

COPY



PHILIPS

Philips Medical Systems

1217 10: APR -6 19:16

Citizen Petition

Heartstream

Via Federal Express

April 2, 2004

Dockets Management Branch
Food and Drug Administration
Department of Health and Human Services
Room 1-23
12420 Parklawn Drive
Rockville, MD 20857

To whom this may concern:

Pursuant to 21 CFR 821.2 and 10.30, Philips Medical Systems, Heartstream is submitting this citizen petition for an exemption of the medical device tracking requirements currently applied to its family of automated external defibrillators that are used outside a user facility. These products were first cleared by the FDA in September 1996 and first commercially introduced onto the US market (and outside the US market) in November 1996. See below for a table that shows the marketing name, 510(k) clearance number, clearance date and date the tracking order was received.

Product Name	510(k) clearance	Clearance Date	Tracking Order Date
ForeRunner series	#K955628	9/10/1996	4/6/1998*
FR2 series	#K003565	12/20/2000	**
FR2+ series (use with M3848A and M3849A)	#K014157	1/17/2002	1/17/2002
HS1 product family (cleared as the M5066A/M5068A)	#K020715	11/2002	11/12/2002

* Philips Medical Systems, Heartstream began fulfilling its tracking obligations upon clearance in 1996. When changes were made to the tracking requirements in 1997, the Company continued to fulfill the tracking obligation even though we did not receive a tracking order until April 1998.

** Philips Medical Systems, Heartstream did not receive a specific tracking order for this clearance but based on the previously received tracking order and the regulations, it implemented the Company's tracking process for this product.

The original intent of the tracking regulations is that manufacturers be able to trace devices to specific patients when the device is used outside a user if the failure of the devices would reasonably likely result in serious health consequences.¹ Initially, tracking provisions were required even if FAA did not issue an order. Section 211 of the FDA

¹ Federal Register. Vol. 58, No. 156, 43422, Section I.A.

2004P.0164
Philips Medical Systems
Citizen Petition

2301 Fifth Avenue, Suite 200
Seattle, WA 98121-1825
Tel. (206) 664 5000, Fax. (206) 664 5001

CP2



Modernization Act (FDAMA) enacted on November 21, 1997 amended section 519(e)(1) of the Federal Food, Drug and Cosmetic Act to authorize FDA, in its discretion, to issue orders that require a manufacturer to track a class II or class III device if the failure of the device would be reasonably likely to have serious adverse health consequences, or the device is intended to be implanted in the human body for more than 1 year, or is life sustaining or life supporting and used outside a device user facility. Based on this amendment, FDA has discretion on whether to order tracking for devices that meet the statutory requirements or to release devices from tracking based on additional guidance factors and other relevant information that comes to the agency's attention. Per the FDA Medical Device Tracking guidance, the following additional factors may be considered to determine whether a tracking order should be issued:

- (A) likelihood of sudden, catastrophic failure;
- (B) likelihood of significant adverse clinical outcome; and
- (C) the need for prompt professional intervention.

The agency may add or remove devices from the list of tracked devices and may consider the additional guidance factors in conjunction with the review of premarket applications, recall data, medical device reporting, inspections, petitions, postmarket surveillance or other information coming to its attention.²

Based on field performance data of Philips Medical Systems, Heartstream automated external defibrillators, the history of use demonstrates that it is reasonably unlikely that removing the tracking requirement for Philips Medical Systems, Heartstream automated external defibrillators will negatively impact public health. Furthermore, consistent with our intended use, users have migrated from medical professionals (primary users at the time the tracking requirements were introduced) to lay users. Due to the increased portability of automated external defibrillators and the sudden nature of cardiac arrest, traditional tracking methods may no longer be effective. Tracking orders are intended to provide for tracing to specific patients yet the majority of sudden cardiac arrest victims have no prior symptoms.³ In addition, Philips Medical Systems, Heartstream has established alternate methods that fulfill the intent such that tracking requirements are no longer relevant. Philips Medical Systems, Heartstream, therefore, is submitting this document to request an exemption from the tracking requirements of the regulations for its automated external defibrillators.

CITIZEN PETITION

The undersigned submits this petition under 21 CFR 821.2 and 10.30 to request the Commissioner of Food and Drugs to revoke the previously issued tracking orders issued to Philips Medical Systems, Heartstream automated external defibrillators.

² Medical Device Tracking Guidance for Industry and FDA Staff; issued May 5, 2003

³ American Heart Association; Sudden Deaths from Cardiac Arrest – Statistics; Statistical Fact Sheet – Miscellaneous; 2004 Update, page 3.



A. ACTION REQUESTED

Copies of the existing tracking orders are included in Attachment 1. These letters state that:

You are notified by this letter of your obligations to adopt a method of tracking for the devices referenced above as authorized by section 519(e) of the Federal Food, Drug and Cosmetic Act, (the Act) as amended by section 211 of the Food and Drug Administration Modernization Act of 1997 (FDAMA). The implementation of section 519(e) of the Act, as amended, requires the Food and Drug Administration (FDA) to issue an order to manufacturers when FDA determines that a person who manufactures and distributes a device meets the relevant statutory requirements and tracking is required to protect public health. This order is effective immediately.

The proposed language in response to this petition is:

Philips Medical Systems, Heartstream automated external defibrillators when used outside a user facility are no longer required to comply with the previously issued tracking orders for the ForeRunner, FR2 series and HS1 defibrillator product families and their associated accessories.

B. STATEMENT OF GROUNDS

The following information is required for this petition by 21 CFR 821.2(b).

(1) Name of the Device

The marketing names for the currently marketed models for which an exemption is sought include:

- Philips ForeRunner Defibrillator;
- Philips HeartStart FR2 Series Defibrillator (which includes the FR2 and FR2+ series) and
- Philips HeartStart HS1 Defibrillator (which includes the Philips OnSite Defibrillator and Philips HeartStart Home Defibrillator).

Note: The ForeRunner, FR2 series and OnSite defibrillators have been or are currently manufactured by Philips Medical Systems, Heartstream that are privately labeled and sold by our distribution partner, Laerdal Medical Corporation, both in the US and outside the US. For ease of reading this document, all of these products will be referred to as "Heartstream" automated external defibrillators.



Note: The ForeRunner defibrillator is no longer manufactured but since the tracking requirements apply to product already distributed, this model is included in this petition.

(2) Device Classification

Automated external defibrillators are currently classified as preamendment, class III medical devices. The classification code is MKJ.

(3) Representative Labeling Showing Intended Use

Representative labeling for each of the products is included in Attachment 2. In addition, the indications for use page that was cleared with each of the product families is included in Attachment 3.

Note: The FR2 and HS1 labeling still includes information on tracking since the exemption is under review. Once the exemption is approved, this information will be removed from the labeling.

(4) Reasons Why Tracking Requirements are Unnecessary

The initial intent of the tracking requirement for automated external defibrillators was to ensure that the devices could be recalled efficiently to ensure safety and effectiveness of the installed base. The safe history of Heartstream automated external defibrillators, designed and developed in its Seattle-based facility, presented in this petition demonstrates the Company's commitment and implementation of design practices ensuring that its products perform reliably and appropriately for their intended environments. Furthermore, in the event of a recall, Philips Medical Systems, Heartstream proposes alternative methods to alert users being consistent with the changes that have occurred in the user profiles.

Technology Evolution

Automated external defibrillator technology has evolved since these devices were initially included in the list of medical devices subject to tracking. Some of the first automated external defibrillators:

- used airway and chest electrodes to obtain the ECG and deliver the shock, were required to be plugged into an alternating current outlet when not in use such that the battery capacity would be sufficient for a emergency use, required manually testing of the defibrillator by the user and the defibrillator had to undergo testing and calibration by the factory or company personal every 6 months;⁴

⁴ Cardiac Resuscitator Corporation Heart-Aid Model 60. Information derived from #K821448.



- were only operational for 15 minutes and were single use devices that required factory maintenance after each use;⁵
- needed at least 14 hours to recharge the battery, recommended batteries be replaced every 12 months and performed no automatic self-testing.⁶

By contrast automated external defibrillator technology has now advanced such that the Heartstream automated external defibrillators (ForeRunner, FR2 Series and HS1) are virtually maintenance free. When Philips Medical Systems, Heartstream was founded in 1992, the design of existing defibrillator products relied on manufacturer-initiated product recalls to prevent potential widespread device failures following the discovery of systemic component or process-related failures. In addition to a very limited amount of automated functionality, defibrillator manufacturers of that era depended principally upon manual user testing of each device in the field to assure its readiness for use. The Company recognized early on that the cost of failure was a part of the overall cost of doing business for a defibrillator manufacturer. Thus, it was imperative to greatly improve upon the historical norms in order to provide a large quantity of reliable products at a reasonable cost to the purchaser. Philips Medical Systems, Heartstream's product development teams use field data, manufacturing data, and significant relevant product line experience to create designs that are simple, robust, and thoroughly self-testable.

All Heartstream automated external defibrillators automatically and without user interaction perform extensive daily, weekly and monthly self-tests to mostly stricter acceptance criteria than those required during normal operating parameters designed to detect errors prior to actual use. Other self-tests are also automatically performed, such as during battery insertion. In the case of the HS1 defibrillators, the pads are pre-connected to the defibrillator such that their readiness is assessed during daily, weekly and monthly self-testing. The battery life for Heartstream non-rechargeable, disposable batteries once installed in the defibrillators is 1 year to 4 years typically, and the remaining capacity is automatically tested during self-testing. Calibration testing is also performed automatically by the defibrillators.

All Heartstream automated external defibrillators alert the user both visually and audibly if a self-test fails. All Heartstream automated external defibrillators are designed such that the visual self-test indicator is active when displaying passing results. This means that unless the defibrillator specifically passes its self-test, the visual indicator indicates a failing status. For instance, the ForeRunner and FR2 status indicators change from a flashing hourglass to a red X when a self-test fails and the HS1 defibrillators status indicator stops flashing its green flashing light emitting diode (LED) if a self-test failure occurs. In addition, all Heartstream

⁵ Physio-Control LifePak 100. Information derived from #K832833.

⁶ Cardiac Resuscitator Corporation Heart-Aid Model 100. Information derived from #K870622.



automated external defibrillators chirp loudly when a self-test does not pass. Furthermore, all Heartstream automated external defibrillator status indicators display a failing status if there is insufficient battery to power the active status indicators. Since no routine maintenance is required, Philips Medical Systems, Heartstream recommends in its labeling that users routinely look at the status indicator and listen for any chirps to help ensure the defibrillator will be ready to use in an emergency situation.

Field Performance of Heartstream Automated External Defibrillators

The field history of Heartstream defibrillators provides support of the Company's design and manufacturing practices with a very low rate of failures occurring during uses (resulting in Medical Device Reports), recalls and service returns (when the self-testing process detected a condition that alerted the user to contact the manufacturer). In accordance with 21 CFR 10.20(j)(2)(ii), the confidential information presented to support this position, meeting the requirements of 21 CFR 10.20(j)(2)(i), is provided separately in Attachment 4. In summary, these field data show that:

- The confirmed failure rate for Heartstream automated external defibrillators during a use is less than 0.0001%.
- Heartstream has initiated one voluntary, reportable recall of a single unit from the field. This specific field correction pertained to the FR2 Defibrillator that had been assembled with a component that allowed the FR2 to meet all performance specifications but may have failed one of its self-tests sooner than expected.

Lay Users

Further supporting the excellent field performance of Heartstream automated external defibrillators, there have been a number of independent studies published in the literature where lay users deployed Heartstream defibrillators with no device malfunctions during an emergency situation occurring.^{7, 8, 9, 10, 11} Other Philips Medical Systems, Heartstream sponsored post-market studies demonstrated that no device malfunctions occurred during emergency situations.^{12, 13, 14, 15} In none of these studies were there any failures of the

⁷ Page RL et al. Use of automated external defibrillators by a us airline. *N Engl J Med.* 2000;343:1210-6.

⁸ Valenzuela TD et al. Outcomes of rapid defibrillation by security officers after cardiac arrest in casinos. *N Engl J Med.* 2000;343:1206-9.

⁹ Caffrey S et al. Public use of automated external defibrillators. *N Engl J Med.* 2002;347:1242-47.

¹⁰ Capucci A et al. Out-of-hospital early defibrillation successfully challenges sudden cardiac arrest: the piacenza progetto vita project. *Ital Heart J.* 2002;3(12):721-5.

¹¹ Public Access Defibrillation trial sponsored by the National Heart, Lung and Blood Institute. Presented at AHA Nov 11, 2003. Also at <http://depts.washington.edu/padctc/resfaq.pdf>.

¹² Schneider T et al. Low-energy biphasic waveform defibrillation minimizes post resuscitation myocardial dysfunction after prolonged cardiac arrest. *Resuscitation.* 1998;37:S42.



defibrillator to function when needed in an emergency situation. Furthermore, there have been no reports in these studies or to Philips Medical Systems, Heartstream of any user, bystander or patient injury caused by a Heartstream automated external defibrillator. The combination of the field experience reported in Attachment 4 and these published reports support the conclusion that the failure rate of the Heartstream families of automated external defibrillators is extremely low.

Automated external defibrillators are highly portable devices intended for multiple patient uses. Due to the multiple patient uses, either through emergency medical systems, public access programs, corporate defibrillation programs (airlines, for instance) or hospitals (the ForeRunner and FR2 are often sold into hospitals for their first responder defibrillation programs), it is not possible for the defibrillator manufacturer to know in advance who the defibrillator user will be or the patient upon whom the defibrillator will be used. In addition, because these devices are so portable, they could easily be shipped to other locations, sold or donated to other entities, transferred among individuals who cannot be effectively required to provide tracking information to the manufacturer. Consequently, Philips would frequently be unaware of the change in the tracking information. These scenarios reinforce the notion that more public methods of notifying the public about potential product issues would be more appropriate for automated external defibrillators and consistent with our field corrective action procedure (Attachment 5).

Cost Considerations

The cost impact to the Company, including implementing, maintaining and auditing a tracked device also warrants consideration. In the original Federal Register tracking notice, it was estimated that it would cost \$62.00 – \$92.00 per device to meet the tracking requirements for devices used outside a user facility.¹⁶ For Philips Medical Systems, Heartstream, it can be estimated that it has cost the Company approximately \$930,000 – \$1,380,000 while only recalling one unit in the past eight years of production. The benefit to public health to maintaining the tracking requirements for Heartstream defibrillators when acceptable alternative methods exist do not appear to outweigh the risks.

¹³ Gliner BE et al. Treatment of out-of-hospital cardiac arrest with a low-energy impedance compensating biphasic waveform automatic external defibrillator. *Biomedical Instrumentation & Technology*. 1998;32:631-44.

¹⁴ Poole JE et al. Low-energy impedance-compensating biphasic waveforms terminate ventricular fibrillation at high rates in victims of out-of-hospital cardiac arrest. *LIFE Investigators. J Cardiovascular Electrophysiology*. 1997 Dec;8(12):1373-85.

¹⁵ Jorgenson et al. AED use in businesses, public facilities and homes by minimally trained first responders. *Resuscitation*. 2003; 59(2)225-33.

¹⁶ Federal Register. Vol. 58 No 156. August 16, 1996 page 43446, Section IV.



(5) Description of Alternative Methods

Based on the design and performance of Heartstream-designed defibrillators in the field, the following methods for initiating a recall if needed for Heartstream automated external defibrillators are sufficient to meet the intent of the tracking requirements and provide the basis for an exemption from the detailed requirements of the tracking regulations:

- Use publicly available methods to alert potential owners, using mainstream methods such as the news media, Philips internet homepage, recall.gov homepage and Consumer Product Safety Commission assistance to provide information related to field corrections.
- Use communications methods and infrastructure of our US channel partners to relay the relevant information.
- Use the extended warranty database that Philips maintains to contact customers via direct mail and/or phone notifications among customers who have provided us this information. Encourage end users to provide information by incentivizing through means such as providing free accessories to registrants.
- Since the tracking requirements apply to the initial distributor for sales outside the United States, globally accepted techniques for communicating with customers who may have time zone and language issues are used. These strategies include the Philips home page, relevant regulatory authorities in these other countries and utilizing the communications and infrastructure of our outside-the-US channel partners.

A copy of the Philips Medical Systems, Heartstream field corrective action procedure that includes these methods is included as Attachment 5.

From a manufacturing standpoint, we will continue our current practice of maintaining lot traceability on key components and finished devices. Items that are currently documented in the manufacturing records, for example are the defibrillator high voltage capacitor, the circuit board(s) used inside the defibrillator and key components on the circuit board(s), including the high voltage switch, micro-processors, and patient isolation resistors. We also trace via manufacturing records and label on the battery and defibrillation pads the associated lot number of the finished devices. These data are used during product investigations to detect any trends and provide additional assurances that potentially affected distributed products could be more easily identified.



(6) Other Information

Each year approximately 450,000 people in the US suffer a cardiac arrest.¹⁷ For the best chance of survival, a shock should be delivered within 5 minutes.¹⁸ Defibrillation is the only effective treatment for sudden cardiac arrest with the out-of-hospital survival rate for sudden cardiac arrest in the US only at 5%.¹⁹ The sudden cardiac arrest survival rate declines 7-10% for each minute that passes since collapse.²⁰ The survival rate is so low mainly because defibrillators do not reach the victims in sufficient time.²¹ The reason defibrillators don't reach SCA victims in time is not due to device malfunctions but more due to EMS response times for a typical community averaging 9 minutes.²² And because time is so critical when treating sudden cardiac arrest, there has been a movement of defibrillators into large organizations such as airlines, corporate offices that distribute to local facilities and large school districts, and places where large groups of people gather, such as airports, sports stadiums and convention centers.

C. ENVIRONMENTAL IMPACT

Philips Medical Systems, Heartstream claims a categorical exclusion under 21 CFR 25.34.

D. ECONOMIC IMPACT

In accordance with 21 CFR 10.30(b), economic impact information has not been provided since it has not been requested by the Commissioner.

¹⁷ American Heart Association. Derived from 2003 Heart and Stroke Statistical Update. Dallas, Tx. American Heart Association, 2004.

¹⁸ American Heart Association. 2001 Heart and Stroke Statistical Update. Dallas, Tx. American Heart Association 2000.

¹⁹ American Heart Association. 2001 Heart and Stroke Statistical Update. Dallas, Tx. American Heart Association 2000.

²⁰ American Heart Association. 2001 Heart and Stroke Statistical Update. Dallas, Tx. American Heart Association 2000.

²¹ American Heart Association. 2001 Heart and Stroke Statistical Update. Dallas, Tx. American Heart Association 2000.

²² Mossesso VN et al. Use of automated external defibrillators by police officers for treatment of out-of-hospital cardiac arrest. Ann Emerg Med. 1998;32:200-7.



PHILIPS

E. CERTIFICATION

The undersigned certifies that to the best knowledge and belief of the undersigned, this petition includes all information and views on which the petition lies, and that it includes representative data and information to the petitioner which are unfavorable to the petition.

Signature: 

Name of petitioner: Philips Medical Systems, a division of Philips Electronics North America Corp.

By: Teresa Skarr

Title: Manager, Regulatory and Medical Affairs

Mailing address: 2301 Fifth Avenue, Suite 200, Seattle, Washington 98121

Telephone number: 206.664.5290

Alternate Contact: Tish Treherne

Mailing Address: 2301 Fifth Avenue, Suite 200, Seattle, Washington 98121

Telephone number: 206.664.5283

Conclusion

Philips Medical Systems, Heartstream has demonstrated a history of extremely reliable service and use for its automated external defibrillators. When a defibrillator manufacturer can demonstrate this level of field performance and commitment to fulfilling the intent of tracking requirements through alternative means, removal of the tracking requirements is well supported and justified without compromising public health. We believe the information provided in this petition supports the revocation of the tracking orders for and exemption from future tracking orders for Philips' ForeRunner, FR2 series and HS1 series of automated external defibrillators.

As a reminder to the Agency, as stated in 21 CFR 821.2(b), the review time for an exemption to the tracking requirements is 90 days.



PHILIPS

We look forward to the Agency's response to this petition. Should there be further questions, please contact me at 206.664.5283 or the alternate contact, Teresa Skarr, Manager of Regulatory and Medical Affairs at 206.664.5290. Thank you for your attention to this matter.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Tish Treherne".

Tish Treherne
Regulatory Affairs Associate
Philips Medical Systems

Enclosure: Original and 4 copies

Attachment 1



Medical Device Tracking Order

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

APR - 6 1998

Ms. Teresa Skarr
• Manager, Regulatory Affairs
Heartstream, Inc.
2401 4th Avenue, Suite 300
Seattle, Washington 98121

RE: DC-defibrillators and paddles

Dear Ms. Skarr:

You are notified by this letter of your obligation to adopt a method of tracking for the devices referenced above, as authorized by section 519(e) of the Federal Food, Drug, and Cosmetic Act, (the Act) as amended by section 211 of the Food and Drug Administration Modernization Act of 1997 (FDAMA). The implementation of section 519(e) of the Act, as amended, requires the Food and Drug Administration (FDA) to issue an order to manufacturers when FDA determines that a person who manufactures and distributes a device meets the relevant statutory requirements and tracking is required to protect the public health. This order is effective immediately. It is my understanding, based on a telephone conversation you had on April 6, 1998, with Mr. Uldriks of my staff, that you have continued to implement tracking voluntarily even though you had not received a tracking order before February 19, 1998.

Section 519(e) of the Act, as amended, states that FDA, "...may by order require a manufacturer to adopt a method of tracking a class II or class III device—

- (A) the failure of which would be reasonably likely to have serious adverse health consequences; or
- (B) which is—
 - (i) intended to be implanted in the human body for more than one year, or
 - (ii) a life sustaining or life supporting device used outside a device user facility."

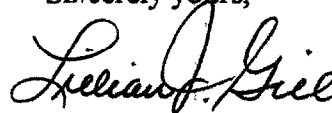
As you know, the corresponding medical device tracking regulations, found in Title 21 Code of Federal Regulations (CFR) Part 821, are intended to ensure that tracked devices can be traced from the device manufacturing facility to the person by whom the device is intended to be used when patient notification (under section 518(a) of the act) or device recall (under section 518(e) of the act) actions are ordered by the agency. The device tracking requirements for exemptions and variances, system and content requirements of tracking, the obligations of persons other than device manufacturers, such as distributors, records and inspection requirements, confidentiality, and record retention requirements,

REC'D APR 13 1998

which were published in the **Federal Register** on August 16, 1993, remain in effect. (21 CFR sections 821.2, 821.25, 821.30, 821.50, 821.55 and 821.60, copy enclosed.)

This order to adopt a tracking method does not change your obligations concerning other existing FDA regulations affecting your device. FDA may publish in the **Federal Register** further announcements concerning your device or the medical device tracking requirements under 21 CFR Part 821. Please contact Chet Reynolds in the Office of Compliance at (301) 594-4618 if you need specific guidance. Other general information on your responsibilities under the Act, or more specific information, such as non-binding guidance on medical device tracking, may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597, or at its internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,

A handwritten signature in cursive script that reads "Lillian J. Gill".

Lillian J. Gill
Director
Office of Compliance
Center for Devices and
Radiological Health

Enclosure



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850**Medical Device Tracking Order**

JAN 17 2002

Ms. Tamara Young
Senior Regulatory Affairs Associate
Philips Medical Systems
2401 Fourth Avenue, Suite 500
Seattle, Washington 98121-1436

RE: DC defibrillators and paddles (this includes automatic external defibrillators-K014157)

Dear Ms. Young:

You are notified by this letter of your obligation to adopt a method of tracking for the devices referenced above, as authorized by section 519(e) of the Federal Food, Drug, and Cosmetic Act, (the Act) as amended by section 211 of the Food and Drug Administration Modernization Act of 1997 (FDAMA). The implementation of section 519(e) of the Act, as amended, requires the Food and Drug Administration (FDA) to issue an order to manufacturers when FDA determines that a person who manufactures and distributes a device meets the relevant statutory requirements and tracking is required to protect the public health. This order is effective immediately.

Section 519(e) of the Act, as amended, states that FDA, "...may by order require a manufacturer to adopt a method of tracking a class II or class III device—

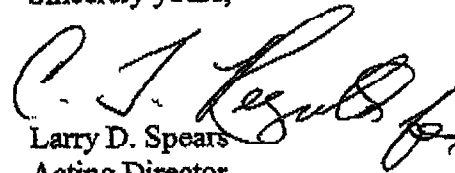
- (A) the failure of which would be reasonably likely to have serious adverse health consequences; or
- (B) which is—
 - (i) intended to be implanted in the human body for more than one year, or
 - (ii) a life sustaining or life supporting device used outside a device user facility."

As you know, the corresponding *medical device tracking regulations, found in Title 21 Code of Federal Regulations (CFR) Part 821*, are intended to ensure that tracked devices can be traced from the device manufacturing facility to the person by whom the device is intended to be used when patient notification (under section 518(a) of the act) or device recall (under section 518(e) of the act) actions are ordered by the agency. The device tracking requirements for exemptions and variances, system and content requirements of tracking, the obligations of persons other than device manufacturers, such as distributors, records and inspection requirements, confidentiality, and record retention requirements, which were published in the **Federal Register** on August 16, 1993, remain in effect. (21 CFR sections 821.2, 821.25, 821.30, 821.50, 821.55 and 821.60, copy enclosed.)

Page 2 – Philips Medical Systems

This order to adopt a tracking method does not change your obligations concerning other existing FDA regulations affecting your device. FDA may publish in the **Federal Register** further announcements concerning your device or the medical device tracking requirements under 21 CFR Part 821. Please contact Chet Reynolds in the Office of Compliance at (301) 594-4618 if you need specific guidance. Other general information on your responsibilities under the Act, or more specific information, such as non-binding guidance on medical device tracking, may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597, or at the internet address www.fda.gov/cdrh.

Sincerely yours,



Larry D. Spears
Acting Director
Office of Compliance
Center for Devices and
Radiological Health

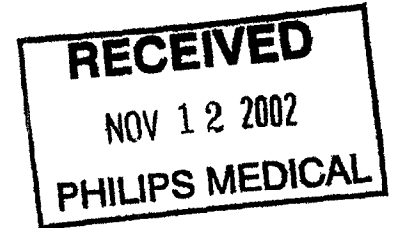
Enclosure



Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

NOV 12 2002

Medical Device Tracking Order



Tamara Yount
Philips Medical Systems
2401 Fourth Avenue, Suite 500
Seattle, WA 98121-1436

RE: Automated External Defibrillator (K020715)

Dear Ms. Yount:

You are notified by this letter of your obligation to adopt a method of tracking for the devices referenced above, as authorized by section 519(e) of the Federal Food, Drug, and Cosmetic Act, (the Act) as amended by section 211 of the Food and Drug Administration Modernization Act of 1997 (FDAMA). The implementation of section 519(e) of the Act, as amended, requires the Food and Drug Administration (FDA) to issue an order to manufacturers when FDA determines that a person who manufactures and distributes a device meets the relevant statutory requirements and tracking is required to protect the public health. This order is effective immediately.

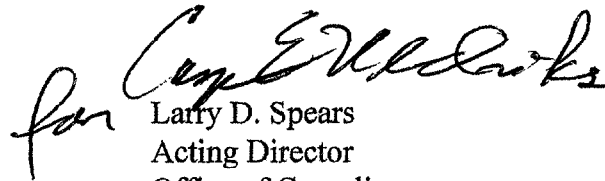
Section 519(e) of the Act, as amended, states that FDA, "...may by order require a manufacturer to adopt a method of tracking a class II or class III device—

- (A) the failure of which would be reasonably likely to have serious adverse health consequences; or
- (B) which is—
 - (i) intended to be implanted in the human body for more than one year, or
 - (ii) a life sustaining or life supporting device used outside a device user facility."

As you know, the corresponding medical device tracking regulations, found in Title 21 Code of Federal Regulations (CFR) Part 821, are intended to ensure that tracked devices can be traced from the device manufacturing facility to the person by whom the device is intended to be used when patient notification (under section 518(a) of the act) or device recall (under section 518(e) of the act) actions are ordered by the agency. The device tracking requirements for exemptions and variances, system and content requirements of tracking, the obligations of persons other than device manufacturers, such as distributors, records and inspection requirements, confidentiality, and record retention requirements, which were published in the **Federal Register** on August 16, 1993, remain in effect. (21 CFR sections 821.2, 821.25, 821.30, 821.50, 821.55 and 821.60, copy enclosed.)

This order to adopt a tracking method does not change your obligations concerning other existing FDA regulations affecting your device. FDA published in the **Federal Register** on February 28, 2002, an amendment to the final rule to revise the scope of the regulation and add certain patient confidentiality requirements, and non-substantive changes to remove outdated references and simplify terminology. (67 FR 6943) Please contact Chet Reynolds in the Office of Compliance at (301) 594-4618 if you need specific guidance. Other general information on your responsibilities under the Act, or more specific information, such as non-binding guidance on medical device tracking, may be obtained from the Division of Small Manufacturers, International, and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597, or at the internet address www.fda.gov/cdrh.

Sincerely yours,

The image shows a handwritten signature in black ink that reads "for Larry D. Spears". The signature is written in a cursive style and is positioned to the left of the typed name.

Larry D. Spears
Acting Director
Office of Compliance
Center for Devices and
Radiological Health

Enclosure

Attachment 2



HEARTSTRE

FORERUNNER

Technology by Hewlett-Packard

THE FORERUNNER

A ON/OFF: Initiates voice and screen prompts. Press again to turn off.

B STATUS INDICATOR: Shows when the FORERUNNER is ready to use based on automatic self tests.

C BATTERY LATCH: Slide to eject the battery.

MICROPHONE: Located behind the battery latch. Records voice information when optional PC voice data card is installed.

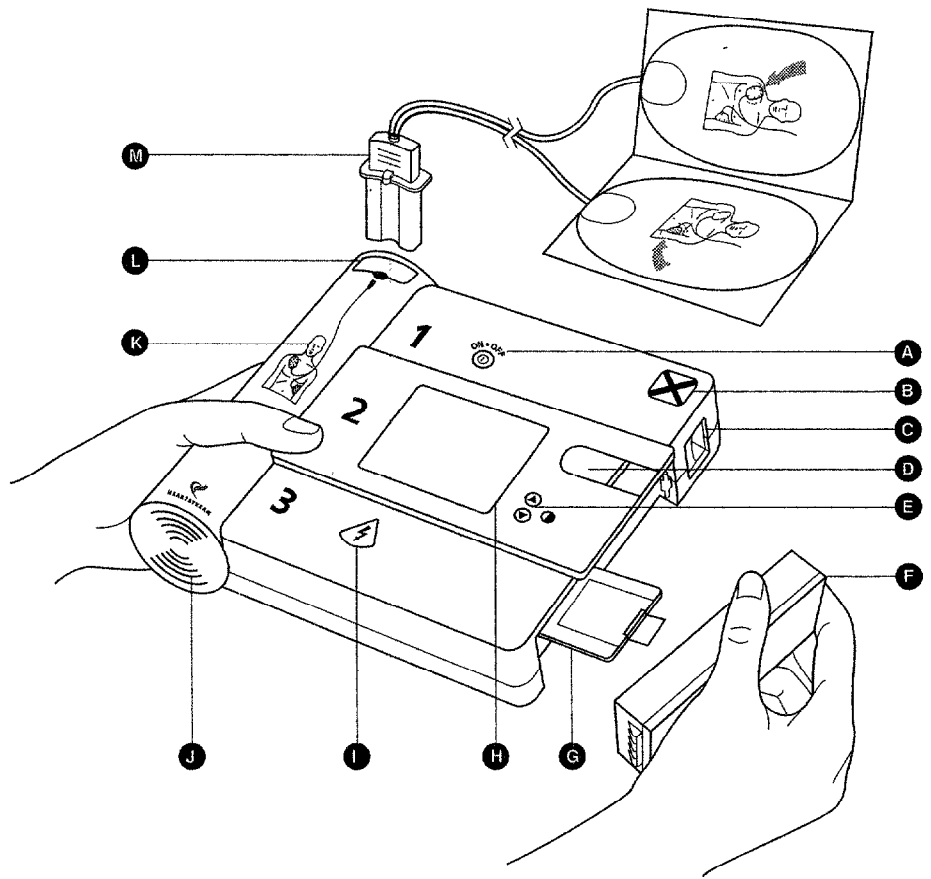
D OPTIONAL MANUAL OVERRIDE BUTTON: (Available on Model EM only) Permits qualified users to manually charge the FORERUNNER and deliver a shock.

E CONTRAST BUTTONS: Adjust LCD screen contrast and are used to control other functions.

F DISPOSABLE/RECYCLABLE BATTERY: Provides power for the FORERUNNER.

G OPTIONAL PC DATA CARD: Stores ECG and event data. An optional card can also store voice data. Separate cards provide setup and training options.

H LCD SCREEN: Displays text prompts and patient/event information. ECG and heart rate can be displayed on Models E and EM.



I SHOCK BUTTON: Controls shock delivery. The button flashes when the FORERUNNER is ready to deliver a shock.

J SPEAKER: Provides audible instructions and information about the FORERUNNER and the patient's status.

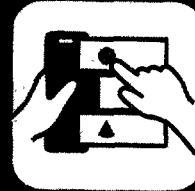
K DEFIBRILLATION PAD PLACEMENT ILLUSTRATION.

L CONNECTOR SOCKET: Insert the defibrillation pads connector into the connector socket. The LED flashes to indicate the socket location. The LED is covered when the defibrillation pad connector is properly inserted in the socket.

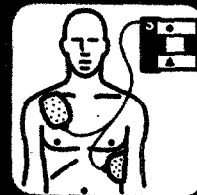
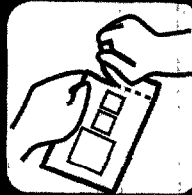
M DEFIBRILLATION PADS: Disposable and self adhesive. Defibrillation pads include attached cable and connector.

PATIENT IS UNCONSCIOUS,
NOT BREATHING, WITHOUT A PULSE:

1 TURN ON



2 FOLLOW
PROMPTS

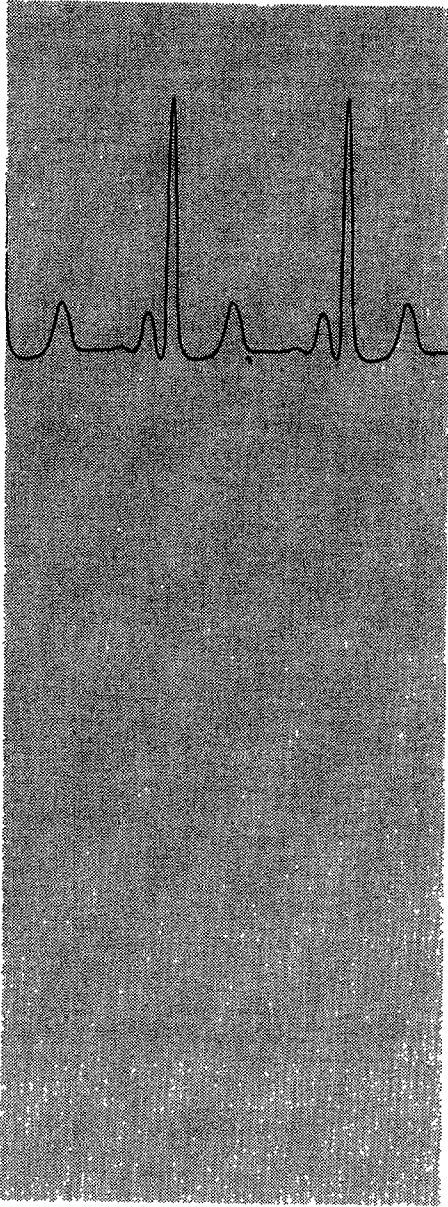


•Remove Pads •Peel off backing •Apply Pad •Plug in Pads connector

3 PRESS SHOCK
BUTTON IF
INSTRUCTED



FORERUNNER SEMI-AUTOMATIC MODE QUICK REFERENCE



FORE  **RUNNER**[®]
semi-automatic defibrillator

User's Guide

For
Model S
Model E
Model EM




Heartstream, the Heartstream logo, FORERUNNER, the FORERUNNER logo, and CODERUNNER are either registered trademarks or trademarks of Hewlett-Packard Company in the United States and/or other countries.

The FORERUNNER semi-automatic defibrillator is sold in some markets as the Laerdal Heartstart FR. Laerdal and Heartstart are registered trademarks of Laerdal Medical Corporation.

FORERUNNER as used in this document, refers to either the HP Heartstream FORERUNNER semi-automatic defibrillator or the Laerdal Heartstart FR.

Specifications are subject to change without notice.

Published in the U.S.A.

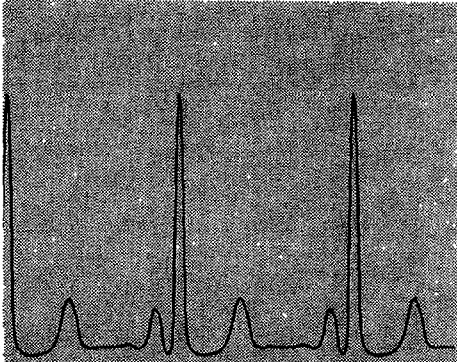
 **CAUTION:** Federal law (USA) restricts this device to sale by or on the order of a physician.

<i>Introduction</i>	<i>1</i>
Overview	1
Indications	3
Contraindications	4
Dangers, Warnings, and Cautions	4
<i>Putting the FORERUNNER into Service</i>	<i>5</i>
How to Put the FORERUNNER into Service	5
Battery Installation and the Battery Insertion Test	6
Status Indicator and Automatic Self Tests	10
<i>Using the FORERUNNER</i>	<i>13</i>
Preparation	14
Analysis and Monitoring	16
Semi-automatic Delivery of Defibrillation Shock	17
Pause for CPR	18
Manual Delivery of Defibrillation Shock	19
Error Conditions, Possible Causes, and Corrective Actions	21
Continued Use	24
<i>Maintaining the FORERUNNER</i>	<i>25</i>
Self Tests and FORERUNNER Maintenance	25
Maintenance Schedule	27
Cleaning	29
Automated Defibrillators: Operator's Check List	30
<i>Event Review Storage and Retrieval</i>	<i>31</i>
Installing the Optional PC Data Card	31
Event Review	33

TABLE OF CONTENTS

<i>FORERUNNER Options</i>	37
FORERUNNER Models	37
Using the FORERUNNER Setup Card	38
Configuring Setup Options	39
Training Options	44
<i>Specifications</i>	45
Technical Specifications	46
Heartstream Clinical Summary and American Heart Association Defibrillation Statement	55
Service and Replaceable Parts	57
<i>Glossary of Symbols</i>	59
FORERUNNER Symbols	60
Screen Symbols	61
PC Card Symbols	62
Battery Symbols	64
<i>Dangers, Warnings, and Cautions</i>	65
General	66
Defibrillation	67
Monitoring	68
Maintenance	68

Introduction



This User's Guide provides information for trained operators about using and maintaining the FORERUNNER semi-automatic external defibrillator (AED). This chapter presents general information that you should know before you begin using the FORERUNNER.

OVERVIEW

The FORERUNNER semi-automatic defibrillator is lightweight, portable, and battery powered. It performs automatic self tests and displays the results of these tests on a Status Indicator. The FORERUNNER has an LCD screen that displays text prompts, patient and event information, and on some models, an electrocardiogram (ECG).


- 1 Overview
- 3 Indications
- 4 Contraindications
- 4 Dangers, Warnings, and Cautions

CHAPTER ONE

Introduction

When connected with Heartstream defibrillation pads to a patient who is unconscious, not breathing, and without a pulse, the FORERUNNER:

- prompts you to take specific actions,
- automatically analyzes the patient's ECG,
- indicates whether a shockable rhythm is present, and if so,
- arms the shock button.

You can deliver the defibrillation shock by pressing the flashing shock button . The FORERUNNER will not deliver a shock unless the shock button is pressed.

The FORERUNNER detects ECG signals and delivers the defibrillation shock using two self adhesive defibrillation pads. The defibrillation pads, cable, and connector are supplied as one disposable assembly.

The FORERUNNER determines proper defibrillation pad contact by monitoring impedance between the two attached defibrillation pads. The FORERUNNER recognizes a shockable rhythm (ventricular fibrillation or certain ventricular tachycardia) based on an ECG analysis system.

The defibrillation shock is delivered using an impedance compensated biphasic waveform with a minimum of 130 Joules delivered to a 50 ohm load. Power is provided by a disposable, recyclable sealed lithium battery installed in the side of the FORERUNNER.

Voice prompts provide instructions and patient information, and are reinforced by messages on the LCD screen. Adjacent pushbuttons control the FORERUNNER.

An optional manual override button is available (Model EM only) for qualified users. It overrides the ECG analysis system and permits the operator to manually charge the FORERUNNER and deliver a shock.

See Appendix B for information about shockable rhythms.

Optional PC data cards can record event information, ECG, voice, and other audible activity. Data stored on a card can be reviewed and reports can be generated using a personal computer. Optional training and setup cards allow the FORERUNNER to perform additional training and setup functions.

Refer to the chapter on event review storage and retrieval for detailed information about using PC data cards and other options.

INDICATIONS

The FORERUNNER, in semi-automatic or manual override mode, is indicated for use on victims of sudden cardiac arrest on whom an apparent lack of circulation is indicated by:

- Unconsciousness
- Absence of breathing
- Absence of detectable pulse

The FORERUNNER is for use by emergency care personnel specifically trained in the operation of the FORERUNNER and qualified by training in advanced cardiac life support, in basic life support, or in other physician-authorized emergency medical response. The FORERUNNER must be used by or on the order of a physician.

The FORERUNNER was not designed or tested to interpret pediatric arrhythmias or administer energy at pediatric joule settings. For children older than 8 years, the American Heart Association recommends that standard operating procedures for AEDs be followed. American Heart Association.

Textbook of Advanced Cardiac Life Support. Dallas, Tex: AHA; 1994.

CHAPTER ONE

Introduction

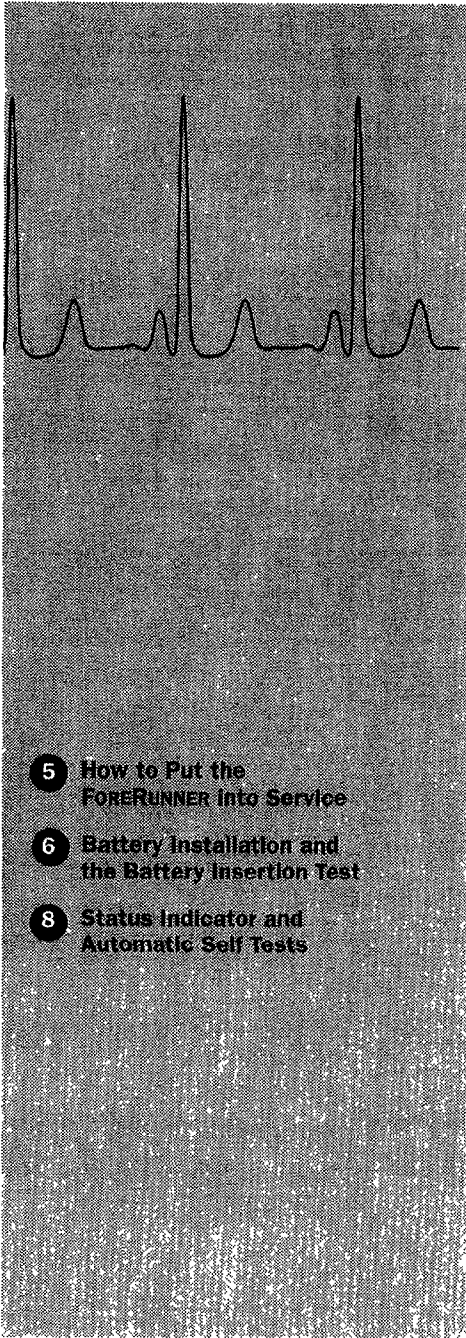
CONTRAINDICATIONS

The FORERUNNER is contraindicated for use on patients exhibiting any one of the following:

- Consciousness
- Presence of breathing
- Presence of detectable pulse

DANGERS, WARNINGS, AND CAUTIONS

This manual contains a list of danger, warning, and caution messages in Appendix D. These terms are used throughout this User's Guide or on the FORERUNNER. Please familiarize yourself with their definitions and significance.



Putting the FORERUNNER into Service

You need three items to put the FORERUNNER into service: the FORERUNNER, its battery, and the package containing the defibrillation pads with attached cable and connector. When you put the FORERUNNER into service, however, it is recommended that you carry a spare package of defibrillation pads, a spare battery, and a spare PC data card if the FORERUNNER uses this option.

HOW TO PUT THE FORERUNNER INTO SERVICE

The FORERUNNER is shipped with standard factory settings and without a PC data card. The settings should be reviewed against your program's protocol and changed as needed. Failure to configure settings correctly may adversely affect use of the FORERUNNER.

Installing a PC data card is optional.

CHAPTER TWO

Putting the FORERUNNER into Service

To put the FORERUNNER into service using the standard factory settings and no PC data card:

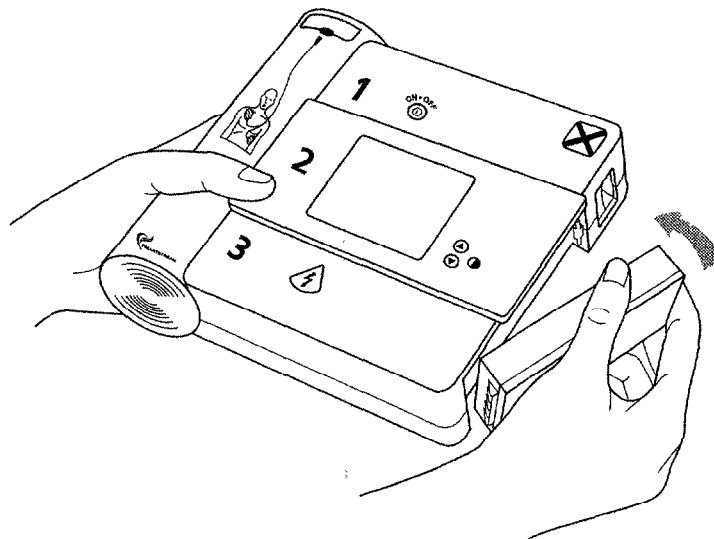
For information about setup options and changing the factory settings, see Appendix A. For information about installing and using PC data cards, see the chapter on event review storage and retrieval.

⚠ CAUTION: Follow all battery labeling instructions. Install the battery prior to the date noted on the battery.

1. Insert the battery and perform the Battery Insertion Test (BIT) as described on the following pages.
2. Put the FORERUNNER in an accessible area with the Status Indicator easily visible. See Appendix B for the environmental standby storage specifications.
3. Observe the Status Indicator daily and as described later in this chapter.

BATTERY INSTALLATION AND THE BATTERY INSERTION TEST

When you are ready to put the FORERUNNER into service, install the battery as shown below. Snap the battery into place using a single motion and firm pressure. The battery should “click” into place when it is properly inserted.




The Battery Insertion Test (BIT)

At the time you install a battery, the FORERUNNER automatically performs a comprehensive self test called the Battery Insertion Test (BIT).

The BIT has two parts: an automatic self test followed by an interactive test. During the automatic part of the BIT, the screen displays information about the progress of the self test. No user interaction is required during the automatic part of the BIT.

If the screen displays a message that a previous self test has failed, the FORERUNNER must complete a BIT before being put into service. A message will also be displayed if the FORERUNNER has been stored outside of the recommended standby temperature range since the last BIT was completed. Storing the FORERUNNER outside of the standby temperature and environmental specifications noted in Appendix B will shorten battery life and prevent the FORERUNNER from performing self tests.

The FORERUNNER performs a complete BIT when you install a battery unless:

- In an emergency, you press the On/Off button  to stop the BIT.
- Defibrillation pads are attached to a patient, indicating that the FORERUNNER is in use.
- Less than five minutes have passed since the last use, indicating that it is likely the FORERUNNER is still in use.
- The FORERUNNER detects that a Training card or a Setup card is installed.
- The battery is completely depleted.
- The FORERUNNER is outside of the operating temperature specification.

If any portion of the BIT fails, replace the battery with a new battery and repeat the BIT. If any portion of the second BIT fails, remove the FORERUNNER from service and contact Heartstream Customer Service.

The Status Indicator tells you if the FORERUNNER passed the BIT. See the section later in this chapter titled *Status Indicator and Automatic Self Tests*.

CHAPTER TWO

Putting the FORERUNNER into Service

PC Data Card Verification

The BIT automatically checks for the presence of the optional PC data card. If the PC data card is installed, the BIT verifies that the card is compatible with the FORERUNNER and that the FORERUNNER is able to communicate with the card. The FORERUNNER screen indicates whether the card has data from a previous event stored on it or is cleared of data.

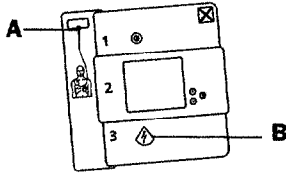


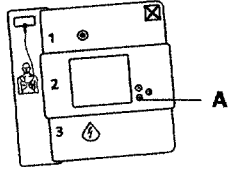





The FORERUNNER screen also indicates if an optional PC data card is not installed, if the card is incompatible with the FORERUNNER, or if the FORERUNNER system is unable to communicate with the card.

If you get a screen prompt that alerts you that there is a data card error, remove the card. Ensure that the card is a Heartstream PC data card and it was installed correctly. If it is a Heartstream PC data card and was installed correctly, remove the card and contact Customer Service for a new card.

Interactive Tests in the BIT

When the automatic part of the BIT and PC data card verification are complete, the BIT begins interactive tests. These tests allow you to verify the correct operation of the screen, buttons, LEDs, and speaker on the FORERUNNER. The FORERUNNER screen guides you through these tests.

Observe each test, follow the prompts as indicated, and note any discrepancies. If any portion of the BIT fails, replace the battery with a new battery and repeat the BIT. If any portion of the second BIT fails, remove the FORERUNNER from service and contact Customer Service. Descriptions of the interactive tests follow.

BIT Interactive Tests	Description and Outcome of the Tests
Speaker/Microphone	An audible test of the speaker occurs when the screen message appears. You should hear two beeps during a successful test.
LEDs 	Observe the two LEDs to verify that they both illuminate: A Connector socket LED. B Shock button LED.
Contrast Buttons  	Press each contrast button when the screen prompt appears. Beeps and a screen message verify the test.
LCD Screen 	Observe the test pattern on the LCD screen to verify operation and adjust the contrast as needed. A Contrast buttons: Press  to increase contrast. Press  to decrease contrast.
Shock Button 	Press the shock button when the screen prompt appears. A beep and screen message verify the test. Pressing the shock button will not deliver a shock during the BIT interactive test.
Manual Override Button (Model EM only) 	If the FORERUNNER is equipped with a manual override button, slide the cover to expose the button. Press the manual override button when prompted. A beep and a screen message verify the test.
On/Off 	Press On/Off when the screen prompt appears. A beep and screen message verify that the interactive portion of the BIT is complete. The FORERUNNER turns off. Observe the Status Indicator to determine if the FORERUNNER passed the BIT.

CHAPTER TWO


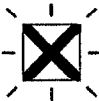
Putting the FORERUNNER into Service


STATUS INDICATOR AND AUTOMATIC SELF TESTS

⚠ WARNING: The BIT and periodic self tests are designed to assess the FORERUNNER's readiness for use. However, no degree of testing can assure performance or detect abuse, damage, or a defect which occurs after the last BIT or self test is completed.

The Status Indicator displays the results of the last complete BIT or periodic self test. The BIT and self tests perform comprehensive checks of the internal electronics of the FORERUNNER. They do not, however, eliminate the need for FORERUNNER maintenance as specified in this User's Guide.

The Status Indicator has three operating conditions:

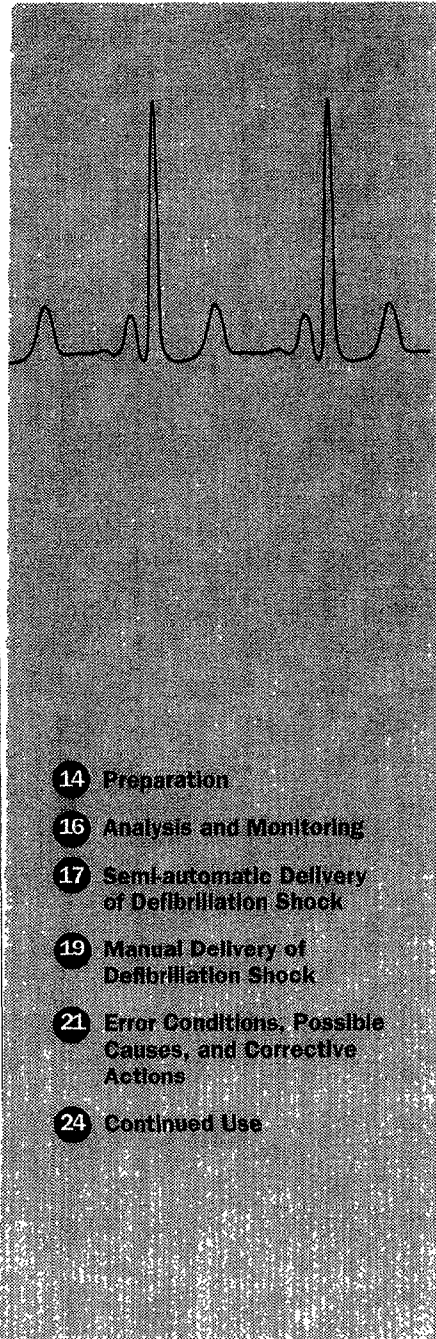
Status Indicator	Condition	Action
<p>Alternates these two shapes</p> 	<p>The FORERUNNER passed the BIT or the last periodic automatic self test.</p>	<p>The FORERUNNER is ready for use.</p>
<p>Displays a flashing red X accompanied by a chirping sound</p> 	<p>The FORERUNNER requires attention. FORERUNNER use is not recommended because the FORERUNNER may not perform properly. A flashing red X can indicate:</p> <ul style="list-style-type: none"> • a low battery • storage of the FORERUNNER outside of the recommended standby temperature range • a self test error 	<ul style="list-style-type: none"> • Remove and reinstall the battery. A screen message will tell you if the standby temperature range has been exceeded. • Check to assure that the FORERUNNER is being stored in the recommended standby temperature range (see Appendix B). • If there is no "low battery" or "replace battery" screen message, remove and reinstall the existing battery and perform the BIT. If the BIT passes, the FORERUNNER is ready for use. If the BIT fails, install a new battery and repeat the BIT a second time. If the BIT passes, the FORERUNNER is ready to use. If the BIT fails, remove the FORERUNNER from service and contact Customer Service.

Status Indicator	Condition	Action
<p data-bbox="217 278 456 304">Displays a solid red X</p> 	<p data-bbox="602 278 894 395">The FORERUNNER is not operable. Do not use the FORERUNNER. The solid red X can indicate:</p> <ul data-bbox="602 421 954 655" style="list-style-type: none"> • a Training card is installed but unused for ten minutes. • a Setup card is installed. • the battery is missing or is completely depleted. • a self test detected a failure. 	<ul data-bbox="987 278 1338 825" style="list-style-type: none"> • Remove the Training or Setup card and reinsert the battery. • Remove and reinstall the battery to perform the BIT. If the BIT passes, the FORERUNNER is ready for use. If the BIT fails, install a new battery and repeat the BIT a second time. If the BIT passes, the FORERUNNER is ready to use. If the BIT fails, remove the ForeRunner from service and contact Customer Service.
<p data-bbox="217 853 553 923">Displays neither alternating hourglass, nor flashing or solid red X</p>	<p data-bbox="602 853 867 910">Possible damage to the FORERUNNER</p>	<p data-bbox="1019 853 1338 1200">Remove and reinstall the battery to perform a BIT. If the BIT passes, the FORERUNNER is ready for use. If the BIT fails, install a new battery and repeat the BIT. If the BIT passes, the ForeRunner is ready for use. If the BIT fails, remove the FORERUNNER from service and contact Customer Service.</p>

CHAPTER TWO

Putting the FORERUNNER into Service

Using the FORERUNNER



This chapter describes how to use the FORERUNNER in an emergency. The FORERUNNER automatically provides appropriate voice and display prompts to guide the operator through a variety of device and patient conditions. The steps for using the FORERUNNER in the semi-automatic mode are explained first. Use of the optional manual override button (Model EM) is described later in this chapter. Finally, this chapter describes corrective actions in cases when warnings or errors occur.

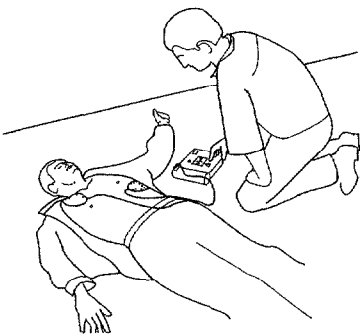
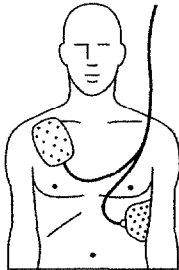
- 14 Preparation
- 16 Analysis and Monitoring
- 17 Semi-automatic Delivery of Defibrillation Shock
- 19 Manual Delivery of Defibrillation Shock
- 21 Error Conditions, Possible Causes, and Corrective Actions
- 24 Continued Use


CHAPTER THREE

Using the FORERUNNER

PREPARATION

1



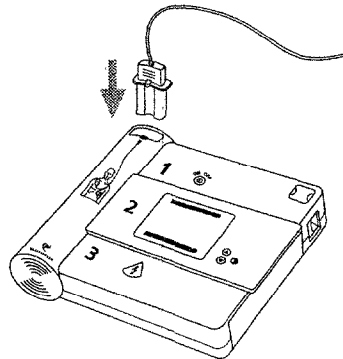
Press the On/Off button  to turn on the FORERUNNER. Follow the instructions provided by the FORERUNNER voice and screen prompts.

Remove clothing from the patient's chest. If necessary, wipe moisture from the patient's chest and clip or shave excessive chest hair.

Open the package containing the defibrillation pads with attached cable and connector. Pull off the protective backing from the defibrillation pads. Ensure the pads are free from obvious signs of damage and that the gel has not dried out. If the pads are damaged or the gel has dried out, use a new set of pads.

Defibrillation pad placement is essential to successful defibrillation. Place one defibrillation pad just below the patient's right clavicle. Place the second defibrillation pad over the ribs on the patient's side in line with the axilla (armpit), and below the patient's left breast. Refer to the diagram on the back of the defibrillation pads.

Insert the defibrillation pads connector in the connector socket located by the flashing light.



⚠ WARNING: Use only Heartstream disposable defibrillation pads, batteries, and other accessories supplied by Heartstream or its authorized distributors. Substitution of non-Heartstream accessories may cause the device to perform improperly.

⚠ CAUTION: Follow all defibrillation pad labeling instructions. Use defibrillation pads prior to expiration date. Discard defibrillation pads after use. Do not reuse defibrillation pads.

⚠ WARNING: Do not place defibrillation pads in the anterior-posterior position. A shock or no shock decision may be inappropriately advised. The FORERUNNER requires that the defibrillation pads be placed in the anterior-anterior position.

⚠ WARNING: Do not allow defibrillation pads to touch each other, or to touch other ECG electrodes, lead wires, dressings, transdermal patches, etc. Such contact can cause electrical arcing and patient skin burns during defibrillation and may divert defibrillating current away from the heart.

⚠ WARNING: During defibrillation, air pockets between the skin and defibrillation pads can cause patient skin burns. To help prevent air pockets, make sure defibrillation pads completely adhere to the skin. Do not use dried out defibrillation pads.

⚠ DANGER: Possible explosion hazard if used in the presence of flammable anesthetics or concentrated oxygen.

⚠ DANGER: The FORERUNNER has not been evaluated or approved for use in hazardous locations as defined in the National Electrical Code standard (Articles 500-503). In compliance with the IEC classification (section 5.5) the FORERUNNER is not to be used in the presence of flammable substance/air mixtures.

⚠ WARNING: Improper use can cause injury. Use the FORERUNNER only as described in the User's Guide. The FORERUNNER delivers electrical energy that can potentially cause death or injury if it is used or discharged improperly. Do not discharge with defibrillation pads together or open and exposed.

⚠ CAUTION: Hazardous electrical output. This equipment is for use only by qualified personnel.

⚠ CAUTION: Aggressive or prolonged CPR to a patient with defibrillation pads attached can cause damage to the pads. Replace the defibrillation pads if they become damaged during use.

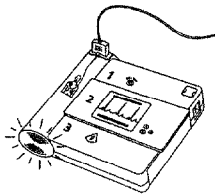
⚠ WARNING: Use of damaged equipment or accessories may cause the device to perform improperly and/or patient or user injury.

CHAPTER THREE

Using the FORERUNNER

ANALYSIS AND MONITORING

2



⚠ WARNING: Handling or transporting the patient during ECG analysis can cause incorrect or delayed diagnosis. Following "Shock Advised" prompts, patient movement and vibration, if present, must be minimized for at least 15 seconds to allow reconfirmation of ECG analysis before delivering a shock.

⚠ WARNING: In patients with cardiac pacemakers, the FORERUNNER may have reduced sensitivity and not detect all shockable rhythms.

⚠ WARNING: Radio frequency (RF) interference from RF devices such as cellular phones and two-way radios may cause improper FORERUNNER operation. In accordance with IEC standard 801.3, a distance of 2 meters (6 feet) between RF devices and the FORERUNNER is recommended.

⚠ WARNING: CPR rates above the American Heart Association guidelines of 100 BPM (beats per minute) can cause incorrect or delayed diagnosis.

Follow the instructions provided by the FORERUNNER voice and screen prompts.

When the FORERUNNER is turned on and detects that the defibrillation pads are connected properly, it automatically begins analyzing ECG data to determine if a defibrillation shock is appropriate therapy. If there is ECG interference, the FORERUNNER provides voice and screen prompts that advise you to take action, such as "DO NOT TOUCH THE PATIENT", until the ECG interference stops.

If No Shock is Advised

Voice and screen prompts inform you when the FORERUNNER determines that no shock is advised. The FORERUNNER continues to monitor ECG data while you provide appropriate care to the patient. While the FORERUNNER is monitoring the patient, voice prompts are suppressed.

While monitoring, if the FORERUNNER detects that the patient's ECG changes to a potentially shockable rhythm or if the FORERUNNER is not able to analyze the rhythm because of interference, it will automatically shift to analyzing mode and give corresponding voice and screen prompts to advise you to respond appropriately.

If No Shock is Advised and the No Shock Advised (NSA) Pause for CPR is Programmed

Voice and screen prompts inform you when the FORERUNNER determines that no shock is advised. The FORERUNNER then pauses to allow time to administer CPR, if needed, without interruption. See *Pause for CPR* later in this chapter for more details.

At the end of the pause for CPR, the FORERUNNER returns to monitoring the patient as described above.

SEMI-AUTOMATIC DELIVERY OF DEFIBRILLATION SHOCK

3





⚠ WARNING: Defibrillation current can cause operator or bystander injury. Do not touch the patient during defibrillation. Do not touch equipment connected to or metal objects in contact with the patient during defibrillation. Disconnect other electrical equipment from the patient before defibrillating. Disconnect the FORERUNNER from the patient prior to use of other defibrillators.

Press the shock button  to deliver the shock.

The FORERUNNER requires five seconds of interference free ECG data to determine if a shock is appropriate therapy. When the FORERUNNER has analyzed the ECG data and determined that a defibrillating shock is appropriate, audible warnings and screen prompts tell you that a shock is advised and to stand clear of the patient. While the FORERUNNER charges, it continues to monitor ECG data.

In the event a patient's heart rhythm spontaneously returns to one for which shock is not advised, the FORERUNNER disarms. Voice and display prompts advise you what action to take.

Note that when the FORERUNNER is fully charged, you can disarm it at any time by pressing the On/Off button  to turn off the FORERUNNER.


The FORERUNNER provides four ways of prompting a shock. Press the shock button  when any of these occur:

- a voice prompt instructs you to deliver a shock
- the shock button flashes
- you hear a steady tone
- you see a screen prompt

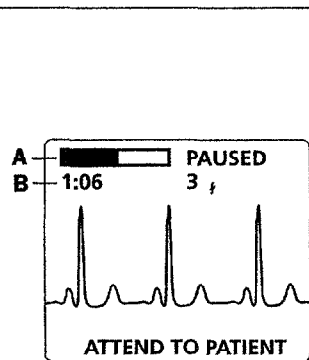
The FORERUNNER will not automatically deliver a shock.

CHAPTER THREE

Using the FORERUNNER

After you press the shock button , a voice prompt confirms that the shock was delivered and the FORERUNNER automatically resumes analyzing the ECG data to determine if the shock was effective. The FORERUNNER continues to provide voice and display prompts that guide you through additional shock sequences, if appropriate. The FORERUNNER also displays the number of shocks that have been delivered. If a series of unsuccessful shocks has occurred, the FORERUNNER will automatically pause for CPR (see Pause for CPR, CS Pause for CPR below).

PAUSE FOR CPR



The FORERUNNER automatically pauses to allow time to administer CPR with associated verbal and screen prompts at the beginning of the pause period. The FORERUNNER suppresses analysis and voice prompts during the pause to allow uninterrupted patient care. The heart rate display also is blank during the pause period.

During a pause for CPR, the screen displays a bar that fills as the pause time elapses.

A Bar indicates time remaining in the pause for CPR

B Elapsed time since the FORERUNNER was turned on and the number of shocks delivered

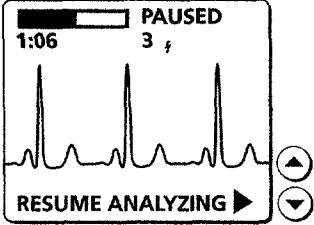
The FORERUNNER can be programmed with a setup card (see Appendix A for instructions) to provide two independent pause periods, a Consecutive Shock (CS) pause and a NO Shock Advised (NSA) pause.

CS Pause


The FORERUNNER can be set up to pause after a series of consecutive unsuccessful shocks. Typically, protocols advise up to three consecutive shocks, followed by a one minute pause for CPR. The FORERUNNER can be programmed, however, to change both the number of consecutive shocks before a pause and the duration of the CS pause period (see Appendix A for instructions).

NSA Pause

A pause for CPR following a No Shock Advised prompt is also available. As with the CS pause, the duration of the NSA pause is programmable.

 <p>If you use the MODEL E or MODEL EM, you can see the patient's ECG trace on the screen.</p>	<p>Resume Analysis During Pause</p> <p>All FORERUNNER models include an option that lets you quit the pause for CPR to manually resume ECG analysis. You can implement this option when you set up the FORERUNNER. See Appendix A for setup instructions. If this option is implemented, the screen includes a text prompt opposite a contrast button during a pause for CPR. To quit the pause for CPR and resume ECG analysis, press the contrast down button (▼).</p> <p>At the end of the pause for CPR or when you resume analysis, the FORERUNNER advises you to stop moving the patient so it can perform analysis on the ECG data without interference. Voice and screen prompts guide you through additional shock sequences, if appropriate.</p>
---	---

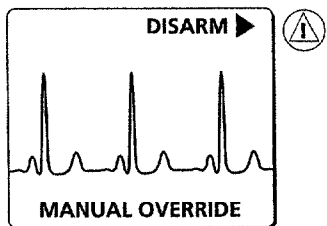
MANUAL DELIVERY OF DEFIBRILLATION SHOCK

 <p>CAUTION: The FORERUNNER manual override button is intended for use only by qualified operators who have been trained in rhythm recognition and treatment through manual charging and delivery of defibrillation shocks.</p>	<p>The FORERUNNER Model EM includes a manual override button to allow qualified personnel the option to deliver a shock regardless of the FORERUNNER's analysis of ECG data.</p> <p>You can use manual override after connecting the defibrillation pads. The manual override button (⚠) does not function if:</p> <ul style="list-style-type: none"> • the FORERUNNER Model EM analysis already indicates a shock is appropriate. • defibrillation pads are not attached.
---	--





CHAPTER THREE



Using the FORERUNNER



⚠ CAUTION: The LCD screen is intended only for basic ECG rhythm identification. The frequency response of the monitor screen is not intended to provide the resolution required for diagnostic and ST segment interpretation.



To use the manual override button:



1. Slide the cover away from the manual override button.
2. Press the manual override button  once to select the manual override mode.
3. Press manual override  again within five seconds to charge the FORERUNNER Model EM so you can deliver a shock. The FORERUNNER is ready to deliver a shock when the shock button  illuminates and flashes, and you hear a steady tone.
4. Press the shock button  to deliver a shock.

If you fail to press the manual override button  a second time within 5 seconds, the FORERUNNER returns to semiautomatic operation; it analyzes the patient's heart rhythm and illuminates the shock button  if analysis determines that a shock is appropriate.

If you decide against delivering the shock after the FORERUNNER Model EM is charged, press the manual override button  to disarm and return to semi-automatic operation. The FORERUNNER automatically disarms and returns to semi-automatic operation after 30 seconds if the shock button  has not been pressed.

ERROR CONDITIONS, POSSIBLE CAUSES, AND CORRECTIVE ACTIONS


If the FORERUNNER detects an error condition or system fault during use, it provides a voice or display prompt, or a combination of both. These are described below.

Error Condition	Possible Cause	Corrective Action
<p>A screen prompt alerts you that the FORERUNNER is not ready for use or that a self test failed. The Status Indicator displays a flashing or solid red x.</p> 	<p>The FORERUNNER performs self tests when you turn it on and while it is in use. A test revealed a failure or error.</p>	<p>Unplug the pads connector from the FORERUNNER. Remove and reinstall the battery to perform a BIT. If the BIT passes, the FORERUNNER is ready for use. If the BIT fails, install a new battery and repeat the BIT. If the BIT passes, the FORERUNNER is ready for use. If the BIT fails, remove the FORERUNNER from service and contact Customer Service.</p> <p>NOTE: You can stop the BIT and resume use of the FORERUNNER as soon as the status indicator changes to the alternating hourglass.</p>
<p>A screen prompt alerts you to a low battery condition.</p>	<p>The FORERUNNER battery is low. Battery failure may be imminent.</p>	<p>Replace the battery as soon as possible.</p>
<p>A screen prompt instructs you to replace the battery immediately. The Status Indicator displays a flashing red x.</p> 	<p>No power remains to continue operating the FORERUNNER. If you do not replace the battery, the FORERUNNER turns off.</p>	<p>Replace the battery immediately.</p>
<p>NOTE: Perform CPR (as necessary) any time there is a delay in FORERUNNER use.</p>		

CHAPTER THREE

Using the FORERUNNER

Error Condition	Possible Cause	Corrective Action
<p>Voice and screen prompts instruct you to attach the defibrillation pads and to plug in the connector.</p>	<p>The defibrillation pads:</p> <ul style="list-style-type: none"> • are not properly applied to the patient. • are not connected to the FORERUNNER. • are touching each other. 	<ul style="list-style-type: none"> • Ensure that the defibrillation pads connector is completely inserted in the connector socket. • Check the defibrillation pads on the patient and ensure that the pads adhere completely to the skin. • If necessary, wipe moisture from the patient's chest and shave or clip excessive chest hair. • Replace the defibrillation pads if the prompt continues.
<p>Voice and screen prompts instruct you to check the defibrillation pads or to press the defibrillation pads firmly to the patient's chest.</p>	<p>The defibrillation pads are not making proper contact with the patient's bare chest.</p>	<ul style="list-style-type: none"> • Check the defibrillation pads on the patient and ensure that the pads adhere completely to the skin. • If necessary, wipe moisture from the patient's chest and shave or clip excessive chest hair. • Replace the defibrillation pads if the prompt continues.
<p>Voice and screen prompts instruct you to replace the defibrillation pads.</p>	<ul style="list-style-type: none"> • The defibrillation pads, cable, or connector may be damaged. • The FORERUNNER has detected a possible short in the defibrillation pads or cable. 	<p>Replace the defibrillation pads.</p>

Error Condition	Possible Cause	Corrective Action
<p>Voice and screen prompts alert you that the ECG analysis has been interrupted.</p>	<ul style="list-style-type: none"> • Patient motion • Radio or electrical sources • Motion around the patient in a dry environment where significant static electricity is present 	<ul style="list-style-type: none"> • Discontinue CPR; do not touch the patient. Attempt to eliminate patient motion, if possible. • Stop the patient transport vehicle if needed. • Check for and remove possible causes of radio and electrical interference.
<p>Voice and screen prompts alert you that a shock was not delivered when you pressed the shock button .</p>	<p>The FORERUNNER will not deliver a shock within specifications if the patient impedance is out of the specified range.</p>	<ul style="list-style-type: none"> • Check the defibrillation pads for proper placement. • Check the defibrillation pads connector. • Press the defibrillation pads firmly to the patient's chest. • Replace the defibrillation pads if necessary.

CHAPTER THREE

Using the FORERUNNER

CONTINUED USE

The FORERUNNER provides a feature called Continued Use to preserve the data recorded during an emergency event when you change a battery or turn the FORERUNNER off briefly. If the FORERUNNER is turned off and then on again during an emergency event, data on the card and in Summary Event Review is preserved and new data appended if:

1. The FORERUNNER is turned off for less than 5 minutes, or
2. The battery is removed for less than 30 seconds. Data preservation is not assured if the battery is removed for more than 30 seconds.


Continued Use also allows you to quickly resume patient care when changing a battery during use. When a Continued Use occurs, the Battery Insertion Test is not done unless the status indicator shows the device is not ready for use. Then the test is run to attempt to clear any error conditions.

Maintaining the FORERUNNER

This chapter describes FORERUNNER automatic self tests and the occasional maintenance that you perform to assure that it is always ready for use.

SELF TESTS AND FORERUNNER MAINTENANCE

The FORERUNNER automatically performs periodic self tests when a battery is installed and has enough power to perform the tests. The FORERUNNER displays a message during these tests indicating that a self test is running.

If you press On/Off  during a self test, you discontinue the test. The test is automatically rescheduled.

The results of the automatic self tests are displayed on the Status Indicator.

- 25 Self Tests and FORERUNNER Maintenance
- 27 Maintenance Schedule
- 29 Cleaning
- 30 Automated Defibrillators: Operator's Check List

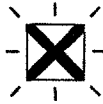
CHAPTER FOUR

Maintaining the FORERUNNER

The Status Indicator displays information about self test results:
Alternates these shapes if the FORERUNNER passed the last self test.



Flashing red **X** accompanied by a chirping sound indicates a self test error occurred or that the battery is low or depleted.



Solid red **X** indicates the battery is completely depleted or a self test failure occurred.



If the FORERUNNER passed its last automatic self test, the Status Indicator alternates between dark square and hourglass shapes.

A self test error, storage of the FORERUNNER outside of the recommended temperature range, or a low or partially depleted battery results in a flashing **X** displayed on the Status Indicator accompanied by a chirping sound. A solid **X** is displayed if a Training or Setup Card is installed, the battery is missing or fully depleted, or a self test failure occurs.

If the Status Indicator displays anything other than the alternating hourglass shapes, such as a constant dark shape or a flashing or solid **X**, remove the FORERUNNER from service. If there is no "low battery" or "replace battery" screen message, remove and reinstall the existing battery and perform the BIT as described in Chapter 2, *Putting the FORERUNNER into Service*. If the BIT passes and the Status Indicator alternates dark and hourglass shapes, return the FORERUNNER to service. If the BIT fails, install a new battery and repeat the BIT a second time. If the BIT passes, return the FORERUNNER to service. If the BIT fails, remove the FORERUNNER from service and contact Customer Service.

The FORERUNNER is designed to be transported, stored, and operated within the environmental conditions specified in Appendix B. FORERUNNER performance may be decreased outside of these conditions.

Self Tests During Use

The FORERUNNER performs a Power On Self Test (POST) each time you turn it on. Self tests continue to monitor the hardware and software systems and battery while the FORERUNNER is in use.

CHAPTER FOUR

Maintaining the FORERUNNER

Frequency	Observe	Take Action
Weekly and after each use	Ensure the exterior of the FORERUNNER and the connector socket are free of cracks and signs of damage.	Perform a BIT if the FORERUNNER is damaged or subjected to abuse. If cracks or damage are noted, remove the FORERUNNER from service and contact Heartstream Customer Service.
After each use	PC data card	Remove the used PC data card and replace it with a spare according to instructions found in Chapter 5, <i>Event Review Storage and Retrieval</i> . Apply the patient ID label to the PC data card and deliver the card to appropriate personnel according to local guidelines and medical protocol.
	Ensure the FORERUNNER exterior and connector socket are free of dirt or contamination	Clean the FORERUNNER, if needed. See the section later in this chapter titled <i>Cleaning</i> .
	Status Indicator	Perform the BIT according to instructions in Chapter 2.

Calibration is unnecessary as the FORERUNNER automatically performs daily self tests and correct operation is verified during the BIT. The FORERUNNER does not require manual verification of energy delivery because monthly automatic self tests verify the waveform delivery system.

The FORERUNNER has no user serviceable parts and Heartstream is the sole repair facility for the unit. As a result, we do not publish Service/Maintenance and Repair Manuals for technical professionals.

⚠ CAUTION: Improper maintenance can cause the FORERUNNER not to function. Maintain the ForeRunner only as described in this User's Guide or as designated by your program's medical director.

⚠ CAUTION: Electrical shock hazard. Dangerous high voltages and currents are present. Do not open unit, remove covers, or attempt repair. There are no user serviceable components in the FORERUNNER. Refer servicing to qualified service personnel.

CLEANING

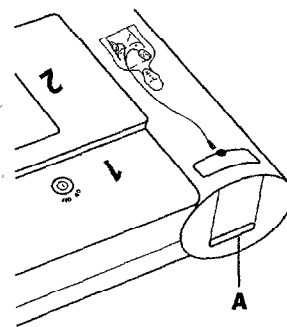
To clean the FORERUNNER, observe the following guidelines:

- The FORERUNNER should only be cleaned with the battery in place to keep fluids out of the PC data card slot and battery contact area.
- Use a soft cloth. Do not use abrasive materials, cleaners, or strong solvents such as acetone, or acetone based cleaners.
- Do not immerse the FORERUNNER in fluids.
- Clean the FORERUNNER and the connector socket with appropriate cleaning agents listed below. The connector socket includes a slot (A) to allow thorough cleaning.

Use only the following cleaning agents:

- Isopropyl alcohol (70 % Solution)
- Soapy water
- Chlorine bleach (30 ml/1 water)
- Ammonia based cleaners
- Glutaraldehyde based cleaners
- Hydrogen peroxide

⚠ CAUTION: Do not immerse any portion of the FORERUNNER in water or other fluids. Do not allow fluids to enter the FORERUNNER. Avoid spilling any fluids on the FORERUNNER or accessories. Spilling fluids into the FORERUNNER may damage it or present a fire or shock hazard. Do not autoclave or gas sterilize the FORERUNNER or accessories.



CHAPTER FOUR
Maintaining the FORERUNNER

The following checklist is provided for your reference.

AUTOMATED DEFIBRILLATORS: OPERATOR'S CHECK LIST

FORERUNNER Model No.: _____ Serial No.: _____

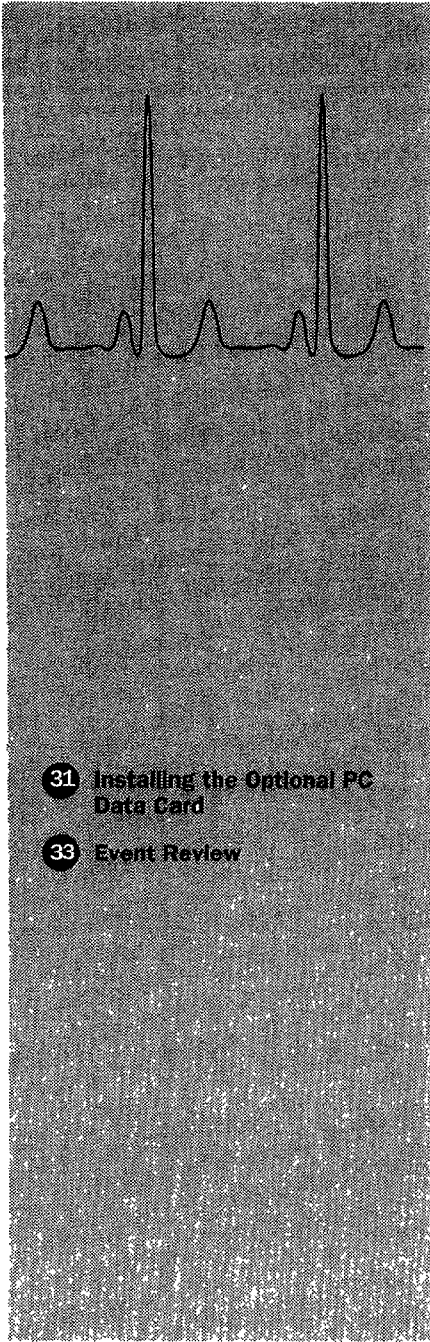
FORERUNNER Location or vehicle ID: _____

Inspect the FORERUNNER at frequencies specified in this chapter or as designated by your medical director. Indicate whether all requirements have been met. Note any corrective action taken. Sign at the bottom of the form.

Date							
Frequency Interval							
FORERUNNER Unit Clean, no dirt or contamination; no damage present							
Supplies Available: a. Two sets defibrillation pads, sealed, within expiration date, undamaged b. Ancillary supplies (Hand towel, scissors, razor) c. Spare unopened battery within "Install Before" date d. PC data card undamaged, with spares*							
Status Indicator a. Self test okay, verify by noting Status Indicator							
Inspected by:							
Remarks, Problems, Corrective Actions							

* Applicable only if unit uses this option.

Event Review Storage and Retrieval



31 Installing the Optional PC Data Card

33 Event Review

The FORERUNNER stores data in its own internal memory and on optional PC data cards supplied by Heartstream. Data stored in the FORERUNNER internal memory and the PC data card can be displayed on the FORERUNNER screen. Heartstream also provides CodeRunner® software to review, archive, and report the information stored on the PC data cards.

INSTALLING THE OPTIONAL PC DATA CARD

If you use the optional PC data card, the FORERUNNER can store and retrieve more detailed information about its own status and about emergency events.

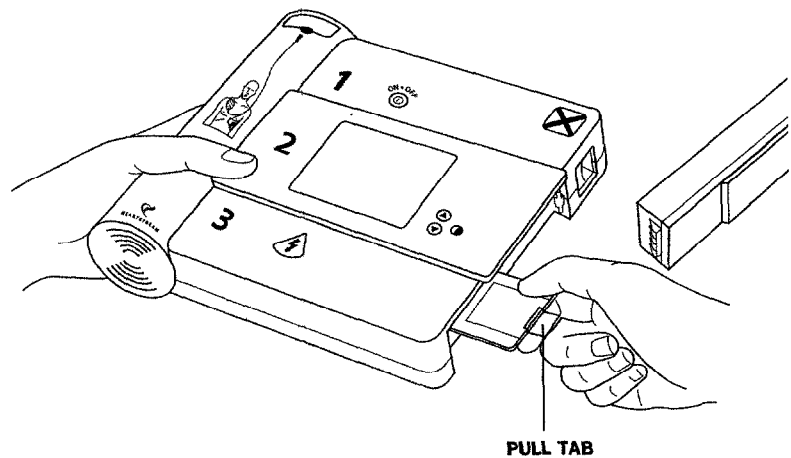
If you choose to use a PC data card, it must be installed before you put the FORERUNNER into service.

CHAPTER FIVE

Event Review Storage and Retrieval

Use only Heartstream PC data cards. Other data cards are not compatible with the FORERUNNER.

To install the optional PC data card:



1. Remove the battery.
2. Make sure the card is clean, dry, and free of old patient identification labels.
3. Insert the PC data card in the slot with the arrow label facing up.
4. Push the card in until it is flush with the slot. Do not force the card into the slot. If the card is hard to insert, remove it and verify that the arrow label faces up.
5. Replace the battery and perform the BIT.

After each FORERUNNER use, replace the PC data card:

1. Remove the battery.
2. Pull the PC data card out by its pull tab.
3. Apply the patient ID label to the PC data card and deliver the card to the appropriate personnel.
4. Insert a new PC data card.
5. Replace the battery and perform the BIT.

EVENT REVIEW

The FORERUNNER automatically stores information about a use of the FORERUNNER in an emergency event even if a PC data card is not used. This information can be displayed on the FORERUNNER screen.

How to Display Event Review




You can display a Summary or Full Event Review at any time unless:

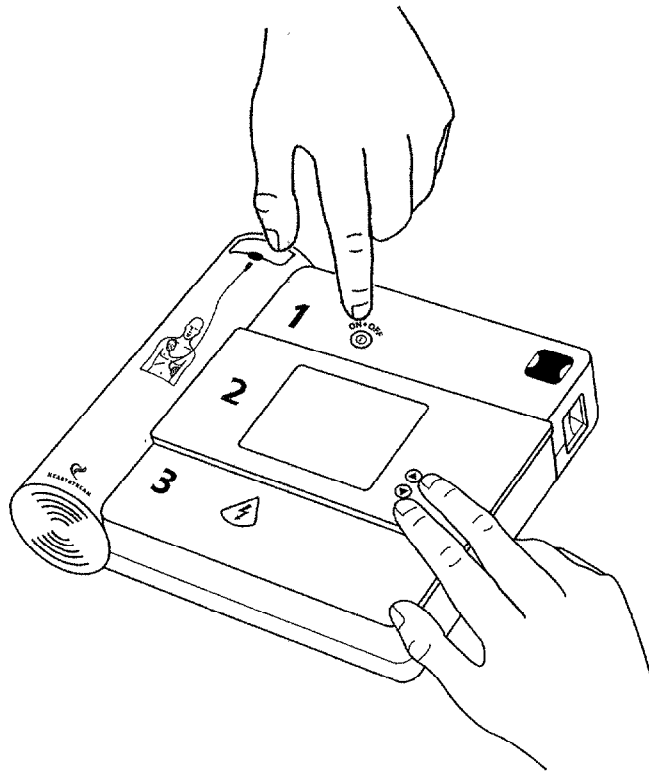
- a FORERUNNER Training card is installed
- a FORERUNNER Setup card is installed

CHAPTER FIVE

Event Review Storage and Retrieval

To display the Event Review:

1. Turn off the FORERUNNER.
2. Press both contrast buttons   while you press the On/Off button  on the FORERUNNER.



Summary Event Review

If a PC data card was not installed during the last emergency event, you can view Summary information on the FORERUNNER screen. Summary Event Review includes:

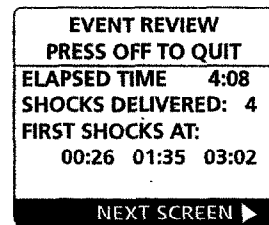
- the elapsed time that the FORERUNNER was on during the emergency event
- the number of shocks delivered

You can display a Summary Event Review for the last emergency event until it is overwritten by the next new use of the FORERUNNER in an emergency event.

Full Event Review


PC data card options add information storage and retrieval capabilities to the Event Review. See Appendix B for information about PC data card capabilities. If a PC data card is installed, the FORERUNNER automatically stores Full Event Review information on the card. Full Event Review information includes:

- the elapsed time that the FORERUNNER was on during the emergency event
- the number of shocks delivered
- the times of the first shocks delivered
- FORERUNNER related events and associated times



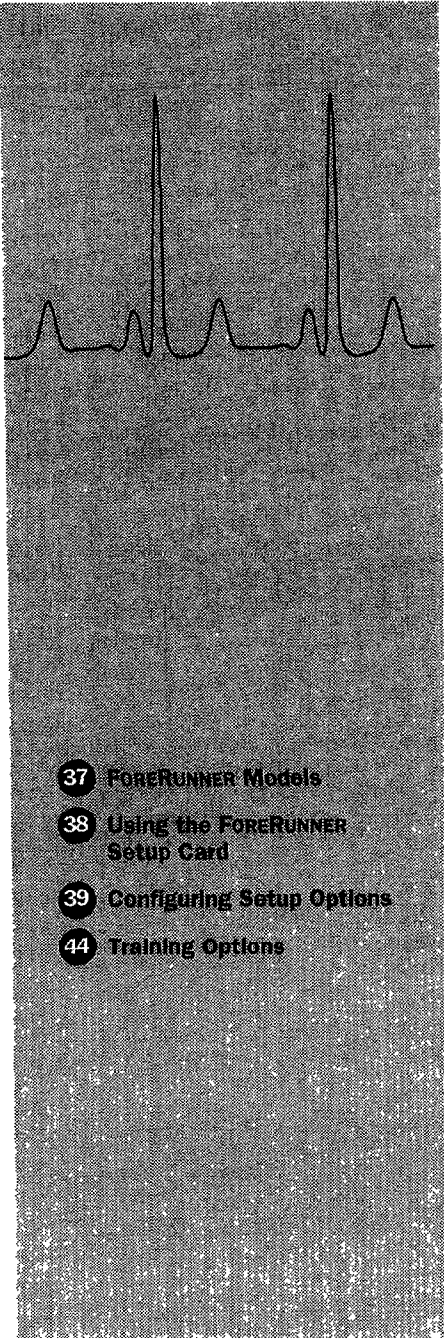
CHAPTER FIVE

Event Review Storage and Retrieval

Full Event Review appears on several screens in a sequence. The highlight bar appears on the lower line. Press the contrast down button  to display the next screen.

The data stored on the PC data card is overwritten by the next new use of the FORERUNNER in an emergency event. The data can be erased from the card by using the optional accessory software.

FORERUNNER Options



- 37 FORERUNNER Models
- 38 Using the FORERUNNER Setup Card
- 39 Configuring Setup Options
- 44 Training Options

FORERUNNER models, setup options, and PC data card models let you customize the FORERUNNER to match your program's protocol. This Appendix describes FORERUNNER options.

FORERUNNER MODELS

The three available models are the FORERUNNER Model S, FORERUNNER Model E, and FORERUNNER Model EM.

The FORERUNNER Model S is the standard model. The FORERUNNER Model S does not display an ECG trace or heart rate.

The FORERUNNER Model E (enhanced) adds the option to display heart rate and an ECG trace. You select the display options using the FORERUNNER Setup card before you put the FORERUNNER into service.

The FORERUNNER Model EM (enhanced manual) always displays heart rate and an ECG trace, and has the manual override button.

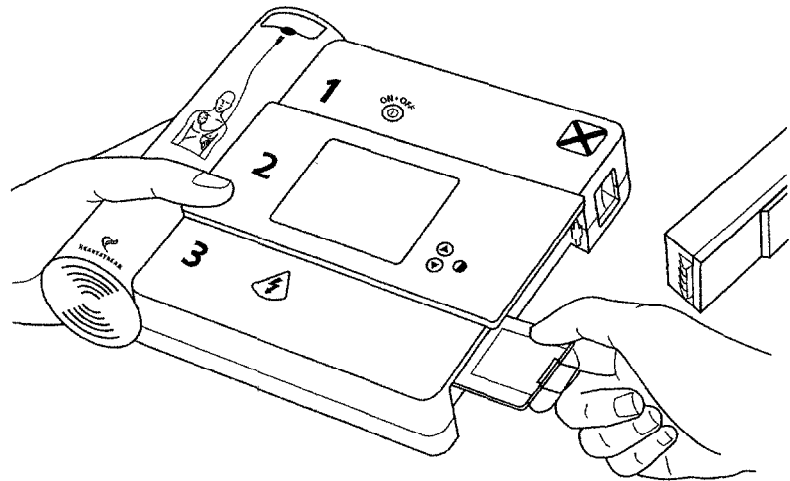
APPENDIX A

FORERUNNER Options

USING THE FORERUNNER SETUP CARD

Before you put a FORERUNNER into service, you should configure options to match your program's protocol using the FORERUNNER Setup card. Failure to configure settings correctly may adversely affect use of the FORERUNNER.


To configure options, install the FORERUNNER Setup card:



1. Remove the battery.
2. Insert the Setup card in the slot with the arrow label facing up.
3. Push the card in until it is flush with the slot. Do not force the card into the slot. If the card is difficult to insert, remove it and verify that the arrow label faces up.
4. Replace the battery.



When you install the Setup card, the FORERUNNER automatically turns on with the setup options displayed on the screen. No BIT takes place.

While the Setup card is installed:

- the On/Off button  is disabled
- the FORERUNNER is operable only for setup functions
- the Status Indicator shows a solid red **X**
- if no buttons are pressed for five minutes, the FORERUNNER “chirps” to prompt you to continue the setup or remove the Setup card

At the completion of the setup, remove the Setup card, replace the battery, and perform the BIT to put the FORERUNNER into service.

CONFIGURING SETUP OPTIONS

Setup options are described below. Press the contrast down button  to move between menu items. Press the contrast up button  to choose or change an option. Setup options are saved automatically in the FORERUNNER when you quit setup.

APPENDIX A

FORERUNNER Options

General Setup Options

Menu Item	Options	Factory Settings
Prompts	<i>Short or Long.</i> Long voice prompts contain more descriptive information. Short voice prompts are intended for use by more experienced responders.	Long
Speaker Volume	1-8. Eight possible settings. 8 is full volume.	8
ECG Record	Std or Low. Std records ECG data on PC data cards at 200 data samples per second; low at 100 samples per second. Low resolution recording provides a longer ECG recording. Std resolution provides research quality ECG recording.	Std
ECG Displayed (Model E only)	<i>Yes or no.</i> ECG is displayed on the screen.	Yes. ECG display on. (ECG is always displayed on Model EM.)
Go to CPR Protocol	Displays options to customize the CPR and Shock sequence.	See CPR Protocol Setup Options that follow.
Go to Device History	Displays Device History.	See Device History information that follows.

CPR Protocol Setup Options

Menu Item	Options	Factory Settings
Shocks	1, 2, or 3. Number of shocks delivered in a sequence before the FORERUNNER will pause for CPR.	3 shocks
Consecutive Shock (CS) CPR Timeout	0, 0.5, 1.0, 1.5, 2.0, 2.5, 3.0, or ∞. CS CPR Timeout is the interval in minutes provided for CPR after each Shock sequence. The FORERUNNER automatically pauses for CPR after the setup number of consecutive shocks. It resumes analyzing automatically at the end of the CPR Timeout or when the Resume Analyzing button is pressed by the user. If CPR Timeout is set to ∞, the automatic resume analyzing is disabled, and the user MUST press the Resume Analyzing button to quit the pause for CPR.	1.0 minute
No Shock Advised (NSA) CPR Timeout	0, .25, 0.5, 1.0, 1.5, 2.0, 3.0, and ∞. NSA CPR Timeout is the interval in minutes provided for CPR immediately after a No Shock Advised condition. See CS CPR Timeout for Resume Analyzing details.	0 minutes

APPENDIX A

FORERUNNER Options

Resume Analysis	<i>ON</i> or <i>OFF</i> . <i>ON</i> activates a Resume Analyzing button to allow you to manually quit the pause for CPR and resume ECG analysis. <i>OFF</i> inhibits activation of the Resume Analyzing button. NOTE: <i>ON</i> is the only choice available if you select a CPR Timeout greater than 60 seconds.	<i>OFF</i> (<i>ON</i> if CPR Timeout is greater than 60 seconds)
------------------------	---	--

FORERUNNER Device History

Information about the FORERUNNER automatically accumulates in its internal memory throughout the FORERUNNER's lifetime. When you select the Device History option on the Setup card, a screen displays the following information.

Device History Display

Screen Display	Options
USES:	The first number is the cumulative number of new uses during the FORERUNNER lifetime. The cumulative time (in minutes) of all FORERUNNER uses in which defibrillation pads were connected to the patient during emergency events is indicated by the second number.
SHOCKS:	Cumulative number of shocks delivered by the FORERUNNER in its lifetime.
TRAINING:	The first number is the cumulative number of times the Training card was inserted and used during the FORERUNNER's lifetime. The cumulative training time (in minutes) is indicated by the second number.
TESTS:	Cumulative number of tests that have been performed during the FORERUNNER's lifetime. A: Number of daily automatic self tests B: Number of weekly automatic self tests C: Number of monthly automatic self tests D: Number of Battery Insertion tests

APPENDIX A

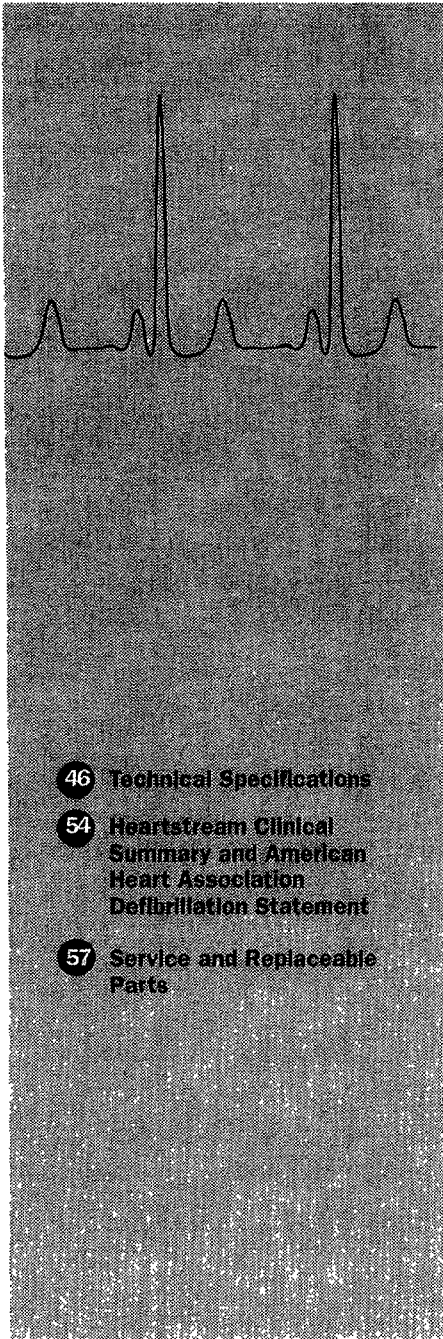
FORERUNNER Options

TRAINING OPTIONS

Heartstream offers an optional FORERUNNER Training card and user's guide. The FORERUNNER Training card includes simulated scripts that guide responders through several emergency events.

A training card must always be installed in the FORERUNNER when using it for training or demonstration purposes. When the training or demonstrations are complete, remove the training card to return the FORERUNNER to service and prevent battery depletion.

Specifications



This appendix presents technical specifications, waveform specifications, a clinical summary, and information about service and replaceable parts.

- 46 Technical Specifications
- 54 Heartstream Clinical Summary and American Heart Association Defibrillation Statement
- 57 Service and Replaceable Parts

APPENDIX B

Specifications

TECHNICAL SPECIFICATIONS

Physical

Category	Specification
Size	2.53 inches high x 8.75 inches wide x 8.0 inches deep (64 mm x 223 mm x 203 mm)
Weight	Approximately 2 kg (4.4 lbs) with battery installed.

Environmental

Category	Specification
Operating Temperature/ Humidity	0 to 50°C (32 to 122°F), 0% to 95% Relative Humidity (non-condensing).
Standby Temperature/Humidity	10 to 43°C (50 to 109°F), 0% to 75% Relative Humidity (non-condensing). FORERUNNER with battery installed, stored with defibrillation pads.
Altitude	-500 to 15,000 feet per MIL-810E 500.3 Procedure II.
Shock/Drop Abuse Tolerance	MIL-STD-810E 516.4 Procedure IV (1 meter, any edge, corner, or surface).
Vibration	MIL-STD-810E 514.4-17.
Sealing	IEC 529 class IP54; Splash Proof, Dust Protected.
ESD	IEC 801-2 Severity Level 4.
EMI (Radiated)	CISPR11 Group 1 Level B.
EMI (Immunity)	IEC 801-3 Level 2.
Transportation Environment	RTCA/DO-160C "Environmental conditions and test procedures for airborne equipment".

Defibrillator


Category	Specification
Waveform	Truncated Exponential Biphasic. Waveform parameters are adjusted as a function of patient defibrillation impedance.
Energy/Energy Selection	Single Energy—a nominal of 150 Joules (minimum of 130 Joules) delivered to a 50 ohm load.
Charge Control	Under control of the Patient Analysis System for semi-automatic operation. The manual override button allows manual charge control (FORERUNNER Model EM only).
Charge Time from Shock Advised	Typically less than 10 seconds. Charge time increases at the end of battery life as well as at temperatures below 10°C.
Shock-to-Shock Cycle Time	Typically less than 20 seconds (including analysis time) in semi-automatic mode.
Charge Complete Indication	FORERUNNER is 'armed' when shock button is flashing and armed tone is activated.
Shock Discharge Control	Shock is delivered by a single shock button.
Disarm—Semi-Automatic Operation	Once the FORERUNNER is charged, it will disarm under any of the following conditions: <ul style="list-style-type: none"> • a no shock decision is reached • the FORERUNNER On/Off button is pressed and the FORERUNNER is turned off • the defibrillation pads are removed from the patient or the pads connector is disconnected from the FORERUNNER
Disarm—Manual Operation	Once the FORERUNNER is charged, it will disarm under any of the following conditions: <ul style="list-style-type: none"> • 30 seconds after charging if a shock is not delivered • manually by pressing the manual override button • the FORERUNNER On/Off button is pressed and the FORERUNNER is turned off • the defibrillator pads are removed from the patient or the pads connector is disconnected from the FORERUNNER

APPENDIX B

Specifications

Category	Specification
Shock Delivery	Via defibrillation pads placed in the anterior-anterior (Lead II) position.

Patient Analysis System

Category	Specification
Patient Analysis	Evaluates defibrillation pads' impedance for proper defibrillation pad contact, and evaluates patient ECG and signal quality to determine if a shock is appropriate.
Protocols	Follows pre-configured settings to match your program's protocols. These settings can be modified using the setup options.
Shockable Rhythms	VF and certain VT rhythms (including ventricular flutter and polymorphic VT).  WARNING: Some very low amplitude or low frequency rhythms may not be interpreted as shockable VF rhythms. Also, some VT rhythms may not be interpreted as shockable rhythms.

Patient Analysis System Performance

Rhythm Class	ECG Test Sample¹ Size	Specification
Shockable Rhythm - VF	300	FORERUNNER meets the AAMI DF39 requirement and AHA recommendation ² of Sensitivity > 90 %
Shockable Rhythm - VT	100	FORERUNNER meets the AAMI DF39 requirement and AHA recommendation ² of Sensitivity > 75 %
Non-shockable rhythm - Normal sinus rhythms	300	FORERUNNER meets the AAMI DF39 requirement of Specificity > 95 % and AHA recommendation ² of Specificity > 99 %
Non-shockable rhythm - Asystole	100	FORERUNNER meets the AAMI DF39 requirement and AHA recommendation ² of Specificity > 95 %
Non-shockable rhythm - all other non-shockable rhythms	450	FORERUNNER meets the AAMI DF39 requirement and AHA recommendation ² of Specificity > 95 %

¹ From Heartstream ECG rhythm databases.

² Automatic External Defibrillators for Public Access Use: Recommendations for Specifying and Reporting Arrhythmia Analysis Algorithm Performance, Incorporation New Waveforms, and Enhancing Safety, American Heart Association (AHA) AED Task Force, Subcommittee on Safety & Efficacy, draft 3/18/96, Table 2.






APPENDIX B*Specifications***ECG Display (Available only on Model E and Model EM)**

Category	Specification
Monitored Lead	ECG information is acquired through defibrillation pads in anterior-anterior (Lead II) placement.
Display Range	Differential: ± 2 mV full scale nominal.
Screen	High resolution LCD with backlight.
Screen Dimensions	2.8 inches wide x 2.3 inches high (70 mm x 58 mm).
Sweep Speed	23 mm/sec. nominal.
Frequency Response (Bandwidth)	Nondiagnostic rhythm monitor 1 Hz to 20 Hz (-3 dB) nominal.
Sensitivity	1.16 cm/mV nominal.
Heart Rate (Normal Sinus Rhythm)	Displays a range of 30 to 300 beats per minute updated each analysis period. Heart rate is displayed only during monitoring mode and if ECG is displayed.

Battery Pack

Category	Specification
Battery	18 VDC 1300 mA AH lithium. Disposable, recyclable, long-life, primary cells.
Capacity	A new battery typically will provide 100 shocks or 5 hours of operating time, or 10 hours of training time at 25°C.
Shelf-Life	Typically 5 years from date of manufacture when stored at standby environmental conditions in original, unopened packaging.
Standby Life	Typically more than one (1) year when stored under standby environmental conditions (1 battery insert test and no uses or training).
Low Battery Detection	Defibrillator detects low battery condition during daily periodic self tests. Replace the battery when the Status Indicator shows a solid or flashing red X .

Controls and Indicators

Category	Specification
Main LCD screen	A high resolution, backlit LCD screen displays ECG (MODELS E and EM) and informational/instructional text messages on all models.
Controls	On/Off button  Shock button  Manual override button (MODEL EM Only)  Contrast up button  Contrast down button 
LED Indicators	Connector socket LED illuminates and flashes to indicate the socket location and is covered when the defibrillation pad connector is properly inserted. The shock button illuminates (flashes) when the defibrillator is armed.
Audio Speaker	An audio speaker provides voice prompts. Volume of voice prompts is adjustable using the Setup card.
Beeper	The beeper chirps as an alert when a self test has failed (standby mode), and generates various warning tones during normal use.
Status Indicator	A Status Indicator LCD displays the results of the last self test.

Defibrillation Pads

Category	Specification
Defibrillation Pads, Cable, and Connector	Disposable and self adhesive. Defibrillation pads have a nominal active surface area of 100 cm ² each and are provided in a sealed package with an integrated 122 cm (48 inch), typical, long cable and connector.
Defibrillation Pad Requirements	Use only Heartstream defibrillation pads with the FORERUNNER. Place the pads in standard anterior-anterior position.

APPENDIX B

Specifications

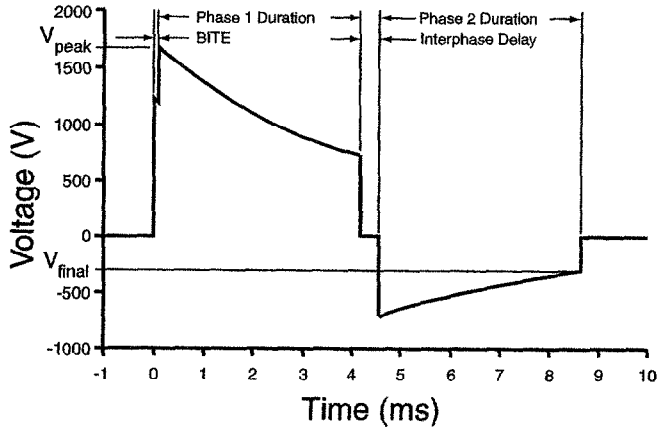
PC Data Cards, Training and Setup Cards (Options)

All FORERUNNER models come equipped with built in hardware and software that enable the defibrillator to perform additional medical control, setup, and training functions when used with optional Heartstream Setup, Training, and PC data cards. The information stored on the data cards can be reviewed using optional software.

Category	Specification
Event Review Card	Provides the FORERUNNER with Event Review capability and 15 minutes of ECG data collection. This card incorporates a real time clock which provides a means for synchronizing the EMS system time with the recorded code events.
Full ECG Card	Provides the FORERUNNER with Event Review capability as well as providing a maximum of 30 minutes of ECG data collection. A real time clock is also incorporated in this card.
Voice and ECG Card	Same as Full ECG Card with the added capability of digitally recording a maximum of 26 minutes per use near area sounds and voices. Sound recording is synchronized with ECG and event data.
Training Card	When the Training card is installed, the FORERUNNER operates in a special training mode which provides several training scenarios. Use of the Training card and training scenarios are described in the Training card user's guide.
Setup Card	Provides the system administrator with a means to tailor the FORERUNNER to your program's protocol.

Waveform Specifications

The FORERUNNER defibrillator delivers patient-compensated biphasic truncated exponential waveforms with a nominal of 150 Joules (minimum of 130 Joules) delivered to a 50 ohm load.



The “BITE” is the biphasic initiation and termination element, and is used to determine whether the load impedance is within an acceptable range. The FORERUNNER defibrillator delivers shocks to load impedances from 25 to 180 ohm. The duration of each phase of the waveform is dynamically adjusted based on delivered charge in order to compensate for patient variability as follows:

Load Resistance (Ω)	Phase 1 Duration (ms)	Phase 2 Duration (ms)	Total Tilt (%)		Delivered Energy (J)	
			min	max	min	max
25 ± 1%	2.83 ± 5%	2.83 ± 5%	88	90	130	182
50 ± 1%	4.09 ± 5%	4.09 ± 5%	78	81	130	178
100 ± 1%	8.95 ± 5%	5.97 ± 5%	75	78	131	176
125 ± 1%	12.00 ± 5%	8.00 ± 5%	77	81	132	178

APPENDIX B

Specifications

Total tilt is defined as the percent voltage decay from the peak voltage of the first phase to the final voltage of the second phase:

$$\text{Total Tilt} = \frac{(V_{peak} - V_{final})}{V_{peak}} \times 100\%$$

The interphase delay between phases of the waveform is $400 \pm 50 \mu\text{sec}$.

HEARTSTREAM CLINICAL SUMMARY AND AMERICAN HEART ASSOCIATION DEFIBRILLATION STATEMENT

Overview and Objective

Heartstream conducted a study to assess the performance of our 150J impedance-compensating biphasic waveform in the out-of-hospital setting on 100 consecutive victims of sudden cardiac arrest treated by a wide range of first-responders, both traditional and non-traditional.

AEDs incorporating 150J impedance-compensating biphasic waveforms were placed into service of 34 EMS systems. Data were obtained from the AED PC data card recording system. The first endpoint was to determine the effectiveness of this waveform at terminating VF. Defibrillation was defined using the standard definition of conversion to an organized rhythm or to asystole. The second endpoint was to determine whether or not the use of such an AED culminated in an organized rhythm at the time of patient transfer to an advanced life support (ALS) team or

emergency department (ED). The third endpoint was to assess the efficiency of the human factors design of the AED by measuring user time intervals.

Results

Thirty-four sites provided data on 286 consecutive AED uses, 100 from SCA victims with VF as their initial rhythm upon attachment of the AED. All 286 patients were correctly identified by the AED as requiring a shock (100 % sensitivity to the 100 VF patients) or not (100 % specificity to the 186 patients not presenting in VF).

The time from emergency call to first shock delivery averaged 9.1 +/- 7.3 minutes. A single 150 J biphasic shock defibrillated the initial VF episode in 86 % of patients. For all 450 episodes of VF in these 100 patients, an average of 86 % +/- 24 % of VF episodes was terminated with a single biphasic shock. Of the 449 VF episodes that received up to three shocks, 97 % +/- 11 % were terminated with three shocks or fewer. The average number of shocks per VF episode was 1.3 +/- 0.7. The average time from AED power-on and pads attached to first defibrillation was 25 +/- 23 seconds. At the time of patient transfer, an organized rhythm was present in 65 % of patients presenting with VF. Asystole was the result in 25 % of patients and VF was in progress in 10 % of patients at the time of transfer.

Conclusions

Low-energy impedance-compensating biphasic waveforms terminate long-duration VF at high rates in out-of-hospital cardiac arrest and provide defibrillation rates exceeding those previously published with high-energy shocks. Use of this waveform allows AED device characteristics consistent with widespread AED deployment and early defibrillation.

Gliner BE, et al. Treatment of out-of-hospital cardiac arrest with a low-energy impedance-compensating biphasic waveform automatic external defibrillator. *Biomedical Instrumentation & Technology*, 1998;32:xx-xx.

APPENDIX B

Specifications

AMERICAN HEART ASSOCIATION DEFIBRILLATION STATEMENT

A recent (April 1998) scientific statement by the American Heart Association determined that the FORERUNNER's waveform is "safe, acceptable and clinically effective." In its conclusions, the AHA gave the use of the low-energy, impedance-compensating biphasic waveform a Class IIb recommendation, making it the only defibrillation waveform to date to receive an AHA class recommendation.

SERVICE AND REPLACEABLE PARTS


There are no user serviceable components in the FORERUNNER. Contact Customer Service about returning a FORERUNNER that has suspected operating problems.

Calibration is unnecessary as the FORERUNNER automatically performs daily self tests and correct operation is verified during the BIT. The FORERUNNER does not require manual verification of energy delivery because monthly automatic self tests verify the waveform delivery system. As a result, we do not publish Service/Maintenance and Repair Manuals for technical professionals.

Items that can be ordered routinely include:

- PC data cards and patient identification labels
- FORERUNNER Training card
- FORERUNNER Setup card
- FORERUNNER battery pack
- FORERUNNER package containing defibrillation pads, cable, and connector
- FORERUNNER carrying case
- Mannequin adaptors
- FORERUNNER accessory software

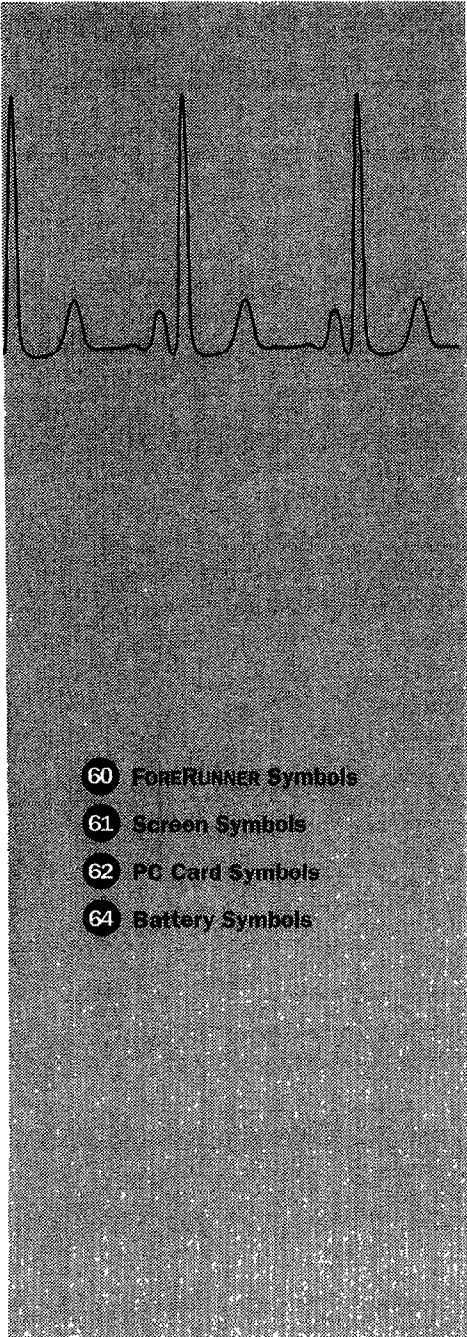
Contact Customer Service or your local distributor for ordering information.

 **CAUTION:** Electrical shock hazard. Dangerous high voltages and currents are present. Do not open unit, remove covers, or attempt repair. There are no user serviceable components in the FORERUNNER. Refer servicing to qualified service personnel.

APPENDIX B

Specifications

Glossary of Symbols











This appendix includes a glossary of symbols.

- 60 FORERUNNER Symbols
- 61 Screen Symbols
- 62 PC Card Symbols
- 64 Battery Symbols

APPENDIX C

Glossary of Symbols

FORERUNNER SYMBOLS


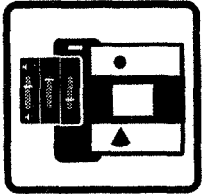



Icon	Description
On/Off button 	Turns the FORERUNNER on or off.
Shock button 	Delivers shock to patient when the FORERUNNER is charged.
Manual override button 	Initiates manual override delivery of shock.
Contrast up button 	Increases the screen contrast or performs the function indicated on the screen.
Contrast down button 	Decreases the screen contrast or performs the function indicated on the screen.
Defibrillation protection 	Defibrillation protected, type BF patient connection.
	High voltage present.
	Refer to operating instructions.

SCREEN SYMBOLS



Icon	Description
HR XX	Heart Rate.
HR ---	Heart Rate not available.
x ⚡	Number of shocks delivered.
XX:XX	Elapsed time since the FORERUNNER was turned on.
⚠ Temperature	The recommended standby storage temperature range has been exceeded since the last BIT was performed. Check to assure that the FORERUNNER is stored within the range specified in Appendix B.
⚠ Setup	The setup options configuration has been lost from memory. The FORERUNNER is using the default factory settings. To clear this message, use the Setup card described in Appendix A. If the message persists after you use the Setup card, call Customer Service.
⚠ REV: XXXX XXXX	The "REV" number identifies the version of software and hardware used in your FORERUNNER.

APPENDIX C
Glossary of Symbols

PC CARD SYMBOLS

Icon	Meaning
<p>Training card</p> 	<p>The Training card includes several simulated scenarios that guide students through several emergency events.</p>
<p>Setup card</p> 	<p>The Setup card allows you to configure options to match your program's protocol.</p>
<p>Event Review card</p> 	<p>Event Review recording capability.</p>
<p>Full ECG card</p> 	<p>Event Review with ECG recording capability.</p>
<p>Voice and ECG card</p> 	<p>Event Review with ECG and voice recording capability.</p>






APPENDIX C
Glossary of Symbols

Icon	Meaning
Insert 	Insert the data card into the FORERUNNER with this side up.
For use until 	The PC data card contains a battery. Do not use the PC data card after the date indicated because the battery may be low or depleted.

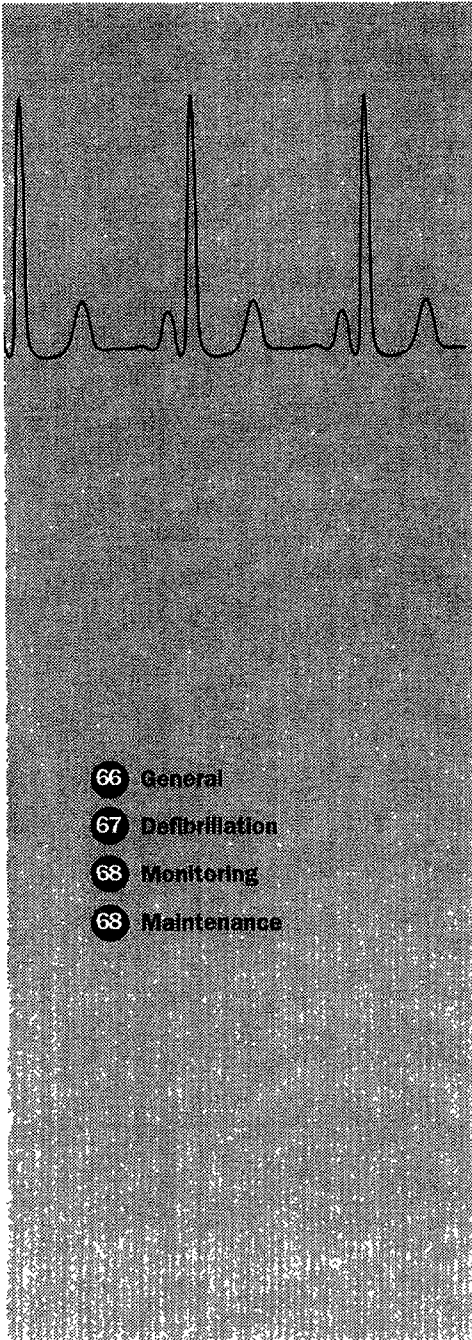
APPENDIX C

Glossary of Symbols

BATTERY SYMBOLS

Icon	Meaning
	Do not crush the battery.
	Do not expose the battery to high heat or open flames. Do not incinerate.
	Do not mutilate the battery or open the battery case.
	Install the battery in the FORERUNNER prior to the date indicated. Do not install the battery after this date.
	Heavy metal substances. Do not dispose of improperly. Collect and recycle separately from household wastes.

Dangers, Warnings, and Cautions



- 66 General
- 67 Defibrillation
- 68 Monitoring
- 68 Maintenance

This Appendix includes the list of danger, warning, and caution messages.

CAUTION

Conditions, hazards, or unsafe practices that can result in minor personal injury, damage to the FORERUNNER, or loss of data.

WARNING

Conditions, hazards, or unsafe practices that can result in serious personal injury or death.

DANGER


Immediate hazards which will result in serious personal injury or death.


APPENDIX D


Dangers, Warnings, and Cautions


GENERAL


Possible Shock or Fire Hazard or Explosion

 **DANGER:** Possible explosion hazard if used in the presence of flammable anesthetics or concentrated oxygen.


 **WARNING:** Improper use can cause injury. Use the FORERUNNER only as described in the User's Guide. The FORERUNNER delivers electrical energy that can potentially cause death or injury if it is used or discharged improperly. Do not discharge with defibrillation pads together or open and exposed.


 **CAUTION:** Hazardous electrical output. This equipment is for use only by qualified personnel.


 **CAUTION:** Do not immerse any portion of the FORERUNNER in water or other fluids. Do not allow fluids to enter the FORERUNNER. Avoid spilling any fluids on the FORERUNNER or accessories. Spilling fluids into the FORERUNNER may damage it or present a fire or shock hazard. Do not autoclave or gas sterilize the FORERUNNER or accessories.


 **DANGER:** The FORERUNNER has not been evaluated or approved for use in hazardous locations as defined in the National Electrical Code standard (Articles 500-503). In compliance with the IEC classification (section 5.5) the ForeRunner is not to be used in the presence of flammable substance/air mixtures.


Possible Improper Device Performance

 **WARNING:** Use only Heartstream disposable defibrillation pads, batteries, and other accessories supplied by Heartstream or its authorized distributors. Substitution of non-Heartstream accessories may cause the device to perform improperly.

 **CAUTION:** Follow all defibrillation pad labeling instructions. Use defibrillation pads prior to their expiration date. Discard defibrillation pads after use. Do not reuse defibrillation pads.

 **CAUTION:** Follow all battery labeling instructions. Install the battery prior to the date noted on the battery.

 **WARNING:** The BIT and periodic self tests are designed to assess the FORERUNNER's readiness for use. However, no degree of testing can assure performance or detect abuse, damage, or a defect which occurs after the last BIT or self test is completed.

 **CAUTION:** Although the FORERUNNER is designed for a wide variety of field use conditions, rough handling beyond specifications can result in damage to the unit. (See Environmental Specifications in Appendix B.)

⚠ WARNING: Aggressive or prolonged CPR to a patient with defibrillation pads attached can cause damage to the pads. Replace the defibrillation pads if they become damaged during use.

⚠ WARNING: Use of damaged equipment or accessories may cause the device to perform improperly and/or patient or user injury.

⚠ WARNING: CPR rates above the American Heart Association guidelines of 100 BPM (beats per minute) can cause incorrect or delayed diagnosis.

Possible Electrical Interference with ECG monitoring

⚠ WARNING: Radio frequency (RF) interference from RF devices such as cellular phones and two-way radios can cause improper FORERUNNER operation. In accordance with IEC standard 801.3, a distance of 2 meters (6 feet) between RF devices and the FORERUNNER is recommended.

DEFIBRILLATION

Possible Shock Hazard

⚠ WARNING: Defibrillation current can cause operator or bystander injury. Do not touch the patient during defibrillation. Do not touch equipment connected to or metal objects in contact with the patient during defibrillation. Disconnect other electrical equipment from the patient before defibrillating. Disconnect the FORERUNNER from the patient prior to use of other defibrillators.

Possible Patient Safety

⚠ CAUTION: The FORERUNNER manual override button is intended for use only by qualified operators who have been trained in rhythm recognition and treatment through manual charging and delivery of defibrillation shocks.

Possible ECG Misinterpretation

⚠ WARNING: Do not place defibrillation pads in the anterior-posterior position. A shock or no shock decision may be inappropriately advised. The FORERUNNER requires that the defibrillation pads be placed in the anterior-anterior position.

⚠ WARNING: Some very low amplitude or low frequency rhythms may not be interpreted as shockable VF rhythms. Also, some VT rhythms may not be interpreted as shockable rhythms.

⚠ WARNING: Handling or transporting the patient during ECG analysis can cause incorrect or delayed diagnosis especially if very low amplitude or low fre-

APPENDIX D

Dangers, Warnings, and Cautions

quency rhythms are present. Following "Shock Advised" prompts, patient movement and vibration, if present, must be minimized for at least 15 seconds to allow reconfirmation of ECG analysis before delivering a shock. This reconfirmation of ECG analysis may result in an appropriate reversal of a "Shock Advised" prompt.

⚠ WARNING: In patients with cardiac pacemakers, the FORERUNNER may have reduced sensitivity and not detect all shockable rhythms.

Possible Burns and Ineffective Energy

⚠ WARNING: Do not allow defibrillation pads to touch each other, or to touch other ECG electrodes, lead wires, dressings, transdermal patches, etc. Such contact can cause electrical arcing and patient skin burns during defibrillation and may divert defibrillating current away from the heart.

⚠ WARNING: During defibrillation, air pockets between the skin and defibrillation pads can cause patient skin burns. To help prevent air pockets, make sure self-adhesive defibrillation pads completely adhere to the skin. Do not use dried out defibrillation pads.

MONITORING

Possible Misinterpretation of ECG Recordings

⚠ CAUTION: The LCD screen is intended only for basic ECG rhythm identification. The frequency response of the monitor screen is not intended to provide the resolution required for diagnostic and ST segment interpretation.

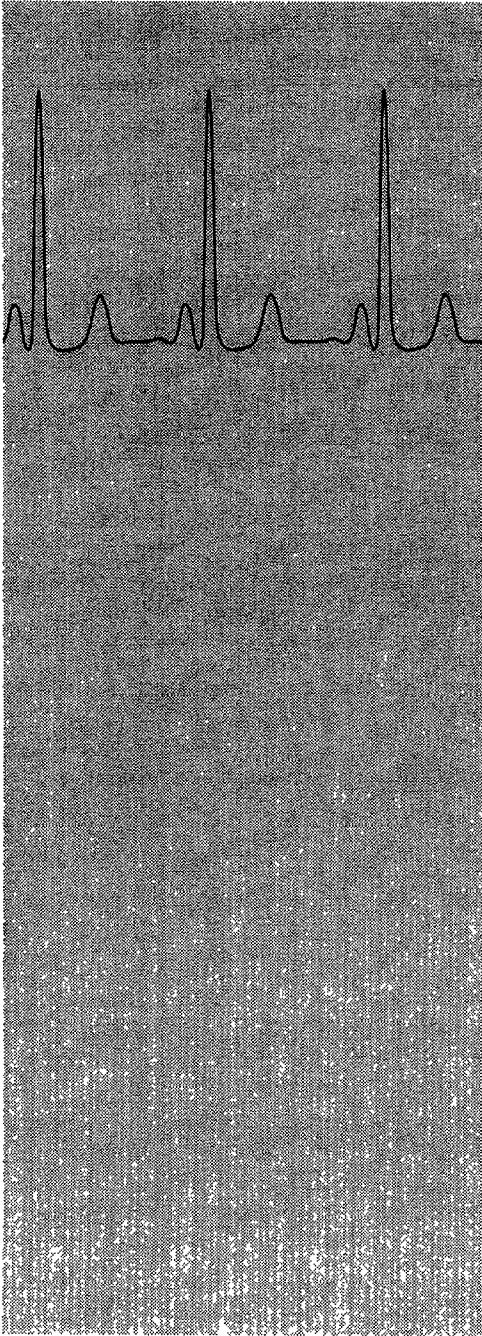
MAINTENANCE

Possible Fire or Shock Hazard

⚠ CAUTION: Electrical shock hazard. Dangerous high voltages and currents are present. Do not open unit, remove covers, or attempt repair. There are no user serviceable components in the FORERUNNER. Refer servicing to qualified service personnel.

Possible Improper Device Performance

⚠ CAUTION: Improper maintenance can cause the FORERUNNER not to function. Maintain the FORERUNNER only as described in this User's Guide or as instructed by your medical director.

**A**

accessories
 available to order 57
 maintaining 27
 adjust contrast during BIT 9
 AED overview 1
 analysis requirements for shock
 decision 17
 applying defibrillation pads to the
 patient 14
 artifact 16, 23, 67
 attaching pads 14

B

battery
 conditions and Status Indicator
 10, 21
 dead or depleted 11, 21
 insertion 6
 maintenance 25, 27
 position during cleaning 29
 specifications 50
 symbols 64
 testing 25
 Battery Insertion Test (BIT) 7
 how to interrupt 7
 interactive tests 8
 biphasic waveform 47, 53
 BIT. See Battery Insertion Test.
 burn hazard 68

C

cautions, warnings, and
 dangers 65
 charge
 release when no shock
 delivered 17
 chirping
 due to low battery or self test
 failure 10, 26
 due to setup card 39
 cleaning
 instructions and precautions 29
 clock on PC data cards 52
 configurable options 40

connecting the defibrillation
 pads 14
 contamination 28
 continued use 24
 contraindications 3
 contrast buttons
 used in Event Review 36
 contrast, adjusting 9
 controls and indicators 51
 corrective actions for error
 conditions 21
 CPR 18
 duration of pause 41
 interrupting to analyze ECG 19
 number of shocks between
 pauses 41
 pause for 18
 protocol 40

D

damage
 checks for mechanical 27
 to connector socket 27
 danger, warnings, and cautions 65
 data card
 compatibility 32
 installation 32
 reading 31
 removing 32
 verification during BIT 8
 defibrillation pads
 applied improperly 22
 applying 14
 expiration date 15, 27, 66
 maintaining 27
 placed improperly 23
 specifications 51
 defibrillator shock
 specification 53
 defibrillator specifications 47
 depleted battery
 and Status Indicator 11, 26
 device history 43
 DISARM 20
 disarming the FORERUNNER 17

INDEX

display the Event Review,
how to 33
display, ECG
specifications 50
display, LCD
adjusting contrast during BIT 9

E

ECG
analysis during CPR 19
data quality 16, 67
display option
(Model E only) 40
misinterpretation 67, 68
monitoring and analysis 16
patient analysis system 48, 49
ECG display specification 50
elapsed time of emergency 18,
34, 35
electrical interference hazard 67
electrode pads
See defibrillation pads.
electrode placement 14
environmental specifications 46
error conditions and corrective
actions 21, 22
Event Review
about 34
displaying information 33
Full 35
Summary 35
explosion hazard 66

F

factory settings 61
for setup options 40
failed self test
and the Status Indicator 25
causes and corrective actions 10
failure 10, 21, 26
FORERUNNER Model E
capabilities 37
options 40
FORERUNNER Model EM
and manual override mode 19

capabilities 37
options 40, 43
FORERUNNER Model S
capabilities 37
options 40, 43
Full Event Review 35

H

heart rate
display option 37
displayed on screen 61
heart rhythms
shockable 2, 48
how to configure options 38
how to deliver shock 17
how to display event review
information 33
how to install the battery 6
how to put the FORERUNNER into
service 5
how to use manual override mode
(Model EM only) 19
HR in screen 61

I

impedance
error conditions and corrective
actions 23
improper device performance
hazard 68
indications and
contraindications 3
information storage and
retrieval 31
Install Before 64
installing a data card 32
installing battery 6
installing Setup card 38
interference 16
during pause for CPR 18
electrical 16, 23, 67
patient motion 23
proper distance from
RF sources 16
radio frequency 16, 67

L

LCD screen
adjust contrast 9
low battery
and Status Indicator 10, 26

M

maintaining
the connector socket 27
the defibrillation pads 27
the FORERUNNER 27
maintenance
after each use 27, 28
daily 27
weekly 27
mannequin adaptor
accessory for training 44
manual delivery of defibrillation
shock 19
MANUAL OVERRIDE 20
manual override
disarming 20
testing 9
manual override mode (Model EM
only) 19
mechanical damage 27
Model E options 40
Model EM options 40
Model S options 41
monitoring
voice prompts suppressed 16

N

new use 24
no shock advised 16
number of shocks delivered
Full Event Review 35
in a single use 34
screen symbol 61
Summary Event Review 35

O

On/Off button
test 9

- to discontinue self tests 25
- to interrupt the BIT 7
- option
 - FORERUNNER Model E 37
 - FORERUNNER Model EM 37
 - FORERUNNER Model S 37
 - hide or display ECG trace (Model E only) 40
 - manual override (Model EM only) 19, 37
 - pause for CPR 18, 41
 - resume analyzing 19, 42
 - setup options 40
 - speaker volume 40
 - training 44

P

- pacemaker
 - use with 16, 67
- pad placement 14
- patient analysis system
 - performance 49
- patient analysis system specifications 48
- patient safety hazard 67
- pause for CPR 18
 - configuring options 40
 - duration 41
 - interrupting 19
- PC data card
 - and accessory software 31
 - categories of 52
 - compatible versions 32
 - installation 32
 - maintenance 28
 - symbols 62
 - uses 35
 - verification during BIT 8
- periodic self test 10
- POST (Power On Self Test) 26
- power
 - battery module
 - specifications 50
 - See On/Off button.
- preparing the patient 14

- prompts
 - setup options 40
- protocols for CPR
 - customizing 41

R

- radio signal interference 16, 23, 67
- recommended distances 16
- removing data card 32
- replaceable parts 57
- resume analysis during CPR 19
 - setup option 42
- RESUME ANALYZING 19
 - configuring option 42
- RF interference 16, 23, 67

S

- screen
 - adjust contrast 9
- self test
 - adjust screen contrast 9
 - BIT 7
 - connector socket LED 9
 - discontinue and reschedule 25
 - failed 21, 25
 - interpreting results 10, 21
 - manual override button 9
 - On/Off button 9
 - results 10, 26
 - shock button 9
 - shock button LED 9
 - speakers 9
- self test failure
 - and Status Indicator 11
- semi-automatic delivery of defibrillating shock 17
- service and replaceable parts 57
- servicing the FORERUNNER 57
- setup 61
- Setup card
 - affecting Status Indicator 10
 - installing and using 38
- setup options
 - factory settings 40, 61

- general 40, 43
- shock
 - CPR protocol 41
 - delivering 17
 - disarming in manual override mode (Model EM) 20
 - disarming in semi-automatic mode 17
 - not advised 16
- shock button
 - testing and verification 9
- shockable rhythms 48
 - and cardiac pacemakers 16
- shocks between CPR pauses 41
- speaker volume
 - adjusting 40
- speakers, testing 9
- specifications
 - battery 50
 - controls and indicators 51
 - defibrillation pads 51
 - defibrillator 47
 - defibrillator shock 53
 - ECG display 50
 - environmental 46
 - patient analysis system 48, 49
 - PC data cards, training, and setup cards 52
 - physical 46
 - waveform 53
- standby temperature 7, 26, 46, 61
- Status Indicator
 - conditions and corrective actions 10, 26
- stored information about an emergency 33, 34
- Summary Event Review 35
- symbols
 - glossary of 60

T

- technical specifications 46
- technical support 57

I N D E X

temperature, standby 7, 26, 46,
61
time
 elapsed 18, 35
 of first shocks 35
 on PC data cards 52
 remaining in pause for CPR 18
timeout for CPR 18
 duration 41
 interrupting 19
Training card 44
 affecting Status Indicator 10

U

use
 appropriate symptoms 3
 elapsed time of 35
 number of shocks delivered 34
 with pacemakers 16
using the data card 31

V

voice prompts
 setup options 40
volume
 changing 40

W

warnings, dangers, and
 cautions 65
waveform 47
 specifications 53
when no shock is advised 16

X

X in Status Indicator, meaning 10

