey labeled **Amplitude**. A scroll box opens where the amplitude can be adjusted by pressing ⏶ or ⏷. When the desired amplitude is set, press the **Rate**, **Amplitude**, or **Back** softkey.

Setting a Performance ECG Signal

The Analyzer is designed to source special test signals on the ECG posts to test the electrical performance of a defibrillator with an ECG monitor. To set these performance waves, press the softkey labeled **Performance** from the ECG main menu.

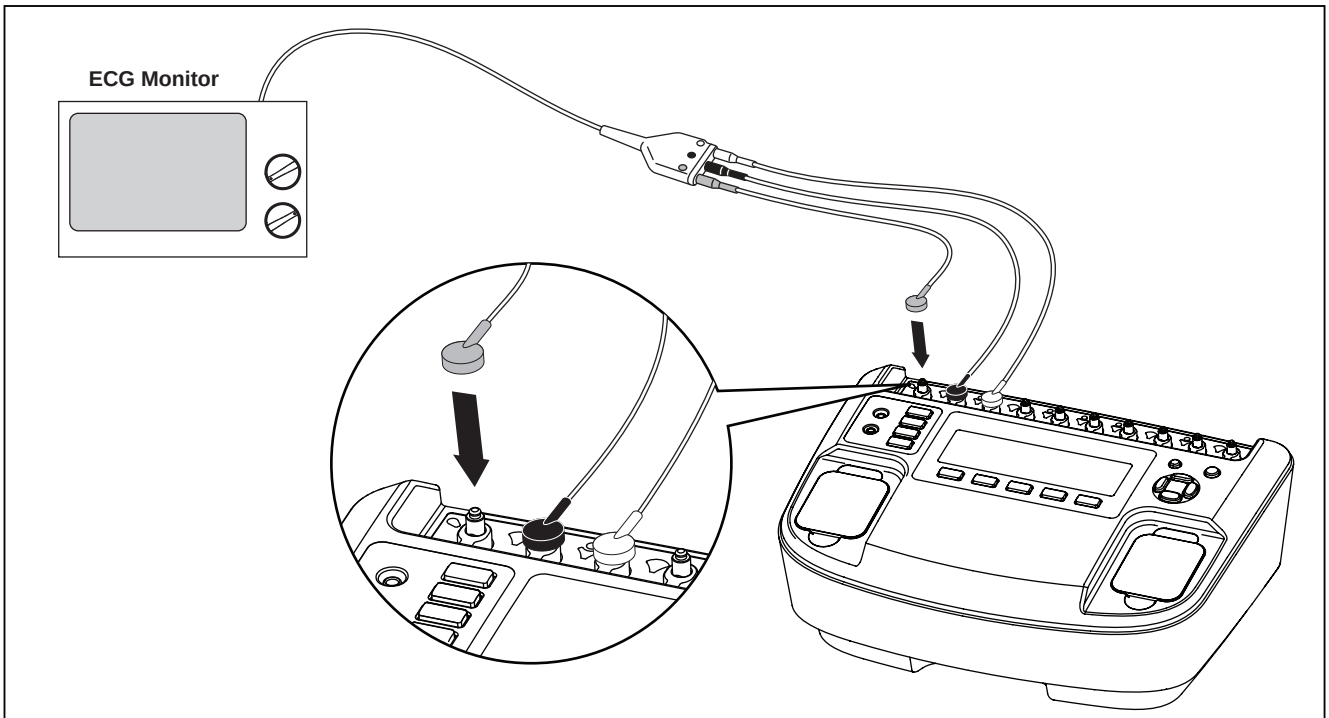
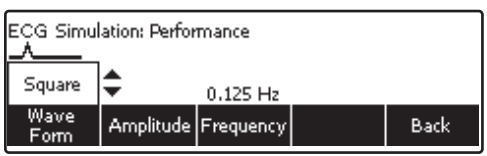


Figure 20. ECG Connections

The performance signal controls consist of a waveform selection, amplitude, and frequency or rate settings. To select a performance waveform, press the softkey labeled **Wave Form**. A scroll box opens where the different wave forms are selected by pressing ⏶ or ⏷. See Figure 21. When the desired wave form is displayed, press the **Wave Form**, **Amplitude**, **Frequency**, or **Rate** softkey.



fak27.eps

Figure 21. Performance Wave Selection

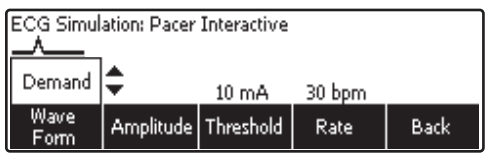
The amplitude, frequency, or rate parameters are set using the same method as the wave form selection.

Setting Pacer Interactive ECG Waves (7000DP only)

When performing Asynchronous and Demand tests on a pacemaker, the ECG signal the pacer senses needs to simulate varying conditions to test the pacer's response. See the "Performing a Pacer Async Test" and "Performing a Pacer Demand Test" sections earlier in this manual.

Setting the ECG Signal for an Interactive ECG/Pacer Demand Mode Simulation

From the ECG main menu, press the softkey labeled **Pacer Interactive**. Next, press the softkey labeled **Wave Form**. If not already displayed above the wave form softkey label, select the Demand wave form by pressing the softkey labeled **Wave Form**. A scroll box opens where Demand is selected by pressing ⏶ or ⏷. See Figure 22.



fak26.eps

Figure 22. Pacer Simulation Interactive Setup Screen

The ECG signal's amplitude, threshold, and rate are set using the same method as that used to select the wave form.

Once all the parameters are set and the scroll box is no longer visible in the display, the Analyzer goes through the ECG signal variations for the Pacer demand test automatically.

Setting the Analyzer for an Interactive ECG/Pacer Asystole Mode Simulation

From the ECG main menu, press the softkey labeled **Pacer Interactive**. Next press the softkey labeled **Wave Form**. If not already displayed above the waveform softkey label, select the Asystole waveform by pressing the softkey labeled **Wave Form**. A scroll box opens where Asystole is selected by pressing ⏶ or ⏷. Set this waveform into the Analyzer by either pressing the **Wave Form** softkey again or one of the other softkeys.

The ECG signal's amplitude and threshold are set using the same method as that used to select the wave form.

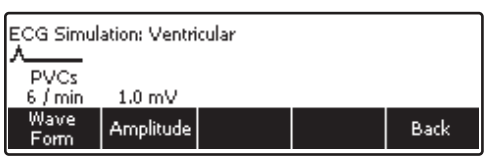
These ECG waves respond to the incoming pacer pulse by simulating the heart's response to it. The threshold is the amplitude of the pacer pulse in mA that is required for the ECG to "see" the pulse and respond to it. Setting it to zero disables threshold checking and allows the ECG to respond to all pacer pulses.

As soon as the demand wave option appears, the Analyzer goes through the ECG signal variations for the Pacer demand test automatically.

Selecting ECG Arrhythmias

The Analyzer is capable of simulating a number of ECG arrhythmia waveforms. From the ECG main menu, press the softkey labeled **More**. Three arrhythmia selections are displayed above the softkeys: Supraventricular, Premature, and Ventricular. Pressing the softkey labeled **More** again, displays the Conduction arrhythmia waveforms.

The process for selecting and setting the parameters of all four arrhythmias are identical. From the ECG main menu, navigate using the softkeys labeled **More** and **Back** until the desired arrhythmia is displayed above one of the softkeys. Next, press the appropriate softkey to select the desired arrhythmia pattern. The next display provides access to the two parameters each arrhythmia pattern has: Wave Form and Amplitude. Figure 23 shows the parameter selections for the Ventricular arrhythmia waveform.



fak20.eps

Figure 23. Ventricular Parameter Selection

To select a waveform, press the softkey labeled **Wave Form**. A scroll box opens above the softkey label and pressing ⏶ or ⏷ scrolls through the selections. To set the

amplitude, press the softkey labeled Amplitude and use ⏶ or ⏷ to scroll through the amplitude selections.

Pressing the softkey labeled **Back** moves back to the ECG main menu.

Selecting TV Paced

From the ECG main menu, press the softkey labeled **More** twice to display the TV Paced selection over one of the softkeys. Next press the softkey labeled **TV Paced**. Figure 24 shows the TV Paced parameter display.

fak21.eps

Figure 24. TV Paced Selection

When the AV Sequential wave form is selected from the TV Paced menu, set Atrial and Ventricular pacer are two softkey selections. The width, polarity, and amplitude of both of these two pacer settings are set separately.

fak22.eps

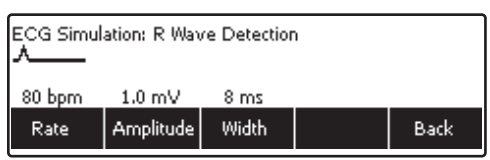
Figure 25. AV Sequential Screen

Testing R Wave Detection

Heart monitors look for the R wave in detecting heartbeats. The R wave is used to calculate heart rate and used for other analysis. The Analyzer simulates an R Wave with user-adjustable rate, width, and amplitude.

From the ECG main menu, press the softkey labeled **More** twice to display the R Wave Detection selection over one of the softkeys. Next press the softkey labeled **R Wave Detection**.

Softkey selections shown in Figure 26 allow for the setting of the R Wave rate, amplitude, and width.



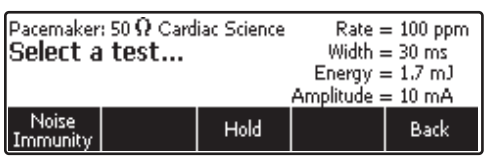
fak25.eps

Figure 26. R Wave Detection Screen

Performing a Noise Immunity Test

This qualitative test verifies the pacemaker's ability to filter line frequency noise at either 50 or 60 Hz, and sense a simultaneously applied simulated ECG signal. The amplitude of the line frequency noise is user-adjustable, while the simulated ECG signal amplitude is fixed.

To get to the Noise Immunity test from the Pacer Test menu, press the softkey labeled **More** repeatedly until Noise Immunity appears above one of the function keys. See Figure 27. Next press the softkey labeled **Noise Immunity**.



fak17.eps

Figure 27. Pacer Noise Immunity Test

There are three variables for the noise immunity test: ECG Wave, Line Frequency, and Amplitude. The softkey labeled **ECG Wave** toggles between on and off. When on, an ECG wave is placed on the pacer leads along with the noise signal.

The softkey labeled **Line Frequency** toggles the frequency of the noise signal between 50 and 60 Hz.

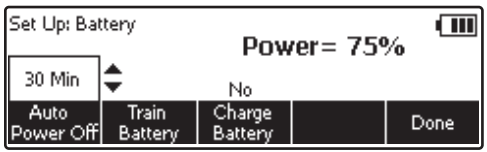
Pressing the softkey labeled **Amplitude**, activates the scroll box for setting the noise signal amplitude. Press ▲ or ▼ to adjust the signal amplitude from 0 to 10 mV in 0.5 mV steps while watching the patient monitor. To set the rate, press the softkey labeled **Rate**. A scroll box opens where the simulated heart rate can be changed by pressing ▲ or ▼. When the desired rate is set, press the **Rate**, **Amplitude**, or **Back** softkey.

Setting Analyzer Setup Functions

The Analyzer has a number of setup functions that are user-adjustable. Press SETUP to open the setup main menu. There are setup functions for the battery, display, sound, instrument information, calibration, and diagnostics.

Setting Up the Battery

Press the softkey labeled **Battery** to access the battery setup menu. See Figure 28. Through this menu, Auto Power off can be set, the battery charger enabled and disabled, and the battery can be trained. Once all the battery setup functions are set, press the softkey labeled **Done** to save the changes.



fak23.eps

Figure 28. Battery Setup Screen

While in the battery setup function, the present condition of the battery is displayed as a percentage of full charge.

Setting Auto Power Off

From the battery setup menu, press the softkey labeled **Auto Power Off**. A scroll box opens above the softkey label indicating the present Auto Power Off setting. Use ⏶ or ⏷ to adjust the Auto Power Off time from no auto power off to 60 minutes in three steps (10, 30, and 60 minutes). Press the softkey labeled **Done** to save the setting.

Training the Battery

Over time, as the Analyzer's battery goes through a number of discharge/recharge cycles, or if the Analyzer is not used for an extended period of time, the battery level indicator gets out of sync with the true condition of the battery. It may become necessary to "retrain" the indicator with the battery if after having the Analyzer charge for 10 or more hours and the charge value indicates less than 95%.

To train the battery, the Analyzer will need to be plugged into the battery charger for up to 15 hours without being used. From the battery setup menu, press the softkey labeled **Train Battery**. When battery training is complete, the charge status light on the rear panel will turn green and "Battery Training Complete" is displayed.

Enabling and Disabling the Battery Charger

While operating from mains power, it is possible to operate and not charge the battery. From the battery setup menu, press the softkey labeled **Charge Battery**. This is a simple toggle function that switches the battery charger on and off.

Note

If the Analyzer is connected to mains power but not turned on, this setting is ignored and battery charging is always enabled.

Setting Up the Display

The display setup functions allow for setting display contrast and the auto back light off function.

Setting the Display Contrast

The Analyzer's display contrast can be set in one of two ways. First, when the Analyzer displays **Select a device…**, pressing ⏶ or ⏷ adjusts the display contrast.

Another method of adjusting contrast is through the display setup menu. From the main setup menu, press the softkey labeled **Display**. Next press the softkey labeled **Contrast**. A scroll box opens above the softkey label when contrast is adjusted by pressing ⏶ (darker) or ⏷ (lighter). Press the softkey labeled **Done** to save the setting. This setting is now the value used when the Analyzer is turned on.

Setting Auto Back Light Off

From the main setup menu, press the softkey labeled **Display**. Next, press the softkey labeled **Auto Back Light Off**. A scroll box opens at which point ⏶ or ⏷ will scroll through Disabled, 30 seconds, and 60 seconds. When the display settings are set, press the softkey labeled **Done** to save the settings.

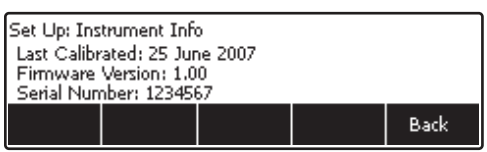
Setting Up Sound

The Analyzer's internal beeper can be enabled or disabled. When enabled, the volume can be set to low, medium, or high. From the setup main menu, press the softkey labeled **Sound**.

Next, pressing the softkey labeled **Beeper** simply toggles the beeper on or off. Pressing the softkey labeled **Volume** opens a scroll box above the softkey label. Use ⏶ or ⏷ to scroll through low, medium, and high volume settings. Once the sound functions are set, press the softkey labeled **Done** to store the settings.

Displaying Instrument Information

From the main setup menu, press the softkey labeled **More** to reveal additional setup selections. Next, press the softkey labeled **Instrument Info** to display the Analyzer's manufacturing date, firmware version, and serial number. See Figure 29. Pressing the softkey labeled **More** displays the last calibration date.



fak24.eps

Figure 29. Analyzer Information Screen

Controlling the Analyzer Remotely

Ansur test automation systems allow a solutions-based approach to complete testing of the medical device under test (DUT). Ansur helps you create standard work using the test template/sequence (which is based on your

written test procedure), and integrates all test results into a single test report which can be printed or archived. Ansur manages your test procedures by allowing both manual and visual automated test sequences.

The software works hand-in-hand with Fluke Biomedical analyzers and simulators, creating a seamless integration for:

- Visual inspections
- Preventive maintenance
- Work procedures
- Performance tests
- Safety tests

Ansur software utilizes plug-in modules to work with a wide array of Fluke Biomedical instruments. The plug-in module is a software interface to the Ansur test program. Plug-ins provide test elements used by Ansur Executive that use the same user interface for all analyzers and simulators supported by an Ansur plug-in.

When you purchase a new Fluke Biomedical analyzer or simulator, you can update your existing Ansur software by installing a new plug-in. Each plug-in module allows you to work only with the options and capabilities you need for the instrument you are testing. The Analyzer's remote control commands are available in the *Ansur Users Manual*.

Note

When the Analyzer is under remote control, the defibrillator under test must be manually operated. For example, to charge and shock.

Note

The stop button on the Ansur program will be disabled when data is being communicated from the Analyzer to the PC.

Maintenance

The Analyzer needs little maintenance or special care. However, treat it as a calibrated measuring instrument. Avoid dropping or other mechanical abuse that could cause a shift in the calibrated settings. The Analyzer has no internal user-serviceable parts.

Cleaning the Analyzer

⚠ Caution

Do not pour fluid onto the Analyzer surface; fluid seepage into the electrical circuitry may cause the Analyzer to fail.

⚠ Caution

Do not use spray cleaners on the Analyzer; such action may force cleaning fluid into the Analyzer and damage electronic components.

Clean the Analyzer occasionally utilizing a damp cloth and mild detergent. Take care to prevent the entrance of liquids.

Wipe down the adapter cables with the same care. Inspect them for damage and deterioration of the insulation. Check the connections for integrity. Keep transducer adapter clean and dry.

Maintaining Peak Battery Condition

To maintain peak battery capacity, the Analyzer should be charged completely at least once a month. If the Analyzer is to be left idle for more than a month and it is inconvenient to periodically connect to the battery charger, keep it connected to the charger while idle.

Note

To obtain the specified performance, use the battery charger specified in this manual.

Accessories

Table 4 lists the accessories for the Analyzer.

Table 4. Accessories

Item	Fluke Biomedical Model Number
GE Medical RESPONDER1500/1700 4mm	3065423
Internal Defib Pdl Contacts 2/set 4mm	3065438
R2 Darox MRL/MDE/NK/Kimberly Clark 4mm	3065450
Med ERS /PhysioControl QUIK COMBO 4mm	3065461
Med ERS/PhysioControl QUIK PACE 4mm	3065477
Med ERS/PhysioControl FAST PATCH 4mm	3065489
Philips/HP/Agilent CODEMASTER 4mm	3065492
Philips/Agilent HEARTSTART FR2/MRX 4mm	3065509
ZOLL Medical PD-2200 MULTIFUNCTION 4mm	3065511
ZOLL Medical NTP/PD1400 4mm	3065527

Specifications

General Specifications

Temperature

Operating	10 °C to 40 °C (50 °F to 104 °F)
Storage	-20 °C to +60 °C (-4 °F to +140 °F)
Humidity	10 % to 90 % non-condensing
Display	LCD display
Communications	USB device port for computer control
Modes of Operation	Manual and remote
Power	Internal rechargeable NiMH battery pack for nine hours (typical) operation after full charge, or the battery charger can operate the Analyzer and charge the battery simultaneously.
Battery Charger	100 to 240 V input, 15 V/1.5 A output. For best performance, the battery charger should be connected to a properly grounded ac receptacle.

Mechanical

Housing	ABS Plastic
Size (H x W x L)	13 cm x 32 cm x 24 cm (5 in x 13 in x 9.5 in)
Weight	3.0 kg (6.6 lb)

Safety Standards

CE	IEC/EN61010-1 2nd Edition; Pollution degree 2
CSA	CAN/CSA-C22.2 No. 61010-1; UL61010-1

Electromagnetic Compatibility Standards (EMC)

European EMC	EN61326-1

Defibrillator Analyzer Specifications

Energy Output Measurement

Compatible Defibrillator Waveshapes.....Lown, Edmark, Trapezoidal, DC Bi-phasic, and AC Pulsed Bi-phasic

Note

AC Pulsed Bi-Phasic waveform has not been approved in the United States.

Autoranged Measurement.....0.1 to 600 J

Accuracy

0.1 to 360 J .....±(1 % of reading + 0.1 J)

360 to 600 J .....±(1 % of reading + 0.1 J), typical

Note

For Pulsed Bi-Phasic defibrillator, specified accuracy is ±(1.5 % of reading + 0.3 J) on both ranges.

Load resistance

Resistance.....50 Ω

Accuracy.....±1 %, non-inductive (<2 µH)

Pulse trigger level .....20 V

Pulse width

Range.....1.0 to 50.0 ms

Accuracy.....±0.1 ms

Voltage

Range.....20 to 5000 V

Accuracy.....±(1 % of reading + 2 V)

Current

Range.....0.4 to 100.0 A

Accuracy.....±(1 % of reading + 0.1 A)

Sample rate ..... 250 kHz (4 µs sample)
Maximum Average Power ..... 12 W, equivalent to 10 defib pulses of 360 J every 5 minutes
Oscilloscope Output
Autorange ..... 2000:1, 400:1 and 80:1: dependant on the range
Waveform Playback
Output ..... BNC
Output impedance ..... 50 Ω (nominal)
Delay ..... 50 ms (nominal)
Accuracy ..... ±5 % of nominal
Charge Time Measurement
Range ..... 0.1 to 100.0 s
Accuracy ..... ±0.05 s, typical
Synchronization Test (Elective Cardioversion)
Delay Time Measurement
Timing window ..... ECG R-wave peak to the defib pulse peak
Range ..... -120 to +380 ms; measures timing from 120 ms prior to the R-wave peak to up to 380 ms following the R-wave peak.
Resolution ..... 1 ms
Accuracy ..... ±1 ms
ECG waves
Normal Sinus Rhythm (NSR) ..... 30 to 180 (by 1) BPM
Atrial fibrillation ..... Coarse and fine
Monomorphic Ventricular Tachycardia ..... 120 to 240 (by 5) BPM
Asystole ..... Flat line

Automated Defibrillator Test ECG Waves

Normal Sinus	30 to 300 (by 1) BPM
Ventricular Fibrillation	Coarse and fine
Monomorphic Ventricular Tachycardia	120 to 300 (by 5) BPM
Polymorphic Ventricular Tachycardia	5 types
Asystole	Flat line

ECG Waves

ECG General

Lead configuration	12-lead simulation. RA, LL, LA, RL, V1-6 with independent outputs
Lead to lead impedance	1000 Ω (nominal)
Rate accuracy	±1 % of nominal

ECG Amplitudes

Reference lead	Lead 1
Settings	0.05 to 0.45 (by 0.05) mV 0.5 to 5.0 (by 0.5) mV
Accuracy	±2 % of setting, lead I and 2 Hz square wave

For performance waves and R-wave detection, other leads are proportional to Lead I in percentage per:

Lead I	100
Lead II	150
Lead III	50
Leads V1 through V6	100

For normal sinus waves, other leads are proportional to Lead I in percentage per:

Lead I	100
Lead II	150
Lead III	50

Lead V1	24
Lead V2	48
Lead V3	100
Lead V4	120
Lead V5	112
Lead V6	80

ECG Normal Sinus

Rates	10 to 360 (by 1) BPM

ECG High Level Output (BNC Jack)

Amplitude	0.2 V/mV of Lead I amplitude
Accuracy	±5 %. 2 Hz Square Wave
Output Impedance	50 Ω output impedance

ECG on Defibrillator Input Load

60 % of Lead I amplitude. Max. 3.5 mV

ECG Performance Waves

Square wave	2.0 and 0.125 Hz
Triangular wave	2.0 and 2.5 Hz
Sine waves	0.05, 0.5, 5, 10, 40, 50, 60, 100, 150, and 200 Hz
Pulse	30 and 60 BPM, 60 ms pulse width

R-Wave Detection

Waveform	Haver-triangle
Amplitude	0.05 to 0.45 (by 0.05) V 0.5 to 5.0 (by 0.5) V
Rate	30, 60, 80, 120, 200, and 250 BPM
Widths	8, 10, 12 ms, and 20 to 200 (by 10) ms
Accuracy	±(1 % setting + 0.2 mV)

Noise Immunity

Wave ..... Sine
Line Frequency.....50 or 60 Hz (± 0.5 Hz)
Amplitude .....0.0 to 10.0 (by 0.5) mV
Accuracy.....± 5%

Transvenous Pacer Pulse Simulation

Widths
Range.....0.1, 0.2, 0.5, 1.0, and 2.0 ms
Accuracy.....±5 % of setting
Amplitudes.....0 (off) and ±2, ±4, ±6, ±8, ±10, ±12, ±14, ±16, ±18, ±20, ±50, ±100, ±200, ±500, and ±700 mV
Accuracy.....± (10 % of setting + 0.2 mV)

Arrhythmia Selections

Pacer Interactive (Transcutaneous pacer, Impulse 7000DP only)
Demand.....30 to 360 (by 1) BPM
Asynchronous
Non-Capture
Non-Function
Threshold (Interactive pacing simulation only) 10 to 250 (by 10) mA
Supraventricular
Atrial Fibrillation Coarse
Atrial Fibrillation fine
Atrial Flutter
Sinus Arrhythmia
Missed Beat
Atrial Tachycardia

Paroxysmal Atrial Tachycardia (PAT)
Nodal Rhythm
Supraventricular Tachycardia
Premature
Atrial PAC
Nodal PNC
PVC1 Left Ventricle
PVC1 LV Early
PVC1 LV R on T
PVC2 Right Ventricle
PVC2 RV Early
PVC2 RV R on T
Multifocal PVCs
Ventricular
PVCs 6/min
PVCs 12/min
PVCs 24/min
Freq Multifocal
Trigeminy
Bigeminy
Pair PVCs
Run 5 PVCs
Run 11 PVCs
Monomorphic Ventricular Tachycardia .....120 to 300 (by 5) BPM
Polymorphic Ventricular Tachycardia .....1 to 5
Ventricular Fibrillation: Coarse and Fine

- Asystole
- Conduction
  - 1° Block
  - 2° Block Type I
  - 2° Block Type II
  - 3° Block
  - Right Bundle Branch Block RBBB
  - Left Bundle Branch Block LBBB
- Transvenous Paced with selectable pacer spike amplitudes and widths
  - Atrial 80 BPM
  - Async 75 BPM
  - Demand with frequent sinus beats
  - Demand with occasional sinus beats
  - AV Sequential
  - Non-Capture
  - Non-Function
  - Selectable pacer pulse parameters for transvenous simulation. (Atrial and Ventricular channels are independently selectable):
    - Atrial Pacer Pulse
      - Width .....0.1, 0.2, 0.5, 1.0, 2.0 ms
      - Polarity .....+ or -
      - Amplitude .....0 (off), 2 to 20 (by 2), 50, 100, 200, 500, 700 mV
    - Ventricular Pacer Pulse
      - Width .....0.1, 0.2, 0.5, 1.0, 2.0 ms
      - Polarity .....+ or -
      - Amplitude .....0 (off), 2 to 20 (by 2), 50, 100, 200, 500, 700 mV

Transcutaneous Pacemaker Analyzer Specifications (Impulse 7000DP only)

Test Load Selections

Defibrillator Input

Fixed Load ..... 50 Ω
Accuracy ..... ±1 %, non-inductive (<2 µH)
Power Rating..... 10 defib pulses of 360 J every 5 minutes

Pacemaker Input

Variable Load..... 50 to 1500 Ω in 50 Ω steps
Accuracy ..... ±1 %, non-inductive (<2 µH)
Power Rating..... 5 W (average), 40 W (peak) @ 1000 Ω

Measurements

Manufacturer Specific Algorithms (plus general purpose default algorithm selection)

GE Responder (1500 & 1700)
MDE 300 (Medical Data Electronics)
Medtronic ERS/Physio Control LIFEPAK
MRL (Medical Research Laboratory/Welch Allyn)
Philips/Agilent/HP
Schiller Medical
ZOLL Medical
(plus a general purpose default algorithm selection)

Current

Range..... 4.00 to 250 mA
Accuracy ..... ±(1% of reading + 0.02 mA)

Pulse Rate

Range.....5.0 to 800 PPM

Accuracy.....±(0.5% of reading + 0.1 PPM)

Pulse Width

Range.....1.00 to 100.0 ms

Accuracy.....±(0.5% of reading + 0.01 ms)

Energy

Range.....1 µJ to 2.00 J

Accuracy.....±(4% of reading + 10 µJ)

Demand and Asynchronous Mode Test

Input Pacer pulse rates.....30 to 200 PPM

ECG NSR wave

Rate.....10 to 300 (by 1) BPM

Amplitude .....1 mV

Underdrive rate.....10 BPM minimum

Overdrive rate.....300 BPM maximum

Sensitivity Test

Automatic Interactive Threshold Detection

Compatible pacer rates ..... 30 to 120 PPM

ECG R wave:

Waveforms ..... Square, Triangle, Sine

Width ..... 1 to 19 (by 1) ms
20 to 95 (by 5) ms
100 to 300 (by 25) ms

Accuracy ..... ± 5% of setting

Amplitude ..... 0.05 to 0.95 (by 0.05) mV
1.0 to 5.0 (by 0.5) mV

Accuracy ..... ± 5% of setting

Refractory Period Tests

Paced Refractory Period ..... 20 to 500 ms

Sensed Refractory Period ..... 15 to 500 ms

Accuracy ..... ±1 ms

Pacer pulse rate ..... 20 to 200 PPM

ECG

Waveform ..... Triangle wave

Pulse width ..... 40 ms

Amplitude ..... 1.0 mV

Appendix A
Impulse 6000D/7000DP Remote Operation

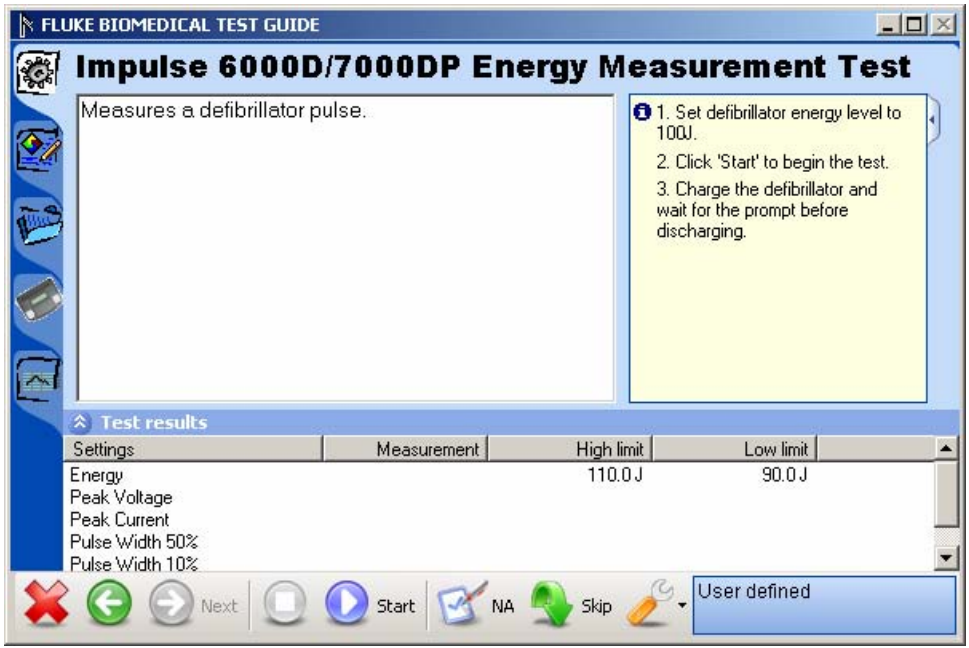
Ansur Test Guide

This appendix describes using the Ansur plug-in software to execute tests on the Analyzer.

When a test is executed with the Impulse 6000D/7000DP Plug-in, the **TEST GUIDE** window opens. Use the **TEST GUIDE** to step through each element in the test procedure. Figure 30 shows the **TEST GUIDE** for an Energy Measurement test. The panes function as follows:

- Left pane – displays either the default explanation or one entered when a custom template was created.
- Right pane – provides step-by-step directions for the test being performed.
- Test results pane – the bottom pane that displays results of the test being run.

In this example, the screen directs the setting of the energy level for the DUT, in this case a defibrillator. Press **Start** on the **TEST GUIDE** toolbar to begin the test. Analyzer measurement results appear in the **Test results** pane.



fcz06.bmp

Figure 30. Ansur Test Guide Window

Defibrillator Tests

The Impulse 6000D/7000DP Plug-in allows testomg of defibrillator performance using a PC running the Ansur software. At the conclusion of each test procedure, Ansur collects the results of the tests to display or to store on a PC.

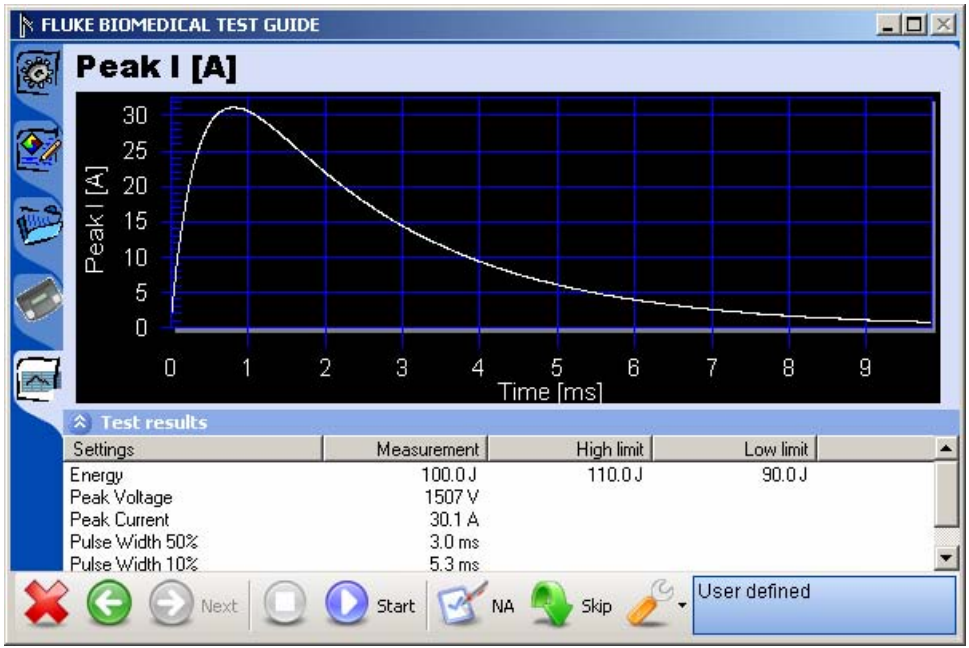
Energy Measurement Test

The energy tests verify the accuracy of the energy delivered by the defibrillator.

To run an Energy Measurement test:

1. First connect the defibrillator to the Analyzer (refer to the Impulse 6000D/7000DP Users Manual for connection instructions) and set the defibrillator to the energy setting displayed in the information block in the right pane of the TEST GUIDE window. Figure 1-31 shows an energy setting with both high and low limits (in Joules).
2. Click Start in the TEST GUIDE toolbar.
3. Charge the defibrillator.
4. Ansur software configures the Analyzer for the defibrillator test, indicating the status in the Test results pane. Wait for Ansur to finish configuring the Analyzer.
5. When configuration is complete, a window displays the prompt to discharge the defibrillator.
6. Discharge the defibrillator. Test results appear in the Test results pane immediately.

To view a graph of the discharge curve, as shown in Figure 31, click the graph tab located along the left side of the **TEST GUIDE**.



fcz07.bmp

Figure 31. Graph of Discharge Curve

Charge Time Test

The Charge Time test measures how long it takes to charge the defibrillator to a specified energy level. This test should use the defibrillator's maximum available energy level.

The steps for this test are similar to the Energy Measurement test; however, the prompts are different, because the Charge Time test tracks *how long* it takes to perform the charge and discharge.

To run a Charge Time test:

1. Connect the defibrillator to the Analyzer.
2. Set the defibrillator to the energy level indicated in the information block in the right pane of the TEST GUIDE window.
3. Click Start in the TEST GUIDE toolbar. A progress window displays "Please wait…" while Ansur configures the Analyzer.
4. Once configuration completes its routines, a five-second countdown starts, and a warning "START CHARGE NOW…" displays.
5. When the warning appears, begin charging the defibrillator.
6. When charging is complete, discharge the defibrillator. Test results appear in the Test results pane.

Sync Time Test

The Sync (Synchronization) Time test determines the ability of the defibrillator to synchronize the discharge of its output pulse with a simulated ECG waveform being generated from the Analyzer.

To run a Sync Test:

1. Connect the defibrillator to the Analyzer and set defibrillator to the energy setting indicated in the TEST GUIDE settings pane.

   The Analyzer outputs an ECG waveform to the defibrillator for this test.
2. Click Start in the TEST GUIDE toolbar.
3. Charge the defibrillator. Ansur configures the Analyzer for the defibrillator test, indicating the status in a Test results pane.
4. Wait for Ansur to finish configuring the Analyzer. When configuration is complete, a window displays the prompt "Defibrillate now."

5. Discharge the defibrillator. Results of the test appear in the Test results pane.

Pacemaker Tests

Pacemaker tests are used to test the basic operation of external transcutaneous pacemakers by measuring various pacemaker outputs and timing.

Pacer Parameter Test

The Pacer Parameter test takes measurements that can be used to determine if the output of a pacemaker is correct.

To run a Pacer Parameter test:

1. Connect a pacemaker to the Analyzer.
2. On the pacemaker, set the pacer rate and pacer output current. The right pane of the TEST GUIDE window indicates the pacemaker current level to be used.
3. Click Start in the TEST GUIDE toolbar.
4. When the Analyzer completes its measurements, Ansur retrieves the results and displays them in the Test results pane.
5. Click Stop in the TEST GUIDE toolbar to conclude the test.
6. Click Next to proceed or click Start to run the test again.

Pacer Refractory Test

The Pacer Refractory test checks the ability of the pacemaker to interact with cardiac activity when the pacemaker is in demand mode. The Ansur program retrieves the Pulsed Refractory Period (PRP) and the Sensed Refractory Period (SRP) timings as measured by the Analyzer.

To run a Pacer Refractory test:

1. Connect the pacemaker to the Analyzer.
2. On the pacemaker, set the pacer rate and pacer output current using information specified in the right pane of the TEST GUIDE window.
3. Click Start in the TEST GUIDE toolbar. Ansur starts the test, and will wait up to two minutes (120 seconds) to complete. The default duration of 120 seconds can be changed to values between 10 and 240 seconds in the Preferences dialog box. This test determines the refractory period (recovery period) of a pacemaker by simulating a series of R-Waves that

vary in rate and making several timing measurements on how the pacer responds. For this reason, the test typically takes 1 - 2 minutes to complete. Tests with low pulses-per-minute may require more than 120 seconds.

When the Analyzer has completed measurements, Ansur retrieves the results and displays them in the Test results pane.

4. Click Next in the TEST GUIDE toolbar to proceed to additional tests, or click Start to repeat this test.

Pacer Sensitivity Test

The Pacer Sensitivity test outputs a waveform and determines what threshold amplitude of ECG signal is needed to trigger the pacemaker.

To run a Pacer Sensitivity test:

1. Connect the pacemaker to the Analyzer.
2. On the pacemaker, set the pacer rate and pacer output current using information specified in the right pane of the TEST GUIDE window.
3. Click Start in the TEST GUIDE toolbar. Ansur starts the test and and displays a message indicating to wait until the test is complete.

When the Analyzer has completed measurements, Ansur retrieves the results and displays them in the Test results pane.

4. Click Next in the TEST GUIDE toolbar to proceed to additional tests, or click Start to repeat this test.

Pacer Demand Mode Test

This Pacer Demand Mode test verifies that the demand mode of the pacemaker is operating correctly over a range of ECG rates.

To run a Pacer Demand Mode test:

1. Follow the directions provided by the DUT equipment manufacturer to connect the ECG leads from the ECG monitor to the Analyzer.
2. Click Start in the TEST GUIDE toolbar.
3. Check whether the ECG monitor responds correctly. Also note that this test can be set up to cycle through a range of ECG rates.
4. Click the Test passed checkbox or the Test failed checkbox to record the observed result of the test.

Asynchronous Mode Test

This test follows the same procedure as the Pacer Demand Mode but is run with the pacer in non-demand mode.

ECG Pacer Interactive Test

The ECG Pacer Interactive test simulates a patient response to a pacemaker.

To run an ECG Pacer Interactive test:

1. Follow the directions provided by the DUT equipment manufacturer to connect the ECG leads from the ECG monitor to the Analyzer.
2. Click Start in the TEST GUIDE toolbar.
3. Check whether the ECG monitor responds correctly based on the settings being used for the test.
4. If the test duration is set to run indefinitely, click Stop in the TEST GUIDE toolbar to conclude the test.
5. Click the Test passed checkbox or the Test failed checkbox to record the observed result of the test.

ECG Waveform Simulation Tests

The ECG Waveform tests are used to verify the correct operation of an ECG monitor.

Normal Sinus Wave Simulation Test

The Analyzer can generate a normal sinus wave between 10 and 360 beats per minute for output to a defibrillator ECG monitor.

To run a Normal Sinus Wave Simulation test:

1. Follow the directions provided by the ECG equipment manufacturer to connect the ECG leads from the ECG monitor to the Analyzer.
2. Click Start in the TEST GUIDE toolbar.

   Wait for activity to appear on the ECG monitor. Note the BPM reading. This short test concludes automatically after a few seconds, as specified by the test procedure.
3. If the test duration is set to run indefinitely, click Stop in the TEST GUIDE toolbar to conclude the test.
4. Enter the BPM observed on the ECG monitor.
5. Click the Test passed checkbox or the Test failed checkbox to record the observed result of the test. If

the BPM is outside the limits specified in the test procedure, the test is automatically marked as failed.

Arrhythmia Wave Test

The Arrhythmia Wave test typically verifies the shock advisory capability of a defibrillator in response to various arrhythmia waveforms.

To run an Arrhythmia Wave Test:

1. Connect the device under test (DUT) to the Analyzer. Set up the shock advisory on the defibrillator, if applicable.
2. Click Start in the TEST GUIDE toolbar. Wait for activity to appear on the ECG monitor and verify the shock advisory was correct. The test concludes automatically after a few seconds, as specified by the test procedure.
3. If the test is set to run indefinitely, click Stop in the TEST GUIDE toolbar at any time to end the test.
4. Click the checkbox Test passed or the checkbox Test failed to record the test result based on what was observed on the monitor.

Performance Wave Simulation

The Performance Wave simulation tests the integrity of a defibrillator monitor using a variety of additional waveform shapes such as square, triangle, sine, and pulse.

Refer to the *Normal Sinus Wave Simulation* test procedure for directions in running this test.

ECG R-Wave Test

The ECG R-Wave (Peak Detection) test determines if the defibrillator can detect an R Wave at a given threshold of width and amplitude. Beats per minute can range between 30 and 250 BPM. This test is set up to test a single R-wave width and amplitude, or it can cycle through several widths or several amplitudes.

To run an ECG R-Wave test:

1. Follow the directions provided by the DUT equipment manufacturer to connect the ECG leads from the ECG monitor to the Analyzer.
2. Click Start in the TEST GUIDE toolbar.
3. Check whether the ECG monitor responds correctly based on the settings being used for the test.
4. If the test duration is set to run indefinitely, click Stop in the TEST GUIDE toolbar to conclude the test.

5. Click the Test passed checkbox or the Test failed checkbox to record the observed result of the test.

ECG Noise Immunity Test

The ECG Noise Immunity test checks the ability of the ECG monitor to reject AC line frequency noise.

To run an ECG Noise Immunity test:

1. Follow the directions provided by the DUT equipment manufacturer to connect the ECG leads from the ECG monitor to the Analyzer.
2. Click Start in the TEST GUIDE toolbar.

   Check the ECG monitor for any 50 Hz or 60 Hz interference.
3. Click Stop in the TEST GUIDE toolbar to conclude the test.
4. Click the Test passed checkbox or the Test failed checkbox to record the observed result of the test.

Battery Performance Tests

The battery performance tests are used to verify the condition of the defibrillator battery.

Battery Capacity Test

The Battery Capacity test can be used to check whether a battery-powered defibrillator can deliver a certain number of discharges per minute and whether or not the charge time remains adequate throughout the test.

To run a Battery Capacity Test:

1. Connect the defibrillator to the Analyzer.
2. Set the defibrillator to the energy level indicated in the information block in the right pane of the TEST GUIDE window.
3. Click Start in the TEST GUIDE toolbar to start the test. A progress window displays “Please wait…” while Ansur configures the Analyzer.

   Once configuration completes its routines, the TEST GUIDE starts a five-second countdown, after which it displays an instructional message, stating “Charge and Discharge (n) times within (t) seconds….” The n represents the actual number of times (n), and the t represents the actual time period recommended.
4. Follow the instructions in the message and begin charging the defibrillator.

5. When charging is complete, discharge the defibrillator. The first test result briefly appears in the right pane of the TEST GUIDE window. A new countdown timer message appears in the Test results pane, showing the time remaining before the next charge/discharge cycle.
6. Wait for the countdown to conclude.
7. Repeat steps 4 through 6 until the test is completed.
8. To abort the text, click Stop in the TEST GUIDE toolbar.
9. When the test is fully complete, the measurement results display in the Test results pane.

Defib Pulse Repetition Test

The Defib Pulse Repetition test is used to determine if a battery-powered defibrillator can deliver a specified number of discharges within a specified amount of time.

To run a Defib Pulse Repetition test:

1. Connect the defibrillator to the Analyzer.
2. Set the defibrillator to the energy level indicated in the information block in the right pane of the TEST GUIDE window.
3. Click Start in the TEST GUIDE toolbar to start the test. A progress window displays “Please wait…” while Ansur configures the Analyzer.
4. When configuration is complete, a prompt displays to repeatedly charge and discharge the defibrillator, along with a countdown timer showing the amount of time available to complete the test..
5. Discharge the defibrillator. Results briefly appear in the right pane of the TEST GUIDE window.
6. Continue to charge and discharge the defibrillator for the remaining specified cycles or until the countdown timer reaches zero.
7. Click Stop in the TEST GUIDE toolbar to abort the test.
8. When the test is complete, the measurement results display in the Test results pane.

Appendix B
Impulse 6000D/7000DP Test Templates

Introduction

This chapter introduces the template capabilities of the Impulse 6000D/7000DP Plug-In and provides guidance for customizing test templates.

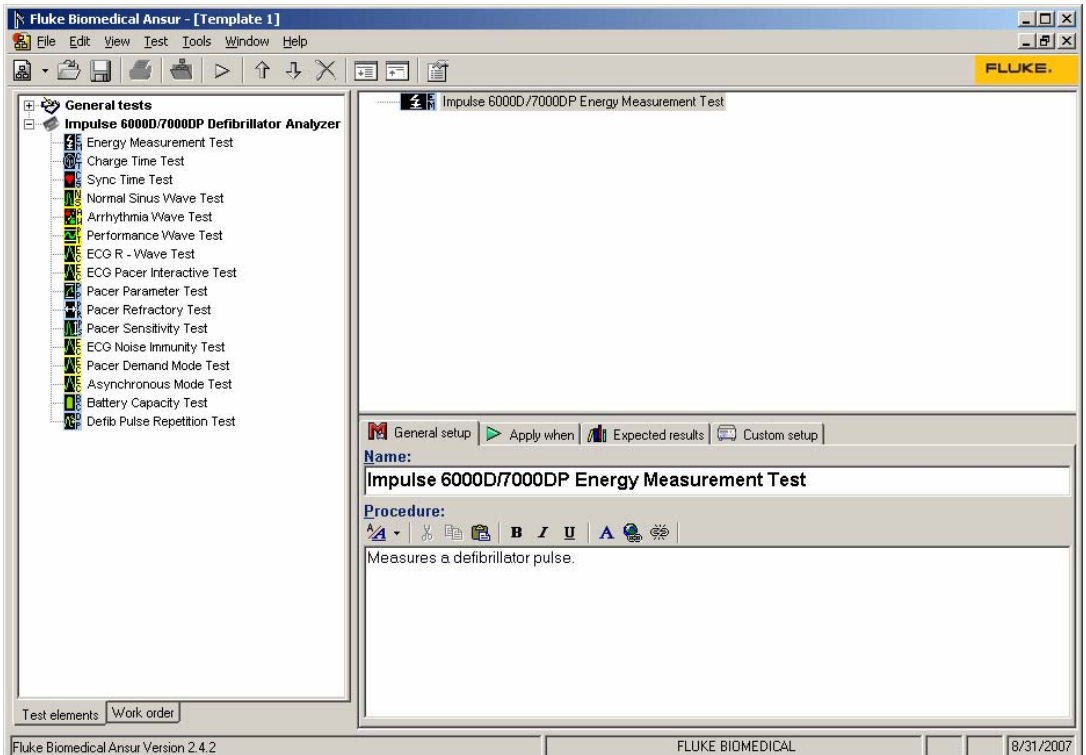
Creating Test Templates

Create, modify, and review test templates using the Ansur **Main Application** window as a template editor. The Impulse 6000D/7000DP Plug-In provides 16 test elements that are used to build new test procedures. These are accessible in **Test Explorer** and are coded as follows:

- Light blue icon – the Analyzer automatically provides test result data to Ansur as the test is completed.
- Yellow icon – resultant data must be manually entered into Ansur by the user.

To build a test template, take the following actions, beginning from the **Main Application** window:

1. Drag a test element from the **Test Explorer** (left pane) into the **Test Template** (right pane), as displayed in Figure 2-32. Clicking the test element in the Test Template highlights the test element and its properties. In this illustration, the highlighted element is the **Impulse 6000D/7000DP Energy Measurement Test**, the first test step to be performed.



fcz08.bmp

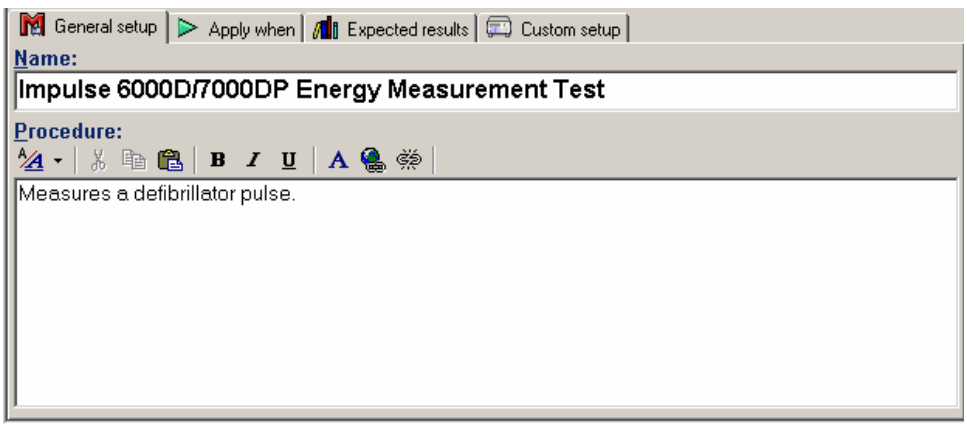
Figure 32. Test Template with Selected Test Element

In the middle of the Test Template window are located the following tabs to allow definition of the properties of the highlighted test element.

- **General setup**
- **Apply when**
- **Expected results**
- **Custom setup**

Test element properties consist of multiple pages, described below.

2. Click the **General setup** tab. A screen opens, allowing entry of a name for the test. See Figure 2-33. In the space below the name, enter the procedures and instructions to be followed when conducting the test.



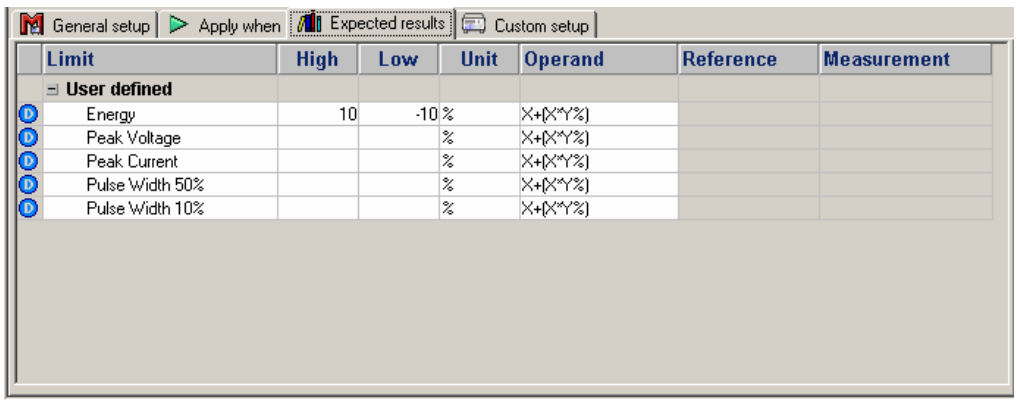
fcz09.bmp

Figure 33. User-Definable Parts of the General Setup Tab

3. Click the **Apply when** tab to assign report levels, standards, and service events to test elements.
4. Click the **Expected results** tab to view or change the measurement limits for tests, as shown in Figure 34.

Note

The **Expected results** page is unavailable when test elements do not return measurement data.



fcz10.bmp

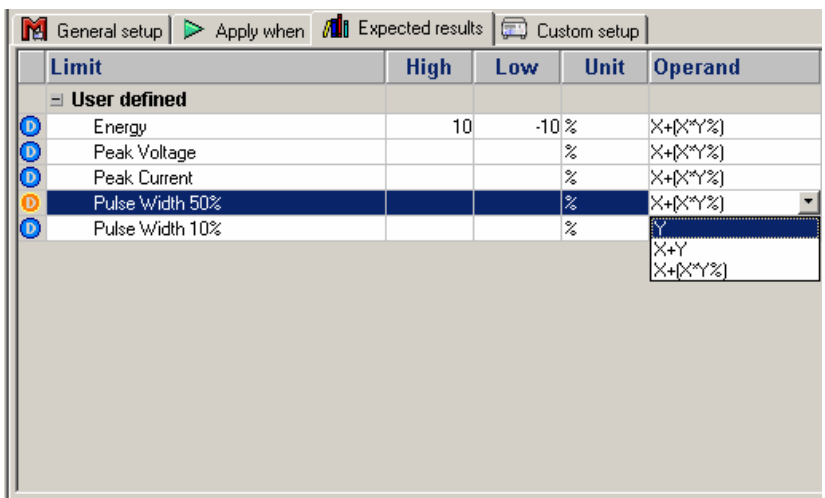
Figure 34. Expected Results Options for User Input

5. To define how Ansur calculates the limit values for certain measurements, click the Operand field to open a drop-down menu, as shown in Figure 2-35.

   The operand can be set to any of the following:

   - Y – an absolute value
   - X + Y – an offset where the limit is calculated as preset value + specified limit
   - X + (X * Y%) – calculated as a percentage deviance from the preset value

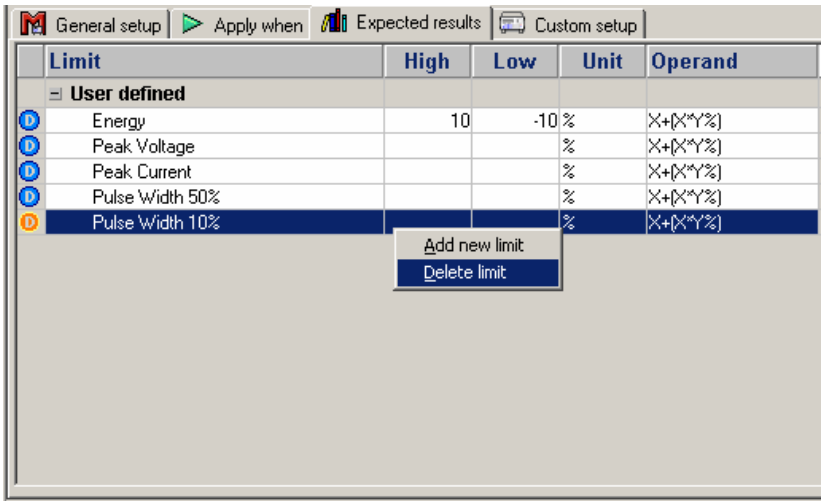
   When the operand is not an absolute limit, the (D) (dynamic) icon appears in the left column, as shown in Figure 2-35. This icon indicates that the limit will be calculated when the test is run.



fcz11.bmp

Figure 35. Changing the Operand in Expected Results

6. To add or delete limits, right click one of the rows of the **Expected results** page and select from the pop-up menu, as shown in Figure 36.



fcz12.bmp

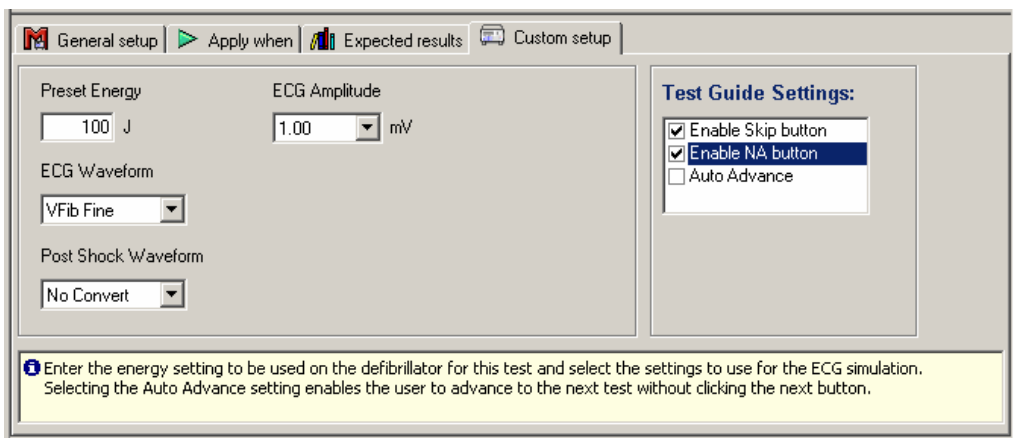
Figure 36. Add or Delete Limits Pop-up Menu

7. Click the Custom setup tab to view and define the parameters used in tests. Test elements have unique custom setups for the capabilities they provide. An example is shown in Figure 2-37.

8. If desired, deselect (uncheck) either or both of the Test Guide Settings checkboxes to disable the Skip and NA button options.

   The Test Guide Settings control whether certain test elements can be skipped altogether or marked as Not Applicable (NA) while the tests run. The Skip and NA buttons, shown below, are enabled by default. If a setting is enabled, the corresponding Skip or NA button is available on the toolbar.

eur022.bm



fcz13.bmp

Figure 37. Custom Setup Page for Pacer Parameter Test Element

Defibrillator tests also have available the Auto Advance option that is disabled by default. This option advances the Test Guide to the next defibrillator test step automatically. If this option is selected for a test element, the field user does not have to click the Start button on the Test Guide toolbar to start the test or click the Next button to advance to the next test step.

Note

*The **Auto Advance** option will not resume after a failed test step.*

Using Defibrillator Test Elements

The defibrillator test elements contained in the Impulse 6000D/7000DP Plug-In are designed to test specific aspects of a defibrillator. This section describes the parameters that can be customized for each test element and the measurement data they provide.

Energy Measurement Test

The Energy Measurement test provides data related to the discharge of a defibrillator and verifies the accuracy of the energy level being delivered. The test provides the measurements listed in Table 5 and uses the custom setup parameters that are shown in Table 6.

Note

*This test element supports the **Auto Advance Test Guide Setting**.*

Table 5. Energy Measurement Test Measurements

Measurement	Unit of Measure	Description
Energy	Joules	Amount of energy discharged by the defibrillator
Peak Voltage	Volts	Peak voltage detected during the discharge
Peak Current	Amperes	Peak current detected during the discharge
Pulse Width 50%	milliseconds	The width of the pulse at 50% of its peak
Pulse Width 10%	milliseconds	The width of the pulse at 10% of its peak

Table 6. Energy Measurement Test Custom Parameters

Parameter	Description
Preset Energy	The energy (in Joules) used for the test The field user is prompted to set the defibrillator to this value.
ECG Waveform	The ECG waveform that the Analyzer should simulate during the test

Charge Time Test

The Charge Time test measures how long a defibrillator takes to charge up to a specified energy level. Typically, this test uses as a parameter the maximum energy level available to the defibrillator. Table 7 lists the measurements taken for this test. Custom parameters available for the Charge Time tests are listed in Table 8.

Note

*This test element supports the **Auto Advance Test Guide Setting**.*

Table 7. Charge Time Test Measurements

Measurement	Unit of Measure	Description
Charge Time	seconds	How long it took for the defibrillator to charge to the preset energy specified.
Energy	Joules	Amount of energy discharged by the defibrillator
Peak Voltage	Volts	Peak voltage detected during the discharge
Peak Current	Amperes	Peak current detected during the discharge
Pulse Width 50%	milliseconds	The width of the pulse at 50% of its peak
Pulse Width 10%	milliseconds	The width of the pulse at 10% of its peak

Table 8. Charge Time Test Custom Parameters

Parameter	Description
Preset Energy	The energy (in Joules) used for the test The field user is prompted to set the defibrillator to this value.
ECG Waveform	The ECG waveform that the Analyzer should simulate during the test

Synchronization Time Test

The Synchronization Time test determines the ability of the defibrillator to synchronize the discharge of its output pulse with the simulated ECG waveform generated by the Analyzer. Synchronization Time test measurements are listed in Table 9. The Synchronization Time test custom parameters are shown in Table 10.

Note

*This test element supports the **Auto Advance Test Guide Setting**.*

Table 9. Synchronization Time Test Measurements

Measurement	Unit of Measure	Description
Sync Time	seconds	The delay between the top of the ECG wave and the discharging of the defibrillator pulse
Energy	Joules	Amount of energy discharged by the defibrillator
Peak Voltage	Volts	Peak voltage detected during the discharge
Peak Current	Amperes	Peak current detected during the discharge

Table Synchronization Time Test Measurements (cont)

Measurement	Unit of Measure	Description
Pulse Width 50%	milliseconds	The width of the pulse at 50% of its peak
Pulse Width 10%	milliseconds	The width of the pulse at 10% of its peak

Table 10. Synchronization Time Test Custom Parameters

Parameter	Description
ECG Waveform	The ECG waveform the Analyzer should simulate during the test
Preset Energy	The energy (in Joules) used for the test The field user is prompted to set the defibrillator to this value.

Using Pacemaker Test Elements (Impulse 7000DP only)

Pacemaker tests confirm the basic operation of external transcutaneous pacemakers by measuring various pacemaker outputs and timing. These tests do not operate with the Impulse 6000D analyzer.

Pacer Parameter Test

The Pacer Parameter test provides data about the accuracy of a pacer's output. Tables 11 and 12 list the Pacer Parameter test measurements and custom parameters.

Table 11. Pacer Parameter Test Measurements

Measurement	Unit of Measure	Description
Pacer Rate	Pulses/minute	Number of pacer pulses detected by the Analyzer during the test
Pulse Amplitude	milliamperes	Peak current detected during the test
Pulse Width	milliseconds	Pacer pulse width as measured by the Analyzer
Pacer Energy	millijoules	Pacemaker energy output

Table 12. Pacer Parameter Test Custom Parameters

Parameter	Description
Input Jacks	Specifies where the pacer leads are attached on the Impulse 7000DP Choose between pacer jacks or defib jacks.
Pacer Load	Defines load used for the test If defib jacks are used for the test, a 50 Ω load is used.
Brand	The brand of defibrillator/pacer being tested can be specified to optimize the accuracy of the test.
DUT Rate	Expected pacer rate; field user prompted to set pacemaker to this rate
DUT Amplitude	Expected pacer amplitude; field user prompted to set the pacemaker output current to this value

Pacer Refractory Test

The Pacer Refractory test checks the ability of the pacemaker to interact with cardiac activity when the pacemaker is in demand mode. Ansur retrieves the Pulsed Refractory Period (PRP) and the Sensed Refractory Period (SRP) timings as measured by the Analyzer. Tables 13 and 14 list the Pacer Refractory test measurements and custom parameters.

Table 13. Pacer Refractory Test Measurements

Measurement	Unit of Measure	Description
Sensed Rp	milliseconds	Sensed Refractory Period: period of time that immediately follows sensing of cardiac activity during which time the pacemaker does not sense further cardiac activity The Analyzer measures SRP from the peak of the first ECG R-wave complex to the next ECG R-wave complex following pacemaker pulse.
Paced Rp	milliseconds	Pulsed Refractory Period: period of time immediately following pacemaker pulse during which time the pacemaker senses no cardiac activity and its output is not inhibited The Analyzer measures PRP from the leading edge of the pacemaker pulse to the peak of the first ECG R-wave complex.

Table 14. Pacer Refractory Test Custom Parameters

Parameter	Description
Input Jacks	Specifies where the pacer leads are attached on the Impulse 7000 Choose between pacer jacks or defib jacks.
Pacer Load	Defines load used for the test If defib jacks are used for the test, a 50 Ω load is used.
Brand	The brand of defibrillator/pacer being tested can be specified to optimize the accuracy of the test.
DUT Rate	Expected pacer rate; field user prompted to set pacemaker to this rate
DUT Amplitude	Expected pacer amplitude; field user prompted to set the pacemaker output current to this value

Pacer Sensitivity Test

The Pacer Sensitivity test determines the threshold of ECG amplitude required to trigger the pacemaker. Tables 15 and 16 list the Pacer Sensitivity test measurements and custom parameters.

Table 15. Pacer Sensitivity Test Measurements

Measurement	Unit of Measure	Description
Sensitivity Threshold Amplitude	millivolts	The ECG amplitude that triggers the pacer

Table 16. Pacer Sensitivity Test Custom Parameters

Parameter	Description
Input Jacks	Specifies where the pacer leads are attached on the Impulse 7000DP Choose between pacer jacks or defibrillator jacks.
Pacer Load	Defines load used for the test If defibrillator jacks are used for the test, a fixed 50 Ω load is used.
Brand	The brand of defibrillator/pacer being tested can be specified to optimize the accuracy of the test.
DUT Rate	Expected pacer rate; field user prompted to set pacemaker to this rate
DUT Amplitude	Expected pacer amplitude; field user prompted to set the pacemaker output current to this value
Waveform Type	The type of ECG waveform output to generate during the test
Waveform Width	The width of each waveform pulse
Waveform Polarity	The ECG waveform polarity that can be specified

ECG Pacer Interactive Test

The ECG Pacer Interactive test simulates a patient response to a pacemaker. Table 17 lists the ECG Pacer Interactive custom test parameters.

Note

This is a visual / audible test; the Analyzer takes no measurements during this test.

Table 17. ECG Pacer Interactive Test Custom Parameters

Parameter	Description
Response Waveform	The type of patient response to simulate: • Demand: Normal sinus rhythm at specified rate. Pacer in demand mode can interact so it paces when the normal rate is too slow. Heart responds to pacer pulses at or above threshold. • Asystole: No heartbeat, but heart responds to pacer pulses at or above threshold. • Non-capture: Same as Asystole, but heart fails to respond to one out of every ten pacer pulses. • Non-function: No heartbeat and no response to pacing.
Rate	Beats per minute to use for the Demand Response Waveform
Duration	How long the simulation should last Setting can range from 1 to 60 seconds. If the “Indefinite” checkbox is checked, the duration is ignored, and the test must be manually stopped by the field user (**Stop** in **TEST GUIDE** toolbar).
Response Threshold	The level of pacing current required to generate a heart response

Pacer Demand Mode Test

The Pacer Demand Mode test is used to verify demand mode pacing over a range of BPM rates. This test is conducted as a pass/fail test. Table 18 lists the custom parameters used for the Pacer Demand Mode test.

Note

This is a visual / audible test; the Analyzer takes no measurements during this test.

Table 18. Pacer Demand Mode Test Custom Parameters

Parameter	Description
Input Jacks	Specifies where the pacer leads are attached on the Impulse 7000DP Choose between pacer jacks or defib jacks.
Pacer Load	Defines load used for the test. If defib jacks are used for the test, a 50 Ω load is used.
Brand	The brand of defibrillator/pacer being tested can be specified to optimize the accuracy of the test
DUT Rate	Expected pacer rate; field user prompted to set pacemaker to this rate
DUT Amplitude	Expected pacer amplitude; field user prompted to set the pacemaker output current to this value
ECG Simulation	This group of parameters establishes a range of BPM values that the test cycles through. The Starting Rate sets the BPM for the start of the test. The Duration Per Step indicates how long the starting rate is used. At the end of the duration time, the BPM is adjusted by the amount specified in the Auto Increment / Decrement Amount parameter. The test concludes when the Ending Rate has been reached.

Asynchronous Mode Test

The Asynchronous Mode Test element requires the same parameters as the Pacer Demand Mode Test, but this test element is used for testing a non-demand mode pacer. Refer to table 18 for the list of custom parameters that this test uses.

Using ECG Waveform Simulation Test Elements

Normal Sinus Wave Simulation

The Analyzer can generate a normal sinus wave between 10 and 360 beats per minute for output to a defibrillator monitor. Table 19 lists the custom parameters for this simulation.

Note

This is a visual / audible test; the Analyzer takes no measurements during this test.

Table 19. Normal Sinus Wave Simulation Test Custom Parameters

Parameter	Description
ECG Amplitude	The voltage amplitude to use during the simulation of the normal sinus wave
Normal Sinus Waveform BPM	The BPM rate to use for the test
Duration	How long the simulation should last Setting can range from 1 to 60 seconds. If the “Indefinite” checkbox is checked, the duration is ignored, and the test must be manually stopped by the field user (**Stop** in **TEST GUIDE** toolbar).

Arrhythmia Wave Test

This test is typically used to verify the shock advisory capability of a defibrillator in response to various arrhythmia waveforms. Table 20 lists test custom parameters.

Note

This is a visual / audible test; the Analyzer takes no measurements during this test.

Table 20. Arrhythmia Wave Advisory Test Custom Parameters

Parameter	Description
Arrhythmia	Selects the category of arrhythmia waveform to use for the test
Arrhythmia Type	Selects the type of arrhythmia to simulate
Poly VTach Type	Provides a choice of 5 types of Poly VTach waveforms when this type of arrhythmia is selected
Mono VTach Rate	BPM value is required when Mono VTach Rate is selected.
ECG Amplitude	The voltage amplitude to use for the arrhythmia simulation
Duration	How long the simulation should last. Setting can range from 1 to 60 seconds. With checkbox **Indefinite** selected, duration is ignored, and the test must be manually stopped by the field user (**Stop** in **TEST GUIDE** toolbar).
Atrial Width, Amplitude, and Polarity	These atrial parameters are needed for some TV Paced arrhythmia simulations.
Ventricular Width, Amplitude, and Polarity	These ventricular parameters are needed for some TV Paced arrhythmia simulations.

Performance Wave Simulation

The Performance Wave simulation can be used to test the integrity of a defibrillator monitor with a variety of additional waveform shapes, such as square, triangle, sine, and pulse. Table 21 lists the custom parameters for this simulation.

Note

This is a visual / audible test; the Analyzer takes no measurements during this test.

Table 21. Performance Wave Simulation Test Custom Parameters

Parameter	Description
ECG Amplitude	Indicates the amplitude that the waveform should have
Performance Wave	Selects the type of Waveform to use for the test Choices are: • Square: 0.125 or 2 Hz • Pulse: 30 or 60 BPM • Sine: 0.05, 0.5, 10, 40, 50, 60, 100, 150, 200 Hz • Triangle: 2 or 2.5 Hz
Duration	How long the simulation should last Setting can range from 1 to 60 seconds. If checkbox **Indefinite** is selected, duration is ignored, and the user must stop the test manually (**Stop** in **TEST GUIDE** toolbar).

ECG R-Wave Test

The ECG R-Wave test checks the ability of the ECG monitor to detect an R-Wave over a range of R-Wave widths and amplitudes. Table 22 lists the custom parameters used by the ECG R-Wave test.

Note

This is a visual / audible test; the Analyzer takes no measurements during this test.

Table 22. ECG R-Wave Test Custom Parameters

Parameter	Description
ECG Amplitude	Indicates the amplitude that the waveform should have
Performance Wave	Selects the type of Waveform to use for the test Choices are: • Square: 0.125 or 2 Hz • Pulse: 30 or 60 BPM • Sine: 0.05, 0.5, 10, 40, 50, 60, 100, 150, 200 Hz • Triangle: 2 or 2.5 Hz
Duration	How long the simulation should last Setting can range from 1 to 60 seconds. If checkbox **Indefinite** is selected, duration is ignored, and the user must stop the test manually (**Stop** in **TEST GUIDE** toolbar).

ECG Noise Immunity Test

The ECG Noise Immunity test checks the ability of the ECG monitor to reject AC line frequency noise. The custom parameters for this test are listed in table 23.

Note

This is a visual / audible test; the Analyzer takes no measurements during this test.

Table 23. ECG Noise Immunity Test Custom Parameters

Parameter	Description
Noise Amplitude	Indicates the amplitude for the waveform
Line Frequency	Selects 50 Hz or 60 Hz line noise simulation
ECG Wave	Option to include an ECG Wave during the test

Using Battery Performance Test Elements

Battery Capacity Test

The Battery Capacity test is used to check whether a battery-powered defibrillator can deliver a certain number of discharges per minute and whether the charge time remains adequate throughout the test. Tables 24 and 25 list the Battery Capacity test measurements and custom parameters.

Table 24. Battery Capacity Test Measurements

Measurement	Unit of Measure	Description
Charge Time	seconds	How long it took for the defibrillator to charge to the preset energy specified The test stores multiple charge times – one per discharge.

Table 25. Battery Capacity Test Custom Parameters

Parameter	Description
Preset Energy	The energy (in Joules) used for the test The field user is prompted to set the defibrillator to this value.
Discharges/Minute	The number of discharges to be completed each minute The default value of 1 should normally be used.
Total Discharges	The number of discharges to be completed during the test

Defib Pulse Repetition Test

The Defib Pulse Repetition test is used to determine if a battery-powered defibrillator can deliver a specified number of discharges within a specified amount of time. Tables 26 and 27 list the Defib Pulse Repetition test measurements and custom parameters.

Table 26. Defib Pulse Repetition Test Measurements

Measurement	Unit of Measure	Description
Energy	Joules	Amount of energy discharged by the defibrillator The test stores multiple energy measurements – one per discharge.

Table 27. Defib Pulse Repetition Test Custom Parameters

Parameter	Description
Preset Energy	The energy (in Joules) used for the test The field user is prompted to set the defibrillator to this value.
Number of Pulses	The number of discharges to be completed during the test
Number of Minutes	The maximum time allowed for this test to be completed