Records processed under FOIA Request 2014-7272; Released 10/23/14 K024071

SECTION 12: 510(k) SUMMARY

This summary of 510(K) safety and effectiveness information is submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

A. Name, Address, Phone and Fax number of Applicant

Guidant Corporation
Cardiac Surgery
3200 Lakeside Drive
Santa Clara, CA 95054

Tel: (408) 845-1910
Fax: (408) 845-1855

B. Contact Person

Debbie Cogan
Regulatory Affairs Associate

C. **Date Prepared**

December 6, 2002

D. Device Name

Trade Name: Syncrus Internal Cardioversion System
Classification Name: ELECTRODE, PACING AND CARDIOVERSION, TEMPORARY, EPICARDIAL
Product Classification Code: NHW
Device Classification: Class 2
Establishment Registration: 2953148

E. Device Description

The Syncrus System consists of three components:

- Three temporary heart wires sutured onto the heart during open-heart surgery. The wires include a unipolar defibrillation heart wire (left atrium), a bipolar pacing/sensing heart wire (right or left ventricle) and a tripolar defibrillation and pacing and sensing heart wire (right atrium).

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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- An attenuator box (External Defibrillator Interface - Module EDIM). The EDIM attenuates the delivered energy from a standard, low energy defibrillator by 97% (50 - 360 Joules to 1.3 – 11.5 Joules).
- A cardioversion extension cable, which connects the defibrillation heart wires to the EDIM.

The user must supply an external, low-energy defibrillator that is capable of synchronized cardioversion, an external pacemaker, and temporary patient cables to connect the pacemaker to the patient. The Syncrus System is designed to perform the following cardiac rhythm management functions:

- Atrial pacing and electrocardiogram sensing
- Ventricular pacing and electrocardiogram sensing
- Atrial defibrillation using low energy, synchronized cardioversion.

F. Intended Use

The Guidant SYNCRUS™ Internal Cardioversion System is indicated for use in post-operative cardiac surgery patients who require temporary atrial or ventricular pacing/sensing and/or atrial cardioversion.

G. Substantial Equivalence

Guidant proposes that the Syncrus System is substantially equivalent to the Syncrus System (K020701). The subject device is substantially equivalent to the predicate device with regard to intended use, indications, device characteristics, method of use, labeling, materials, and safety feature.

H. Device Testing Results and Conclusions

Guidant Cardiac Surgery performed bench testing to confirm that the Syncrus System may be used with a biphasic defibrillator. All bench testing results met specified requirements.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 1 4 2003

Guidant Corporation
c/o Ms. Debbie Cogan
Regulatory Affairs Associate
Guidant Cardiac Surgery
3200 Lakeside Drive
Santa Clara, CA 95054

Re: K024071
Trade Name: Guidant Syncrus™ Internal Cardioversion System
Regulation Number: 21 CFR 870.3680
Regulation Name: Electrode, Pacing and Cardioversion, Temporary, Epicardial
Regulatory Class: Class II (two)
Product Code: NHW
Dated: January 10, 2003
Received: January 15, 2003

Dear Ms. Cogan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4646. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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STATEMENT OF INDICATIONS FOR USE

510(k) Number (if known): K024071

Device Name: Guidant Syncrus™ Internal Cardioversion System

Indications For Use: The Guidant SYNCRUS™ Internal Cardioversion System is indicated for use in post-operative cardiac surgery patients who require temporary atrial or ventricular pacing/sensing and/or atrial cardioversion.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use ____

(Per 21 CFR 801.109)

(Optional Format 1-2-96)

Ashley Boone for BDZ

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K024071

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 1 4 2003

Guidant Corporation
c/o Ms. Debbie Cogan
Regulatory Affairs Associate
Guidant Cardiac Surgery
3200 Lakeside Drive
Santa Clara, CA 95054

Re: K024071
Trade Name: Guidant Syncrus™ Internal Cardioversion System
Regulation Number: 21 CFR 870.3680
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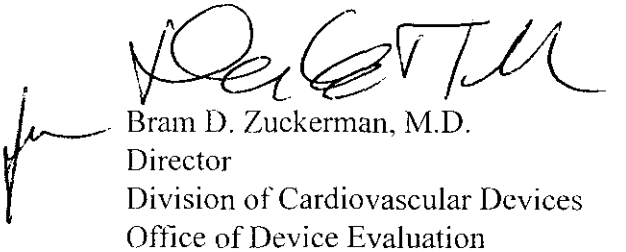
Sincerely yours,



Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2014-7272; Released 10/23/14

STATEMENT OF INDICATIONS FOR USE

510(k) Number (if known): K024071

Device Name: Guidant Syncrus™ Internal Cardioversion System

Indications For Use: The Guidant SYNCRUS™ Internal Cardioversion System is indicated for use in post-operative cardiac surgery patients who require temporary atrial or ventricular pacing/sensing and/or atrial cardioversion.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR (Per 21 CFR 801.109) Over-The-Counter Use ____

(Optional Format 1-2-96)

Ashley Barnes for BDZ

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K024071

3

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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DEPARTMENT OF HEALTH AND HUMAN SERVICES Public Health Service

Food and Drug Administration
Center for Devices and
Radiological Health
Office of Device Evaluation
Document Mail Center (HFZ-401)
9200 Corporate Blvd.
Rockville, Maryland 20850

December 23, 2002

GUIDANT CARDIAC SURGERY
3200 LAKESIDE DR.
SANTA CLARA, CA 95054
ATTN: DEBBIE COGAN

510(k) Number: K024071
Product: GUIDANT SYNCRUS INTERNAL CARDIOVERSION SYSTEM

We are holding your above-referenced Premarket Notification (510(k)) for 30 days pending receipt of the additional information that was requested by the Office of Device Evaluation. Please remember that all correspondence concerning your submission MUST cite your 510(k) number and be sent in duplicate to the Document Mail Center (HFZ-401) at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification submission. Also, please note the new Blue Book Memorandum regarding Fax and E-mail Policy entitled, "Fax and E-Mail Communication with Industry about Premarket Files Under Review. Please refer to this guidance for information on current fax and e-mail practices at www.fda.gov/cdrh/ode/a02-01.html.

The deficiencies identified represent the issues that we believe need to be resolved before our review of your 510(k) submission can be successfully completed. In developing the deficiencies, we carefully considered the statutory criteria as defined in Section 513(i) of the Federal Food, Drug, and Cosmetic Act for determining substantial equivalence of your device. We also considered the burden that may be incurred in your attempt to respond to the deficiencies. We believe that we have considered the least burdensome approach to resolving these issues. If, however, you believe that information is being requested that is not relevant to the regulatory decision or that there is a less burdensome way to resolve the issues, you should follow the procedures outlined in the "A Suggested Approach to Resolving Least Burdensome Issues" document. It is available on our Center web page at: http://www.fda.gov/cdrh/modact/leastburdensome.html

If after 30 days the requested information, or a request for an extension of time, is not received, we will discontinue review of your submission and proceed to delete your file from our review system. Pursuant to 21 CFR 20.29, a copy of your 510(k) submission will remain in the Office of Device Evaluation. If you then wish to resubmit this 510(k) notification, a new number will be assigned and your submission will be considered a new premarket notification submission.

Please remember that the Safe Medical Devices Act of 1990 states that you may not place this device into commercial distribution until you receive a decision letter from FDA allowing you to do so.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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If you have procedural or policy questions, please contact the Division of Small Manufacturers International and Consumer Assistance (DSMICA) at (301) 443-6597 or at their toll-free number (800) 638-2041, or contact me at (301) 594-1190.

Sincerely yours,

Marjorie Shulman
Supervisor Consumer Safety Officer
Premarket Notification Section
Office of Device Evaluation
Center for Devices and
Radiological Health

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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DEPARTMENT OF HEALTH AND HUMAN SERVICES Public Health Service

Food and Drug Administration
Center for Devices and
Radiological Health
Office of Device Evaluation
Document Mail Center (HFZ-401)
9200 Corporate Blvd.
Rockville, Maryland 20850

December 10, 2002

GUIDANT CARDIAC SURGERY
3200 LAKESIDE DR.
SANTA CLARA, CA 95054
ATTN: DEBBIE COGAN

510(k) Number: K024071
Received: 10-DEC-2002
Product: GUIDANT SYNCRUS INTERNAL CARDIOVERSION SYSTEM

The Center for Devices and Radiological Health (CDRH), Office of Device Evaluation (ODE), has received the Premarket Notification you submitted in accordance with Section 510(k) of the Federal Food, Drug, and Cosmetic Act (Act) for the above referenced product. We have assigned your submission a unique 510(k) number that is cited above. Please refer prominently to this 510(k) number in any future correspondence that relates to this submission. We will notify you when the processing of your premarket notification has been completed or if any additional information is required. YOU MAY NOT PLACE THIS DEVICE INTO COMMERCIAL DISTRIBUTION UNTIL YOU RECEIVE A LETTER FROM FDA ALLOWING YOU TO DO SO.

As a reminder, we would like to mention that FDA requires all 510(k) submitters to provide an indications for use statement on a separate page. If you have not included this indications for use statement in addition to your 510(k) summary (807.92), or a 510(k) statement (807.93), and your Truthful and Accurate statement, please do so as soon as possible. If the above mentioned requirements have been submitted, please do not submit them again. There may be other regulations or requirements affecting your device such as Postmarket Surveillance (Section 522(a)(1) of the Act) and the Device Tracking regulation (21 CFR Part 821). Please contact the Division of Small Manufacturers, International and Consumer Assistance (DSMICA) at the telephone or web site below for more information.

Please remember that all correspondence concerning your submission MUST be sent to the Document Mail Center (DMC)(HFZ-401) at the above letterhead address. Correspondence sent to any address other than the DMC will not be considered as part of your official premarket notification submission. Also, please note the new Blue Book Memorandum regarding Fax and E-mail Policy entitled, "Fax and E-Mail Communication with Industry about Premarket Files Under Review. Please refer to this guidance for information on current fax and e-mail practices at www.fda.gov/cdrh/ode/a02-01.html.

You should be familiar with the manual entitled, "Premarket Notification 510(k) Regulatory Requirements for Medical Devices" available from DSMICA. If you have other procedural or policy questions, or want information on how to check on the status of your submission (after 90 days from the receipt date), please contact DSMICA at (301) 443-6597 or its toll-free number (800) 638-2041, or at their Internet address http://www.fda.gov/cdrh/dsmamain.html or me at (301) 594-1190.

Sincerely yours,

Marjorie Shulman
Consumer Safety Officer
Premarket Notification Staff
Office of Device Evaluation
Center for Devices and Radiological Health

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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K024071

GUIDANT

December 9, 2002

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Center for Devices and Radiological Health
Food and Drug Administration
9200 Corporate Boulevard
Rockville, Maryland 20850

FDA/CDRH/ODE/PMO
2002 DEC 10 A 10: 39
RECEIVED

RE: Special 510(k) Notification for the Guidant Syncrus™ System

Dear Ms. Moynahan,

In accordance with 21 CFR 807, Subpart E, and FDA's "Premarket Notification 510(k): Regulatory Requirements for Medical Devices", enclosed is a Special 510(k) Notification submission for the Guidant Syncrus System. The Guidant Syncrus System is intended for use in post-operative surgery patients who require temporary atrial or ventricular pacing/sensing and/or atrial cardioversion.

In a teleconference held on November 6th, 2002, Guidant informed the FDA it had successfully completed verification testing of the Syncrus System thereby qualifying it for use with biphasic defibrillators. As a result, Guidant proposes to remove the current restriction of usage with monophasic defibrillators only. Additionally, Guidant intends to modify the maintenance procedures for the EDIM in the Operator's Manual as well as update the Syncrus IFU and Operator's Manual with an alternative method for Heart Wire placement. Following a discussion of the proposed modifications it was agreed that Guidant would submit a Special 510(K) to the FDA documenting all of the changes. A copy of the teleconference minutes may be found attached to this letter.

No changes are proposed for the design, components, materials or manufacture of the Syncrus System. All the proposed modifications are incorporated in the IFU and Operator's manual. A summary of the information submitted within is as follows:

- The Syncrus System has been found to perform as intended with Medtronic Physio-Control LIFEPAK 12 and LIFEPAK 20 biphasic defibrillators and Agilent (Philips Medical) Heartstream or Heartstart XL and XLT defibrillators.
- The Zoll M Series biphasic defibrillator will not discharge energy into the EDIM and is not compatible for use with the Syncrus System.
- The full maintenance testing schedule has been revised from "monthly" to "every 3 months".
- The list of test equipment needed to perform full maintenance test procedure has been revised:

Guidant Corporation
3200 Lakeside Drive, Santa Clara, CA 95054-2807
Tel 408.845.3100 Fax 408.845.1800
www.guidant.com

SK 11 CV II 145

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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- An electrical safety analyzer or leakage current analyzer has been added to the test equipment list.
- The requirement for a hi-pot tester has been replaced with an ohmmeter.
- Deletion of the need for an oscilloscope.
- Deletion of listing of specific manufacturer and brand for the defibrillator analyzer.
- Addition of temporary pacemaker to Pacing System Analyzer (PSA) device for establishing baseline. A temporary pacemaker will obtain the same results as PSA, which many hospitals do not carry.

- The sequence of maintenance tests has been reordered based on equipment set up and use, to improve efficiency of testing.
- The "Dielectric Withstand" test has been modified to a "Safety Switch Isolation" test.
- Modifications have been made to the "Leakage current test" to clarify the test equipment needed to perform this maintenance test.
- A notation has been added indicating that a monophasic external defibrillator is required to perform the "Over-Voltage Protection" test.
- The "Waveform verification" test has been deleted.
- An alternative method for Heart Wire placement has been added.

A rationale for the above modifications may be found in section 7 of the attached submission, "Comparison of Modified Device to Cleared Device".

Guidant Cardiac Surgery has taken precautions to protect the confidentiality of this information, and requests FDA to hold the contents of this submission as confidential, under the maximum protection provided by the law. Furthermore, Guidant understands that the submission to the government of false information is prohibited by 18 USC 1001 and 21 USC 331(q).

We believe this submission to be complete and in order. We would appreciate your earliest attention to this submission.

If you have any questions, please contact Debbie Cogan, Regulatory Affairs Associate, by phone at (408) 845-1910 or by e-mail at dcogan@guidant.com.

Sincerely,

Debbie Cogan

Debbie Cogan
Regulatory Affairs Associate

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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GUIDANT

Cardiac Surgery

REGULATORY PHONE LOG

REGULATORY AGENCY: FDA/CDRH/ODE (Pacemakers, Defibrillators and Leads branch)

SUBMISSION: Syncrus System - K020701

DATE: 6-Nov-02 **TIME:** 9:00 am PT

GUIDANT CONTACT: Ziad Rouag, Debbie Cogan, Kobby Danwah, Frank Layden, Debbie Lin

AGENCY CONTACT: Megan Moynahan (Branch Chief)

PHONE NUMBER: NA

CARDIAC INITIATED: YES: ☒ NO: ☐

REASON FOR CALL: Results of biphasic design verification testing/alterations to IFU and Operator Manual.

A teleconference was held to discuss the results of design verification testing to qualify the Syncrus System for use with biphasic defibrillators. Participants included, from the FDA, Ms. Megan Moynahan, Branch Chief, Pacing, Defibrillators and Leads Branch and from Guidant Cardiac Surgery Ziad Rouag, Dir. Regulatory and Clinical Affairs, Kobby Dankwah, Dir. R&D, Frank Layden, R&D Engineer, Debbie Lin, Product Manager, Debbie Cogan, Regulatory Affairs Associate.

Debbie Cogan opened the discussion and reported to Ms. Moynahan that design verification compatibility testing was successfully completed for two biphasic defibrillators: Agilent (Philips Medical) Heartstream XL and Medtronic Physio-Control Lifepak 12. The testing included Synchronization, Waveform Integrity, and Attenuation and was similar to the testing conducted for verification with monophasic defibrillators submitted in the 510k pre-market notification cleared (K020701). Guidant requested permission to incorporate changes to the IFU and Operator Manual for the Syncrus Internal Cardioversion System without filing a submission, reasoning that since the testing was conducted under Guidant's design control and quality system and since no changes would be made to the indications for use, a submission was not necessary.

Ms. Moynahan asked for clarifications regarding the testing and whether all the units tested had successfully passed the tests. Ziad Rouag noted that a third biphasic defibrillator, Zoll M Series defibrillator, was not tested, due to its impedance reader, which inhibits the device from discharging energy into the EDIM.

Ms. Moynahan said the incompatibility of the Zoll M series defibrillators would have to be noted in either the warnings or precautions of the IFU. Overall she felt the scope of the changes

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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warranted a submission and she thought a Special 510k would be sufficient. Additionally Ms. Moynahan requested that we include the verification data for the biphasic testing in the submission as well as a justification for the need to qualify the device for use with Biphasic Defibrillators. Guidant agreed to file a Special 510k.

Additionally, Guidant requested to make several changes to the EDIM maintenance instructions found in the Operator Manual. Key changes were discussed. The changes include 1) revising the recommended frequency for the full maintenance testing from "monthly" to "at least but not limited to every 3 months". This was based on the maintenance schedule of defibrillators. 2) Revise the "Dielectric withstand" test instructions to be conducted using an ohmmeter instead of a hi-pot tester and 3) delete the "Waveform verification" test since the EDIMs undergo 100% inspection. Debbie Lin and Frank Layden presented the rationale for the changes and Ms. Moynahan agreed they were acceptable and suggested that Guidant detail the rationale for the change clearly in the submission.

Finally, Guidant requested to include alternative methods for heartwire placement in the IFU. Ms. Moynahan noted it was important to ~~maintain~~ emphasize that the wire placement technique ~~from~~ used in the clinical trial were associated with the study results, but that Guidant could ~~add~~ mention additional techniques to IFU.

The meeting concluded with Guidant agreeing to file a Special 510k for the above changes. Ms. Moynahan said the reviewer for the submission would be Mr. ~~Ulmar~~ Kwame Ulmer. Since he is unfamiliar with the Syncrus System she suggested that in the interest of saving time during the review process we include in the submission a detailed introduction. Guidant thanked her for her time and assistance and will follow up with the Special 510(k).

Signature: Debbie Lin Date 12/9/02

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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GUIDANT

Special 510(k) Notification

Syncrus™ Internal Cardioversion System

K020701

Submitted:
December 9, 2002

Guidant Corporation
Cardiac Surgery
3200 Lakeside Drive
Santa Clara, CA 95054
Tel: 408 845-3000
Fax: 408 845-1855

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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SECTION 1. SUBMISSION SUMMARY

The Guidant Syncrus™ Internal Cardioversion System (Syncrus System) is indicated for use in post-operative cardiac surgery patients requiring temporary atrial or ventricular pacing/sensing and/or atrial cardioversion. When used with a compatible external defibrillator, the Syncrus System reduces the energy derived from a low energy defibrillator to approximately 3% and delivers the low-energy cardioversion shock directly to the atria. Currently, the Syncrus System is recognized as compatible with monophasic, low energy defibrillators. The purpose of this submission is to provide data in support of the Syncrus System's compatibility with two biphasic defibrillators in addition to the monophasic defibrillators, noted in the 510k premarket notification cleared on May 24, 2002.

Since FDA clearance of the Syncrus System, Guidant Cardiac Surgery has become aware of a growing trend among medical facilities to convert from monophasic to biphasic defibrillators. Initially biphasic waveforms were introduced with the implantable (or internal) defibrillators and this technology has been gradually replacing the existing external defibrillators since the late 1990s because the biphasic waveform allows for a lower energy to be used to terminate (defibrillate) ventricular tachyarrhythmias. The biphasic waveform impetus was also widely accepted with automatic external defibrillators (AEDs) due to the fact that the waveform is able to defibrillate at lower energies conferring definite size and weight reductions in the design of the AED units.

In light of these market trends, Guidant Cardiac Surgery has conducted design verification testing to confirm that the Syncrus System is compatible with the biphasic defibrillators currently found in many medical facilities. No changes have been made to the design, components, materials or manufacturing process of the Syncrus System.

There are three major manufacturers of biphasic external defibrillators, Medtronic/Physio Control, HP/Agilent/Philips and Zoll. The first two use a biphasic truncated exponential waveform, the same version as employed in the low impedance implantable systems. The Zoll biphasic defibrillator however differs from the first two in that it utilizes a Rectilinear biphasic waveform. Three tests were conducted to confirm compatibility:

- Preservation of waveform integrity
- Attenuation of energy
- Synchronization

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Modifications to the Syncrus System IFU and Operator's Manual are submitted within. The changes reflect the removal of the limitation of use with monophasic low energy defibrillators and a listing of biphasic defibrillators tested and proven to be compatible with the Syncrus System. Additionally, based on physician feedback, additional options for Heart Wire placement have been added to the IFU and Operator's Manual. Furthermore, in response to feedback from hospital biotechnical staff, modifications have been made to the maintenance procedures to enhance and improve maintenance for the EDIM. Finally, grammatical and administrative corrections have been captured and corrected.

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SECTION 2. CDRH COVERSHEET

Section A		Type of Submission		
PMA Original Submission ☐ Modular Submission ☐ Amendment ☐ Report ☐ Report Amd	PMA Supplement ☐ Regular ☐ Special ☐ Panel Track ☐ 30-day Supplement ☐ 30-day Notice ☐ 135-day Supplement ☐ Real-time Review ☐ Amendment to PMA Supplement	PDP ☐ Presubmission Summary ☐ Original PDP ☐ Notice of intent to start clinical trials ☐ Intention to submit Notice of Completion ☐ Notice of Completion ☐ Amendment to PDP ☐ Report	510(k) Original Submission ☐ Traditional ☒ Special ☐ Abbreviated ☐ Additional Information: ☐ Traditional ☐ Special ☐ Abbreviated ☐ Report Amendment	Meeting ☐ Pre-IDE mtg. ☐ Pre-PMA mtg. ☐ Pre-PDP mtg. ☐ 180-Day mtg. ☐ Other (specify):
IDE ☐ Original submission ☐ Amendment ☐ Supplement	Humanitarian Device Exemption ☐ Original Submission ☐ Amendment ☐ Supplement ☐ Report	Class II Exemption ☐ Original Submission ☐ Additional Information	Evaluation of Automatic Class III Designation ☐ Original Submission ☐ Additional Information	Other Submission Describe Submission:

Section B		Applicant or Sponsor	
Company/Institution Name: Guidant Corporation		Establishment registration number: 2953148	
Division Name (if applicable): Cardiac Surgery		Phone number (include area code): (408) 845-1910	
Street Address: 3200 Lakeside Drive		Fax number (include area code): (408) 845-1855	
City: Santa Clara	State/Province: CA	Zip Code: 95054	Country: USA
Contact Name: Debbie Cogan			
Contact Title: Regulatory Affairs Associate		Contact e-mail address: dcogan@guidant.com	

Section C Submission Correspondent (if different from above)	
Company/Institution Name:	Establishment registration number:
Division Name (if applicable):	Phone number (include area code):

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Street Address		Fax number (include area code):	
City:	State/Province:	Zip Code:	Country:
Contact Name:			

Section D1 Reason for Submission – PMA, PDP, or HDE

☐ New Device ☐ Change in design, component, or specification: ☐ Location Change:
☐ Withdrawal ☐ Software ☐ Manufacturer
☐ Additional or Expanded Indications ☐ Color Additive ☐ Sterilizer
☐ Licensing Agreement ☐ Material ☐ Packager
☐ Specifications ☐ Distributor
☐ Other (specify below)
☐ Processing Change:
☐ Manufacturing ☐ Labeling Change: ☐ Report Submission:
☐ Sterilization ☐ Indications ☐ Annual or Periodic
☐ Packaging ☐ Instructions ☐ Post Approval Study
☐ Other (specify below) ☐ Performance Characteristics ☐ Adverse Reaction
☐ Shelf Life ☐ Device Defect
☐ Response to FDA correspondence: ☐ Trade Name ☐ Amendment
☐ Request for applicant hold ☐ Other (specify below)_
☐ Request for removal of applicant hold
☐ Request for extension ☐ Change in Ownership
☐ Request to remove or add manufacturing site ☐ Change in correspondent

☐ Other Reason (specify):

Section D2 Reason for Submission – IDE

☐ New Device Change in: ☐ Response to FDA letter concerning:
☐ Addition of institution ☐ Correspondent ☐ Conditional approval
☐ Expansion/extension of study ☐ Design ☐ Deemed approval
☐ IRB Certification ☐ Informed consent ☐ Deficient final report
☐ Request hearing ☐ Manufacturer ☐ Deficient progress report
☐ Request waiver ☐ Manufacturing process ☐ Deficient investigator report
☐ Termination of study ☐ Protocol – feasibility ☐ Disapproval
☐ Withdrawal of application ☐ Protocol – other ☐ Request extension for time to
☐ Unanticipated adverse event ☐ Sponsor respond to FDA
☐ Notification of emergency use ☐ Request meeting
☐ Compassionate use request ☐ Report Submission:
☐ Treatment IDE ☐ Current investigator
☐ Continuing availability request ☐ Annual progress
☐ Site waiver limit reached
☐ Final
☐ Other reason (specify):

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Section D3	Reason for Submission – 510(k)

☐ New Device ☐ Change in technology ☐ Change in materials
☐ Additional or expanded process ☐ Change in design ☐ Change in manufacturing indications
☒ Other reason (specify): Qualified to be used with biphasic defibrillators; change to maintenance instructions; additional options for heartwire placement

Section E: Additional Information on 510(k) Submissions

Product codes of devices to which substantial equivalence is claimed:				Summary of, or statement concerning safety and effectiveness data: ☒ 510(k) summary attached ☐ 510(k) statement
1 NHW	2	3	4	
5	6	7	8	

Information on devices to which substantial equivalence is claimed:

510(k) Number	Trade or Proprietary or model name	Manufacturer
1 K020701	Syncrus Internal Cardioversion System	Guidant Corporation

Section F Product Information – Applicable to All Applications

Common or usual name or classification name: ELECTRODE, PACING AND CARDIOVERSION, TEMPORARY, EPICARDIAL

Trade or proprietary or model name	Model Number
1 Syncrus Heart Wires	1 TX-3000
2 Syncrus External Defibrillator Interface Module	2 TX-5000
3 Syncrus External Cable	3 TX-5100

FDA document numbers of all prior related submissions (regardless of outcome):

1 K970449	2 K970332	3 K011735	4 Pre-IDE I010314	5 K020701	6
7	8	9	10	11	12

Data included in submission: ☒ Laboratory Testing ☐ Animal Trials ☐ Human Trials

Section G Product Classification – Applicable to All Applicants

Product code: NHW	C.F.R. Section 870.3680(a) temporary pacemaker electrode; 870.5300(A) low energy DC defibrillator	Device Class: ☐ Class I ☒ Class II ☐ Class III ☐ Unclassified
Classification Panel: Cardiovascular		
Indications (from labeling): The Syncrus System is indicated for use in post-operative cardiac surgery patients who require temporary atrial or ventricular pacing/sensing and/or atrial cardioversion.		
Note: Submission of this information does not affect the need to submit a 2891 or 2891a Device Establishment Registration form.		FDA Document Number:

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Section H Manufacturing/Packaging/Sterilization Sites Relating to a Submission		
☒ Original ☐ Add ☐ Delete	FDA establishment registration number: 2953148	☒ Manufacturer ☐ Contract Sterilizer ☐ Contract Manufacturer ☐ Repackager/relabeler

Company/Institution Name: Guidant Corporation		Establishment registration number: 2953148	
Division name (if applicable): Cardiac Surgery		Phone number (include area code): (408) 845-1910	
Street Address: 3200 Lakeside Drive		FAX number (include area code): (408) 845-1855	
City : Santa Clara	State/Province: CA	Zip code: 95054	Country: USA
Contact name: Debbie Cogan			
Contact title: Regulatory Affairs Associate		Contact e-mail address: dcogan@guidant.com	

☒ Original ☐ Add ☐ Delete	FDA establishment registration number: (b)(4) [redacted]	☐ Manufacturer ☒ Contract Sterilizer ☐ Contract Manufacturer ☐ Repackager/relabeler

(b)(4) [redacted]

☒ Original ☐ Add ☐ Delete	FDA establishment registration number: (b)(4) [redacted]	☐ Manufacturer ☒ Contract Sterilizer ☐ Contract Manufacturer ☐ Repackager/relabeler

(b)(4) [redacted]

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SECTION 3. PREMARKET NOTIFICATION TRUTHFUL AND ACCURATE STATEMENT

[As required by 21 CFR §807.87(j)]

I certify that, in my capacity as Regulatory Affairs Associate at Guidant Cardiac Surgery, to the best of my knowledge, all data and information submitted in the premarket notification are truthful and accurate and that no material fact has been omitted.

Debbie Cogan
Regulatory Affairs Associate

12/9/02
Date

[510(k) Number]

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SECTION 4. DEVICE DESCRIPTION

The Syncrus System consists of three components:

- Three temporary heart wires sutured onto the heart during open-heart surgery. The wires include a unipolar defibrillation heart wire (left atrium), a bipolar pacing/sensing heart wire (right or left ventricle) and a tripolar defibrillation and pacing and sensing heart wire (right atrium).
- An attenuator box (External Defibrillator Interface - Module EDIM). The EDIM attenuates the delivered energy from a standard, low energy defibrillator by 97% (50 - 360 Joules to 1.3 – 11.5 Joules).
- A cardioversion extension cable, which connects the defibrillation heart wires to the EDIM.

The user must supply an external, low-energy defibrillator that is capable of synchronized cardioversion, an external pacemaker, and temporary patient cables to connect the pacemaker to the patient. The Syncrus System is designed to perform the following cardiac rhythm management functions:

- Atrial pacing and electrocardiogram sensing
- Ventricular pacing and electrocardiogram sensing
- Atrial defibrillation using low energy, synchronized cardioversion.

See Figure 1 on the following page for a schematic representation of the Syncrus System in use.

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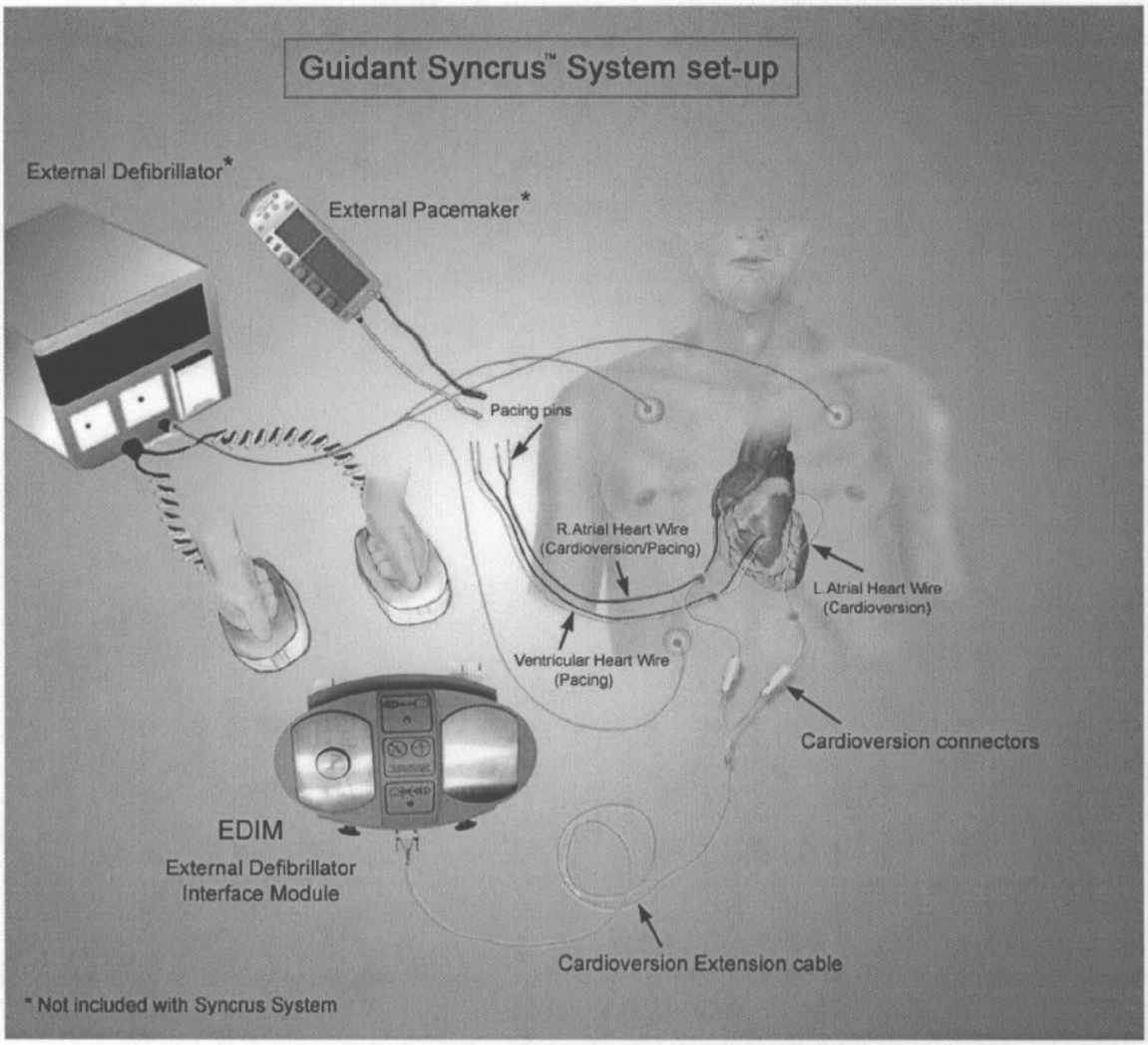
Figure 1- Syncrus System Usage



DEVICE CHARACTERISTICS

Heart Wires

The Syncrus System includes three types of heart wires offered in a pre-sterile package:

- a tripolar defibrillation and pacing and sensing heart wire (right atrium) (Fig. 2)
- a bipolar pacing/sensing heart wire (right or left ventricle) (Fig. 3)
- a unipolar defibrillation heart wire (left atrium) (Fig. 4)

The wires include curved needle(s), attached to lead(s) on the distal end. Insulation covers most of the wires length. A straight needle is attached to the leads on the

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proximal end of the wires. Cardioversion connectors are provided to attach to the cardioversion heart wire proximal leads. Pacing connector pins are pre-assembled onto the pacing heart wires.

The Syncrus heart wires are affixed to the surface of the heart in much the same way as temporary heart wires are routinely placed, during or immediately following open-heart surgery, before the median sternotomy is closed. The unipolar atrial wire is placed on the left atrium, the tripolar atrial wire is placed on the right atrium, and the bipolar ventricular wire is placed on either ventricle, according to physician preference. If all of the heart wires are implanted, the atrial and ventricular temporary sensing and pacing ability can be performed. The cardioversion feature would only be used if the patient developed post-operative AF. Both the unipolar atrial wire and the tripolar atrial wires are required to perform a cardioversion. The ventricular wire is not required for cardioversion.

The pacing leads are inserted into the heart tissue of the atrium and ventricle using the curved needles. Location and pattern of the leads are not critical, as the lead simply requires tissue contact. The "bullet" (the tapered, tubular, ground electrode found on the pacing and sensing wires) on the ground wire is then pulled through the hole formed by the curved needle and buried in the epicardium.
To enable the cardioversion feature the atrial wires are sutured onto the exterior surfaces of the atria using the curved needles. They are sewn in a pattern that encompasses the maximum atrial muscle mass between the electrode areas. This enables an electric field through the atria that can cardiovert the heart back to sinus rhythm.

The straight needles are pulled through the chest and left external to the skin. The needles are removed by cutting the un-insulated leads close to the needle. After removal of the needle the un-insulated leads and pacing pins are exposed. Cardioversion connectors and protective pacing pin tubing are provided to cover and insulate the un-insulated leads and pacing pins.

Pacing pins, which are pre-assembled on the pacing wires, attach to a compatible pacing extension cable and a standard external pacing unit (both user supplied). The pacing pins are designed to be compatible with the following pacing cables:
Medtronic 5433A Reusable EPG atrial safety cables.

Medtronic 5433V Reusable EPG ventricular safety cables.

Medtronic 5487 6 ft. sterile disposable patient safety cables.

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Cardioversion connectors are attached to the cardioversion lead of the tripolar atrial wire and unipolar atrial wire. To cardiovert the patient the cardioversion connectors are attached to the Syncrus Cardioversion Extension Cable, and the extension cable is attached to the Syncrus EDIM. Figure 1 demonstrates the Syncrus System in use.

EDIM

The EDIM is primarily designed as a safety feature to limit the amount of energy delivered to the heart tissue, even when the external defibrillator is set to its maximum energy output. The EDIM when used with a compatible external defibrillator reduces the energy to approximately 3% and delivers the low-energy cardioversion shock directly to the atria. The clinician performs a routine synchronized cardioversion, except that the defibrillator paddles rest on the paddle plates of the EDIM rather than on the patient's chest. The maximum output for the EDIM is 0.032 x the input Joules of the External Defibrillator. The EDIM specification for the conversion factor is 0.026 to 0.032. For example, the range of acceptable maximum output for a 360 Joule input is 9.4 Joules to 11.5 Joules. Table 1 provides the minimum and maximum energy transferred to the patient by the EDIM given the input energy of the External Defibrillator.

At the end of the post-operative period, the heart wires are removed by applying light traction, in the same manner as currently available temporary pacing wires.

Table 1: Minimum and Maximum Energy Output of the EDIM

Input from External Defibrillator (Joules)	Output Energy from EDIM (Joules)	
	MIN	MAX
50	1.3	1.6
100	2.6	3.2
150	3.9	4.8
200	5.2	6.4
250	6.5	8.0
300	7.8	9.6
350	9.1	11.2
360	9.4	11.5

PRINCIPLES OF OPERATION

ATRIAL PACING AND SENSING

In order to perform atrial pacing and sensing, three components are required:

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1) Syncrus Atrial Tripolar Heart Wire
2) A user-supplied patient cable
3) A user-supplied external pacemaker

The patient cable is connected to the external pacemaker and then to the pacing pins of the Syncrus tripolar heart wire attached to the right atria. After the atrial heart wires have been affixed and externalized, protective tubing is placed over the pacing pins. The proximal ends of the heart wires may then be taped to the patient's body until needed. After the heart wires are no longer needed (usually just prior to patient discharge from the hospital), they are removed by gentle traction, using standard surgical technique.

VENTRICULAR PACING AND SENSING

In order to perform ventricular pacing and sensing, three components are required:

1) Syncrus Bipolar Ventricular Heart Wire
2) A user-supplied patient cable
3) A user-supplied external pacemaker.

The Syncrus bipolar ventricular heart wire is a bipolar lead with collinear electrodes. One electrode is used for pacing/sensing, and the other electrode is used as a ground. After the bipolar heart wire has been affixed to either the right or left ventricle and the straight needle has been externalized and cut off, protective tubing covers may be placed over the pacing pin and taped to the patient's body until needed. After the bipolar heart wire is no longer needed (usually just prior to patient discharge from the hospital), it is removed by gentle traction using standard surgical technique.

ATRIAL DEFIBRILLATION (CARDIOVERSION) THERAPY

During cardioversion, an electrical field, generated by the energy transmitted from the external defibrillator and attenuated by the Syncrus External Defibrillator Interface Module (EDIM), is created between the cardioversion electrodes of the left and right atrial heart wires. The electrical field depolarizes the atrial cells within the field, which enables the atria to start beating in sinus rhythm.

The Syncrus atrial defibrillation heart wires are supplied in pairs. The tripolar heart wire has one electrode for cardioversion and two electrodes for atrial pacing and sensing. The left atrial heart wire is a unipolar lead consisting of a cardioversion electrode that is used in conjunction with the cardioversion electrode of the right atrial heart wire. The Syncrus atrial heart wires are affixed to the surfaces of the right and left atria using standard surgical technique in locations specified in the Instructions for Use (Appendix A). After the heart wires have been affixed and externalized, cardioversion connectors

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are attached to the end of each proximal cardioversion lead. The connectors are usually taped to the patient's body until needed.

The Syncrus EDIM provides several functions. Foremost, it enables the use of an external defibrillator to perform a postoperative internal cardioversion. The cardioversion connectors of the Syncrus atrial heart wires are connected directly to the Syncrus EDIM using the Syncrus Cardioversion Extension Cable. The external defibrillator paddles are then placed on the surface paddle contacts of the Syncrus EDIM to complete the circuit. For electrocardiogram synchronization, the external defibrillator must also be connected to temporary ECG skin electrodes affixed to the patient. Second, the EDIM also attenuates the energy delivered by the external defibrillator by approximately 97%. For example, a cardioversion shock of 360 joules delivered from the external defibrillator will be attenuated to about 11.5 joules before being sent to the cardioversion electrodes of the Syncrus atrial heart wires. Finally, the Syncrus EDIM provides electrical isolation for safety purposes while the patient is electrically connected to the module.

CONSTRUCTION DETAILS

(b)(4) [redacted]

[redacted]

(b)(4) [redacted]

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(b)(4)

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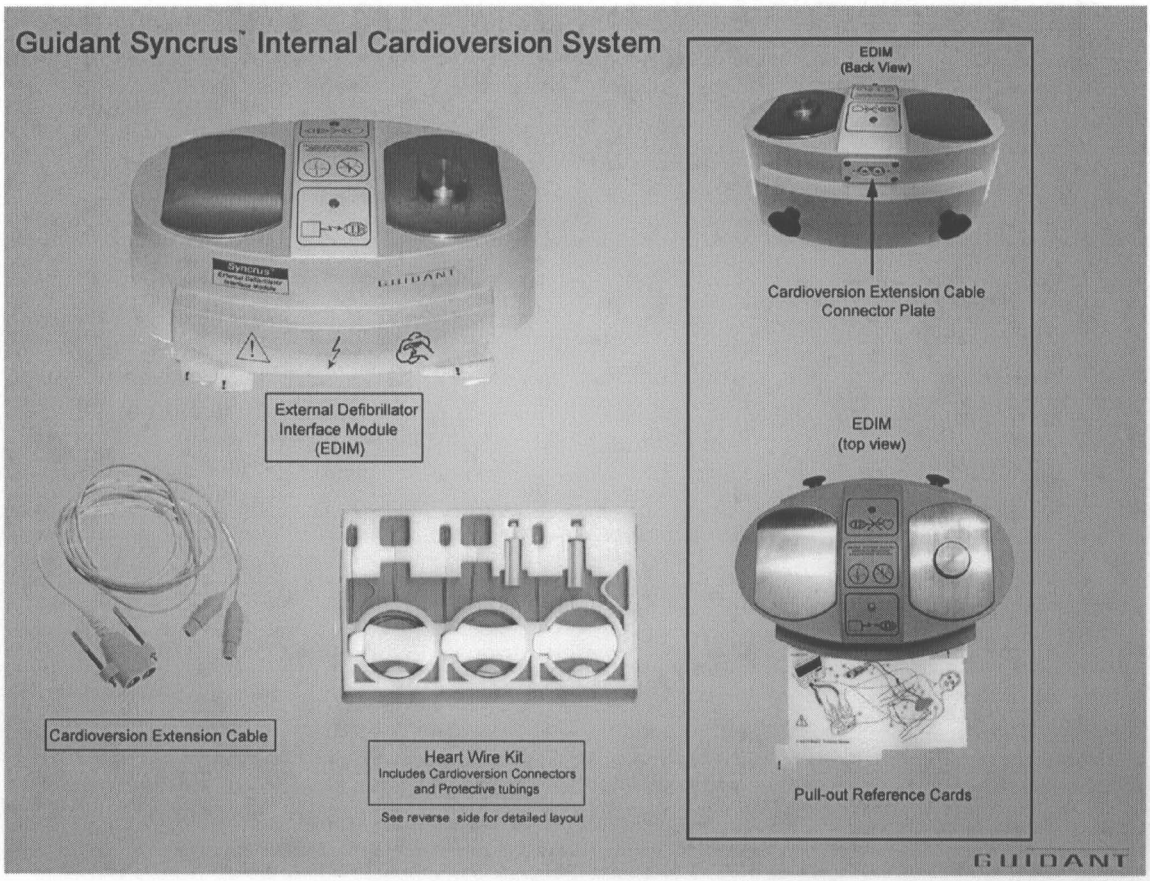
Figure 5 - EDIM, Heart Wire Set and Cable



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a. EDIM Safety Features

The Syncrus External Defibrillator Interface Module is equipped with the following safety features:

- ***UL approved:*** The device was designed and tested in accordance with applicable Underwriters Laboratories standards.
- ***Electrical isolation via mechanical spring-loaded plunger:*** The device is not electrically connected to the patient until the plunger has been fully depressed with the right defibrillator paddle by the physician.
- ***Paddle plate electrodes can not be touched by the user while the device is in operation:*** The physician must use both hands to hold the defibrillator paddles, making the EDIM paddle plates inaccessible during the moment that the shock is delivered. The paddle plates were designed to be completely covered by the paddles when in use.
- ***Shrouded patient cable:*** There are no exposed conductors at the interface between the EDIM and the cardioversion extension cable. The interface between the cable and EDIM is of an exclusive design. This inhibits connecting either cables (pacing cables) to the EDIM or using the cardioversion cable for pacing purposes.
- ***Internal surge arrestors protect against voltage overload:*** A shock greater than 360 joules will be internally dissipated by conversion to heat in the EDIM, resulting in no shock to the patient.
- ***Internal surge arrestors protect against inadvertent application of line voltage and/or ground fault:*** The patient and physician are both protected from line voltage (120-240 volt) single fault conditions.
- ***Light indicators:*** Notify the physician of the status of the just-completed shock.

Finally, a maintenance procedure documented in the Operator's Manual has been developed for the EDIM to ensure proper function. Test components needed to perform this maintenance procedure have been developed and are included with the EDIM. The test components, a maintenance test fixture and cable test adapter, are seen below in Figure 7. The maintenance procedure is described in the Operator's Manual (Appendix B).

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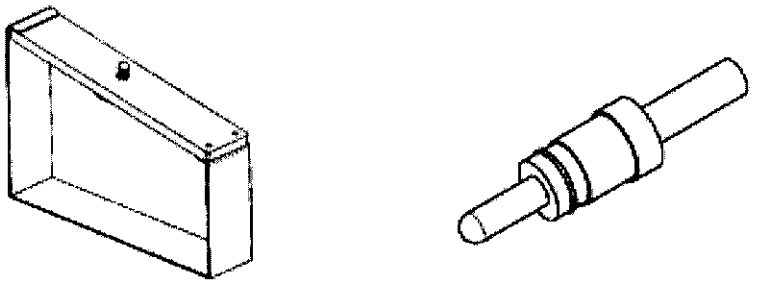
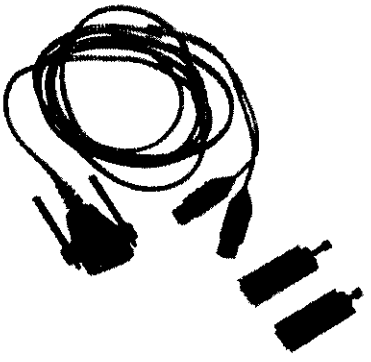
Figure 7- Syncrus EDIM maintenance test fixture and Syncrus EDIM cable test adapter



External Cable

The Cardioversion Extension Cable consists of two insulated conductors that are terminated uniquely on either end for the Syncrus System. On one end there are two gold contacts that are over molded to produce the EDIM connector to interface with the EDIM. Two jack-screws act as a retention feature when connected to the EDIM. On the other end there are two identical heart wire sockets that contain gold sockets to interface with the heart wire cardioversion connectors. Near the heart wire socket end a fixed grommet is molded in place to prevent separation of the two conductors. A graphic of the External Cable and heart wire cardioversion connectors is provided in Figure 8.

Figure 8 - External Cables



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SECTION 5. BENCH TESTING

Introduction

The original Design Verification Testing (DVT) for the Syncrus System was conducted by (b)(4) [redacted], and verified compliance of the EDIM to the product specification for use with monophasic defibrillators only. The design verification testing reported below was also conducted by (b)(4) [redacted] and is intended to verify the safety and efficacy of the EDIM when used with biphasic defibrillators.

The original DVTs for the Syncrus System were intended to address two parameters:

1) (b)(4) [redacted]

2) (b)(4) [redacted] (b)(4) [redacted]

When planning the validation of the system for use with biphasic defibrillators, not all of the tests performed during the original verification of the Syncrus system were determined to be relevant. The following table lists the tests originally performed, a determination regarding the applicability of the test for additional verification with a biphasic defibrillator and a rational for the determination.

Table 2: EDIM Verification Tests

Test Number[1]	Test Name	Applicable to Biphasic Verification Testing	Rationale
(b)(4) [redacted]			

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Test Number[1]	Test Name	Applicable to Biphasic Verification Testing	Rationale
(b)(4) [redacted]			

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Test Number[1]	Test Name	Applicable to Biphasic Verification Testing	Rationale

(b)(4)

[redacted]

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Test Number[1]	Test Name	Applicable to Biphasic Verification Testing	Rationale

(b)(4)

[redacted]

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Test Number[1]	Test Name	Applicable to Biphasic Verification Testing	Rationale
(b)(4) [redacted]			

(b)(4) [redacted] **Design Verification Testing**

(b)(4) [redacted]

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EQUIPMENT AND METHODS

(b)(4)

[redacted]

The following table summarizes the test methods and acceptance criteria for the biphasic DVTs conducted.

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Table 3: Test Methods and Acceptance Criteria

Test	Equipment	Purpose	Acceptance Criteria
(b)(4) [redacted]			

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RESULTS

(b)(4)

[redacted]

Conclusion

The Syncrus System met all applicable requirements of the Guidant Syncrus Product Specification using Agilent Heartstream XL (Philips Medical) and Physio-Control Lifepak [redacted] biphasic defibrillators.

(b)(4)

[redacted]

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SECTION 6. SUBSTANTIAL EQUIVALENCY

The predicate device for the modified Syncrus Internal Cardioversion System is the Syncrus System cleared through premarket notification on May 24, 2002. The modifications to the system are limited to qualification of the system for usage with a biphasic defibrillator and changes to the maintenance procedures and schedule. All of the changes are contained within the labeling. There are no changes to the design, components or manufacture of the Syncrus System.

Table 5 : Substantial Equivalency Chart

	K020701	Modified Device
Indication for Use	The Guidant SYNCRUS™ Internal Cardioversion System is indicated for use in post-operative cardiac surgery patients who require temporary atrial or ventricular pacing/sensing and/or atrial cardioversion.	Same
Target Population	Cardiac surgery patients requiring temporary post-operative pacing and sensing and/or atrial defibrillation	Same
Design	Pacing/Sensing Electrodes: Two stainless steel electrodes located at the distal end of Heart Wire, for bipolar pacing and sensing, and two connector pin assemblies located at the proximal end, for connection to external instrumentation. Optional defibrillator interface: two electrode wires, for placement on each atrium, connected to an external defibrillator interface module that is connected to an external defibrillator	Same
	Temporary implant for post-surgical hospital stay; removed by gentle external traction prior to patient discharge	Same
Materials	Pacing Leads: Stainless steel with multifilament conductor Defibrillator Conduit: Stainless	Same

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	K020701	Modified Device
	steel with multifilament conductor	
Performance	Market released in June of 2002. Approximately 500 patients implanted to date.	Same.
Sterility	Heart wires validated for Gamma radiation sterilization	Same
Biocompatibility	Biocompatibility testing demonstrated that the patient contact components and materials are biocompatible for their intended use	Same
Anatomical sites	Positioned on the surface of the atrial or ventricle (pacing/sensing only) following open heart surgery	Same
Energy Used and Delivered	External pacemaker, compatible monophasic defibrillators and electro physiology equipment Defibrillator wire – max. low energy delivered to patient is 11J	External pacemaker, compatible monophasic or biphasic defibrillator and electro physiology equipment Defibrillator wire – max. low energy delivered to patient is 11J
Compatibility with environment	Substantial bench, animal, clinical and market experience demonstrates compatibility with environment	Same
Compatibility with other Devices	External pacemaker: Medtronic Dual-Chamber Model 5388 External (Temporary) Pulse Generator Medtronic Single-Chamber Model 5348 External (Temporary) Pulse Generator Pacing cables: Medtronic 5433A Reusable EPG atrial safety cables Medtronic 5433V Reusable EPG ventricular safety cables Medtronic 5487 6 ft. sterile disposable patient safety cables Monophasic, low-energy external defibrillator with R-wave synchronization capability: Medtronic Physio-Control LifePak™ 9, 10, 11, 12	External pacemaker: Medtronic Dual-Chamber Model 5388 External (Temporary) Pulse Generator Medtronic Single-Chamber Model 5348 External (Temporary) Pulse Generator Pacing cables: Medtronic 5433A Reusable EPG atrial safety cables Medtronic 5433V Reusable EPG ventricular safety cables Medtronic 5487 6 ft. sterile disposable patient safety cables Biphasic, low energy external defibrillator with R-wave synchronization capability and external paddles: Medtronic Physio-Control

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	K020701	Modified Device
	(excluding 3D Biphasic™ Technology) defibrillator Agilent (Hewlett Packard) Codemaster™ defibrillator Zoll Medical Corporation defibrillator	LIFEPAK® 12 and LIFEPAK® 20 defibrillators Agilent (Philips Medical) Heartstream™ or HeartStart XL and XLT defibrillators Monophasic, low energy external defibrillator with R-wave synchronization capability: Medtronic Physio-Control LIFEPAK® 9, 10, 11, 12 defibrillators Agilent (Philips Medical) CodeMaster™ defibrillator Zoll M Series defibrillator with monophasic capability
Usage	Directly on heart Hospital setting	Same
Standards Met	FDA Performance Standard for Electrode Lead Wires and Patient Cables (CFR Chapter 21, Part 898) – Categorical Exemption ANSI/AAMI:Cardiac Defibrillator Device Standards	Same
Mechanical/Electrical/Thermal Safety	IEC-601-1;EN 60601-1; UL	Same

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SECTION 7. COMPARISON OF MODIFIED DEVICE TO CLEARED DEVICE

Modifications to the Syncrus Internal Cardioversion System (K020701) include changes to the Instructions For Use and Operator's Manual. The changes reflect the removal of the limitation of use with monophasic low energy defibrillators and the inclusion of a listing of biphasic defibrillators tested and proven to be compatible with the Syncrus System. Additionally, in response to feedback from hospital biotechnical staff, modifications have been made to the maintenance procedures to enhance and improve maintenance for the EDIM. Furthermore, in response to surgeon feedback, additional options for Heart Wire placement have been added to the IFU and Operator's Manual. Finally, grammatical and administrative corrections have been captured and corrected (these are not detailed in Table 6 below).

The following provides a summary and rationalization for the proposed modifications to the IFU and Operator's Manual.

Compatibility with Biphasic Defibrillators:

a. No changes have been made to the design, components, materials or manufacture of the Syncrus System.

b. The Syncrus System has been found to perform as intended with Medtronic Physio-Control LIFEPAK 12 and LIFEPAK 20 biphasic defibrillators and Agilent (Philips Medical) Heartstream or Heartstart XL and XLT defibrillators.

c. The Syncrus System is not compatible with the Zoll M Series biphasic defibrillator, as this device will not discharge energy into the EDIM.

Changes to Maintenance Procedure:

d. The full maintenance testing schedule has been revised from "monthly" to "every 3 months". Based on feedback from hospital biomedical engineers, full maintenance checks on external defibrillators are performed at a frequency of 3 to 6 months. Additionally, the functionality of the EDIM is tested for a minimum of 550 cycles as part of Guidant's Design Verification Testing. It is reasonable to assume that the likelihood of a

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hospital applying >550 shocks within a 3 month period is extremely low and therefore monthly testing is not deemed necessary for the EDIM.

e. A revision has been made to the list of test equipment needed to perform full maintenance test procedure:
   - Addition of an electrical safety analyzer or leakage current analyzer (see modification to leakage current test, **h** below).
   - The requirement for a hi-pot tester has been replaced with an ohmmeter (see dielectric withstand, **g** below).
   - Deletion of the need for an oscilloscope (see waveform verification, **j** below).
   - Deletion of listing of specific manufacturer and brand for the defibrillator analyzer.
   - Addition of temporary pacemaker to Pacing System Analyzer (PSA) device for establishing baseline. A temporary pacemaker will obtain the same results as PSA, which many hospitals do not carry.

f. Reordered sequence of tests based on equipment set up and use to improve efficiency of testing.

g. The "Dielectric Withstand" test has been revised to a "Safety Switch Isolation" test. The current maintenance procedure requires a hi-pot tester to perform the "Dielectric Withstand" test whereas the "Safety Switch Isolation" test can be performed with an ohmmeter. Feedback from several hospital biomed groups (U.S. and Europe) noted that a hi-pot tester is not standard test equipment in most hospitals and therefore difficulty would be encountered performing this maintenance test. The revised "Safety Switch Isolation" procedure tests for a complete failure of the safety switches and will provide similar results as the "Dielectric Withstand" test. Although the "Dielectric Withstand" procedure allows for the testing of a partial failure of the switches, such a failure is considered to be highly unlikely due to the following:
   - Redundant safety switch design
   - Safety switches are each rated for 1 million cycles
   - EDIM is designed and tested for a minimum of 550 cycles
   - Energy does not arc across the safety switches. Energy is transferred only after the switches have been closed and are in direct contact.

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h. Modification to the "Leakage current test" to clarify the test equipment needed to perform this maintenance test. Performance of this test with the mains on the applied part (left paddle plate) is redundant and unnecessary since the surge protectors are bi-directional components and should function the same in both directions. Modifications are:
   - Specified the use of an electrical safety or leakage current analyzer.
   - Deleted instructions to perform test with mains on the applied part (i.e. re-perform test with the analyzer hooked up to the left paddle plate).

i. Added notation a monophasic external defibrillator is required to perform the "Over-Voltage Protection" test. This test verifies that the over-voltage protectors limit the output voltage from the EDIM to less than 800-volts. A monophasic external defibrillator is required for this test in order to achieve a voltage greater than 800-volts at the voltage protectors, when no load is connected to the EDIM output.

j. Deletion of the "Waveform verification" test. Waveform integrity was tested in design verification testing and is verified 100% in manufacturing. Waveform would not be affected by an EDIM component failure. Proper energy transfer is also verified in the attenuation test already performed as part of the EDIM maintenance procedure.

<u>Modifications to the instructions for Heart Wire placement in the IFU and Operator's Manual:</u>

k. Minor modifications to the graphics and description of the Heart Wire placement technique used in clinical trials.

l. Added an alternative method for Heart Wire placement as used in clinical practice.

Table 6 provides a comparison of the proposed and current Instructions for Use and Operator's Manual. A redlined and clean copy of the proposed IFU and proposed Operator's Manual may be found in Appendices A and B and the current IFU and Operator's Manual may be found in Appendices D and E, respectively.

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Table 6: Comparison of Modified and 510(K) Cleared IFU and Operators Manual

	Type of Change	K020701 -IFU	Modified IFU
1	Removed restriction to use with only "monophasic" external defibrillators. Substituted "monophasic" with "compatible"	A reusable External Defibrillator Interface Module (EDIM), *which interfaces between a monophasic*, low energy, external defibrillator and the Heart Wires. The EDIM reduces the output energy from the defibrillator to a low energy shock delivered through the Heart Wires.	A reusable External Defibrillator Interface Module (EDIM), *which interfaces between a* compatible low energy external defibrillator and the Heart Wires. The EDIM reduces the output energy from the defibrillator to a low energy shock delivered through the Heart Wires.
2		The Syncrus System components must be used in conjunction with a monophasic, low energy external *defibrillator, an external pacemaker, and pacing cables* that connect the Heart Wires to the external pacemaker. The user supplies the external defibrillator, external pacemaker, and pacing cables.	The SYNCRUS™ System components must be used in conjunction with a compatible low energy external defibrillator, an external pacemaker, and pacing cables that connect the Heart Wires to the external pacemaker. The user supplies the external defibrillator, external pacemaker, and pacing cables.
3			Refer to the SYNCRUS™ System Operator's Manual (*Required User Supplied Components* section) for a list of compatible external defibrillators, external pacemakers and pacing cables that have been tested with the Guidant SYNCRUS™ System.
4		The Guidant Syncrus System is compatible with monophasic low energy external defibrillators only.	The SYNCRUS™ System is not compatible with all low energy external defibrillators. Refer to the SYNCRUS™ System Operator's Manual (*Required User Supplied Components* section) for a list of compatible external defibrillators.
5		The EDIM attenuates the energy output of a monophasic, low-energy external defibrillator down to 3% of its original joule output. The EDIM produces an energy transfer of 3% (+/- 1%) on the input energy from the defibrillator. Since the circuitry of the EDIM consists	The EDIM attenuates the energy output of a compatible low energy external defibrillator down to 3% of its original joule output. The EDIM produces an energy transfer of 3% (+/- .2/-.4%) on the input energy from the defibrillator. Since the

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		of a passive voltage divider network, the attenuation consists of a uniform reduction of input voltage, resulting in an output waveform identical to that of the defibrillators waveform, except reduced in magnitude (Figure 5).	circuitry of the EDIM consists of a passive voltage divider network, the attenuation consists of a uniform reduction of input voltage, resulting in an output waveform identical to that of the defibrillators waveform, except reduced in magnitude (Figure 5).
6	Deleted sentence: "Figures 2 through 4 illustrate heart wire placement as performed in clinical trials." (The modified version of the IFU demonstrates two methods of heart wire placement, one method used *in clinical practice* and an alternative method used in the European clinical trial *for details see Appendix A*)	Figures 2 through 4 illustrate heart wire placement as performed in clinical trials.	Figures 2 through 3 illustrate examples of alternative Heart Wire placement techniques as used in clinical practice. Figure 2. SYNCRUS Heart Wire Placement Technique A Figure 3. SYNCRUS Heart Wire Placement Technique B (used in clinical trials in Europe).
7	Minor modifications to graphics and description of Heart Wire placement technique:	**Left Atrial Heart Wire (unipolar)** • *Cardioversion Electrode (yellow wire):* Use the attached curved needle to affix the cardioversion electrode to the left atrial myocardium on the atrioventricular (AV) groove between the left and right pulmonary veins in an "S" pattern as illustrated in Figure 2 for optimal results. After the cardioversion electrode is affixed, cut off the curved needle and discard it. Place a slight bend or kink at the end of the electrode. Pulmonary veins AV groove **Right Atrial Heart Wire (tripolar)** • *Cardioversion Electrode (yellow wire):* Use the attached curved needle to affix the cardioversion electrode into the right atrial myocardium in an "S" pattern as shown in Figure 3 for optimal results. After the	**Left Atrial Heart Wire (unipolar)** Cardioversion Electrode (yellow wire): Use the attached curved needle to affix the cardioversion electrode to the left atrial myocardium. After the cardioversion electrode is affixed (see Figures 2a and 3a), cut off the curved needle and discard it. Place a slight bend or kink at the end of the electrode. **Right Atrial Heart Wire (tripolar)** Cardioversion Electrode (yellow wire): Use the attached curved needle to affix the cardioversion electrode to the right atrial myocardium. After the cardioversion electrode is affixed (see Figures 2b and 3b), cut off the curved needle and discard it. Place a slight bend or kink at the

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		cardioversion electrode is affixed, cut off the curved needle and discard it. Place a slight bend or kink at the end of the electrode. *Placement should be made to maximize the atrial* muscle mass between the right atrial cardioversion electrode and the left atrial cardioversion electrode. *Pacing Electrode (black and blue wires):* Use the attached curved needle to affix the bipolar pacing electrodes into the right atrial myocardium. For optimal cardiac pacing, bury both the anode and cathode in the myocardium. After the pacing electrodes are affixed, cut off the needle and discard it. Place a slight bend or kink at the end of the anode electrode. **Ventricular Heart Wire (bipolar)** • *Pacing Electrodes (black and white wires):* Use the attached curved needle to affix the bipolar pacing electrodes into the myocardial tissue of either the right or left ventricle as illustrated in Figure 4 for optimal results. The positive pacing electrode (anode) is attached to the needle, while the negative electrode *(cathode) is contained in the 4 mm long bullet. For* optimal cardiac pacing, bury both the anode and cathode in the myocardium. After pacing electrodes are affixed, cut off the curved needle and discard it. Place a slight bend or kink at the end of the anode electrode.	end of the electrode. Placement should be made to maximize the atrial muscle mass between the right atrial *cardioversion electrode and the left atrial* cardioversion electrode. Pacing Electrodes (black and blue wires): Use the attached curved needle to affix the bipolar pacing electrodes to the right atrial myocardium. For optimal cardiac pacing, bury both the pacing electrode and bullet in the myocardium. After the pacing electrodes are affixed (see Figures 2b and 3b), cut off the needle and discard it. Place a slight bend or kink at the end of the pacing electrode. **Ventricular Heart Wire (bipolar)** Pacing Electrodes (black and white wires): Use the attached curved needle to affix the bipolar pacing electrodes into the myocardial tissue of either the right or left ventricle. For optimal cardiac pacing, bury both the pacing electrode and bullet in the myocardium. After the pacing electrodes are affixed (see Figures 2c and 3c), cut off the curved needle and discard it. Place a slight bend or kink at the end of the pacing electrode.
8	Added description of the alternative HW placement technique.		See Redlined IFU in Appendix A for additional Heart Wire placement option
9	Reworded step 4 in the Instructions for Use.	Attach a yellow cardioversion connector provided with the Syncrus Left and Right Atrial Heart Wires. This is done by threading the Heart Wire cardioversion lead through the pinhole on the backside of the connector and pushing the pin into the connector. Make sure there is good electrical contact between the Heart Wire	Attach the yellow cardioversion connectors provided with the SYNCRUS™ Heart Wires to the yellow cardioversion wires on the Left and Right Atrial Heart Wires. This is done by threading the Heart Wire cardioversion lead through the pinhole on the backside of the connector and pushing the

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		cardioversion lead and the yellow cardioversion connector.	pin into the connector. Make sure there is good electrical contact between the Heart Wire cardioversion lead and the yellow cardioversion connector.
	Type of Change	**K020701-Operators Manual**	**Modified Operators Manual**
10	Deleted "monophasic" and added "compatible" from reference to defibrillator	A reusable External Defibrillator Interface Module (EDIM), which interfaces between a monophasic, low-energy, external defibrillator and the Heart Wires. The EDIM reduces the output energy from the defibrillator to a low energy shock delivered through the Heart Wires.	A reusable External Defibrillator Interface Module (EDIM), which interfaces between a compatible low energy external defibrillator and the Heart Wires. The EDIM reduces the output energy from the defibrillator to a low energy shock delivered through the Heart Wires.
11	Deleted "monophasic" and added "compatible" from reference to defibrillator Added referral to list of compatible defibrillators.	The Syncrus System components must be used in conjunction with a monophasic, low energy external defibrillator, an external pacemaker, and pacing cables that connect the Heart Wires to the external pacemaker. The user supplies the external defibrillator, external pacemaker, and pacing cables.	The SYNCRUS™ System components must be used in conjunction with a compatible low energy external defibrillator, an external pacemaker, and pacing cables that connect the Heart Wires to the external pacemaker. The user supplies the external defibrillator, external pacemaker, and pacing cables. Refer to section on *Required User Supplied Components* for a list of compatible external defibrillators, external pacemakers and pacing cables that have been tested with the Guidant SYNCRUS™ System.
12	Deleted "monophasic" and added "compatible" from reference to defibrillator	To perform internal atrial cardioversion, the cardioversion connectors on the Left and Right Atrial Heart Wires must be connected to the Syncrus™ Cardioversion Extension Cable and EDIM. The hospital must supply a monophasic low energy external defibrillator.	To perform internal atrial cardioversion, the cardioversion wires on the Left and Right Atrial Heart Wires must be connected to the SYNCRUS™ Cardioversion Extension Cable and EDIM. The hospital must supply a compatible low energy external defibrillator.
13	Added "compatible" to description of defibrillator.	The Syncrus™ EDIM is a non-sterile and reusable device that allows the energy from an external	The SYNCRUS™ EDIM is a non-sterile and reusable device that allows the energy from a

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		defibrillator to be transmitted through the Left and Right Atrial Heart Wires directly to the patient's myocardium.	compatible external defibrillator to be transmitted through the Left and Right Atrial Heart Wires *directly to the patient's myocardium.*
14	Deleted "monophasic" added "compatible" Added referral to *Required User Supplied Components* section.	The EDIM should only be used with a monophasic, low-energy external defibrillator. Perform functional checks on the Syncrus™ EDIM daily and monthly (see section on *Maintenance and Calibration*).	The EDIM should only be used with a compatible low energy external defibrillator (see section on *Required User Supplied Components*). Perform functional checks on the SYNCRUS™ EDIM as described in the Maintenance and Calibration section.
15	*Added a list of the biphasic* external defibrillators. Specified need for biphasic external defibrillators with external paddles. Added note: Zoll biphasic defibrillators will not discharge energy into the EDIM. Corrected identification of monophasic defibrillators: Deleted the exclusion of biphasic defibrillators from the Medtronic Physio-Control LIFEPAK® listing. Used proper manufacturer's names and trademarking. Specified monophasic model for the Zoll M Series defibrillator.	**6.0 REQUIRED USER SUPPLIED COMPONENTS** To apply Syncrus™ atrial cardioversion therapy, the user must supply a monophasic low energy external defibrillator, an external pacemaker, and the appropriate pacing cables. Below is a list of compatible external defibrillators, pacemakers and pacing cables that have been tested with the Guidant Syncrus™ System. External pacemaker: • Medtronic Dual-Chamber Model 5388 External (Temporary) Pulse Generator • Medtronic Single-Chamber Model 5348 External (Temporary) Pulse Generator Pacing cables: • Medtronic 5433A Reusable EPG atrial safety cables • Medtronic 5433V Reusable EPG ventricular safety cables • Medtronic 5487 6 ft. sterile disposable patient safety cables	**6.0 REQUIRED USER SUPPLIED COMPONENTS** To apply SYNCRUS™ atrial cardioversion therapy, the user must supply a compatible low energy external defibrillator, an external pacemaker, and the appropriate pacing cables. Below is a list of compatible external defibrillators, pacemakers and pacing cables that have been tested with the Guidant SYNCRUS™ System. External pacemaker: • Medtronic Dual-Chamber Model 5388 External (Temporary) Pulse Generator • Medtronic Single-Chamber Model 5348 External (Temporary) Pulse Generator Pacing cables: • Medtronic 5433A Reusable EPG atrial safety cables • Medtronic 5433V Reusable EPG ventricular safety cables

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		Monophasic, low-energy external defibrillator with R-wave synchronization capability: • Medtronic Physio-Control LifePak™ 9, 10, 11, 12 (excluding 3D Biphasic™ • Technology) defibrillator • Agilent (Hewlett Packard) Codemaster™ defibrillator • Zoll Medical Corporation defibrillator	• Medtronic 5487 6 ft. sterile disposable patient safety cables Biphasic, low energy external defibrillator with R-wave synchronization capability and external paddles: • Medtronic Physio-Control LIFEPAK® 12 and LIFEPAK® 20 defibrillators • Agilent (Philips Medical) Heartstream™ or HeartStart XL and XLT defibrillators Note:The Zoll M Series biphasic defibrillator will not discharge energy into the SYNCRUS™ EDIM. Monophasic, low energy external defibrillator with R-wave synchronization capability: • Medtronic Physio-Control LIFEPAK® 9, 10, 11, 12 defibrillators • Agilent (Philips Medical) CodeMaster™ defibrillator • Zoll M Series defibrillator with monophasic capability
16	SECTION 7.0 WARNINGS	The Guidant Syncrus System is compatible with monophasic low energy external defibrillators only.	The SYNCRUS™ System is not compatible with all low energy external defibrillators. See section on *Required User Supplied Components* for a list of compatible external defibrillators.
17	Added temporary pacemaker to PSA device for establishing baseline A temporary pacemaker will obtain the same results as a pacing system analyzer, which many hospitals do not	Wire fracture, dislodgement, abrasion and/or an incomplete connection can cause a periodic or continual loss of pacing and sensing, possibly resulting in inappropriate delivery of conversion therapy. Connect the pacing connector pins for baseline measurements to a pacing system analyzer (PSA) and evaluate the placement by determining R-wave amplitude, pacing	Wire fracture, dislodgement, abrasion and/or an incomplete connection can cause a periodic or continual loss of pacing and sensing, possibly resulting in inappropriate delivery of conversion therapy. Connect the pacing connector pins for baseline measurements to a pacing system analyzer (PSA) or temporary pacemaker and

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	which many hospitals do not carry.	threshold, and pacing lead impedance. Secure the Syncrus Heart Wires by taping the cardioversion connectors and pacing pins to the patient's body until needed.	evaluate the placement by determining R-wave amplitude, pacing threshold, and pacing lead impedance. Secure the SYNCRUS™ Heart Wires by taping the cardioversion connectors and pacing pins to the patient's body until needed.
18	Section 9.0 ATTACHING THE SYNCRUS™ HEART WIRES TO THE MYOCARDIUM	Same as IFU, see rows 6 and 7 above.	Same as IFU, see rows 6 and 7 above.
19	SECTION 11.1 MAINTENANCE AND CALIBRATION: Changed daily maintenance to every three months. (Refer to changes to maintenance procedure, bullet '**d**' above).	It is recommended that the following maintenance procedure be performed on a daily basis to ensure proper function of the Syncrus™ EDIM.	It is recommended that the following maintenance procedure be performed every 3 months to ensure proper function of the SYNCRUS™ EDIM. Also perform a full maintenance test if the EDIM has been dropped onto a hard surface prior to using the EDIM again.
20	SECTION 11.2.1 MAINTENANCE AND CALIBRATION: Revised list of test equipment needed to perform full maintenance test procedure: Added electrical safety analyzer or leakage current analyzer Replaced hi pot tester with ohmmeter Deleted need for an oscilloscope Deleted listing of specific	11.2.1 Other Equipment • External defibrillator (see section on Required User Supplied Components for compatible defibrillators) • Impulse 3000 or 4000 defibrillator analyzer (DNI Nevada, Inc., Carson City, NV, USA) or equivalent. • Syncrus™ EDIM maintenance test fixture (Guidant Cardiac Surgery order #TX-5200) • Syncrus™ Cardioversion Cable test adapter; two required (Guidant Cardiac Surgery order #TX-5300). Hypertronics p/n YPN025-002G may also be used. • Hi-pot tester capable of 4 kV AC output • Oscilloscope with high voltage probe	11.2.1 Other Equipment • External defibrillator (see section on *Required User Supplied Components* for compatible defibrillators) • Ohmmeter • Electrical safety analyzer or leakage current analyzer • Defibrillator analyzer SYNCRUS™ EDIM maintenance test fixture (Guidant Cardiac Surgery order #TX-5200)

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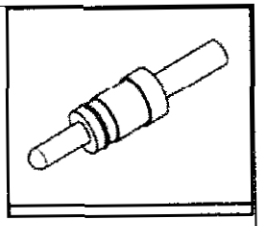
	manufacturer and brand for the defibrillator analyzer	 Syncrus™ EDIM maintenance test Syncrus™Cardioversion Cable test adapter fixture TX-5200 TX-5300 (2 required)	 SYNCRUS™ Cardioversion Cable test adapters – two required (Guidant Cardiac Surgery order #TX-5300). Hypertronics p/n YPN025-002G may also be used.
21	Reordered sequence of tests based on equipment set up and use, to improve efficiency of testing.	See Operator's Manual, Appendix E	See Draft Operators Manual, Appendix B
22	Revised the "Dielectric withstand" test that requires a hi pot tester to a "Safety switch isolation" test that performs the test with an ohmmeter. (Refer to changes to maintenance procedure, bullet '**g**' above).	7.0 Dielectric withstand Test Setup: 7.1 Connect the Syncrus™ Cardioversion Extension Cable to the Syncrus™ EDIM. 7.2 Connect the Cardioversion Cable test adapters to the Syncrus™ Cardioversion Extension Cable. 7.3 Electrically short the output terminals on the test adapters. 7.4 Attach the EDIM maintenance test fixture to the Syncrus™ EDIM. The test fixture should wrap around the **left** side of the EDIM and the latching mechanism should be located on the same side as the EDIM output terminals when properly installed for this test (see Figure 6). 7.5 Connect the positive hi-pot output lead to the Syncrus™ EDIM left paddle plate via the electrical connector on the EDIM maintenance test fixture. 7.6 Connect the negative hi-pot lead to the shorted output terminals on the Cardioversion Cable test	2.0 Check safety switch isolation Equipment Used: Ohmmeter SYNCRUS™ Cardioversion Cable test adapters (2) Test Setup: Connect the SYNCRUS™ Cardioversion Extension Cable to the SYNCRUS™ EDIM. Connect the Cardioversion Cable test adapters to the output connectors on the SYNCRUS™ Cardioversion Extension Cable. Connect an ohmmeter lead to each of the test adapters. With the safety push button on the EDIM in its normal "up" position, the ohmmeter should read open (i.e. no continuity). With the safety push

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		output terminals on the Cardioversion Cable test adapters. **Figure 6.** The EDIM maintenance test fixture shown properly installed to the Syncrus™ EDIM. Set the hi-pot tester to output 4000 Volts AC. The EDIM right safety push button should not be depressed for this check. Slowly raise the voltage to 4000 Volts AC and remain at that voltage for 1 minute. There should be no arcing or tripping of the hi-pot's limit detector and the current flow should be less than 33 mA.	button depressed, the ohmmeter should read between 55 – 65 ohms.
23	Simplified the "Leakage current test": Specified the use of an electrical safety or leakage current analyzer to perform test. Deleted need to perform test with mains on the applied part (i.e. redoing test with the analyzer hooked up to	1 Check leakage current Note: the leakage current limits specified are for the Syncrus™ EDIM only. Any leakage current inherent in the leakage tester must be identified and deducted from the tester readout before applying the leakage current limits. Patient Leakage Current (Mains on Paddle Plates) Test Setup: 1.1 Connect the Syncrus™ Cardioversion Extension	Check leakage current Equipment Used: Electrical safety analyzer or leakage current analyzer SYNCRUS™ Cardioversion Cable test adapters (2) SYNCRUS™ EDIM maintenance test fixture Note: the leakage current limits specified are for

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	the left paddle plate) The modifications are intended to clarify test equipment needed to perform the test. Additionally, performing test with the mains on the applied part (left paddle plate) is redundant and unnecessary. The surge protectors are bi-directional components and should function the same in both directions.	Cable to the Syncrus™ EDIM. 1.2 Connect a Cardioversion Cable test adapter to each output connector on the Syncrus™ Cardioversion Extension Cable. Electrically short the two output terminals on the test adapters. 1.3 Connect a current measuring device to the shorted output terminals of the test adapters. 1.4 Attach the EDIM maintenance test fixture to the Syncrus™ EDIM. The test fixture should wrap around the right side of the EDIM and the latching mechanism should be located on the same side as the EDIM output terminals when properly installed for this test (see Figure 5). 1.5 Depress the Syncrus™ EDIM safety push button with the movable arm of the test fixture. Latch the movable arm and verify that the EDIM safety push button is fully depressed. **Figure 5.** The EDIM maintenance test fixture shown properly installed to the Syncrus™ EDIM. The Syncrus™ EDIM shall not allow greater than 10μA	the SYNCRUS™ EDIM only. Any leakage current inherent in the leakage tester must be identified and deducted from the tester readout before applying the leakage current limits. Patient Leakage Current (Mains on Paddle Plates) Test Setup: Connect the SYNCRUS™ Cardioversion Extension Cable to the SYNCRUS™ EDIM. Connect the Cardioversion Cable test adapters to the output connectors on the SYNCRUS™ Cardioversion Extension Cable. Electrically short the two output terminals on the test adapters. Connect the shorted test adapters to the ground terminal on the electrical safety or leakage current analyzer. Attach the EDIM maintenance test fixture to the SYNCRUS™ EDIM. The test fixture should wrap around the right side of the EDIM and the latching mechanism should be located on the same side as the EDIM output terminals when properly installed for this test (see Figure 5). Depress the SYNCRUS™ EDIM safety push button with the movable arm of the test fixture. Latch the movable arm and verify that the EDIM safety push button is fully depressed. Make an electrical connection between the EDIM maintenance test fixture (via the lock nut) and an ECG terminal of the analyzer (i.e. RL connection). Using the appropriate setting for the analyzer, apply either 120-volts or 240-volts (determined by the voltage powering the analyzer) to the EDIM. Descriptors for the analyzer test mode may include

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		leakage current when a 240-volt source is connected (or 5μA leakage current when a 120 volt source is connected) to the left paddle plate and the current measuring device is attached to the output jacks electrically tied together and shorted to ground. The EDIM safety push button should be depressed for this check. Patient Leakage Current (Mains on the Applied Part) - The Syncrus™ EDIM shall not allow greater than 10 μA leakage current when a 240 volt source is connected (or 5μA leakage current when a 120 volt source is connected) to the output jacks electrically tied together and the measuring device is attached to the left paddle plate and shorted to ground. The EDIM safety push button should be depressed for this check. **CAUTION:** Do not depress the Syncrus™ EDIM safety push button with anything that is electrically common with your body. Serious injury may occur.	"Lead Isolation to Ground" or "Patient Lead Isolation Test". The SYNCRUS™ EDIM shall not allow greater than 10μA leakage current when 240-volts are applied by the analyzer (or 5μA leakage current when 120-volts are applied) to the EDIM. **CAUTION:** *Do not depress the SYNCRUS™* EDIM safety push button with anything that is electrically common with your body. Serious injury may occur.
24	Note added to test #5 (#4 in modified version) that a monophasic external defibrillator needs to be used to perform the "Over-voltage protection" test.		Note: This test verifies that the over-voltage protectors limit the output voltage from the EDIM to less than 800-volts. A monophasic external defibrillator needs to be used for this test in order to achieve a voltage greater than 800-volts at the voltage protectors when there is no load connected to the EDIM output.
25	Deleted the "waveform verification" test Waveform integrity was tested in design verification testing and is verified 100% in manufacturing. Waveform would not be affected by an EDIM component failure. Proper	8. Waveform verification Test Setup – Part 1: 1. Connect the external defibrillator paddles to the defibrillator analyzer. 2. Connect the oscilloscope to the oscilloscope output jack on the defibrillator analyzer. 3. Set the defibrillator to 10 joules output. Use the	

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	energy transfer is also verified in the attenuation test already performed as part of the EDIM maintenance procedure.	oscilloscope to capture the waveform of the external defibrillator discharging directly into the defibrillator analyzer. Label this waveform "External Defibrillator Waveform". Test Setup – Part 2: 1. Connect the Syncrus™ Cardioversion Extension Cable to the Syncrus™ EDIM. 2. Connect the Cardioversion Cable test adapters to the Syncrus™ Cardioversion Extension Cable. 3. Connect the test adapters to the defibrillator analyzer. 4. Connect the oscilloscope to the oscilloscope output jack on the defibrillator analyzer. 5. Set the external defibrillator to 360 joules output. Discharge the external defibrillator into the Syncrus™EDIM. Capture the output waveform of the EDIM with the oscilloscope. Label this waveform "Syncrus™ EDIM Waveform". Compare the two waveforms from Part 1 and 2 of this test. They should be very similar in shape, maximum voltage, and duration. If any voltage spikes or "noise" are present on the EDIM waveform that are not present on the external defibrillator waveform after the initial discharge of the external defibrillator, discontinue use of the Syncrus™ EDIM and contact Guidant Cardiac Surgery (Santa Clara, CA) for further instructions. NOTE: There may be some voltage spikes or "noise" present in the external defibrillator waveform that are not present on the Syncrus™ EDIM output waveform. This is a normal condition.	

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SECTION 8. PRODUCT LABELING

PACKAGING LABELS

There have been no changes to the Product labels. Labels may be found in Appendix F.

INSTRUCTIONS FOR USE

The revised IFU may be found in Appendix A.

OPERATORS MANUAL

The revised Operator's Manual may be found in Appendix C

INDICATIONS FOR USE STATEMENT

No changes have been made to the indications for use. Refer to Section 11 for Indications for Use Statement.

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SECTION 9. DESIGN CONTROL ACTIVITIES SUMMARY

Guidant has a Design Control and Risk Management procedure. A Risk Management profile is created by the contributing effort of representatives from different functional groups, for example: R&D, Quality, Manufacturing, Regulatory Affairs, Marketing, and Clinical Affairs. The project leader and quality engineer on the project are responsible for developing, implementing, and ensuring that control measures are performed, data is recorded, and the Project Risk Management is updated as necessary.

Method of Risk Analysis

An analysis of potential failure modes for the Syncrus System was conducted in accordance with Guidant's Project Risk Management procedure and consists of a review of the Risk Analysis for the Syncrus System, The design FMEA for the Extension Cable, heart wires and EDIM. This procedure complies with ANSI/ASQC ISO/EN 46001 Quality Assurance in Design/Development, Production, Installation and Service; ANSI/ASQC ISO/EN 46004 Quality Management and Quality System Elements – Guidelines; FDA Design Control Guidance for Medical Device Manufactures; 21 CFR 820 Quality System Regulation and EN ISO 14971: 2000 Medical Devices – Application of risk management to medical devices.

The Risk Analysis and FMEA documents may be found in Appendix G

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SECTION 10. DECLARATION OF CONFORMITY

As required by the risk analysis, all verification and validation activities for the Syncrus System were performed by the designated individual(s) and the results of the activities demonstrated that the predetermined acceptance criteria were met.

Janine Hanson
Director of Quality

12/9/02
Date

Guidant Cardiac Surgery's manufacturing facility is in conformance with the design control procedure requirements as specified in 21 CFR 820.30 and the records are available for review.

Wendy Gin
Director of Operations

12/9/02
Date

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SECTION 11: STATEMENT OF MODIFICATIONS

The modifications to the Syncrus System have not altered the fundamental technology of the Predicate Device.

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SECTION 12: 510(k) SUMMARY

This summary of 510(K) safety and effectiveness information is submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

A. Name, Address, Phone and Fax number of Applicant

Guidant Corporation
Cardiac Surgery
3200 Lakeside Drive
Santa Clara, CA 95054

Tel: (408) 845-1910
Fax: (408) 845-1855

B. Contact Person

Debbie Cogan
Regulatory Affairs Associate

C. **Date Prepared**

December 6, 2002

D. Device Name

Trade Name: Syncrus Internal Cardioversion System
Classification Name: ELECTRODE, PACING AND CARDIOVERSION, TEMPORARY, EPICARDIAL
Product Classification Code: NHW
Device Classification: Class 2
Establishment Registration: 2953148

E. Device Description

The Syncrus System consists of three components:

- Three temporary heart wires sutured onto the heart during open-heart surgery. The wires include a unipolar defibrillation heart wire (left atrium), a bipolar pacing/sensing heart wire (right or left ventricle) and a tripolar defibrillation and pacing and sensing heart wire (right atrium).

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- An attenuator box (External Defibrillator Interface - Module EDIM). The EDIM attenuates the delivered energy from a standard, low energy defibrillator by 97% (50 - 360 Joules to 1.3 – 11.5 Joules).
- A cardioversion extension cable, which connects the defibrillation heart wires to the EDIM.

The user must supply an external, low-energy defibrillator that is capable of synchronized cardioversion, an external pacemaker, and temporary patient cables to connect the pacemaker to the patient. The Syncrus System is designed to perform the following cardiac rhythm management functions:

- Atrial pacing and electrocardiogram sensing
- Ventricular pacing and electrocardiogram sensing
- Atrial defibrillation using low energy, synchronized cardioversion.

F. Intended Use

The Guidant SYNCRUS™ Internal Cardioversion System is indicated for use in post-operative cardiac surgery patients who require temporary atrial or ventricular pacing/sensing and/or atrial cardioversion.

G. Substantial Equivalence

Guidant proposes that the Syncrus System is substantially equivalent to the Syncrus System (K020701). The subject device is substantially equivalent to the predicate device with regard to intended use, indications, device characteristics, method of use, labeling, materials, and safety feature.

H. Device Testing Results and Conclusions

Guidant Cardiac Surgery performed bench testing to confirm that the Syncrus System may be used with a biphasic defibrillator. All bench testing results met specified requirements.

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Guidant ~~Synerus~~SYNCRUS™ System

Post Cardiac Surgery Atrial Cardioversion and Temporary Cardiac Pacing

INSTRUCTIONS FOR USE

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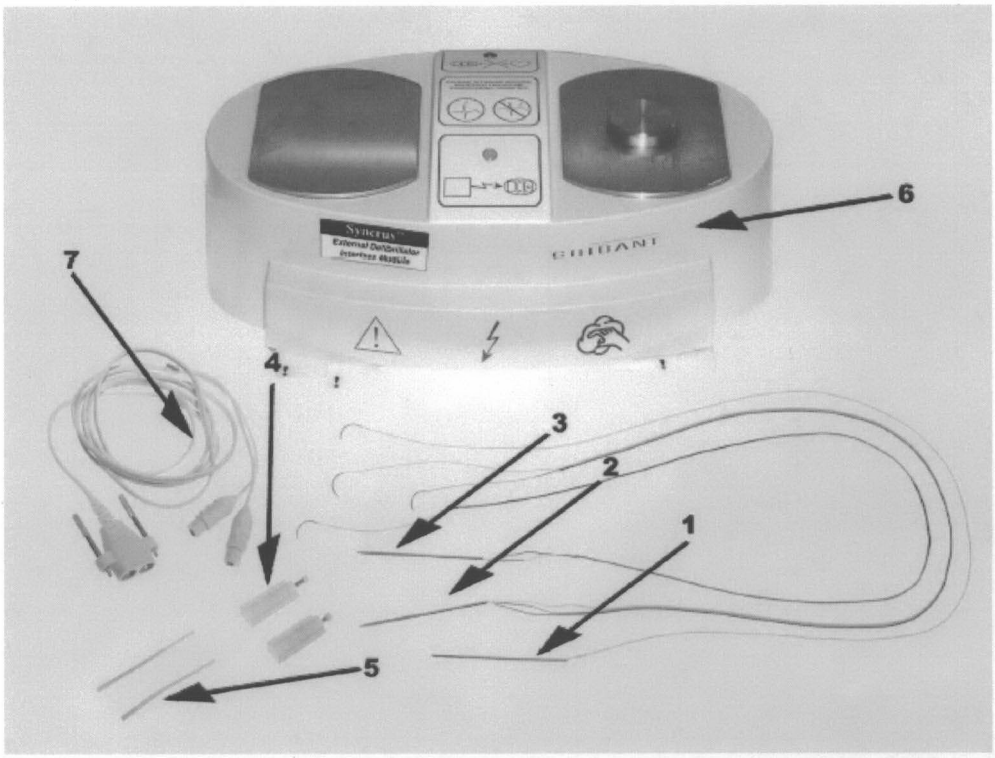

Figure 1.

Guidant ~~Synerus~~SYNCRUS™ System

1. Left Atrial Heart Wire (unipolar)
2. Right Atrial Heart Wire (tripolar)
3. Ventricular Heart Wire (bipolar)
4. Yellow Cardioversion Connectors
5. Protective Tubings
6. External Defibrillator Interface Module (EDIM)
7. Cardioversion Extension Cable

Note: The Heart Wires (with yellow cardioversion connectors and protective tubings) are sold separately from the EDIM and Cardioversion Extension Cable.

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INSTRUCTIONS FOR USE

Carefully read all instructions prior to use. Observe all warnings and precautions noted throughout these instructions.

SYSTEM DESCRIPTION:

The Guidant ~~Syncrus~~SYNCRUS™ System provides low energy internal cardioversion therapy to treat postoperative atrial fibrillation via ~~Syncrus~~SYNCRUS™ Heart Wires placed directly on the patient's heart. The ~~system~~ System's functions also include temporary atrial and ventricular pacing and ECG sensing capabilities.

The ~~Syncrus~~SYNCRUS™ System consists of the following components:

- Three single use Heart Wires that are attached to the myocardial tissue of the left atrium, right atrium, and right or left ventricle during cardiac surgery. The Heart Wires transmit low energy shocks to the patient's heart for electrical atrial cardioversion. The Heart Wires also provide for temporary cardiac pacing and ECG sensing capabilities.

- A reusable External Defibrillator Interface Module (EDIM), which interfaces between a ~~monophasic,~~ compatible low-energy~~,~~ external defibrillator and the Heart Wires. The EDIM reduces the output energy from the defibrillator to a low energy shock delivered through the Heart Wires.

- A reusable Cardioversion Extension Cable that connects the Heart Wires to the EDIM.

The ~~Syncrus~~SYNCRUS™ System components must be used in conjunction with a ~~monophasic,~~ compatible low energy external defibrillator, an external pacemaker, and pacing cables that connect the Heart Wires to the external pacemaker. The user supplies the external defibrillator, external pacemaker, and pacing cables.

Refer to the SYNCRUS™ System Operator's Manual (*Required User Supplied Components* section) for a list of compatible external defibrillators, external pacemakers and pacing cables that have been tested with the Guidant SYNCRUS™ System.

INDICATIONS FOR USE:

The Guidant ~~Syncrus~~SYNCRUS™ Internal Cardioversion System is indicated for use in post-operative cardiac surgery patients who require temporary atrial or ventricular pacing/sensing and/or atrial cardioversion.

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CONTRAINDICATIONS:

There are no known general contraindications for temporary post surgical heart wire leads. Patient anatomy and medical condition, however, should determine the use and implantation procedure.

WARNINGS:

- The ~~Guidant Syncrus~~SYNCRUS™ System is not compatible with ~~monophasic~~ all low energy external defibrillators ~~only~~. Refer to the SYNCRUS™ System Operator's Manual (*Required User Supplied Components* section) for a list of compatible external defibrillators.

- Perform synchronized cardioversion only. Unsynchronized shocks may result in ventricular fibrillation, causing patient injury or death.

- The ~~Syncrus~~SYNCRUS™ Heart Wires provide a direct path for electrical current flow to the patient's heart. DO NOT touch the ~~heart wire~~Heart Wire leads or the EDIM (when connected to the Heart Wires) with your bare hands or with anything that may deliver static (electrostatic discharge). Avoid the possibility of unintentional contact between the wire leads, including extension cable, and any equipment used as well as any conductive surface contact. Line powered equipment used in the vicinity of the patient must be properly grounded.

- The ~~Syncrus~~SYNCRUS™ EDIM and Cardioversion Extension Cable are designed solely for use with ~~Syncrus~~the SYNCRUS™ Heart Wires.

- DO NOT connect the Heart Wires to any equipment other than that specified in these instructions and the ~~Syncrus~~SYNCRUS™ System Operator's Manual. Patient injury or death may result.

- If the ~~Syncrus~~SYNCRUS™ ~~System~~ EDIM has been dropped ~~onto a hard surface~~, perform a FULL maintenance test as described in the ~~Syncrus~~SYNCRUS™ System Operator's Manual (*Maintenance and Calibration* section) prior to using the EDIM again. Dropping the EDIM may damage internal components, possibly rendering the device inoperable or out of specification.

- Wire fracture, dislodgement, abrasion and/or an incomplete connection can cause a periodic or continual loss of pacing and sensing, possibly resulting in inappropriate delivery of conversion therapy. Connect the pacing connector pins for baseline measurements to a pacing system analyzer (PSA) or temporary pacemaker and evaluate the placement by determining R-wave amplitude, pacing threshold, and pacing lead impedance. Secure the ~~Syncrus~~SYNCRUS™ Heart Wires by taping the cardioversion connectors and pacing pins to the patient's body until needed.

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- Although pliable, the lead body is not designed to tolerate excessive flexing, bending, or tension. This could cause structural weakness, conductor discontinuity, and/or lead dislodgement. Secure the cardioversion connectors and pacing pins to the patient's body until needed. Minimize manipulation of the ~~heart wires~~Heart Wires.

- Equipment and accessories connected to the Guidant ~~Syncrus~~SYNCRUS™ System shall comply with IEC-601-1, type CF.

PRECAUTIONS:

- ~~Syncrus~~SYNCRUS™ Heart Wires are for single use only. DO NOT RESTERILIZE. DO NOT REUSE.

- The ~~Syncrus~~SYNCRUS™ Heart Wires are gamma sterilized after packaging. When they are received, they are sterile and ready for use. Should the seal or package be wet, damaged, punctured, or if the seal is broken, do not use or attempt to resterilize. Contact the local Guidant representative.

- Pre-clinical testing supports the use of this device up to 7 cardioversion attempts. Cardioversion attempts ranged from 1 to 9 attempts in clinical trials. Physicians should treat patients in accordance with judgment and experience. Assessment of the patient's overall condition and physician discretion should dictate the number of attempts to treat.

- It is recommended that defibrillation equipment and a pacing sensor system analyzer (PSA) or temporary pacemaker be readily available during lead placement and removal.

INSTRUCTIONS FOR USE:

1. Attach the ~~Syncrus~~SYNCRUS™ Heart Wires to the patient's myocardial surface during cardiac surgery in the following order and before the patient's chest is closed. The described fixation techniques ~~is~~are furnished for informational purposes only. The physician may choose to vary the fixation technique in accordance with judgment and experience. The selected fixation technique of each Heart Wire placement should always allow for ease of extraction through gentle traction. Proper surgical procedures and techniques are the responsibility of the medical professional~~. Figures 2 through 3 illustrate heart wire placement as performed in clinical trials~~.

   Left Atrial Heart Wire (unipolar)

   - *Cardioversion Electrode (yellow wire)*: Use the attached curved needle to affix the cardioversion electrode to the left atrial myocardium. After the cardioversion electrode is affixed (see Figures 2a and 3a), cut off the curved needle and discard it. Place a slight bend or kink at the end of the electrode.

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Right Atrial Heart Wire (tripolar)

- *Cardioversion Electrode (yellow wire)*: Use the attached curved needle to affix the cardioversion electrode to the right atrial myocardium. After the cardioversion electrode is affixed (see Figures 2b and 3b), cut off the curved needle and discard it. Place a slight bend or kink at the end of the electrode.

  Placement should be made to maximize the atrial muscle mass between the right atrial cardioversion electrode and the left atrial cardioversion electrode.

- *Pacing Electrodes (black and blue wires)*: Use the attached curved needle to affix the bipolar pacing electrodes to the right atrial myocardium. For optimal cardiac pacing, bury both the pacing electrode and bullet in the myocardium. After the pacing electrodes are affixed (see Figures 2b and 3b), cut off the needle and discard it. Place a slight bend or kink at the end of the pacing electrode.

Ventricular Heart Wire (bipolar)

- *Pacing Electrodes (black and white wires)*: Use the attached curved needle to affix the bipolar pacing electrodes into the myocardial tissue of either the right or left ventricle. For optimal cardiac pacing, bury both the pacing electrode and bullet in the myocardium. After the pacing electrodes are affixed (see Figures 2c and 3c), cut off the curved needle and discard it. Place a slight bend or kink at the end of the pacing electrode.

Figures 2 through 3 illustrate two examples of Heart Wire placement techniques as used in clinical practice.

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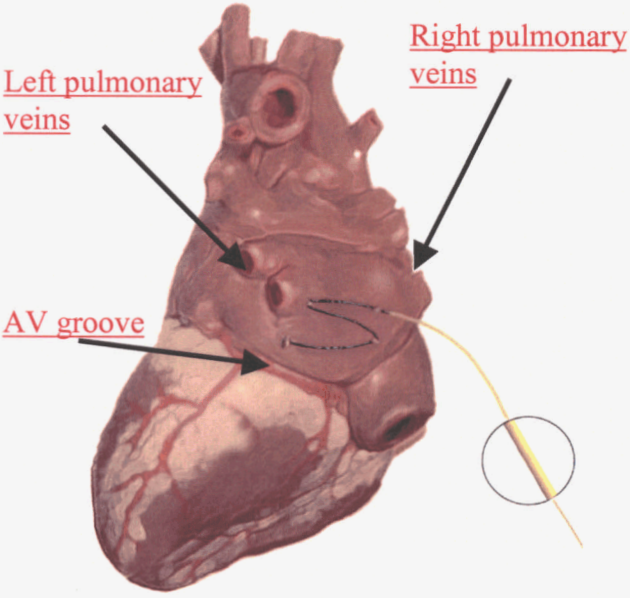
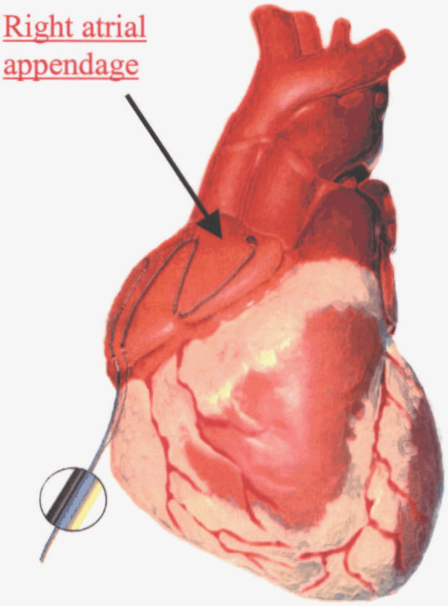
Figure 2. SYNCRUS™ Heart Wire Placement Technique A (used in clinical trials in Europe)



2a. Left Atrial Wire Placement
Figure shows the cardioversion electrode placed in an "S" pattern between the atrioventricular (AV) groove and the left and right pulmonary veins.

(Lateral-posterior view)



2b. Right Atrial Wire Placement
Figure shows the cardioversion electrode placed in an "S" pattern on the right atrial appendage.

The pacing electrode and bullet are shown placed on the right atrial myocardium.

(Anterior view)

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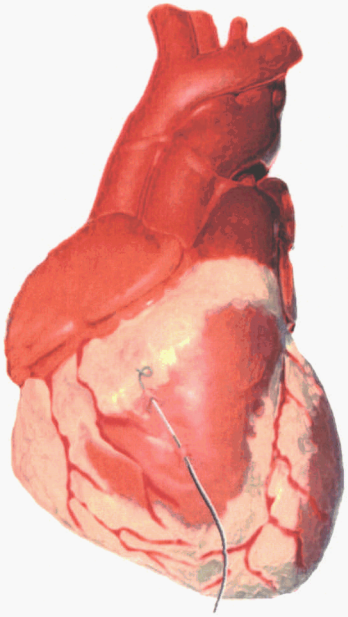
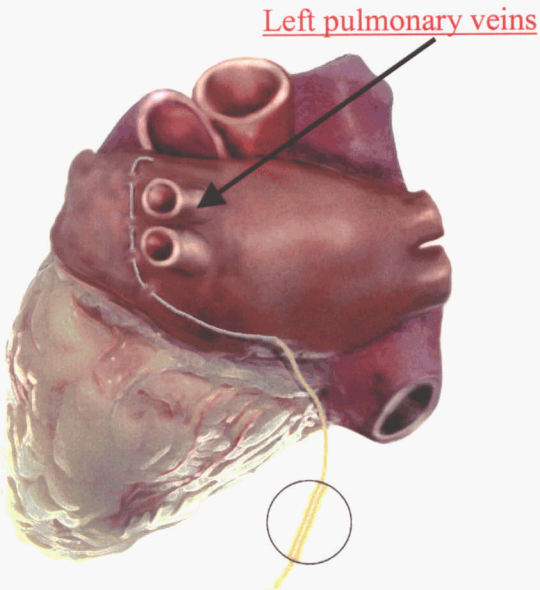


2c. Ventricular Wire Placement
Figure shows the pacing electrode and bullet placed on the right ventricle.

(Anterior view)

Figure 3. SYNCRUS™ Heart Wire Placement Technique B



3a. Left Atrial Wire Placement
Figure shows the cardioversion electrode placed within 5 mm anterior of the left pulmonary veins.

(Lateral-posterior view)

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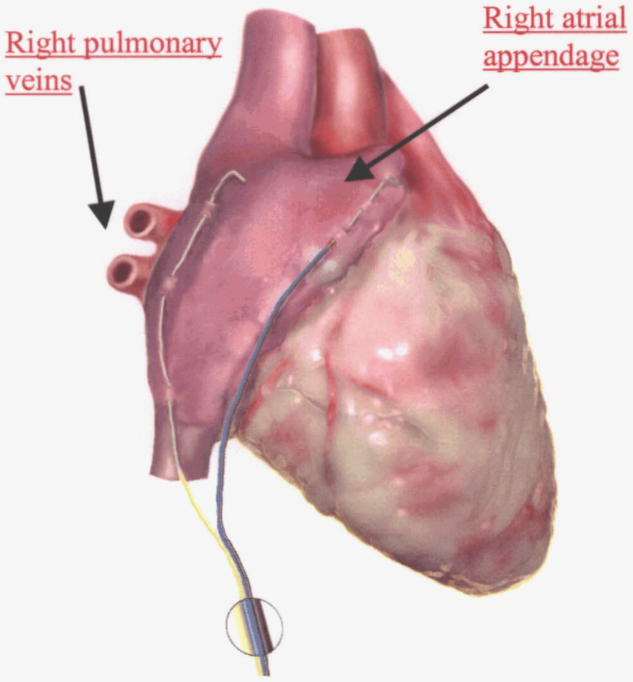
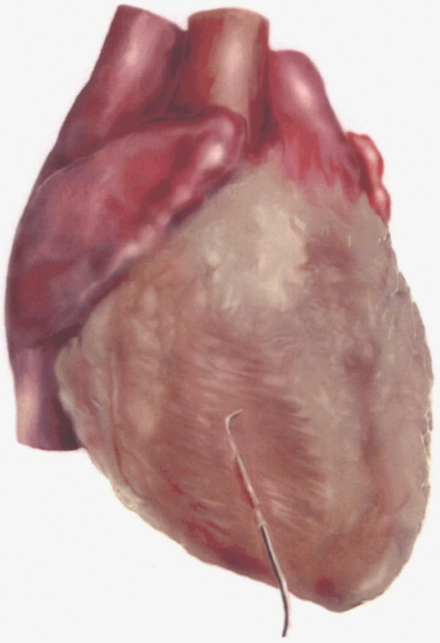


3b. Right Atrial Wire Placement
Figure shows the cardioversion electrode placed by the inferior vena cava and up towards the right pulmonary veins within 5 mm of the SA node.

The pacing electrode and bullet are shown placed on the right atrial appendage.

(Lateral view)



3c. Ventricular Wire Placement
Figure shows the pacing electrode and bullet placed on the right ventricle.

(Anterior view)

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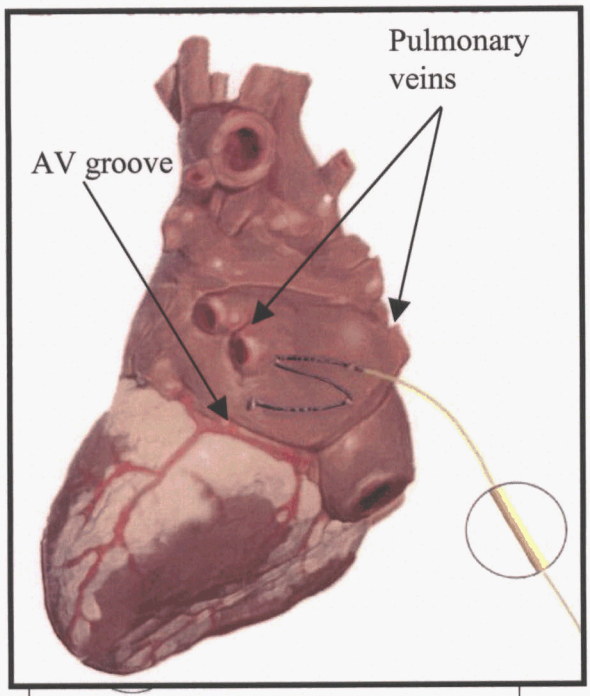

Lateral-posterior view

~~Left Atrial Heart Wire (unipolar)~~

- ~~*Cardioversion Electrode (yellow wire)*: Use the attached curved needle to affix the cardioversion electrode to the left atrial myocardium on the atrioventricular (AV) groove between the left and right pulmonary veins in an "S" pattern as illustrated in Figure 2 for optimal results. After the cardioversion electrode is affixed, cut off the curved needle and discard it. Place a slight bend or kink at the end of the electrode.~~

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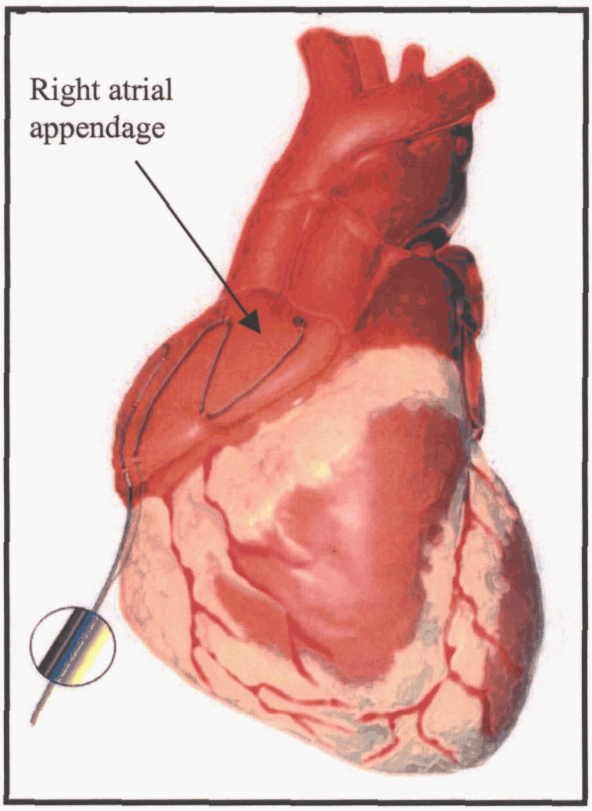

Anterior view

~~Right Atrial Heart Wire (tripolar)~~

- ~~*Cardioversion Electrode (yellow wire)*: Use the attached curved needle to affix the cardioversion electrode into the right atrial myocardium in an "S" pattern as shown in Figure 3 for optimal results. After the cardioversion electrode is affixed, cut off the curved needle and discard it. Place a slight bend or kink at the end of the electrode.~~

- ~~Placement should be made to maximize the atrial muscle mass between the right atrial cardioversion electrode and the left atrial cardioversion electrode.~~

- ~~*Pacing Electrodes (black and blue wires):* Use the attached curved needle to affix the bipolar pacing electrodes into the right atrial myocardium. For optimal cardiac pacing, bury both the anode and cathode in the myocardium. After the pacing electrodes are affixed, cut off the needle and discard it. Place a slight bend or kink at the end of the anode electrode.~~

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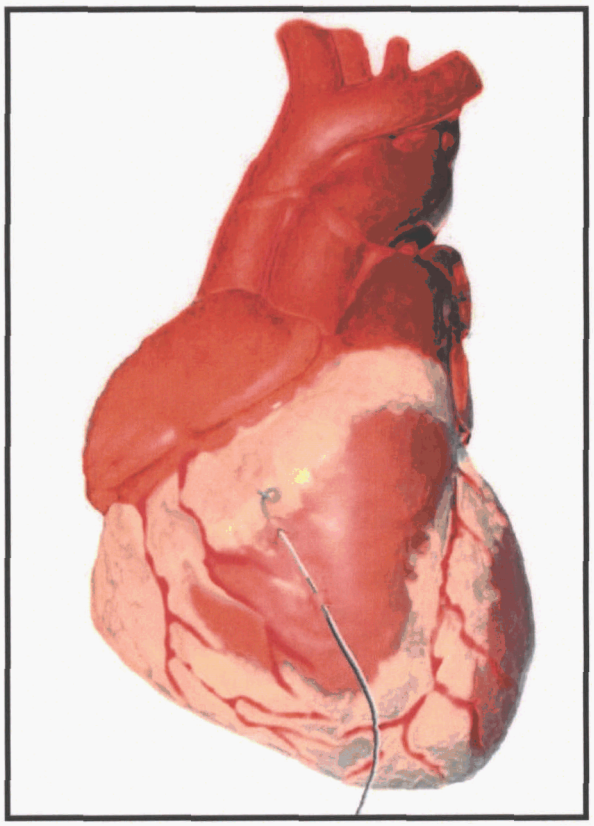
~~**Figure 4. SYNCRUS Ventricular Heart Wire Placement**~~



Anterior view

~~Ventricular Heart Wire (bipolar)~~

- ~~*Pacing Electrodes (black and white wires)*: Use the attached curved needle to affix the bipolar pacing electrodes into the myocardial tissue of either the right or left ventricle as illustrated in Figure 4 for optimal results. The positive pacing electrode (anode) is attached to the needle, while the negative electrode (cathode) is contained in the 4 mm long bullet. For optimal cardiac pacing, bury both the anode and cathode in the myocardium. After pacing electrodes are affixed, cut off the curved needle and discard it. Place a slight bend or kink at the end of the anode electrode.~~

2. Once the cardioversion and pacing electrodes have been affixed to the patient's heart, visualize the paths that the Heart Wires will travel as they are extracted.

3. Use the straight needle on the proximal end of each ~~Syncrus~~SYNCRUS™ Heart Wire to externalize the Heart Wires through the chest wall and skin. Once the Heart Wires are externalized, cut off the thoracic needles, maximizing the length of the exposed cardioversion leads. Discard the thoracic needles appropriately.

4. Attach the yellow cardioversion connectors provided with the SYNCRUS™ Heart Wires to the yellow cardioversion wires on the Left and Right Atrial Heart Wires. ~~Attach a yellow cardioversion connector provided with the Syncrus Left and Right Atrial Heart Wires.~~ This is done by threading the Heart Wire cardioversion lead through the pinhole on the backside of the connector and pushing the pin into the connector. Make sure there is good electrical contact between the Heart Wire cardioversion lead and the yellow cardioversion connector.

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5. Connect the pacing connector pins for baseline measurements to a pacing system analyzer (PSA) or temporary pacemaker and evaluate the placement by determining R-wave amplitude, pacing threshold, and pacing lead impedance.

6. Cover the pacing connector pins on the Right Atrial Heart Wire (black and blue wires) and Ventricular Heart Wire (black and white wires) with the protective tubings provided with the ~~Synerus~~ SYNCRUS™ Heart Wires~~.~~. Secure the ~~Synerus~~ SYNCRUS™ Heart Wires by taping the cardioversion connectors and pacing pins to the patient's body until needed.

7. When ~~Synerus~~ SYNCRUS™ atrial cardioversion therapy is needed, connect the yellow cardioversion connectors to the ~~Synerus~~ SYNCRUS™ Cardioversion Extension Cable. Ensure that the Cable is connected to the EDIM. Apply internal atrial cardioversion by placing external defibrillator paddles on the paddle plates of the ~~Synerus~~ SYNCRUS™ EDIM and deliver~~ing~~ energy. The EDIM will attenuate the external defibrillator output energy by approximately 97% (for example, a 100--joule external shock will result in an approximate 3-joule internal cardioversion shock to the heart).

8. When temporary cardiac pacing and ECG sensing are needed, remove the protective tubing from the pacing connector pins. Connect the pacing connector pins into the appropriate pacing cables. Ensure that the pacing cables are connected to an external pacemaker. Administer cardiac pacing therapy.

9. To remove the ~~Synerus~~ SYNCRUS™ Heart Wires, remove any tape holding the Heart Wires in place. Apply gentle and continuous external traction to remove the Heart Wires from the patient~~.~~. Special care should be taken when removing the ~~lead~~ wires from the~~—~~ ~~atrium~~atria, due to the relatively thin atrial wall.

10. Discard the three externalized Heart Wires appropriately.

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ADVERSE EVENTS:

Two studies were conducted with the original ~~Syncrus~~ SYNCRUS™ System (TADpole System) in Europe[1]. Results from both studies demonstrated that the Guidant ~~Syncrus~~ SYNCRUS™ System was safe and effective for its intended use.

Table 1. Adverse Events Reported Across Studies

Complications	# of pts with AE's (n=538)	% of pts with AE's
Wire dislodgement	1	0.19%
Cardiac Arrest/VF	1	0.19%
Difficult wire extraction	2	0.37%
Infection	1	0.19%
Hypoventilation	1	0.19%
Death*	2	0.37%
Total Complications	**8**	**1.48%**

POTENTIAL ADVERSE EVENTS:

Based on the literature and ~~Syncrus~~ SYNCRUS™ ~~heart wire~~Heart Wire implant experience, the possible physical effects from implantation are listed below.

- Allergic reaction
- Atrial wall rupture
- Bleeding
- Cardiac tamponade
- Difficult wire removal
- Displacement dislodgement
- Erosion/extrusion
- Fibrotic tissue formation
- Hematoma
- Histotoxic reaction
- Inappropriate therapy
- Incomplete connection with pulse generator
- Infection
- Lead abrasion
- Lead failure
- Lead fracture or insulation break
- Lead tip deformation and/or breakage
- Local tissue reaction
- Loss of sensing or under sensing
- Myocardial injury
- Myocardial irritability
- Over sensing
- Post-shock rhythm disturbances
- Random component failures
- Threshold elevation

CLINICAL TRIALS:

* Deaths were unrelated to therapy with the ~~Syncrus~~SYNCRUS™ System.
[1] For clinical study details refer to *Clinical Trial* section.

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The ~~Syncrus~~ SYNCRUS™ System was studied in the following (2) trials: Pilot Clinical Investigation for the InControl TADpole Heart Wires (Temporary Atrial Cardioversion Post-Op Low Energy) and The TADpole™ System for Post-Cardiac Surgery Atrial Cardioversion and Atrial/Ventricular Pacing and Sensing.

Pilot Clinical Investigation for the InControl TADpole Heart Wires (Temporary Atrial Cardioversion Post-Op Low Energy)

This investigation was designed as an observational non-randomized study to evaluate the features and functionality of the therapy. The final analysis covers 466 implanted patients. The mean implant duration of the study population was 7.1 days.

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Table 2. Description of the Study Population

Characteristic	
Number of patients	n=466
Gender	
Male	348
Female	116
Unknown	2
Age at Time of Implant	
Range (years)	23 – 83
Mean ± Standard Deviation	64.2 ± 9.2
Cardiovascular Procedures*	
CABG	420
Valve Replacement	43
Valve Repair	9

*Cardiovascular procedures are not mutually exclusive of one another.

Arrhythmia Treatment Success and Energy Delivered

Eighty-one patients experiencing a total of 95 AF episodes were treated with the therapy. A per patient cardioversion overall success rate of 74% and a per episode success rate of 78% were recorded. The mean number of joules delivered to the patient per successful attempt was 6.02 Joules. There were an average number of 2.54 cardioversion attempts per successful episode.

Table 3. Per Patient and Per Episode Therapy Success Summary

Cardioversion Success	n (%)
81 Patients with Arrhythmias	
Success No	21 (26%)
Success Yes	60 (74%)
95 Episodes	
Success No	21 (22%)
Success Yes	74 (78%)
Joules Delivered per Successful Attempt	
Mean	6.02
SD	2.50
Range	1.5 - 10.8
Average number of Attempts per Successful Episode	2.54

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Table 4. Per Attempt and Cumulative Therapy Success Summary

Attempts	Success Yes/No	Total # of Attempts	Success Rate per Attempt (%)	Cumulative Success Rate (%)*
1st Attempt	Success Yes	40	42.11	42.11
	Success No	55		
2nd Attempt	Success Yes	30	45.45	73.70
	Success No	36		
3rd Attempt	Success Yes	16	41.03	90.54
	Success No	23		
4th Attempt	Success Yes	6	37.50	96.85
	Success No	10		
5th Attempt	Success Yes	2	33.33	98.95
	Success No	4		
6th Attempt	Success Yes	1	33.33	100.00
	Success No	2		
7th Attempt	Success Yes	0	0.00	
	Success No	2		
8th Attempt	Success Yes	0	0.00	
	Success No	2		
9th Attempt	Success Yes	0	0.00	
	Success No	1		

- From the total of successful cardioversions attempts, the cumulative success rate is calculated as the percentage of successful cardioversions after the first, second, third, fourth etc... attempts using the total successful attempts as the denominator. For example, 42.10 % of the total successful cardioversions resulted from a first cardioversion attempt. Data illustrates that over 90 % of the total successful cardioversions occurred within the first three cardioversion attempts. Incremental cardioversion successes were observed as a result of additional attempts.

Summary of Adverse Events

A total of eight adverse events in seven patients were recorded throughout the duration of the study.

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Table 5. Adverse Events

	# of pts with AE's (n=466)	% of pts with AE's
Complications (total)	8	1.71%
Wire dislodgement	1	0.21%
Cardiac Arrest/VF	1	0.21%
Difficult wire extraction	2	0.43%
Infection	1	0.21%
Hypoventilation	1	0.21%
Death*	2	0.43%

* Two deaths were not related to the TADpole System.

The TADpole™ System for Post-Cardiac Surgery Atrial Cardioversion and Atrial/Ventricular Pacing and Sensing

This investigation was designed as a confirmatory observational non-randomized study intended to optimize the effectiveness of the therapy including ~~heart wire~~Heart Wire placement. Heart wire placement is illustrated in Figures 1 through 3. The study is an analysis of 72 implanted patients. The mean implant duration of the study population was 6.2 days.

Table 6. Description of the Study Population

Characteristic	**n (%)**
Number of patients	72
Gender	
Male	50
Female	21
Unknown	1
Age at Time of Implant (years)	
Range	32 – 89
Mean ± Standard Deviation	65.26 ± 10.6
Mean Ejection Fraction ± Standard Deviation (%)	57.43 ± 16.96 (93%)
Cardiovascular Procedures	
CABG	71
Mitral Valve Replacement	1

Arrhythmia Treatment Success and Energy Delivered

Thirteen patients experiencing a total of 14 AF episodes were treated with the therapy. A per patient cardioversion overall success rate of 92.3% and a per episode success rate of 92.8% were recorded. The mean number of Joules delivered to the patient per successful attempt

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was 7.72 Joules. There were an average number of 1.54 cardioversion attempts per successful episode.

Table 7. Per Patient and Per Episode Therapy Success Summary

Cardioversion Success	n (%)
13 Patients with Arrhythmias	
Success No	1(7.69%)
Success Yes	12 (92.3%)
14 Episodes	
Success No	1 (7.14%)
Success Yes	13 (92.8%)
Joules Delivered per Successful Attempt	
Mean	7.72
SD	1.73
Range	6 - 10.8
Average number of Attempts per Successful Episode	1.54

Table 8. Per Attempt and Cumulative Therapy Success Summary

Attempts	Success Yes/No	Total # of Attempts	Success Rate per Attempt (%)	Cumulative Success Rate (%)*
1st Attempt	Success Yes	10	71.42	66.67*
	Success No	4		
2nd Attempt	Success Yes	4	66.66	93.33
	Success No	2		
3rd Attempt	Success Yes	0	0	93.33
	Success No	2		
4th Attempt	Success Yes	1	100.00	100.00
	Success No	0		

- From the total of successful cardioversions attempts, the cumulative success rate is calculated as the percentage of successful cardioversions after the first, second, third and fourth attempts. For example 66.67% of the total successful cardioversions resulted from a first cardioversion attempt using the total successful attempts as the denominator. Data illustrates that over 90 % of the total successful cardioversions occurred within the first 3 cardioversion attempts. Incremental cardioversion successes were observed as a result of additional attempts.

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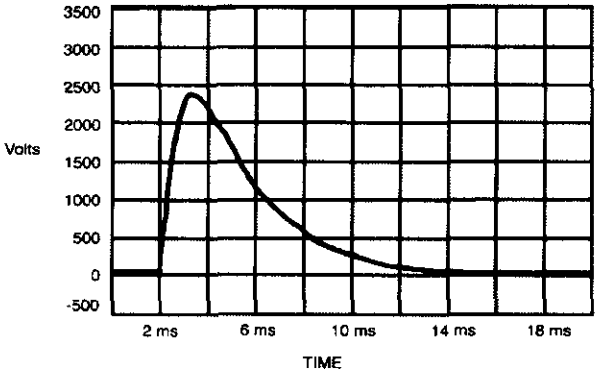
Summary of Adverse Events
No adverse events were observed in this study.

ENERGY INPUT/OUT ATTENUATION:

The EDIM attenuates the energy output of a ~~monophasic,~~compatible low-_energy external defibrillator down to 3% of its original joule output. ~~The EDIM produces an energy transfer of 3% (+/- 1%) on the input energy from the defibrillator.~~ Since the circuitry of the EDIM consists of a passive voltage divider network, the attenuation consists of a uniform reduction of input voltage, resulting in an output waveform identical to that of the defibrillators waveform, except reduced in magnitude (Figure 5).

Figure 5. EDIM Input Output Waveform

External Defibrillator Output Waveform **EDIM Output Waveform**



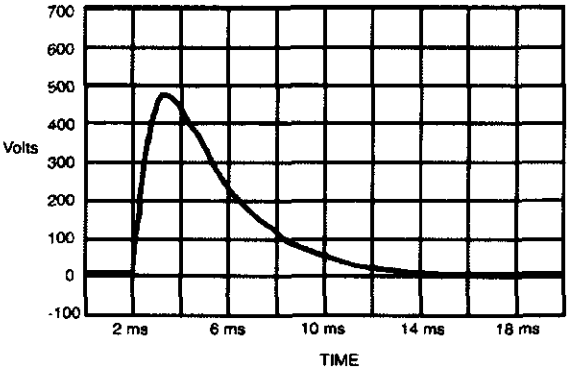


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Table 9. Minimum and Maximum Energy Output of the EDIM

Input from External Defibrillator (Joules)	Output Energy from EDIM (Joules)	
	MIN	MAX
50	1.~~4~~3	1.~~5~~6
100	2.~~9~~6	3.~~1~~2
150	~~4.3~~3.9	4.~~6~~8
200	~~5.8~~5.2	6.~~2~~4
250	~~7.2~~6.5	~~7.7~~8.0
300	~~8.7~~7.8	9.~~3~~6
350	~~10~~9.1	~~10.8~~11.2
360	~~10~~9.4	11.~~1~~5

HOW SUPPLIED:

The ~~Syncrus~~ SYNCRUS™ Heart Wires are supplied STERILE in an unopened and undamaged package. The ~~Syncrus~~ SYNCRUS™ Heart Wires have been sterilized using gamma irradiation and are for single use only. DO NOT RESTERILIZE. DO NOT REUSE.

The ~~Syncrus~~ SYNCRUS™ External Defibrillator Interface Module (EDIM) is supplied non-sterile and is reusable. One ~~Syncrus~~ SYNCRUS™ Cardioversion ~~External~~ Extension Cable, one maintenance test fixture, and two extension cable test adapters are also supplied with the EDIM.

To perform internal atrial cardioversion, the hospital must supply a compatible low energy~~,~~ external~~, monophasic~~ defibrillator. To perform temporary cardiac pacing and ECG sensing, the hospital must supply an external pacemaker and appropriate pacing cables. A list of compatible external defibrillators, external pacemakers and pacing cables are provided in the ~~Syncrus~~ SYNCRUS™ System Operator's Manual (*Required User Supplied Components* section) for your convenience.

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

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WARRANTY:
Guidant Corporation warrants that its Products substantially conform to Guidant Corporation published specifications for such Product for a period of twelve (12) months from the date of shipment, and will replace ~~and~~ any ~~p~~Products confirmed by Guidant Corporation as defective Products, at Guidant Corporation's sole option, during said period. This warranty is contingent upon proper use of Products in the application for which they ~~are~~ were intended as indicated in the ~~product~~ Product label claims, and Guidant Corporation makes no warranty (express, implied, or statutory) for Products that are modified or subjected to unusual physical or electrical stress. With regard to Guidant Corporation Products which are labeled ~~for~~ FOR SINGLE USE ONLY or DO NOT REUSE~~. This~~, this warranty is null and void following the single use of the Products. Guidant Corporation doe not provide a warranty for those Products subject to resterilization and/or reuse unless the Products are specifically designed and labeled for reuse.

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May be manufactured under one or more of the following patents: 5,674,253; 5,766,224; and RE 35,779.

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Guidant SYNCRUS™ System

Post Cardiac Surgery Atrial Cardioversion and Temporary Cardiac Pacing

INSTRUCTIONS FOR USE

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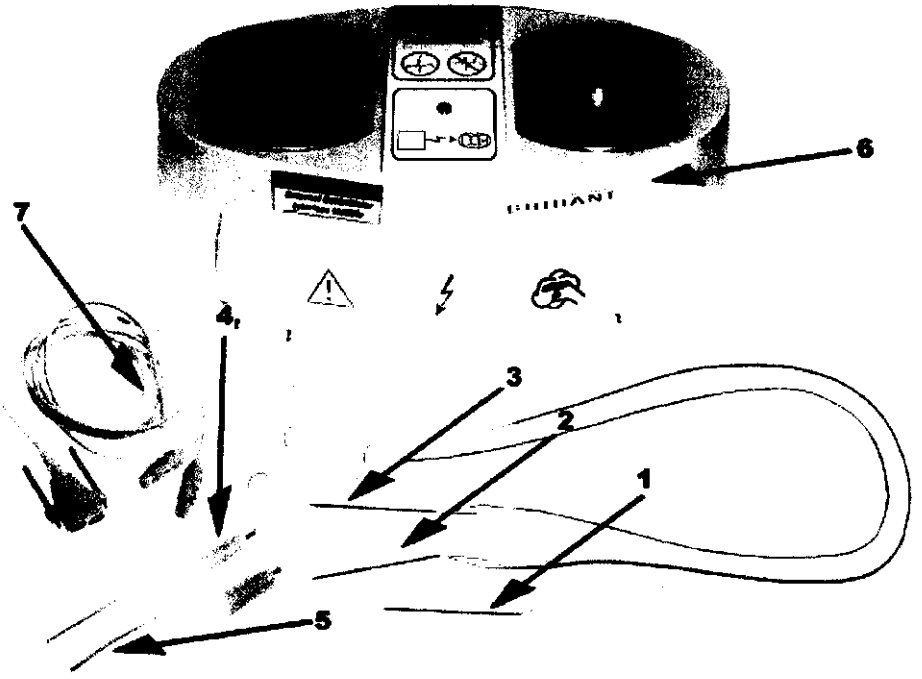

Figure 1.

Guidant SYNCRUS™ System

1. Left Atrial Heart Wire (unipolar)
2. Right Atrial Heart Wire (tripolar)
3. Ventricular Heart Wire (bipolar)
4. Yellow Cardioversion Connectors
5. Protective Tubings
6. External Defibrillator Interface Module (EDIM)
7. Cardioversion Extension Cable

Note: The Heart Wires (with yellow cardioversion connectors and protective tubings) are sold separately from the EDIM and Cardioversion Extension Cable.

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INSTRUCTIONS FOR USE

Carefully read all instructions prior to use. Observe all warnings and precautions noted throughout these instructions.

SYSTEM DESCRIPTION:

The Guidant SYNCRUS™ System provides low energy internal cardioversion therapy to treat postoperative atrial fibrillation via SYNCRUS™ Heart Wires placed directly on the patient's heart. The System's functions also include temporary atrial and ventricular pacing and ECG sensing capabilities.

The SYNCRUS™ System consists of the following components:

- Three single use Heart Wires that are attached to the myocardial tissue of the left atrium, right atrium, and right or left ventricle during cardiac surgery. The Heart Wires transmit low energy shocks to the patient's heart for electrical atrial cardioversion. The Heart Wires also provide for temporary cardiac pacing and ECG sensing capabilities.

- A reusable External Defibrillator Interface Module (EDIM), which interfaces between a compatible low energy external defibrillator and the Heart Wires. The EDIM reduces the output energy from the defibrillator to a low energy shock delivered through the Heart Wires.

- A reusable Cardioversion Extension Cable that connects the Heart Wires to the EDIM.

The SYNCRUS™ System components must be used in conjunction with a compatible low energy external defibrillator, an external pacemaker, and pacing cables that connect the Heart Wires to the external pacemaker. The user supplies the external defibrillator, external pacemaker, and pacing cables.

Refer to the SYNCRUS™ System Operator's Manual (*Required User Supplied Components* section) for a list of compatible external defibrillators, external pacemakers and pacing cables that have been tested with the Guidant SYNCRUS™ System.

INDICATIONS FOR USE:

The Guidant SYNCRUS™ Internal Cardioversion System is indicated for use in post-operative cardiac surgery patients who require temporary atrial or ventricular pacing/sensing and/or atrial cardioversion.

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CONTRAINDICATIONS:

There are no known general contraindications for temporary post surgical heart wire leads. Patient anatomy and medical condition, however, should determine the use and implantation procedure.

WARNINGS:

- The SYNCRUS™ System is not compatible with all low energy external defibrillators. Refer to the SYNCRUS™ System Operator's Manual (*Required User Supplied Components* section) for a list of compatible external defibrillators.

- Perform synchronized cardioversion only. Unsynchronized shocks may result in ventricular fibrillation, causing patient injury or death.

- The SYNCRUS™ Heart Wires provide a direct path for electrical current flow to the patient's heart. DO NOT touch the Heart Wire leads or the EDIM (when connected to the Heart Wires) with your bare hands or with anything that may deliver static (electrostatic discharge). Avoid the possibility of unintentional contact between the wire leads, including extension cable, and any equipment used as well as any conductive surface contact. Line powered equipment used in the vicinity of the patient must be properly grounded.

- The SYNCRUS™ EDIM and Cardioversion Extension Cable are designed solely for use with the SYNCRUS™ Heart Wires.

- DO NOT connect the Heart Wires to any equipment other than that specified in these instructions and the SYNCRUS™ System Operator's Manual. Patient injury or death may result.

- If the SYNCRUS™ EDIM has been dropped, perform a FULL maintenance test as described in the SYNCRUS™ System Operator's Manual (*Maintenance and Calibration* section) prior to using the EDIM again. Dropping the EDIM may damage internal components, possibly rendering the device inoperable or out of specification.

- Wire fracture, dislodgement, abrasion and/or an incomplete connection can cause a periodic or continual loss of pacing and sensing, possibly resulting in inappropriate delivery of conversion therapy. Connect the pacing connector pins for baseline measurements to a pacing system analyzer (PSA) or temporary pacemaker and evaluate the placement by determining R-wave amplitude, pacing threshold, and pacing lead impedance. Secure the SYNCRUS™ Heart Wires by taping the cardioversion connectors and pacing pins to the patient's body until needed.

- Although pliable, the lead body is not designed to tolerate excessive flexing, bending, or tension. This could cause structural weakness, conductor discontinuity, and/or lead

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dislodgement. Secure the cardioversion connectors and pacing pins to the patient's body until needed. Minimize manipulation of the Heart Wires.

- Equipment and accessories connected to the Guidant SYNCRUS™ System shall comply with IEC-601-1, type CF.

PRECAUTIONS:

- SYNCRUS™ Heart Wires are for single use only. DO NOT RESTERILIZE. DO NOT REUSE.

- The SYNCRUS™ Heart Wires are gamma sterilized after packaging. When they are received, they are sterile and ready for use. Should the seal or package be wet, damaged, punctured, or if the seal is broken, do not use or attempt to resterilize. Contact the local Guidant representative.

- Pre-clinical testing supports the use of this device up to 7 cardioversion attempts. Cardioversion attempts ranged from 1 to 9 attempts in clinical trials. Physicians should treat patients in accordance with judgment and experience. Assessment of the patient's overall condition and physician discretion should dictate the number of attempts to treat.

- It is recommended that defibrillation equipment and a pacing sensor system analyzer (PSA) or temporary pacemaker be readily available during lead placement and removal.

INSTRUCTIONS FOR USE:

1. Attach the SYNCRUS™ Heart Wires to the patient's myocardial surface during cardiac surgery in the following order and before the patient's chest is closed. The described fixation techniques are furnished for informational purposes only. The physician may choose to vary the fixation technique in accordance with judgment and experience. The selected fixation technique of each Heart Wire placement should always allow for ease of extraction through gentle traction. Proper surgical procedures and techniques are the responsibility of the medical professional.

   Left Atrial Heart Wire (unipolar)

   - *Cardioversion Electrode (yellow wire)*: Use the attached curved needle to affix the cardioversion electrode to the left atrial myocardium. After the cardioversion electrode is affixed (see Figures 2a and 3a), cut off the curved needle and discard it. Place a slight bend or kink at the end of the electrode.

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Right Atrial Heart Wire (tripolar)

- *Cardioversion Electrode (yellow wire)*: Use the attached curved needle to affix the cardioversion electrode to the right atrial myocardium. After the cardioversion electrode is affixed (see Figures 2b and 3b), cut off the curved needle and discard it. Place a slight bend or kink at the end of the electrode.

  Placement should be made to maximize the atrial muscle mass between the right atrial cardioversion electrode and the left atrial cardioversion electrode.

- *Pacing Electrodes (black and blue wires)*: Use the attached curved needle to affix the bipolar pacing electrodes to the right atrial myocardium. For optimal cardiac pacing, bury both the pacing electrode and bullet in the myocardium. After the pacing electrodes are affixed (see Figures 2b and 3b), cut off the needle and discard it. Place a slight bend or kink at the end of the pacing electrode.

Ventricular Heart Wire (bipolar)

- *Pacing Electrodes (black and white wires)*: Use the attached curved needle to affix the bipolar pacing electrodes into the myocardial tissue of either the right or left ventricle. For optimal cardiac pacing, bury both the pacing electrode and bullet in the myocardium. After the pacing electrodes are affixed (see Figures 2c and 3c), cut off the curved needle and discard it. Place a slight bend or kink at the end of the pacing electrode.

Figures 2 through 3 illustrate two examples of Heart Wire placement techniques as used in clinical practice.

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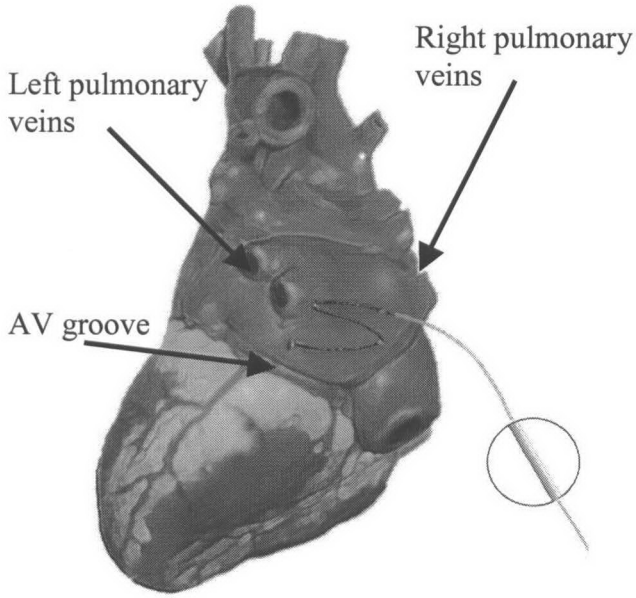
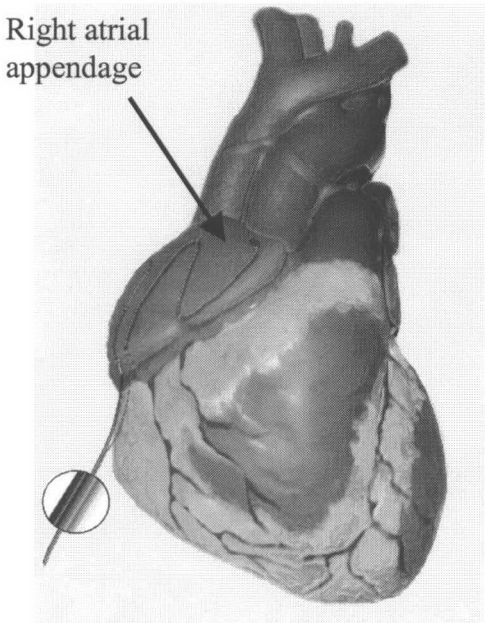
Figure 2. SYNCRUS™ Heart Wire Placement Technique A (used in clinical trials in Europe)



2a. Left Atrial Wire Placement
Figure shows the cardioversion electrode placed in an "S" pattern between the atrioventricular (AV) groove and the left and right pulmonary veins.

(Lateral-posterior view)



2b. Right Atrial Wire Placement
Figure shows the cardioversion electrode placed in an "S" pattern on the right atrial appendage.

The pacing electrode and bullet are shown placed on the right atrial myocardium.

(Anterior view)

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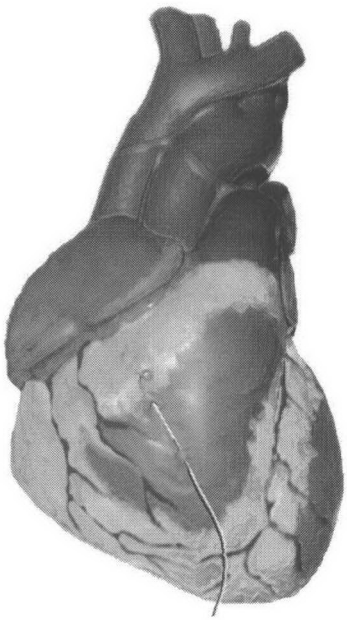
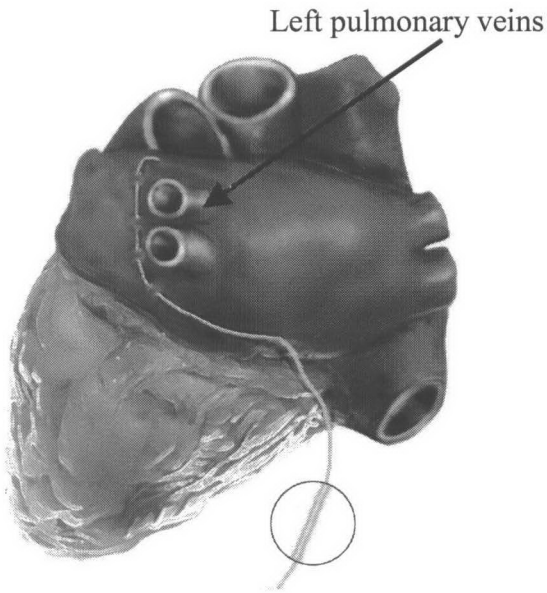


2c. Ventricular Wire Placement
Figure shows the pacing electrode and bullet placed on the right ventricle.

(Anterior view)

Figure 3. SYNCRUS™ Heart Wire Placement Technique B



3a. Left Atrial Wire Placement
Figure shows the cardioversion electrode placed within 5 mm anterior of the left pulmonary veins.

(Lateral-posterior view)

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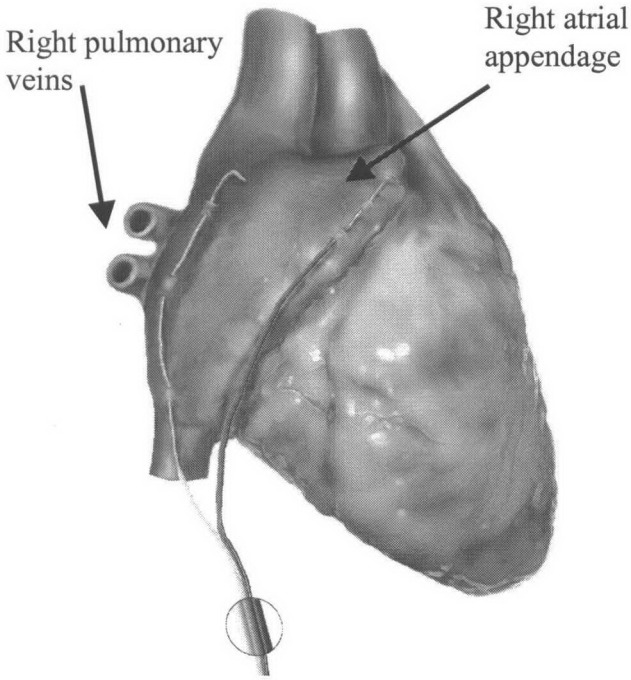
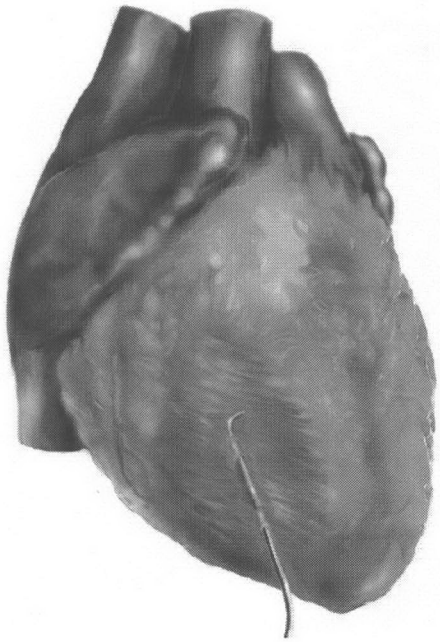


3b. Right Atrial Wire Placement
Figure shows the cardioversion electrode placed by the inferior vena cava and up towards the right pulmonary veins within 5 mm of the SA node.

The pacing electrode and bullet are shown placed on the right atrial appendage.

(Lateral view)



3c. Ventricular Wire Placement
Figure shows the pacing electrode and bullet placed on the right ventricle.

(Anterior view)

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2. Once the cardioversion and pacing electrodes have been affixed to the patient's heart, visualize the paths that the Heart Wires will travel as they are extracted.

3. Use the straight needle on the proximal end of each SYNCRUS™ Heart Wire to externalize the Heart Wires through the chest wall and skin. Once the Heart Wires are externalized, cut off the thoracic needles, maximizing the length of the exposed cardioversion leads. Discard the thoracic needles appropriately.

4. Attach the yellow cardioversion connectors provided with the SYNCRUS™ Heart Wires to the yellow cardioversion wires on the Left and Right Atrial Heart Wires. This is done by threading the Heart Wire cardioversion lead through the pinhole on the backside of the connector and pushing the pin into the connector. Make sure there is good electrical contact between the Heart Wire cardioversion lead and the yellow cardioversion connector.

5. Connect the pacing connector pins for baseline measurements to a pacing system analyzer (PSA) or temporary pacemaker and evaluate the placement by determining R-wave amplitude, pacing threshold, and pacing lead impedance.

6. Cover the pacing connector pins on the Right Atrial Heart Wire (black and blue wires) and Ventricular Heart Wire (black and white wires) with the protective tubings provided with the SYNCRUS™ Heart Wires. Secure the SYNCRUS™ Heart Wires by taping the cardioversion connectors and pacing pins to the patient's body until needed.

7. When SYNCRUS™ atrial cardioversion therapy is needed, connect the yellow cardioversion connectors to the SYNCRUS™ Cardioversion Extension Cable. Ensure that the Cable is connected to the EDIM. Apply internal atrial cardioversion by placing external defibrillator paddles on the paddle plates of the SYNCRUS™ EDIM and deliver energy. The EDIM will attenuate the external defibrillator output energy by approximately 97% (for example, a 100-joule external shock will result in an approximate 3-joule internal cardioversion shock to the heart).

8. When temporary cardiac pacing and ECG sensing are needed, remove the protective tubing from the pacing connector pins. Connect the pacing connector pins into the appropriate pacing cables. Ensure that the pacing cables are connected to an external pacemaker. Administer cardiac pacing therapy.

9. To remove the SYNCRUS™ Heart Wires, remove any tape holding the Heart Wires in place. Apply gentle and continuous external traction to remove the Heart Wires from the patient. Special care should be taken when removing the wires from the atria, due to the relatively thin atrial wall.

10. Discard the three externalized Heart Wires appropriately.

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ADVERSE EVENTS:
Two studies were conducted with the original SYNCRUS™ System (TADpole System) in Europe[1]. Results from both studies demonstrated that the Guidant SYNCRUS™ System was safe and effective for its intended use.

Table 1. Adverse Events Reported Across Studies

Complications	# of pts with AE's (n=538)	% of pts with AE's
Wire dislodgement	1	0.19%
Cardiac Arrest/VF	1	0.19%
Difficult wire extraction	2	0.37%
Infection	1	0.19%
Hypoventilation	1	0.19%
Death*	2	0.37%
Total Complications	**8**	**1.48%**

POTENTIAL ADVERSE EVENTS:
Based on the literature and SYNCRUS™ Heart Wire implant experience, the possible physical effects from implantation are listed below.

- Allergic reaction
- Atrial wall rupture
- Bleeding
- Cardiac tamponade
- Difficult wire removal
- Displacement dislodgement
- Erosion/extrusion
- Fibrotic tissue formation
- Hematoma
- Histotoxic reaction
- Inappropriate therapy
- Incomplete connection with pulse generator
- Infection
- Lead abrasion
- Lead failure
- Lead fracture or insulation break
- Lead tip deformation and/or breakage
- Local tissue reaction
- Loss of sensing or under sensing
- Myocardial injury
- Myocardial irritability
- Over sensing
- Post-shock rhythm disturbances
- Random component failures
- Threshold elevation

CLINICAL TRIALS:
The SYNCRUS™ System was studied in the following (2) trials: Pilot Clinical Investigation for the InControl TADpole Heart Wires (Temporary Atrial Cardioversion Post-Op Low

* Deaths were unrelated to therapy with the SYNCRUS™ System.
[1] For clinical study details refer to *Clinical Trial* section.

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Energy) and The TADpole™ System for Post-Cardiac Surgery Atrial Cardioversion and Atrial/Ventricular Pacing and Sensing.

Pilot Clinical Investigation for the InControl TADpole Heart Wires (Temporary Atrial Cardioversion Post-Op Low Energy)

This investigation was designed as an observational non-randomized study to evaluate the features and functionality of the therapy. The final analysis covers 466 implanted patients. The mean implant duration of the study population was 7.1 days.

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Table 2. Description of the Study Population

Characteristic	
Number of patients	n=466
Gender	
Male	348
Female	116
Unknown	2
Age at Time of Implant	
Range (years)	23 – 83
Mean ± Standard Deviation	64.2 ± 9.2
Cardiovascular Procedures*	
CABG	420
Valve Replacement	43
Valve Repair	9

*Cardiovascular procedures are not mutually exclusive of one another.

Arrhythmia Treatment Success and Energy Delivered

Eighty-one patients experiencing a total of 95 AF episodes were treated with the therapy. A per patient cardioversion overall success rate of 74% and a per episode success rate of 78% were recorded. The mean number of joules delivered to the patient per successful attempt was 6.02 Joules. There were an average number of 2.54 cardioversion attempts per successful episode.

Table 3. Per Patient and Per Episode Therapy Success Summary

Cardioversion Success	n (%)
81 Patients with Arrhythmias	
Success No	21 (26%)
Success Yes	60 (74%)
95 Episodes	
Success No	21 (22%)
Success Yes	74 (78%)
Joules Delivered per Successful Attempt	
Mean	6.02
SD	2.50
Range	1.5 - 10.8
Average number of Attempts per Successful Episode	2.54

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Table 4. Per Attempt and Cumulative Therapy Success Summary

Attempts	Success Yes/No	Total # of Attempts	Success Rate per Attempt (%)	Cumulative Success Rate (%)*
1st Attempt	Success Yes	40	42.11	42.11
	Success No	55		
2nd Attempt	Success Yes	30	45.45	73.70
	Success No	36		
3rd Attempt	Success Yes	16	41.03	90.54
	Success No	23		
4th Attempt	Success Yes	6	37.50	96.85
	Success No	10		
5th Attempt	Success Yes	2	33.33	98.95
	Success No	4		
6th Attempt	Success Yes	1	33.33	100.00
	Success No	2		
7th Attempt	Success Yes	0	0.00	
	Success No	2		
8th Attempt	Success Yes	0	0.00	
	Success No	2		
9th Attempt	Success Yes	0	0.00	
	Success No	1		

- From the total of successful cardioversions attempts, the cumulative success rate is calculated as the percentage of successful cardioversions after the first, second, third, fourth etc... attempts using the total successful attempts as the denominator. For example, 42.10 % of the total successful cardioversions resulted from a first cardioversion attempt. Data illustrates that over 90 % of the total successful cardioversions occurred within the first three cardioversion attempts. Incremental cardioversion successes were observed as a result of additional attempts.

Summary of Adverse Events

A total of eight adverse events in seven patients were recorded throughout the duration of the study.

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Table 5. Adverse Events

	# of pts with AE's (n=466)	% of pts with AE's
Complications (total)	8	1.71%
Wire dislodgement	1	0.21%
Cardiac Arrest/VF	1	0.21%
Difficult wire extraction	2	0.43%
Infection	1	0.21%
Hypoventilation	1	0.21%
Death*	2	0.43%

* Two deaths were not related to the TADpole System.

The TADpole™ System for Post-Cardiac Surgery Atrial Cardioversion and Atrial/Ventricular Pacing and Sensing

This investigation was designed as a confirmatory observational non-randomized study intended to optimize the effectiveness of the therapy including Heart Wire placement. Heart wire placement is illustrated in Figures 1 through 3. The study is an analysis of 72 implanted patients. The mean implant duration of the study population was 6.2 days.

Table 6. Description of the Study Population

Characteristic	**n (%)**
Number of patients	72
Gender	
Male	50
Female	21
Unknown	1
Age at Time of Implant (years)	
Range	32 – 89
Mean ± Standard Deviation	65.26 ± 10.6
Mean Ejection Fraction ± Standard Deviation (%)	57.43 ± 16.96 (93%)
Cardiovascular Procedures	
CABG	71
Mitral Valve Replacement	1

Arrhythmia Treatment Success and Energy Delivered

Thirteen patients experiencing a total of 14 AF episodes were treated with the therapy. A per patient cardioversion overall success rate of 92.3% and a per episode success rate of 92.8% were recorded. The mean number of Joules delivered to the patient per successful attempt

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was 7.72 Joules. There were an average number of 1.54 cardioversion attempts per successful episode.

Table 7. Per Patient and Per Episode Therapy Success Summary

Cardioversion Success	n (%)
13 Patients with Arrhythmias	
Success No	1(7.69%)
Success Yes	12 (92.3%)
14 Episodes	
Success No	1 (7.14%)
Success Yes	13 (92.8%)
Joules Delivered per Successful Attempt	
Mean	7.72
SD	1.73
Range	6 - 10.8
Average number of Attempts per Successful Episode	1.54

Table 8. Per Attempt and Cumulative Therapy Success Summary

Attempts	Success Yes/No	Total # of Attempts	Success Rate per Attempt (%)	Cumulative Success Rate (%)*
1st Attempt	Success Yes	10	71.42	66.67*
	Success No	4		
2nd Attempt	Success Yes	4	66.66	93.33
	Success No	2		
3rd Attempt	Success Yes	0	0	93.33
	Success No	2		
4th Attempt	Success Yes	1	100.00	100.00
	Success No	0		

- From the total of successful cardioversions attempts, the cumulative success rate is calculated as the percentage of successful cardioversions after the first, second, third and fourth attempts. For example 66.67% of the total successful cardioversions resulted from a first cardioversion attempt using the total successful attempts as the denominator. Data illustrates that over 90 % of the total successful cardioversions occurred within the first 3 cardioversion attempts. Incremental cardioversion successes were observed as a result of additional attempts.

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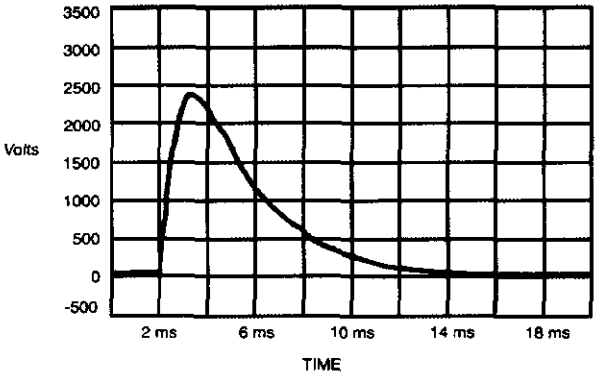
Summary of Adverse Events
No adverse events were observed in this study.

ENERGY INPUT/OUT ATTENUATION:
The EDIM attenuates the energy output of a compatible low energy external defibrillator down to 3% of its original joule output. Since the circuitry of the EDIM consists of a passive voltage divider network, the attenuation consists of a uniform reduction of input voltage, resulting in an output waveform identical to that of the defibrillators waveform, except reduced in magnitude (Figure 5).

Figure 5. EDIM Input Output Waveform

External Defibrillator Output Waveform **EDIM Output Waveform**



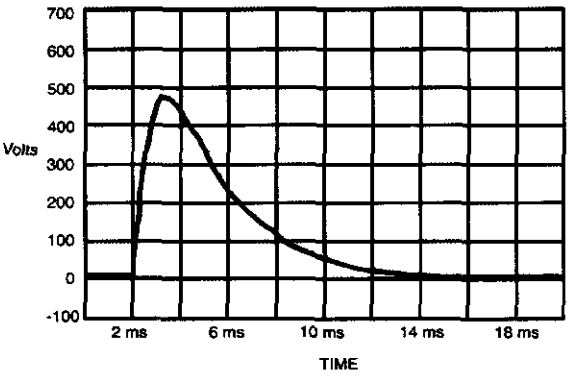


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Table 9. Minimum and Maximum Energy Output of the EDIM

Input from External Defibrillator (Joules)	Output Energy from EDIM (Joules)	
	MIN	MAX
50	1.3	1.6
100	2.6	3.2
150	3.9	4.8
200	5.2	6.4
250	6.5	8.0
300	7.8	9.6
350	9.1	11.2
360	9.4	11.5

HOW SUPPLIED:
The SYNCRUS™ Heart Wires are supplied STERILE in an unopened and undamaged package. The SYNCRUS™ Heart Wires have been sterilized using gamma irradiation and are for single use only. DO NOT RESTERILIZE. DO NOT REUSE.

The SYNCRUS™ External Defibrillator Interface Module (EDIM) is supplied non-sterile and is reusable. One SYNCRUS™ Cardioversion Extension Cable, one maintenance test fixture, and two extension cable test adapters are also supplied with the EDIM.

To perform internal atrial cardioversion, the hospital must supply a compatible low energy external defibrillator. To perform temporary cardiac pacing and ECG sensing, the hospital must supply an external pacemaker and appropriate pacing cables. A list of compatible external defibrillators, external pacemakers and pacing cables are provided in the SYNCRUS™ System Operator's Manual (*Required User Supplied Components* section) for your convenience.

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

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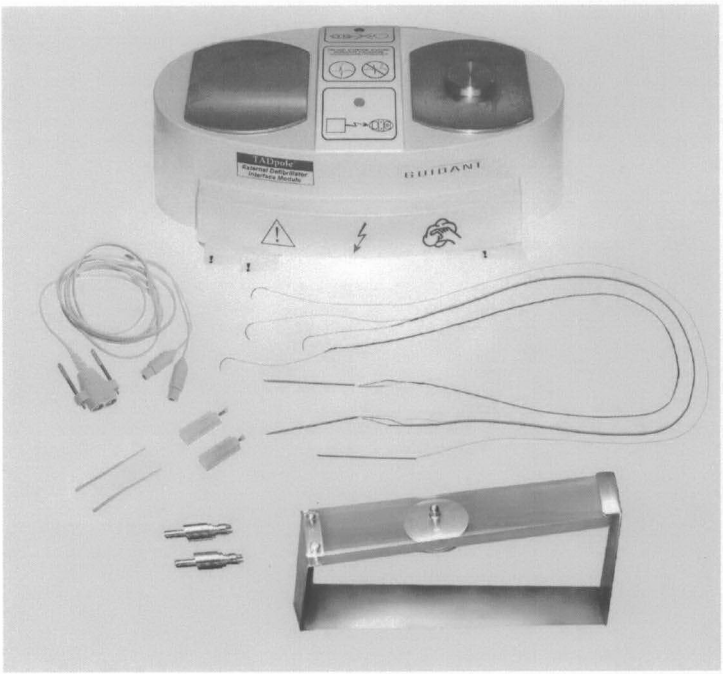
Guidant ~~Synerus~~SYNCRUS™ System

Post Cardiac Surgery Atrial Cardioversion
And
Temporary Cardiac Pacing



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1.0 ~~SYNCRUS~~SYNCRUS™ ATRIAL CARDIOVERSION THERAPY

The Guidant ~~Syncrus~~SYNCRUS™ System provides low energy internal cardioversion therapy to treat postoperative atrial fibrillation in conjunction with temporary cardiac pacing and ECG sensing.

During cardiac surgery, ~~Syncrus~~SYNCRUS™ Heart Wires are attached to appropriate locations on the patient's myocardium using standard surgical technique. The proximal ends of the ~~Syncrus~~SYNCRUS™ Heart Wires are externalized through the patient's chest wall and connected to appropriate cables attached to the ~~Syncrus~~SYNCRUS™ External Defibrillator Interface Module (EDIM) and a temporary external pacemaker.

In the event of post cardiac surgery atrial fibrillation, the clinician performs a routine synchronized electrical cardioversion, except that the external defibrillator paddles rest on the paddle plates of the ~~Syncrus~~SYNCRUS™ EDIM, rather than on the patient's chest. The patient is sedated at the physician's discretion. The *maximum* energy level administered through the ~~Syncrus~~SYNCRUS™ EDIM to the ~~Syncrus~~SYNCRUS™ Heart Wires is approximately 11 joules directly to the patient's myocardium, compared to 360 joules if delivered transthoracically with external defibrillator paddles.

The ~~Syncrus~~SYNCRUS™ Heart Wires are designed to also provide temporary cardiac pacing and ECG sensing before and after internal atrial cardioversion without requiring the physician to rearrange cables and wires.

Carefully read all instructions prior to use. Observe all warnings and precautions noted throughout these instructions.

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2.0 SYSTEM DESCRIPTION

The Guidant ~~Synerus~~SYNCRUS™ System provides low energy internal cardioversion therapy to treat postoperative atrial fibrillation via ~~Synerus~~SYNCRUS™ Heart Wires placed directly on the patient's heart. The S~~s~~ystem's functions also include temporary atrial and ventricular pacing and ECG sensing capabilities.

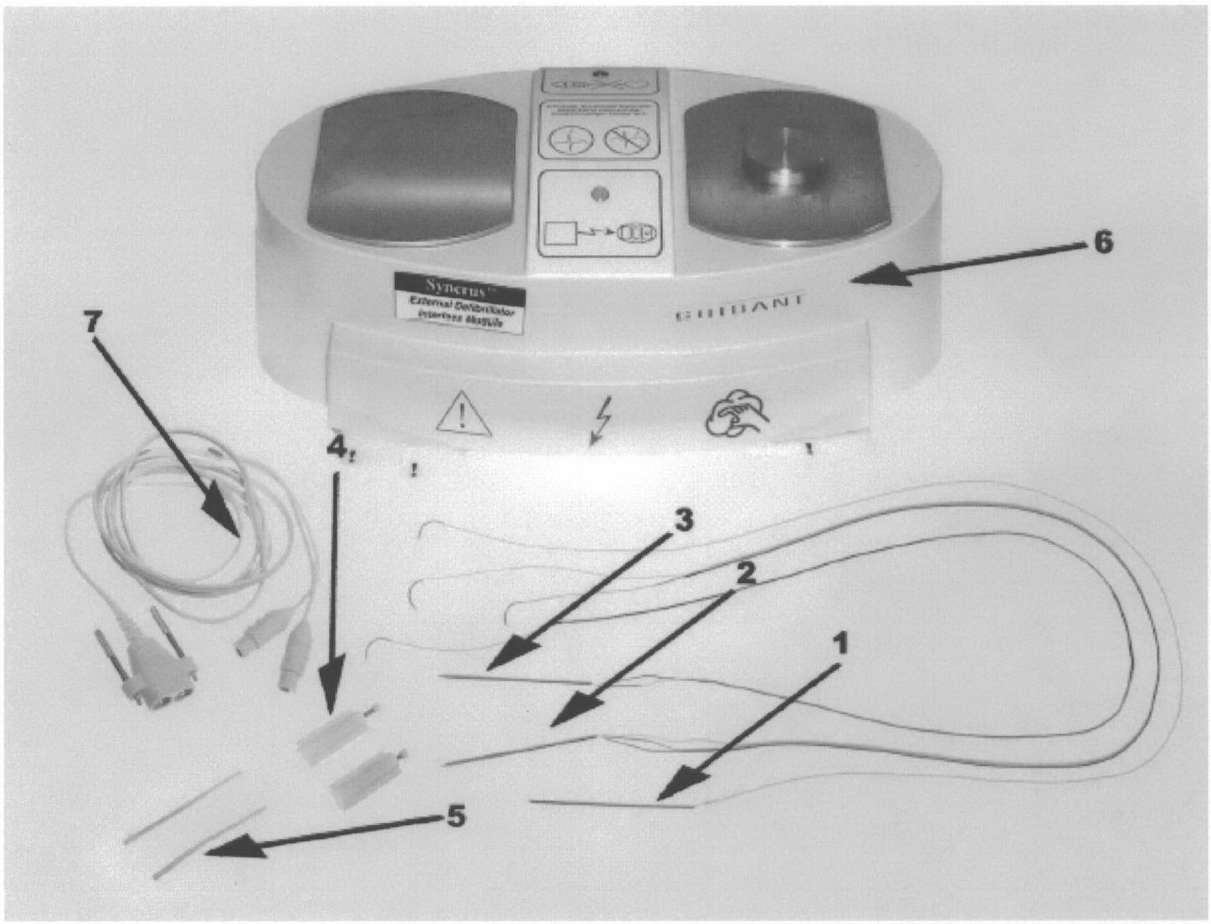

Figure 1. Guidant ~~Synerus~~SYNCRUS™ System

1. Left Atrial Heart Wire (unipolar)
2. Right Atrial Heart Wire (tripolar)
3. Ventricular Heart Wire (bipolar)
4. Yellow Cardioversion Connectors
5. Protective Tubings
6. External Defibrillator Interface Module (EDIM)
7. Cardioversion Extension Cable

Note: The Heart Wires (with yellow cardioversion connectors and protective tubings) are sold separately from the EDIM and Cardioversion Extension Cable.

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The ~~Syncrus~~SYNCRUS™ System consists of the following components:

- Three single use Heart Wires that are attached to myocardial tissue of the left atrium, right atrium, and right or left ventricle during cardiac surgery. The Heart Wires transmit low energy shocks to the patient's heart for electrical atrial cardioversion. The Heart Wires also provide temporary cardiac pacing and ECG sensing capabilities.

~~B~~A reusable External Defibrillator Interface Module (EDIM), which interfaces between
- a compatible ~~monophasic,~~ low- energy~~,~~ external defibrillator and the Heart Wires. The EDIM reduces the output energy from the defibrillator to a low energy shock delivered through the Heart Wires.

- A reusable Cardioversion Extension Cable that connects the Heart Wires to the EDIM.

The ~~Syncrus~~SYNCRUS™ System components must be used in conjunction with a compatible ~~monophasic,~~ low energy external defibrillator, an external pacemaker, and pacing cables that connect the Heart Wires to the external pacemaker. The user supplies the external defibrillator, external pacemaker, and pacing cables.

Refer to section on *Required User Supplied Components* for a list of compatible external defibrillators, external pacemakers and pacing cables that have been tested with the Guidant SYNCRUS™ System.

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3.0 INDICATIONS FOR USE

The Guidant ~~Syncrus~~SYNCRUS™ Internal Cardioversion System is indicated for use in post-operative cardiac surgery patients who require temporary atrial or ventricular pacing/sensing and/or atrial cardioversion.

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4.0 COMPONENTS DESCRIPTION

4.1 ~~Syncrus~~SYNCRUS™ Heart Wires

The ~~Syncrus~~SYNCRUS™ Heart Wires consist of three myocardial wires: a unipolar Heart Wire for the left atrium, a tripolar Heart Wire for the right atrium, and a bipolar Heart Wire for the left or right ventricle. The ~~Syncrus~~SYNCRUS™ Heart Wires are for single use only and should not be reused or resterilized.

The Left Atrial Heart Wire is a unipolar ~~lead~~ wire with a cardioversion electrode for atrial cardioversion. The Right Atrial Heart Wire is tripolar with one electrode for atrial cardioversion (that is used in conjunction with the cardioversion electrode on the Left Atrial Heart Wire) and a bipolar pacing lead with one electrode for atrial pacing and ECG sensing and a second electrode for grounding. The Ventricular Heart Wire is a bipolar pacing lead with one electrode for ventricular pacing and ECG sensing and a second electrode for grounding.

The ~~Syncrus~~SYNCRUS™ Heart Wire electrodes are placed on appropriate locations in the myocardium and the proximal ends of the Heart Wires are passed through the patient's chest wall and skin ~~of the patient~~ using a straight thoracic needle attached to each Heart Wire. The thoracic needles are cut off after externalization and yellow cardioversion connectors are attached to the cardioversion lead (yellow wire) on the Left and Right Atrial Heart Wires. The pacing connector pins on the Right Atrial Heart Wire (black and blue wires) and Ventricular Heart Wire (black and white wires) are covered with a protective tubing. The cardioversion and pacing connectors are usually taped to the patient's body until needed. After the ~~Syncrus~~SYNCRUS™ Heart Wires are no longer needed (usually just prior to patient discharge from the hospital), the Heart Wires are removed from the patient with gentle and continuous external traction.

To perform internal atrial cardioversion, the cardioversion ~~connectors~~ wires on the Left and Right Atrial Heart Wires must be connected to the ~~Syncrus~~SYNCRUS™ Cardioversion Extension Cable and EDIM. The hospital must supply a ~~monophasic~~ compatible low energy external defibrillator.

To perform atrial and ventricular pacing and ECG sensing, the pacing connector pins on the Right Atrial Heart Wire and Ventricular Heart Wire must be connected to the appropriate pacing cables and an external pacemaker. The hospital must supply both the external pacemaker and pacing cables.

4.2 ~~Syncrus~~SYNCRUS™ External Defibrillator Interface Module (EDIM)

The ~~Syncrus~~SYNCRUS™ EDIM is a non-sterile and reusable device that allows the energy from ~~an~~ compatible external defibrillator to be transmitted through the Left and Right Atrial Heart Wires directly to the patient's myocardium.

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To perform internal electrical cardioversion, external defibrillator paddles are placed on the paddle plates and safety push button of the ~~Synerus~~SYNCRUS™ EDIM. The EDIM reduces the output energy from an external ~~monophasic~~ defibrillator by approximately 97% and delivers a low energy internal cardioversion shock to the left and right atrial myocardium. For every 100 joules input from the external defibrillator, approximately 3 joules are actually delivered to the patient's heart.

4.3 ~~Synerus~~SYNCRUS™ Cardioversion Extension Cable

The ~~Synerus~~SYNCRUS™ Cardioversion Extension Cable is a reusable cable that connects the cardioversion connectors on the Left and Right Atrial Heart Wires to the ~~Synerus~~SYNCRUS™ EDIM.

4.4 EDIM Maintenance Test Fixture and Cardioversion Cable Test Adapters

The EDIM maintenance test fixture and Cardioversion Cable test adapters are used to perform the full maintenance test on the Guidant ~~Synerus~~SYNCRUS™ System as described in the *Maintenance and Calibration* ~~Section~~section.

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5.0 MAINTAINING SYSTEM EFFECTIVENESS

5.1 ~~Synerus~~SYNCRUS™ Heart Wires

- The ~~Synerus~~SYNCRUS™ Heart Wires are for single use only. DO NOT RESTERILIZE. DO NOT REUSE.

5.2 ~~Synerus~~SYNCRUS™ EDIM and Cardioversion Extension Cable

- The EDIM should only be used with a ~~monophasic,~~compatible low-energy external defibrillator (see section on *Required User Supplied Components*).

- Perform functional checks on the ~~Synerus~~SYNCRUS™ EDIM ~~daily and monthly (see section on *Maintenance and Calibration*).~~as described in the *Maintenance and Calibration* section.

- Do not use conductive gel or paste on the external defibrillator paddles or ~~Synerus~~SYNCRUS™ EDIM paddle plates.

- Do not immerse the ~~Synerus~~SYNCRUS™ EDIM or Cardioversion Extension Cable in liquid.

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6.0 REQUIRED USER SUPPLIED COMPONENTS

To apply ~~Syncrus~~SYNCRUS™ atrial cardioversion therapy, the user must supply a compatible ~~monophasic~~ low energy external defibrillator, an external pacemaker, and the appropriate pacing cables. Below is a list of compatible external defibrillators, pacemakers and pacing cables that have been tested with the Guidant ~~Syncrus~~SYNCRUS™ System.

External pacemaker:

- Medtronic Dual-Chamber Model 5388 External (Temporary) Pulse Generator
- Medtronic Single-Chamber Model 5348 External (Temporary) Pulse Generator

Pacing cables:

- Medtronic 5433A Reusable EPG atrial safety cables
- Medtronic 5433V Reusable EPG ventricular safety cables
- Medtronic 5487 6 ft. sterile disposable patient safety cables

Biphasic, low energy external defibrillator with R-wave synchronization capability and external paddles:

- Medtronic Physio-Control LIFEPAK® 12 and LIFEPAK® 20 defibrillators
- Agilent (Philips Medical) Heartstream™ or HeartStart XL and XLT defibrillators

Note: The Zoll M Series biphasic defibrillator will not discharge energy into the SYNCRUS™ EDIM.

Monophasic, low-energy external defibrillator with R-wave synchronization capability:

- Medtronic Physio-Control ~~LifePak™~~ LIFEPAK® 9, 10, 11, 12 ~~(excluding 3D Biphasic™ Technology)~~ defibrillators
- Agilent (Philips Medical)~~(Hewlett Packard)~~ ~~Codemaster~~CodeMaster™ defibrillator
- Zoll ~~Medical Corporation~~M Series defibrillator with monophasic capability

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7.0 WARNINGS

- The ~~Guidant Syncrus~~SYNCRUS™ System is not compatible with ~~monophasic~~all low energy external defibrillators ~~only~~. See section on *Required User Supplied Components* for a list of compatible external defibrillators.
- Perform synchronized cardioversion only. Unsynchronized shocks may result in ventricular fibrillation, causing patient injury or death.
- The ~~Syncrus~~SYNCRUS™ Heart Wires provide a direct path for electrical current flow to the patient's heart. DO NOT touch the heart wire leads or the EDIM (when connected to the Heart Wires) with your bare hands or with anything that may deliver static (electrostatic discharge). Avoid the possibility of unintentional contact between the wire leads, including extension cable, and any equipment used as well as any conductive surface contact. Line powered equipment used in the vicinity of the patient must be properly grounded.
- The ~~Syncrus~~SYNCRUS™ EDIM and Cardioversion Extension Cable are designed solely for use with the ~~Syncrus~~SYNCRUS™ Heart Wires.
- DO NOT connect the Heart Wires to any equipment other than that specified in these instructions and the ~~Syncrus~~SYNCRUS™ System Operator's Manual. Patient injury or death may result.
- If the ~~Syncrus~~SYNCRUS™ ~~System~~ EDIM has been dropped ~~onto a hard surface~~, perform a FULL maintenance test as described in the ~~Syncrus~~SYNCRUS™ System Operator's Manual (*Maintenance and Calibration* section) prior to using the EDIM again. Dropping the EDIM may damage internal components, possibly rendering the device inoperable or out of specification.
- Wire fracture, dislodgement, abrasion and/or an incomplete connection can cause a periodic or continual loss of pacing and sensing, possibly resulting in inappropriate delivery of conversion therapy. Connect the pacing connector pins for baseline measurements to a pacing system analyzer (PSA) or temporary pacemaker and evaluate the placement by determining R-wave amplitude, pacing threshold, and pacing lead impedance. Secure the ~~Syncrus~~SYNCRUS™ Heart Wires by taping the cardioversion connectors and pacing pins to the patient's body until needed.
- Although pliable, the lead body is not designed to tolerate excessive flexing, bending, or tension. This could cause structural weakness, conductor discontinuity, and/or lead dislodgement. Secure the cardioversion connectors and pacing pins to the patient's body until needed. Minimize manipulation of the ~~heart wires~~Heart Wires.
- Equipment and accessories connected to the Guidant ~~Syncrus~~SYNCRUS™ System shall comply with IEC-601-1, type CF.

8.0 PRECAUTIONS

- ~~Syncrus~~SYNCRUS™ Heart Wires are for single use only. DO NOT RESTERILIZE. DO NOT REUSE.

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- The ~~Syncrus~~SYNCRUS™ Heart Wires are gamma sterilized after packaging. When they are received, they are sterile and ready for use. Should the seal or package be wet, damaged, punctured, or if the seal is broken, do not use or attempt to resterilize. Contact the local Guidant representative.
- Pre-clinical testing supports the use of this device up to 7 cardioversion attempts. Cardioversion attempts ranged from 1 to 9 attempts in clinical trials. Physicians should treat patients in accordance with judgment and experience. Assessment of the patient's overall condition and physician discretion should dictate the number of attempts to treat.
- It is recommended that defibrillation equipment and a pacing sensor system analyzer (PSA) or temporary pacemaker be readily available during lead placement and removal.

9.0 ATTACHING THE ~~SYNCRUS~~SYNCRUS™ HEART WIRES TO THE MYOCARDIUM

1. Attach the ~~Syncrus~~SYNCRUS™ Heart Wires to the patient's myocardial surface during cardiac surgery in the following order and before the patient's chest is closed. The described fixation techniques ~~is~~are furnished for informational purposes only. The physician may choose to vary the fixation technique in accordance with judgment and experience. The selected fixation technique of each Heart Wire placement should always allow for ease of extraction through gentle traction. Proper surgical procedures and techniques are the responsibility of the medical professional. ~~Figures 2 through 4 illustrate heart wire placement as performed in clinical trials.~~

Left Atrial Heart Wire (unipolar)

- *Cardioversion Electrode (yellow wire)*: Use the attached curved needle to affix the cardioversion electrode to the left atrial myocardium. After the cardioversion electrode is affixed (see Figures 2a and 3a), cut off the curved needle and discard it. Place a slight bend or kink at the end of the electrode.

Right Atrial Heart Wire (tripolar)

- *Cardioversion Electrode (yellow wire)*: Use the attached curved needle to affix the cardioversion electrode to the right atrial myocardium. After the cardioversion electrode is affixed (see Figures 2b and 3b), cut off the curved needle and discard it. Place a slight bend or kink at the end of the electrode.

  Placement should be made to maximize the atrial muscle mass between the right atrial cardioversion electrode and the left atrial cardioversion electrode.

- *Pacing Electrodes (black and blue wires)*: Use the attached curved needle to affix the bipolar pacing electrodes to the right atrial myocardium. For optimal cardiac pacing, bury both the pacing electrode and bullet in the myocardium. After the

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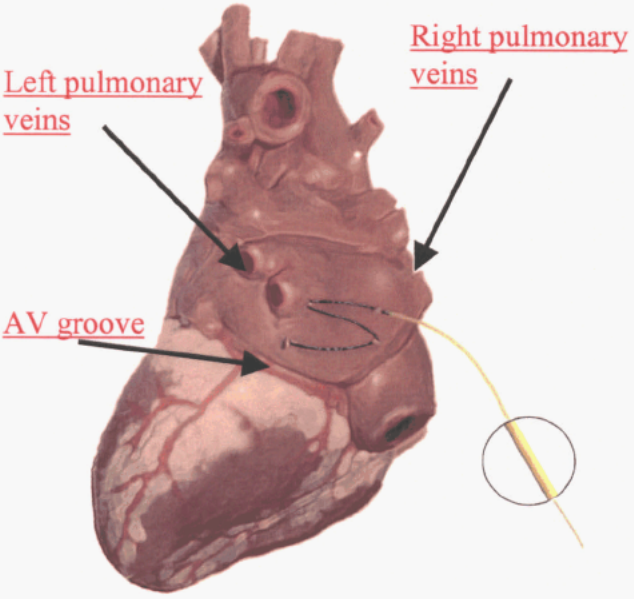
pacing electrodes are affixed (see Figures 2b and 3b), cut off the needle and discard it. Place a slight bend or kink at the end of the pacing electrode.

- Ventricular Heart Wire (bipolar)
  Pacing Electrodes (black and white wires): Use the attached curved needle to affix the bipolar pacing electrodes into the myocardial tissue of either the right or left ventricle. For optimal cardiac pacing, bury both the pacing electrode and bullet in the myocardium. After the pacing electrodes are affixed (see Figures 2c and 3c), cut off the curved needle and discard it. Place a slight bend or kink at the end of the pacing electrode.

Figures 2 through 3 illustrate two examples of Heart Wire placement techniques as used in clinical practice.

Figure 2. SYNCRUS™ Heart Wire Placement Technique A (used in clinical trials in Europe)



2a. Left Atrial Wire Placement
Figure shows the cardioversion electrode placed in an "S" pattern between the atrioventricular (AV) groove and the left and right pulmonary veins.

(Lateral-posterior view)

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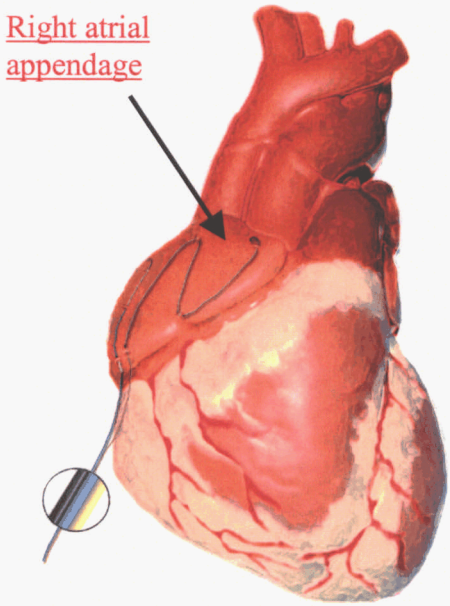
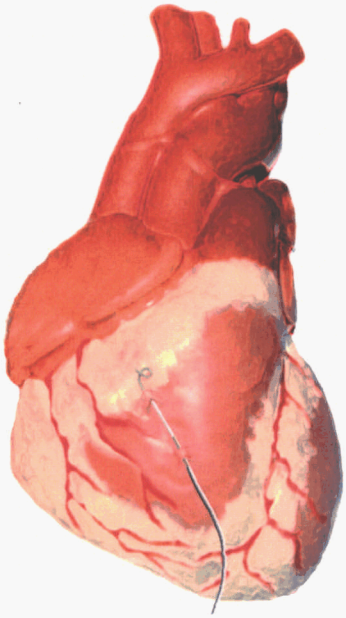


2b. Right Atrial Wire Placement
Figure shows the cardioversion electrode placed in an "S" pattern on the right atrial appendage.

The pacing electrode and bullet are shown placed on the right atrial myocardium.

(Anterior view)



2c. Ventricular Wire Placement
Figure shows the pacing electrode and bullet placed on the right ventricle.

(Anterior view)

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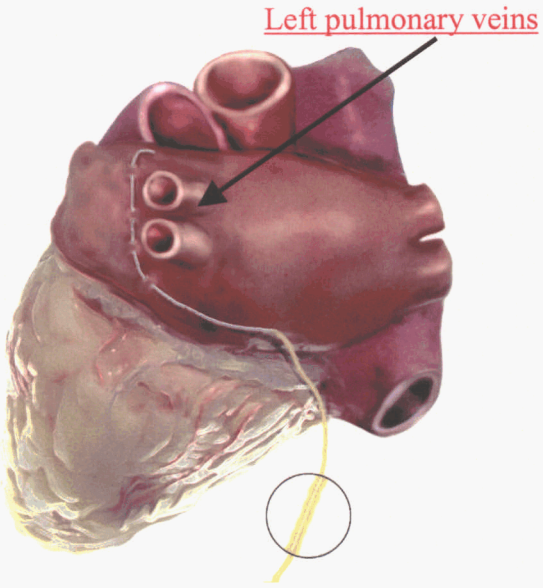
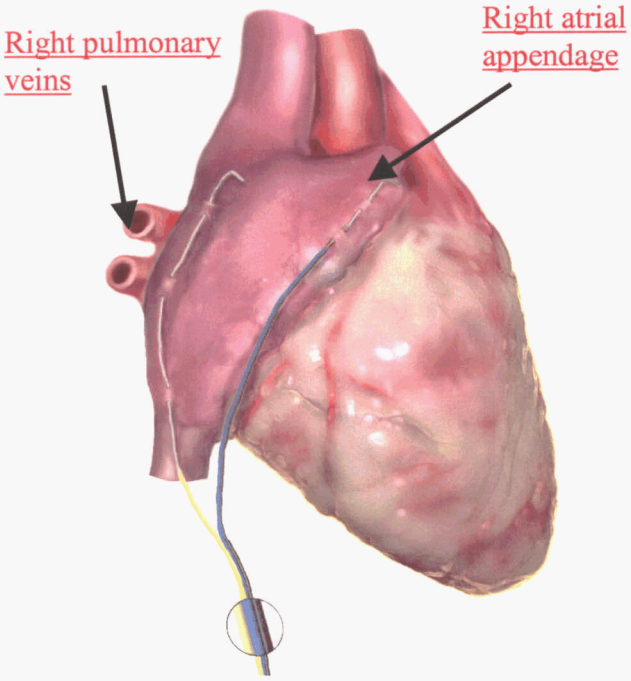
Figure 3. SYNCRUS™ Heart Wire Placement Technique B



3a. Left Atrial Wire Placement
Figure shows the cardioversion electrode placed within 5 mm anterior of the left pulmonary veins.

(Lateral-posterior view)



3b. Right Atrial Wire Placement
Figure shows the cardioversion electrode placed by the inferior vena cava and up towards the right pulmonary veins within 5 mm of the SA node.

The pacing electrode and bullet are shown placed on the right atrial appendage.

(Lateral view)

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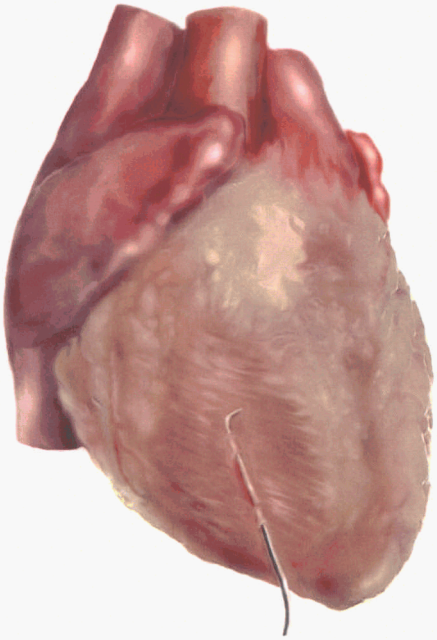
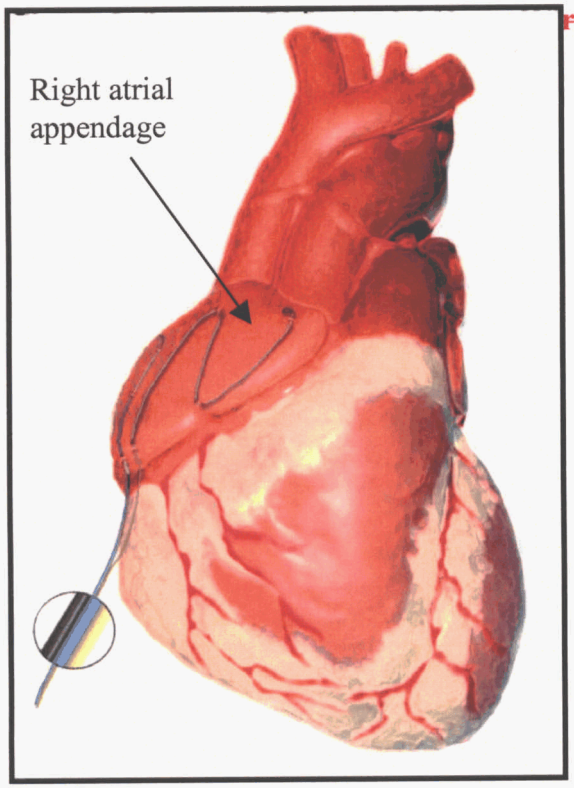


3c. Ventricular Wire Placement
Figure shows the pacing electrode and bullet placed on the right ventricle.

(Anterior view)



Anterior view

~~Right Atrial Heart Wire (tripolar)~~

- ~~*Cardioversion Electrode (yellow wire):* Use the attached curved needle to affix the cardioversion electrode into the right atrial myocardium in an "S" pattern as shown in Figure 3 for optimal results. After the cardioversion electrode is affixed, cut off the curved needle and discard it. Place a slight bend or kink at the end of the electrode.~~

~~*Pacing Electrode (black and blue wires):* Use the attached curved needle to affix the bipolar pacing electrodes into the right atrial myocardium. For optimal cardiac pacing, bury both the anode and cathode in the myocardium. After the pacing electrodes are affixed, cut off the needle and discard it. Place a slight bend or kink at the end of the anode electrode.~~

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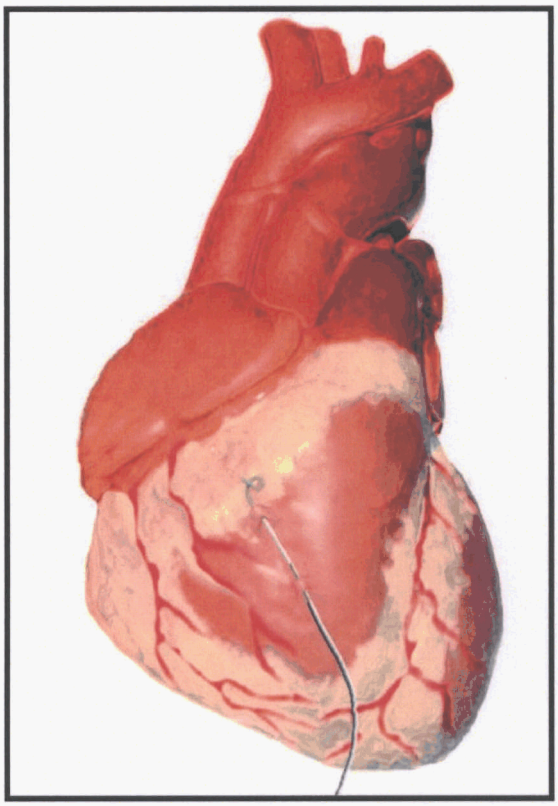
~~Figure 4. Syncrus Ventricular Heart Wire Placement~~



Anterior view

~~Ventricular Heart Wire (bipolar)~~

- ~~*Pacing Electrodes (black and white wires)*: Use the attached curved needle to affix the bipolar pacing electrodes into the myocardial tissue of either the right or left ventricle as illustrated in Figure 4 for optimal results. The positive pacing electrode (anode) is attached to the needle, while the negative electrode (cathode) is contained in the 4 mm long bullet. For optimal cardiac pacing, bury both the anode and cathode in the myocardium. After pacing electrodes are affixed, cut off the curved needle and discard it. Place a slight bend or kink at the end of the anode electrode.~~

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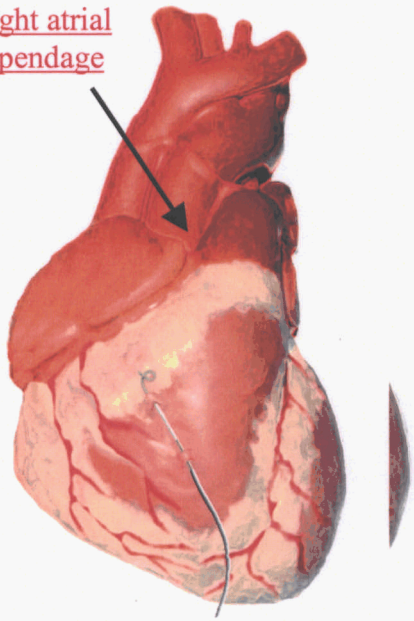
2. Right atrial appendage



odes have been affixed to the patient's heart,
ll travel as they are extracted.

3. U
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ximal end of each ~~Syncrus~~SYNCRUS™
through the chest wall and skin. Once the
horacic needles, maximizing the exposed
needles appropriately.

4. A
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's provided with the SYNCRUS™ Heart
n the Left and Right Atrial Heart Wires.
~~rovided with the Syncrus Left and Right~~
ing the Heart Wire cardioversion lead
connector and pushing the pin into the
cal contact between the Heart Wire
ersion connector.

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5. _Connect the pacing connector pins for baseline measurements to a pacing system analyzer (PSA) or temporary pacemaker and evaluate the placement by determining R-wave amplitude, pacing threshold, and pacing lead impedance.

6. _Cover the pacing connector pins on the Right Atrial Heart Wire (black and blue wires) and Ventricular Heart Wire (black and white wires) with the protective tubings provided with the ~~Synerus~~ SYNCRUS™ Heart Wires. Secure the ~~Synerus~~ SYNCRUS™ Heart Wires by taping the cardioversion connectors and pacing pins to the patient's body until needed.

7. _When ~~Synerus~~ SYNCRUS™ atrial cardioversion therapy is needed, connect the yellow cardioversion connectors to the ~~Synerus~~ SYNCRUS™ Cardioversion Extension Cable. Ensure that the Cable is connected to the EDIM. Apply internal atrial cardioversion by placing external defibrillator paddles on the paddle plates of the ~~Synerus~~ SYNCRUS™ EDIM and deliver~~ing~~ energy. The EDIM will attenuate the external defibrillator output energy by approximately 97% (for example, a 100--joule external shock will result in an approximate 3-joule internal cardioversion shock to the heart).

8. _When temporary cardiac pacing and ECG sensing are needed, remove the protective tubing from the pacing connector pins. Connect the pacing connector pins into the appropriate pacing cables. Ensure that the pacing cables are connected to an external pacemaker. Administer cardiac pacing therapy.

9. _To remove the ~~Synerus~~ SYNCRUS™ Heart Wires, remove any tape holding the Heart Wires in place. Apply gentle and continuous external traction to remove the Heart Wires from the patient. Special care should be taken when removing the lead from the atrium, due to the relatively thin atrial wall.

10. Discard the three externalized Heart Wires appropriately.

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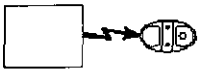
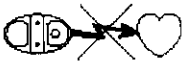
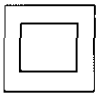
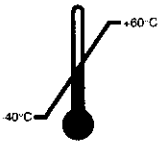
10.0 DEFINITION OF SYMBOLS

Below is a description of the symbols used in this manual and on the Guidant ~~Syncrus~~SYNCRUS™ System labels and packaging.

	WARNING: **Shock hazard.** Hazardous voltage may be present. Do not touch the paddle plates when the device is connected to the patient.
	WARNING: Read Instructions for Use.
	WARNING: Do not shock on T-wave. Synchronize shock with patient's R-wave.
	(Green indicator flashes): Energy has been transmitted from the external defibrillator to the ~~Syncrus~~SYNCRUS™ EDIM.
	(Red indicator flashes): Overvoltage condition in ~~Syncrus~~SYNCRUS™ EDIM. No energy was transmitted to patient. Refer to the Operator's Manual.
	Clean paddle plates before each use with a 70% isopropyl alcohol wipe.
	Type CF equipment.
	Class II equipment.
	Reference information; please read.
	Store at temperature between -40°C and 60°C.

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11.0 MAINTENANCE AND CALIBRATION

The ~~Syncrus~~SYNCRUS™ EDIM is a passive electrical device that relies on a user supplied external defibrillator for its power source. There are no user serviceable parts inside. This maintenance procedure is intended for the use of the hospital biomedical engineering department to verify proper function of the device and its safety features. If the device exhibits any discrepancies in any of these periodic checks, discontinue use of the device at once and contact Guidant Cardiac Surgery (Santa Clara, CA) for return instructions. **All maintenance procedures requiring an external defibrillator should be conducted with a compatible external defibrillator (see section on *Required User Supplied Components* for compatible defibrillators).**

11.1 Daily Maintenance

It is recommended that the following maintenance procedure be performed on a daily basis to ensure proper function of the ~~Syncrus~~SYNCRUS™ EDIM.

CAUTION: Perform all maintenance **BEFORE** connecting the ~~Syncrus~~SYNCRUS™ EDIM to the patient.

1. Clean the paddle plates and safety push button ~~(right side)~~ (see Figure 4) with a 70% isopropyl alcohol wipe before each use. A buildup of dirt on these conductive surfaces can cause degradation of electrical conduction and can prevent proper energy transmission.

2. Verify that the spring-loaded safety push button on the right side of the device can be depressed completely and that it returns to its extended position when the force is removed.

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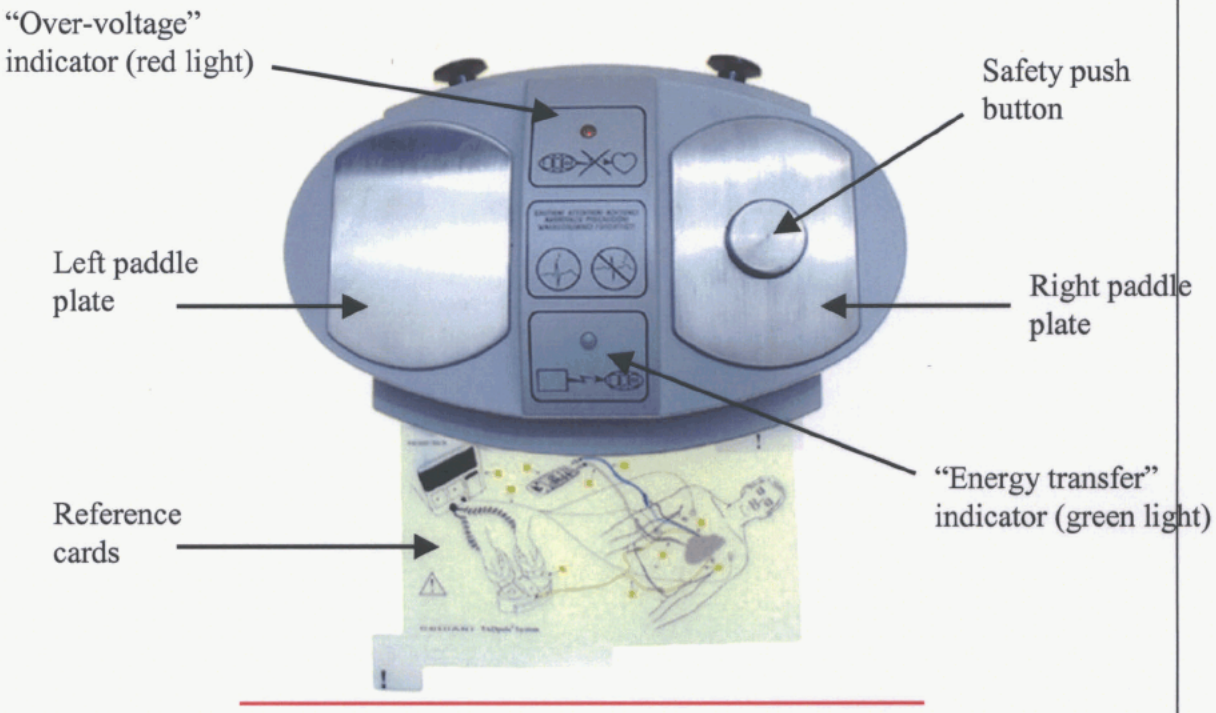
Figure 4. Top view of the SYNCRUS™ External Defibrillator Interface Module (EDIM)



11.2 Full Maintenance ~~(monthly)~~

It is recommended that the following maintenance procedure be performed ~~on a monthly basis~~every 3 months to ensure proper function of the ~~Syncrus~~SYNCRUS™ EDIM. Also perform a full maintenance test if the EDIM has been dropped onto a hard surface prior to using the EDIM again.

11.2.1 Other Equipment

- External defibrillator (see section on *Required User Supplied Components* for compatible defibrillators)
- Ohmmeter
- Electrical safety analyzer or leakage current analyzer
- Defibrillator analyzer

~~Impulse 3000 or 4000 defibrillator analyzer (DNI Nevada, Inc., Carson City, NV, USA) or equivalent.~~

~~Syncrus™ EDIM maintenance test fixture (Guidant Cardiac Surgery order #TX-5200)~~

~~□Syncrus™ Cardioversion Cable test adapter; two required (Guidant Cardiac Surgery order #TX-5300). Hypertronics p/n YPN025-002G may also be used.~~

~~□Hi-pot tester capable of 4 kV AC output~~

~~□Oscilloscope with high voltage probe~~

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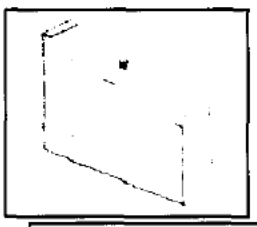
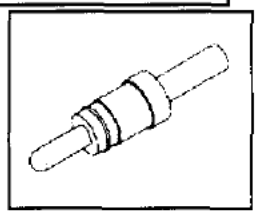
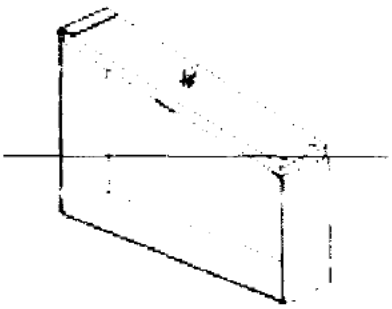
- SYNCRUS™ EDIM maintenance test fixture (Guidant Cardiac Surgery order #TX-5200)

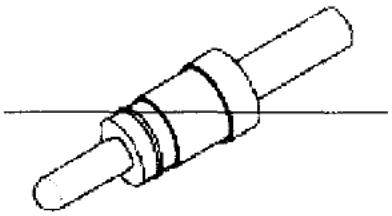


- SYNCRUS™ Cardioversion Cable test adapters – two required (Guidant Cardiac Surgery order #TX-5300). Hypertronics p/n YPN025-002G may also be used.





~~Syncrus™ EDIM maintenance test fixture TX-5200~~



~~Syncrus™ Cardioversion Cable test adapter TX-5300 (2 required)~~

11.2.2 Full Maintenance Procedure

1. Check safety push button

Verify that the spring-loaded safety push button on the right side of the SYNCRUS™ EDIM can be depressed completely and that it returns to its extended position when the force is removed.

2. Check safety switch isolation

Equipment Used:
- Ohmmeter
- SYNCRUS™ Cardioversion Cable test adapters (2)

Test Setup:

2.1 Connect the SYNCRUS™ Cardioversion Extension Cable to the SYNCRUS™ EDIM.

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2.2 Connect the Cardioversion Cable test adapters to the output connectors on the SYNCRUS™ Cardioversion Extension Cable.
2.3 Connect an ohmmeter lead to each of the test adapters.

With the safety push button on the EDIM in its normal "up" position, the ohmmeter should read open (i.e. no continuity). With the safety push button depressed, the ohmmeter should read between 55 – 65 ohms.

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~~1~~—Check leakage current
3.

Equipment Used:

- Electrical safety analyzer or leakage current analyzer
- SYNCRUS™ Cardioversion Cable test adapters (2)
- SYNCRUS™ EDIM maintenance test fixture

Note: the leakage current limits specified are for the ~~Synerus~~SYNCRUS™ EDIM only. Any leakage current inherent in the leakage tester must be identified and deducted from the tester readout before applying the leakage current limits.

Patient Leakage Current (Mains on Paddle Plates)

Test Setup:

~~1.1~~3.1 Connect the ~~Synerus~~SYNCRUS™ Cardioversion Extension Cable to the ~~Synerus~~SYNCRUS™ EDIM.

3.2 Connect the Cardioversion Cable test adapters to the output connectors on the SYNCRUS™ Cardioversion Extension Cable. Electrically short the two output terminals on the test adapters.

3.3 ~~1.2~~—Connect the shorted test adapters to the ground terminal on the electrical safety or leakage current analyzer.~~a Cardioversion Cable test adapter to each output connector on the Synerus™ Cardioversion Extension Cable. Electrically short the two output terminals on the test adapters~~

3.4 Attach the EDIM maintenance test fixture to the SYNCRUS™ EDIM. The test fixture should wrap around the right side of the EDIM and the latching mechanism should be located on the same side as the EDIM output terminals when properly installed for this test (see Figure 5).

3.5 Depress the SYNCRUS™ EDIM safety push button with the movable arm of the test fixture. Latch the movable arm and verify that the EDIM safety push button is fully depressed.

3.6 Make an electrical connection between the EDIM maintenance test fixture (via the lock nut) and an ECG terminal of the analyzer (i.e. RL connection).

3.7 Using the appropriate setting for the analyzer, apply either 120-volts or 240-volts (determined by the voltage powering the analyzer) to the EDIM. Descriptors for the analyzer test mode may include "Lead Isolation to Ground" or "Patient Lead Isolation Test".

~~1.3Connect a current measuring device to the shorted output terminals of the test adapters.~~

~~Attach the EDIM maintenance test fixture to the Synerus™ EDIM. The test fixture should wrap around the right side of the EDIM and the latching mechanism should be located on the same side as the EDIM output terminals when properly installed for this test (see Figure 5).~~

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~~1.5Depress the Syncrus™ EDIM safety push button with the movable arm of the test fixture. Latch the movable arm and verify that the EDIM safety push button is fully depressed.~~

The SYNCRUS™ EDIM shall not allow greater than 10μA leakage current when 240-volts are applied by the analyzer (or 5μA leakage current when 120-volts are applied) to the EDIM.

CAUTION: Do not depress the SYNCRUS™ EDIM safety push button with anything that is electrically common with your body. Serious injury may occur.

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Figure 5. The EDIM maintenance test fixture shown properly installed on the right side of the SYNCRUS™ EDIM.

~~**Figure 5.** The EDIM maintenance test fixture shown properly installed to the Syncrus™ EDIM.~~

~~The Syncrus™ EDIM shall not allow greater than 10μA leakage current when a 240-volt source is connected (or 5μA leakage current when a 120 volt source is connected) to the left paddle plate and the current measuring device is attached to the output jacks electrically tied together and shorted to ground. The EDIM safety push button should be depressed for this check.~~

~~Patient Leakage Current (Mains on the Applied Part) - The Syncrus™ EDIM shall not allow greater than 10 μA leakage current when a 240 volt source is connected (or 5μA leakage current when a 120 volt source is connected) to the output jacks electrically tied~~

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~~together and the measuring device is attached to the left paddle plate and shorted to ground. The EDIM safety push button should be depressed for this check.~~

~~**CAUTION:** Do not depress the Syncrus™ EDIM safety push button with anything that is electrically common with your body. Serious injury may occur.~~

4. Check over-voltage protection

Equipment Used:
- External defibrillator

Discharge a 360 joule shock from the external defibrillator into the SYNCRUS™ EDIM using the external paddles, but with no load connected to the output terminals.

Note: This test verifies that the over-voltage protectors limit the output voltage from the EDIM to less than 800-volts. A monophasic external defibrillator needs to be used for this test in order to achieve a voltage greater than 800-volts at the voltage protectors when there is no load connected to the EDIM output.

The "over-voltage" indicator (red) on the top panel of the EDIM should flash momentarily. The "energy transfer" indicator (green) will also flash momentarily.

If the "energy transfer" indicator (green) does not flash, verify that the external defibrillator is delivering at least 360 joules by connecting a defibrillator analyzer directly to the defibrillator (remove the EDIM from the circuit). If the external defibrillator is delivering at least 360 joules, discontinue use of the EDIM. If the external defibrillator is not delivering at least 360 joules (and is set for 360 joules output), discontinue use of the external defibrillator.~~2. Check mechanical isolation~~

~~Verify that the spring-loaded safety push button on the right side of the Syncrus™ EDIM can be depressed completely and that it returns to its extended position when the force is removed.~~

5. Check "energy transfer" indicator

Equipment Used:
- External defibrillator
- Defibrillator analyzer
- SYNCRUS™ Cardioversion Cable test adapters (2)

Test Setup:

5.1 Connect the SYNCRUS™ Cardioversion Extension Cable to the SYNCRUS™ EDIM.

5.2 Connect the Cardioversion Cable test adapters to the output connectors on the SYNCRUS™ Cardioversion Extension Cable.

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5.3 Connect the test adapters to the defibrillator analyzer.
5.4 Place the external defibrillator paddles on the SYNCRUS™ EDIM paddle plates. Assure that the right safety push button is fully depressed by the paddle.

Discharge a 100 joule shock from the external defibrillator into the SYNCRUS™ EDIM using the external paddles. The "energy transfer" indicator (green) will flash momentarily, while the "over-voltage" indicator (red) will not flash. Repeat the check with a 360 joule shock. The "energy transfer" indicator (green) will flash momentarily, while the "over-voltage" indicator (red) will not flash.

6. ~~3.~~ *Check attenuation level*

Equipment Used:

- External defibrillator
- Defibrillator analyzer
- SYNCRUS™ Cardioversion Cable test adapters (2)

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Test Setup:

~~3.1~~6.1 Connect the ~~Syncrus~~SYNCRUS™ Cardioversion Extension Cable to the ~~Syncrus~~SYNCRUS™ EDIM.

~~3.2~~6.2 Connect the Cardioversion Cable test adapters to the output connectors on the SYNCRUS™ Cardioversion Extension Cable.~~Connect a Cardioversion Cable test adapter to each output connector on the Syncrus™ Cardioversion Extension Cable.~~

~~3.3~~6.3 Connect the test adapters to the defibrillator analyzer.

~~3.4~~6.4 Place the external defibrillator paddles on the ~~Syncrus~~SYNCRUS™ EDIM paddle plates. Assure that the right safety push button is fully depressed by the paddle.

Use the defibrillator analyzer to verify the ~~Syncrus~~SYNCRUS™ EDIM attenuation level:

External defibrillator setting*	~~Syncrus~~SYNCRUS™ EDIM output*
360 joule	10.4 - 11.1 joule

* If the external defibrillator does not deliver exactly 360 joules, the lower and upper ~~Syncrus~~SYNCRUS™ EDIM output energy limits may be calculated by multiplying the external defibrillator input energy by 0.0289 and 0.0309, respectively.

7. Check shock delivery delay

Equipment Used:

- External defibrillator
- Defibrillator analyzer
- SYNCRUS™ Cardioversion Cable test adapters (2)

Test Setup:

7.1 Connect the SYNCRUS™ Cardioversion Extension Cable to the SYNCRUS™ EDIM.

7.2 Connect the Cardioversion Cable test adapters to the output connectors on the SYNCRUS™ Cardioversion Extension Cable.

7.3 Connect the test adapters to the defibrillator analyzer.

7.4 Connect the defibrillator analyzer's normal sinus ECG output signal (60 bpm) to the synchronization input of the external defibrillator.

7.5 Place the external defibrillator paddles on the SYNCRUS™ EDIM paddle plates. Assure that the right safety push button is fully depressed by the paddle.

Using synchronized cardioversion mode, discharge a 200 joule shock from the external defibrillator into the SYNCRUS™ EDIM using the external paddles.

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Use the defibrillator analyzer to measure actual delay time from the peak of the generated R-wave to the leading edge of the defibrillator discharge waveform, measured at the output of the SYNCRUS™ EDIM. The delay time must be less than 60 milliseconds.~~4. Check shock delivery delay~~

~~Test Setup:~~

~~4.1Connect the Syncrus™ Cardioversion Extension Cable to the Syncrus™ EDIM.~~

~~Connect a Cardioversion Cable test adapter to each output connector on the Syncrus™ Cardioversion Extension Cable.~~

~~4.3 Connect the test adapters to the defibrillator analyzer.~~

~~4.4Connect the defibrillator analyzer's normal sinus ECG output signal (60 bpm) to the synchronization input of the external defibrillator.~~

~~Place the external defibrillator paddles on the Syncrus™ EDIM paddle plates. Assure that the right safety push button is fully depressed by the paddle.~~

~~4.6 Discharge the external defibrillator at 360 joules, using synchronized cardioversion mode.~~

~~Use the defibrillator analyzer to measure actual delay time from the peak of the generated R-wave to the leading edge of the defibrillator discharge waveform, measured at the output of the Syncrus™ EDIM. The delay time must be less than 60 milliseconds.~~

~~5. Check over voltage protection~~

~~Discharge a 360 joule shock from the external defibrillator into the Syncrus™ EDIM using the external paddles, but with no load connected to the output terminals. The "over-voltage" indicator on the top panel of the EDIM should flash momentarily (red color). The "energy transfer" indicator (green) will also flash momentarily.~~

~~If the "energy transfer" indicator does not flash, verify that the external defibrillator is delivering at least 360 joules by connecting the defibrillator analyzer directly to the defibrillator (remove the EDIM from the circuit). If the external defibrillator is delivering at least 360 joules, discontinue use of the EDIM. If the external defibrillator is not delivering at least 360 joules (and is set for 360 joules output), discontinue use of the external defibrillator.~~

~~6. Check "energy transfer" indicator~~

~~Test Setup:~~

~~6.1Connect the Syncrus™ Cardioversion Extension Cable to the Syncrus™ EDIM.~~

~~6.2Connect a Cardioversion Cable test adapter to each output connector on the Syncrus™ Cardioversion Extension Cable.~~

~~6.3 Connect a 60 ohm, 100 watt resistor across the terminals of the test adapters.~~

~~6.4 Place the external defibrillator paddles on the Syncrus™ EDIM paddle plates. Assure that the right safety push button is fully depressed by the paddle.~~

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~~Discharge a 100 joule shock from the external defibrillator into the Syncrus™ EDIM using the external paddles. The "energy transfer" indicator (green) will flash momentarily, while the "over-voltage" indicator (red) will not flash. Repeat the check with a 360 joule shock. The "energy transfer" indicator will flash momentarily, while the "over-voltage" indicator will not flash.~~

~~7.Dielectric withstand~~

~~Test Setup:~~

~~7.1 Connect the Syncrus™ Cardioversion Extension Cable to the Syncrus™ EDIM.~~

~~7.2 Connect the Cardioversion Cable test adapters to the Syncrus™ Cardioversion Extension Cable.~~

~~7.3 Electrically short the output terminals on the test adapters.~~

~~7.4Attach the EDIM maintenance test fixture to the Syncrus™ EDIM. The test fixture should wrap around the **left** side of the EDIM and the latching mechanism should be located on the same side as the EDIM output terminals when properly installed for this test (see Figure 6).~~

~~7.5Connect the positive hi-pot output lead to the Syncrus™ EDIM left paddle plate via the electrical connector on the EDIM maintenance test fixture.~~

~~7.6Connect the negative hi-pot lead to the shorted output terminals on the Cardioversion Cable test adapters.~~

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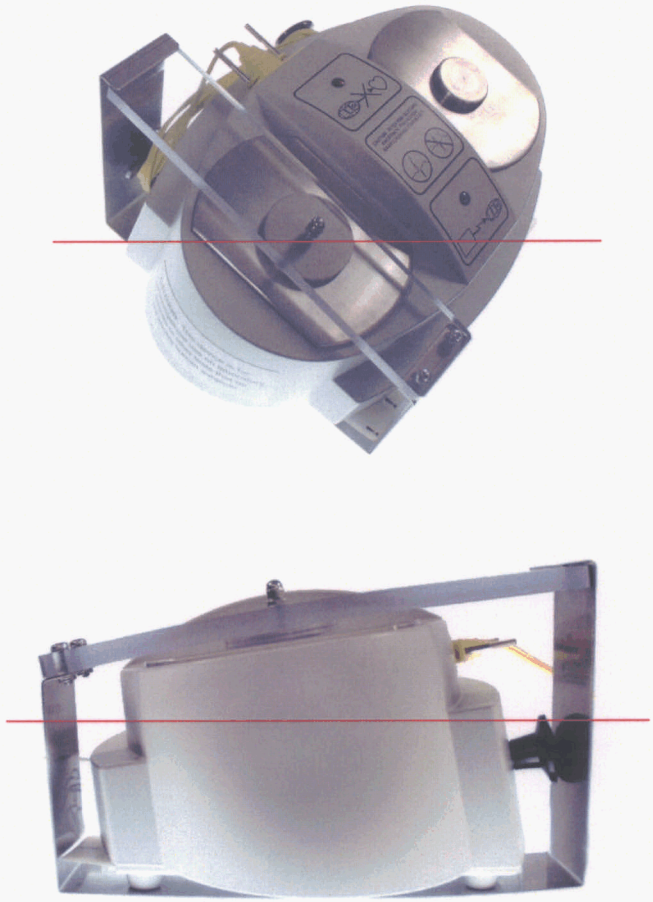

~~**Figure 6.** The EDIM maintenance test fixture shown properly installed to the Syncrus™ EDIM.~~

~~Set the hi-pot tester to output 4000 Volts AC. The EDIM right safety push button should not be depressed for this check.~~

~~Slowly raise the voltage to 4000 Volts AC and remain at that voltage for 1 minute. There should be no arcing or tripping of the hi-pot's limit detector and the current flow should be less than 33 mA.~~

~~8.Waveform verification~~

~~Test Setup – Part 1:~~

~~1. Connect the external defibrillator paddles to the defibrillator analyzer.~~
~~2. Connect the oscilloscope to the oscilloscope output jack on the defibrillator analyzer.~~
~~3. Set the defibrillator to 10 joules output.~~

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~~Use the oscilloscope to capture the waveform of the external defibrillator discharging directly into the defibrillator analyzer. Label this waveform "External Defibrillator Waveform".~~

~~Test Setup – Part 2:~~

~~1.Connect the Syncrus™ Cardioversion Extension Cable to the Syncrus™ EDIM.~~

~~2. Connect the Cardioversion Cable test adapters to the Syncrus™ Cardioversion Extension Cable.~~

~~3. Connect the test adapters to the defibrillator analyzer.~~

~~4. Connect the oscilloscope to the oscilloscope output jack on the defibrillator analyzer.~~

~~5. Set the external defibrillator to 360 joules output.~~

~~Discharge the external defibrillator into the Syncrus™ EDIM. Capture the output waveform of the EDIM with the oscilloscope. Label this waveform "Syncrus™ EDIM Waveform". Compare the two waveforms from Part 1 and 2 of this test. They should be very similar in shape, maximum voltage, and duration. If any voltage spikes or "noise" are present on the EDIM waveform that are not present on the external defibrillator waveform after the initial discharge of the external defibrillator, discontinue use of the Syncrus™ EDIM and contact Guidant Cardiac Surgery (Santa Clara, CA) for further instructions.~~

~~NOTE: There may be some voltage spikes or "noise" present in the external defibrillator waveform that are not present on the Syncrus™ EDIM output waveform. This is a normal condition.~~

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12.0 TROUBLESHOOTING

12.1 Internal Atrial Cardioversion

1. Recheck all electrical connections
2. If the atrial fibrillation episode was not terminated *and* no shock impulse was seen on the ECG monitor *and* the green indicator light on the ~~Synerus~~SYNCRUS™ EDIM did not flash while the shock was delivered *and* the patient did not experience an involuntary thoracic muscle spasm, then it is likely that that the external defibrillator's energy did not reach the patient.
3. If the red indicator light on the ~~Synerus~~SYNCRUS™ EDIM flashed during the cardioversion attempt, the internal voltage protection circuit prevented the shock from reaching the patient. Reduce the energy setting on the external defibrillator and attempt another cardioversion or substitute another external defibrillator and try another cardioversion.
4. Deliver another cardioversion shock, while watching the ECG monitor for a shock.
5. If a cardioversion shock was observed on the monitor and the atrial fibrillation episode does not terminate, even briefly, a Heart Wire electrode may be dislodged. Discontinue ~~Synerus~~SYNCRUS™ atrial cardioversion therapy and revert to traditional therapy.
6. If no cardioversion shock is observed on the monitor and the atrial fibrillation episode is not terminated, the ~~Synerus~~SYNCRUS™ EDIM or Cardioversion Extension Cable may be defective. If a spare unit is available, replace the ~~Synerus~~SYNCRUS™ EDIM. If the same problem persists, replace the Cardioversion Extension Cable. Ask your Biomedical Engineering Department to test the ~~Synerus~~SYNCRUS™ EDIM and Cardioversion Extension Cable per the maintenance procedure in the *Maintenance and Calibration* section.

12.2 Temporary Cardiac Pacing and ECG Sensing

1. Check the settings of the external pacemaker.
2. Recheck all electrical connections.
3. Check the batteries in the external pacemaker.
4. Check that the proper Heart Wire pacing connector pins are connected to the proper input(s) on the external pacemaker.
5. Check that the polarity of the pacing connector pins is correct and consistent to the external pacemaker. If incorrect, reverse the connectors between the Heart Wires and the patient cable.
6. Try using a different pacing cable.
7. Try connecting to a different (positive) electrode. If this corrects the situation, the problem lies either within the pacing wire or at the pacing electrode's connection to the heart. You can either continue pacing with this configuration, or install an indifferent electrode on the patient's skin.

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8. Try connecting to a different stimulation (negative) electrode. If this corrects the situation, the problem lies either within the pacing wire or at the pacing electrode's connection to the heart. This situation cannot be corrected on this patient.

13.0 WARRANTY AND SERVICE

The ~~Syncrus~~SYNCRUS™ External Defibrillator Interface Module (EDIM) is warranted for one (1) year from the date of purchase. If the device fails to perform as intended during the warranty period, return it to Guidant Cardiac Surgery (Santa Clara, CA) for a replacement unit.

The ~~Syncrus~~SYNCRUS™ EDIM is not user serviceable. Do not attempt to open the module case. Warranty is void if the tamper resistant seal on the EDIM is broken. Proper device function must be verified ~~monthly~~ by your Biomedical Engineering or Equipment Maintenance Department. Refer to the section on *Maintenance and Calibration* for maintenance procedures.

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~~Fax: (888) 899-2874~~

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May be manufactured under one or more of the following patents: 5,674,253; 5,766,224; and RE 35,779.

P/N ~~PPL2036625 Rev. A~~PPL2038200 Rev. A

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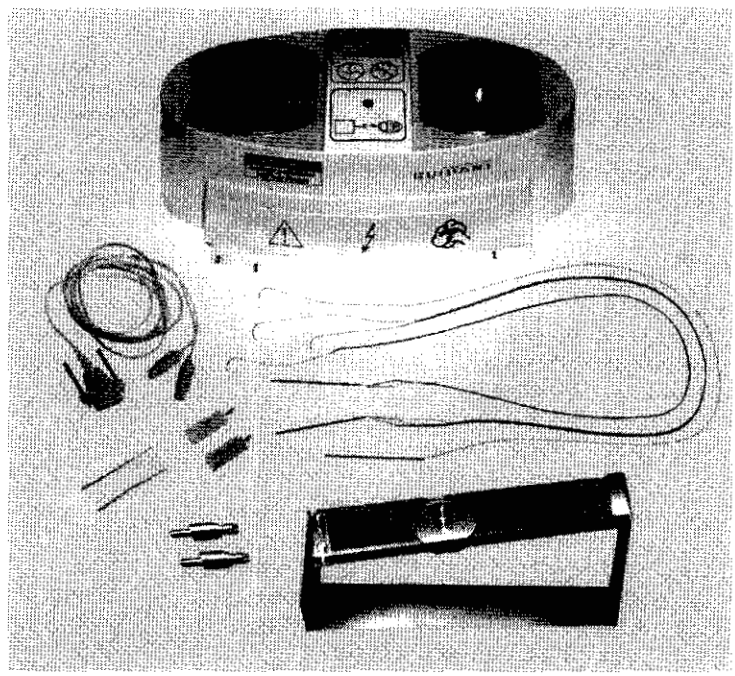
Guidant SYNCRUS™ System

Post Cardiac Surgery Atrial Cardioversion
And
Temporary Cardiac Pacing



OPERATOR'S MANUAL

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1.0 SYNCRUS™ ATRIAL CARDIOVERSION THERAPY

The Guidant SYNCRUS™ System provides low energy internal cardioversion therapy to treat postoperative atrial fibrillation in conjunction with temporary cardiac pacing and ECG sensing.

During cardiac surgery, SYNCRUS™ Heart Wires are attached to appropriate locations on the patient's myocardium using standard surgical technique. The proximal ends of the SYNCRUS™ Heart Wires are externalized through the patient's chest wall and connected to appropriate cables attached to the SYNCRUS™ External Defibrillator Interface Module (EDIM) and a temporary external pacemaker.

In the event of post cardiac surgery atrial fibrillation, the clinician performs a routine synchronized electrical cardioversion, except that the external defibrillator paddles rest on the paddle plates of the SYNCRUS™ EDIM, rather than on the patient's chest. The patient is sedated at the physician's discretion. The *maximum* energy level administered through the SYNCRUS™ EDIM to the SYNCRUS™ Heart Wires is approximately 11 joules directly to the patient's myocardium, compared to 360 joules if delivered transthoracically with external defibrillator paddles.

The SYNCRUS™ Heart Wires are designed to also provide temporary cardiac pacing and ECG sensing before and after internal atrial cardioversion without requiring the physician to rearrange cables and wires.

Carefully read all instructions prior to use. Observe all warnings and precautions noted throughout these instructions.

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2.0 SYSTEM DESCRIPTION

The Guidant SYNCRUS™ System provides low energy internal cardioversion therapy to treat postoperative atrial fibrillation via SYNCRUS™ Heart Wires placed directly on the patient's heart. The System's functions also include temporary atrial and ventricular pacing and ECG sensing capabilities.

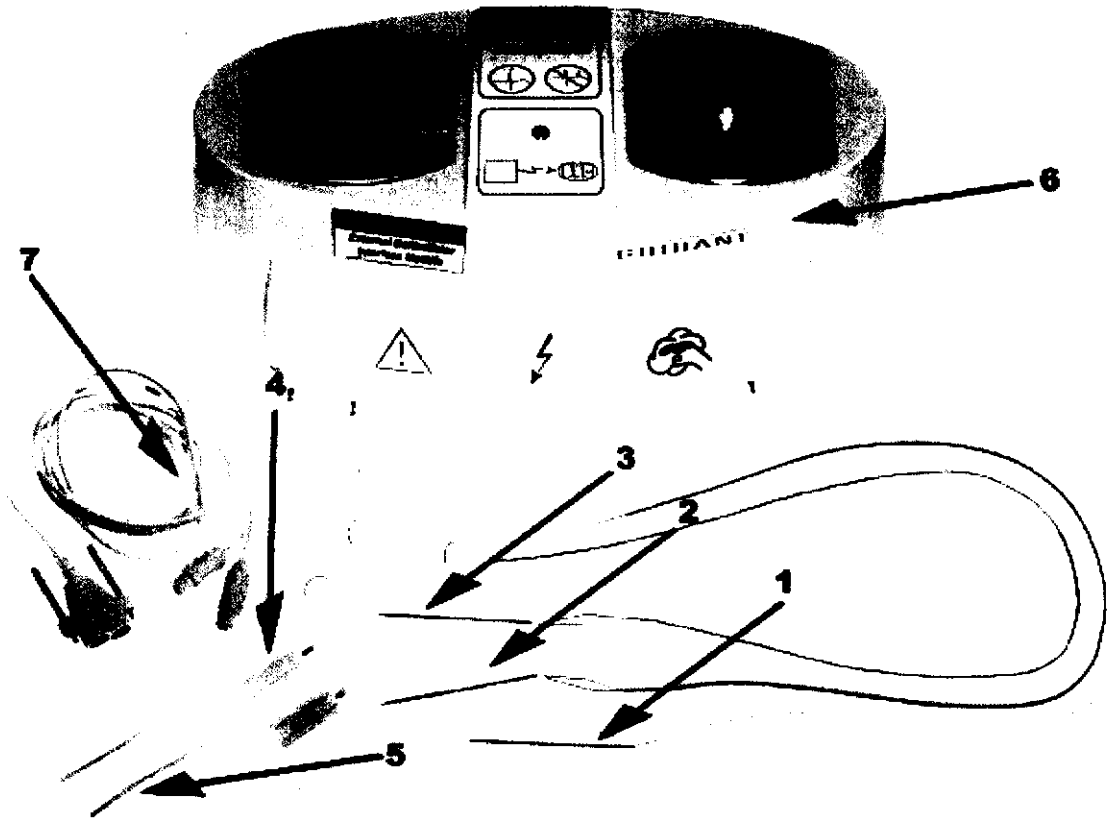

Figure 1. Guidant SYNCRUS™ System

1. Left Atrial Heart Wire (unipolar)
2. Right Atrial Heart Wire (tripolar)
3. Ventricular Heart Wire (bipolar)
4. Yellow Cardioversion Connectors
5. Protective Tubings
6. External Defibrillator Interface Module (EDIM)
7. Cardioversion Extension Cable

Note: The Heart Wires (with yellow cardioversion connectors and protective tubings) are sold separately from the EDIM and Cardioversion Extension Cable.

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The SYNCRUS™ System consists of the following components:

- Three single use Heart Wires that are attached to myocardial tissue of the left atrium, right atrium, and right or left ventricle during cardiac surgery. The Heart Wires transmit low energy shocks to the patient's heart for electrical atrial cardioversion. The Heart Wires also provide temporary cardiac pacing and ECG sensing capabilities.

- A reusable External Defibrillator Interface Module (EDIM), which interfaces between a compatible low energy external defibrillator and the Heart Wires. The EDIM reduces the output energy from the defibrillator to a low energy shock delivered through the Heart Wires.

- A reusable Cardioversion Extension Cable that connects the Heart Wires to the EDIM.

The SYNCRUS™ System components must be used in conjunction with a compatible low energy external defibrillator, an external pacemaker, and pacing cables that connect the Heart Wires to the external pacemaker. The user supplies the external defibrillator, external pacemaker, and pacing cables.

Refer to section on *Required User Supplied Components* for a list of compatible external defibrillators, external pacemakers and pacing cables that have been tested with the Guidant SYNCRUS™ System.

3.0 INDICATIONS FOR USE

The Guidant SYNCRUS™ Internal Cardioversion System is indicated for use in post-operative cardiac surgery patients who require temporary atrial or ventricular pacing/sensing and/or atrial cardioversion.

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4.0 COMPONENTS DESCRIPTION

4.1 SYNCRUS™ Heart Wires

The SYNCRUS™ Heart Wires consist of three myocardial wires: a unipolar Heart Wire for the left atrium, a tripolar Heart Wire for the right atrium, and a bipolar Heart Wire for the left or right ventricle. The SYNCRUS™ Heart Wires are for single use only and should not be reused or resterilized.

The Left Atrial Heart Wire is a unipolar wire with a cardioversion electrode for atrial cardioversion. The Right Atrial Heart Wire is tripolar with one electrode for atrial cardioversion (that is used in conjunction with the cardioversion electrode on the Left Atrial Heart Wire) and a bipolar pacing lead with one electrode for atrial pacing and ECG sensing and a second electrode for grounding. The Ventricular Heart Wire is a bipolar pacing lead with one electrode for ventricular pacing and ECG sensing and a second electrode for grounding.

The SYNCRUS™ Heart Wire electrodes are placed on appropriate locations in the myocardium and the proximal ends of the Heart Wires are passed through the patient's chest wall and skin using a straight thoracic needle attached to each Heart Wire. The thoracic needles are cut off after externalization and yellow cardioversion connectors are attached to the cardioversion lead (yellow wire) on the Left and Right Atrial Heart Wires. The pacing connector pins on the Right Atrial Heart Wire (black and blue wires) and Ventricular Heart Wire (black and white wires) are covered with a protective tubing. The cardioversion and pacing connectors are usually taped to the patient's body until needed. After the SYNCRUS™ Heart Wires are no longer needed (usually just prior to patient discharge from the hospital), the Heart Wires are removed from the patient with gentle and continuous external traction.

To perform internal atrial cardioversion, the cardioversion wires on the Left and Right Atrial Heart Wires must be connected to the SYNCRUS™ Cardioversion Extension Cable and EDIM. The hospital must supply a compatible low energy external defibrillator.

To perform atrial and ventricular pacing and ECG sensing, the pacing connector pins on the Right Atrial Heart Wire and Ventricular Heart Wire must be connected to the appropriate pacing cables and an external pacemaker. The hospital must supply both the external pacemaker and pacing cables.

4.2 SYNCRUS™ External Defibrillator Interface Module (EDIM)

The SYNCRUS™ EDIM is a non-sterile and reusable device that allows the energy from a compatible external defibrillator to be transmitted through the Left and Right Atrial Heart Wires directly to the patient's myocardium.

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To perform internal electrical cardioversion, external defibrillator paddles are placed on the paddle plates and safety push button of the SYNCRUS™ EDIM. The EDIM reduces the output energy from an external defibrillator by approximately 97% and delivers a low energy internal cardioversion shock to the left and right atrial myocardium. For every 100 joules input from the external defibrillator, approximately 3 joules are actually delivered to the patient's heart.

4.3 SYNCRUS™ Cardioversion Extension Cable

The SYNCRUS™ Cardioversion Extension Cable is a reusable cable that connects the cardioversion connectors on the Left and Right Atrial Heart Wires to the SYNCRUS™ EDIM.

4.4 EDIM Maintenance Test Fixture and Cardioversion Cable Test Adapters

The EDIM maintenance test fixture and Cardioversion Cable test adapters are used to perform the full maintenance test on the Guidant SYNCRUS™ System as described in the *Maintenance and Calibration* section.

5.0 MAINTAINING SYSTEM EFFECTIVENESS

5.1 SYNCRUS™ Heart Wires

- The SYNCRUS™ Heart Wires are for single use only. DO NOT RESTERILIZE. DO NOT REUSE.

5.2 SYNCRUS™ EDIM and Cardioversion Extension Cable

- The EDIM should only be used with a compatible low energy external defibrillator (see section on *Required User Supplied Components*).
- Perform functional checks on the SYNCRUS™ EDIM as described in the *Maintenance and Calibration* section.
- Do not use conductive gel or paste on the external defibrillator paddles or SYNCRUS™ EDIM paddle plates.
- Do not immerse the SYNCRUS™ EDIM or Cardioversion Extension Cable in liquid.

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6.0 REQUIRED USER SUPPLIED COMPONENTS

To apply SYNCRUS™ atrial cardioversion therapy, the user must supply a compatible low energy external defibrillator, an external pacemaker, and the appropriate pacing cables. Below is a list of compatible external defibrillators, pacemakers and pacing cables that have been tested with the Guidant SYNCRUS™ System.

External pacemaker:

- Medtronic Dual-Chamber Model 5388 External (Temporary) Pulse Generator
- Medtronic Single-Chamber Model 5348 External (Temporary) Pulse Generator

Pacing cables:

- Medtronic 5433A Reusable EPG atrial safety cables
- Medtronic 5433V Reusable EPG ventricular safety cables
- Medtronic 5487 6 ft. sterile disposable patient safety cables

Biphasic, low energy external defibrillator with R-wave synchronization capability and external paddles:

- Medtronic Physio-Control LIFEPAK® 12 and LIFEPAK® 20 defibrillators
- Agilent (Philips Medical) Heartstream™ or HeartStart XL and XLT defibrillators

Note: The Zoll M Series biphasic defibrillator will not discharge energy into the SYNCRUS™ EDIM.

Monophasic, low energy external defibrillator with R-wave synchronization capability:

- Medtronic Physio-Control LIFEPAK® 9, 10, 11, 12 defibrillators
- Agilent (Philips Medical) CodeMaster™ defibrillator
- Zoll M Series defibrillator with monophasic capability

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7.0 WARNINGS

- The SYNCRUS™ System is not compatible with all low energy external defibrillators. See section on *Required User Supplied Components* for a list of compatible external defibrillators.
- Perform synchronized cardioversion only. Unsynchronized shocks may result in ventricular fibrillation, causing patient injury or death.
- The SYNCRUS™ Heart Wires provide a direct path for electrical current flow to the patient's heart. DO NOT touch the heart wire leads or the EDIM (when connected to the Heart Wires) with your bare hands or with anything that may deliver static (electrostatic discharge). Avoid the possibility of unintentional contact between the wire leads, including extension cable, and any equipment used as well as any conductive surface contact. Line powered equipment used in the vicinity of the patient must be properly grounded.
- The SYNCRUS™ EDIM and Cardioversion Extension Cable are designed solely for use with the SYNCRUS™ Heart Wires.
- DO NOT connect the Heart Wires to any equipment other than that specified in these instructions and the SYNCRUS™ System Operator's Manual. Patient injury or death may result.
- If the SYNCRUS™ EDIM has been dropped, perform a FULL maintenance test as described in the SYNCRUS™ System Operator's Manual (*Maintenance and Calibration* section) prior to using the EDIM again. Dropping the EDIM may damage internal components, possibly rendering the device inoperable or out of specification.
- Wire fracture, dislodgement, abrasion and/or an incomplete connection can cause a periodic or continual loss of pacing and sensing, possibly resulting in inappropriate delivery of conversion therapy. Connect the pacing connector pins for baseline measurements to a pacing system analyzer (PSA) or temporary pacemaker and evaluate the placement by determining R-wave amplitude, pacing threshold, and pacing lead impedance. Secure the SYNCRUS™ Heart Wires by taping the cardioversion connectors and pacing pins to the patient's body until needed.
- Although pliable, the lead body is not designed to tolerate excessive flexing, bending, or tension. This could cause structural weakness, conductor discontinuity, and/or lead dislodgement. Secure the cardioversion connectors and pacing pins to the patient's body until needed. Minimize manipulation of the Heart Wires.
- Equipment and accessories connected to the Guidant SYNCRUS™ System shall comply with IEC-601-1, type CF.

8.0 PRECAUTIONS

- SYNCRUS™ Heart Wires are for single use only. DO NOT RESTERILIZE. DO NOT REUSE.

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- The SYNCRUS™ Heart Wires are gamma sterilized after packaging. When they are received, they are sterile and ready for use. Should the seal or package be wet, damaged, punctured, or if the seal is broken, do not use or attempt to resterilize. Contact the local Guidant representative.
- Pre-clinical testing supports the use of this device up to 7 cardioversion attempts. Cardioversion attempts ranged from 1 to 9 attempts in clinical trials. Physicians should treat patients in accordance with judgment and experience. Assessment of the patient's overall condition and physician discretion should dictate the number of attempts to treat.
- It is recommended that defibrillation equipment and a pacing sensor system analyzer (PSA) or temporary pacemaker be readily available during lead placement and removal.

9.0 ATTACHING THE SYNCRUS™ HEART WIRES TO THE MYOCARDIUM

1. Attach the SYNCRUS™ Heart Wires to the patient's myocardial surface during cardiac surgery in the following order and before the patient's chest is closed. The described fixation techniques are furnished for informational purposes only. The physician may choose to vary the fixation technique in accordance with judgment and experience. The selected fixation technique of each Heart Wire placement should always allow for ease of extraction through gentle traction. Proper surgical procedures and techniques are the responsibility of the medical professional.

   Left Atrial Heart Wire (unipolar)

   - *Cardioversion Electrode (yellow wire)*: Use the attached curved needle to affix the cardioversion electrode to the left atrial myocardium. After the cardioversion electrode is affixed (see Figures 2a and 3a), cut off the curved needle and discard it. Place a slight bend or kink at the end of the electrode.

   Right Atrial Heart Wire (tripolar)

   - *Cardioversion Electrode (yellow wire)*: Use the attached curved needle to affix the cardioversion electrode to the right atrial myocardium. After the cardioversion electrode is affixed (see Figures 2b and 3b), cut off the curved needle and discard it. Place a slight bend or kink at the end of the electrode.

     Placement should be made to maximize the atrial muscle mass between the right atrial cardioversion electrode and the left atrial cardioversion electrode.

   - *Pacing Electrodes (black and blue wires):* Use the attached curved needle to affix the bipolar pacing electrodes to the right atrial myocardium. For optimal cardiac pacing, bury both the pacing electrode and bullet in the myocardium. After the pacing electrodes are affixed (see Figures 2b and 3b), cut off the needle and discard it. Place a slight bend or kink at the end of the pacing electrode.

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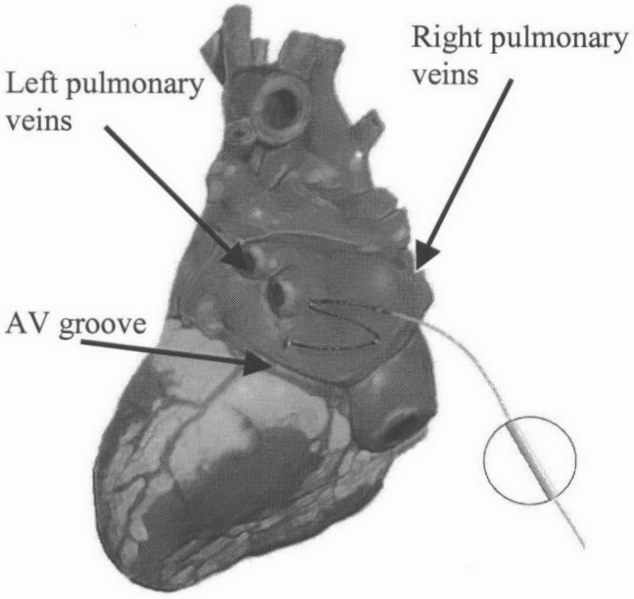
- Ventricular Heart Wire (bipolar)
  Pacing Electrodes (black and white wires): Use the attached curved needle to affix the bipolar pacing electrodes into the myocardial tissue of either the right or left ventricle. For optimal cardiac pacing, bury both the pacing electrode and bullet in the myocardium. After the pacing electrodes are affixed (see Figures 2c and 3c), cut off the curved needle and discard it. Place a slight bend or kink at the end of the pacing electrode.

Figures 2 through 3 illustrate two examples of Heart Wire placement techniques as used in clinical practice.

Figure 2. SYNCRUS™ Heart Wire Placement Technique A (used in clinical trials in Europe)



2a. Left Atrial Wire Placement
Figure shows the cardioversion electrode placed in an "S" pattern between the atrioventricular (AV) groove and the left and right pulmonary veins.

(Lateral-posterior view)

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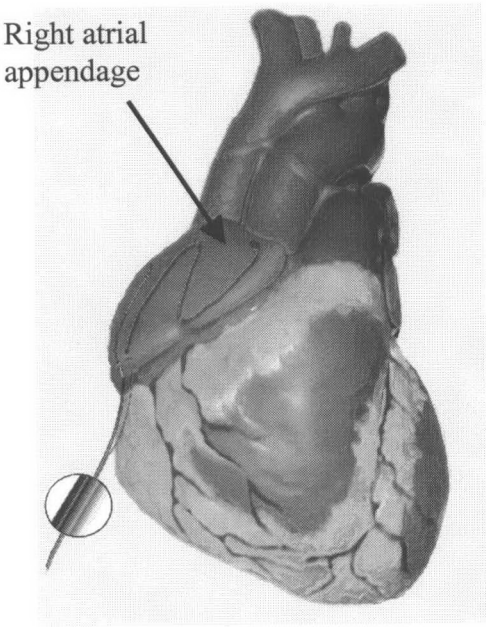
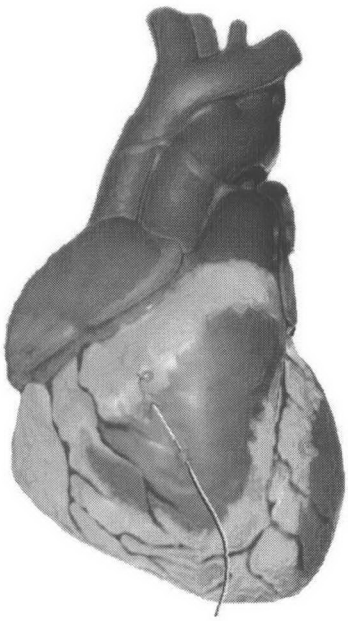


2b. Right Atrial Wire Placement
Figure shows the cardioversion electrode placed in an "S" pattern on the right atrial appendage.

The pacing electrode and bullet are shown placed on the right atrial myocardium.

(Anterior view)



2c. Ventricular Wire Placement
Figure shows the pacing electrode and bullet placed on the right ventricle.

(Anterior view)

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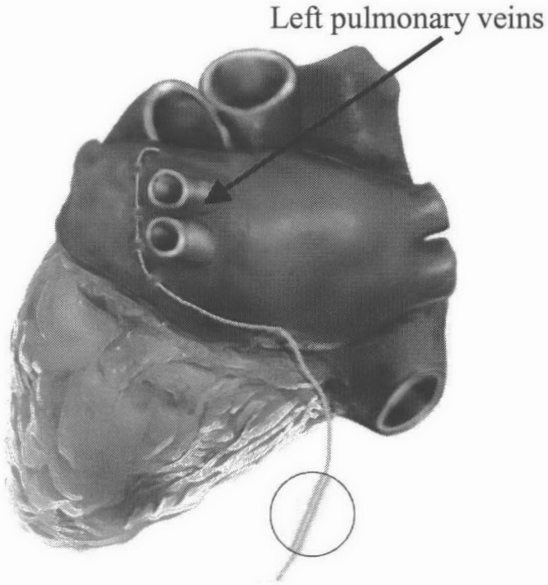
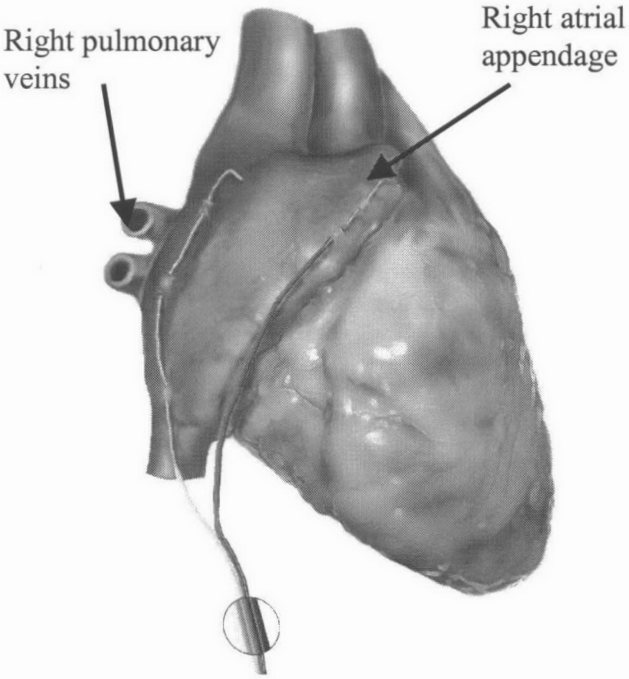
Figure 3. SYNCRUS™ Heart Wire Placement Technique B



3a. Left Atrial Wire Placement
Figure shows the cardioversion electrode placed within 5 mm anterior of the left pulmonary veins.

(Lateral-posterior view)



3b. Right Atrial Wire Placement
Figure shows the cardioversion electrode placed by the inferior vena cava and up towards the right pulmonary veins within 5 mm of the SA node.

The pacing electrode and bullet are shown placed on the right atrial appendage.

(Lateral view)

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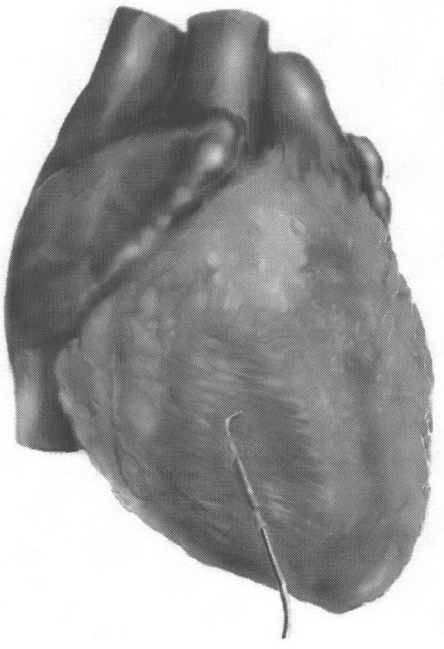

3c. Ventricular Wire Placement
Figure shows the pacing electrode and bullet placed on the right ventricle.

(Anterior view)

2. Once the cardioversion and pacing electrodes have been affixed to the patient's heart, visualize the paths that the Heart Wires will travel as they are extracted.

3. Use the straight thoracic needle on the proximal end of each SYNCRUS™ Heart Wire to externalize the Heart Wires through the chest wall and skin. Once the Heart Wires are externalized, cut off the thoracic needles, maximizing the exposed cardioversion leads. Discard the thoracic needles appropriately.

4. Attach the yellow cardioversion connectors provided with the SYNCRUS™ Heart Wires to the yellow cardioversion wires on the Left and Right Atrial Heart Wires. This is done by threading the Heart Wire cardioversion lead through the pinhole on the backside of the connector and pushing the pin into the connector. Make sure there is good electrical contact between the Heart Wire cardioversion lead and the yellow cardioversion connector.

5. Connect the pacing connector pins for baseline measurements to a pacing system analyzer (PSA) or temporary pacemaker and evaluate the placement by determining R-wave amplitude, pacing threshold, and pacing lead impedance.

6. Cover the pacing connector pins on the Right Atrial Heart Wire (black and blue wires) and Ventricular Heart Wire (black and white wires) with the protective tubings provided with the SYNCRUS™ Heart Wires. Secure the SYNCRUS™ Heart Wires by taping the cardioversion connectors and pacing pins to the patient's body until needed.

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7. When SYNCRUS™ atrial cardioversion therapy is needed, connect the yellow cardioversion connectors to the SYNCRUS™ Cardioversion Extension Cable. Ensure that the Cable is connected to the EDIM. Apply internal atrial cardioversion by placing external defibrillator paddles on the paddle plates of the SYNCRUS™ EDIM and deliver energy. The EDIM will attenuate the external defibrillator output energy by approximately 97% (for example, a 100-joule external shock will result in an approximate 3-joule internal cardioversion shock to the heart).

8. When temporary cardiac pacing and ECG sensing are needed, remove the protective tubing from the pacing connector pins. Connect the pacing connector pins into the appropriate pacing cables. Ensure that the pacing cables are connected to an external pacemaker. Administer cardiac pacing therapy.

9. To remove the SYNCRUS™ Heart Wires, remove any tape holding the Heart Wires in place. Apply gentle and continuous external traction to remove the Heart Wires from the patient. Special care should be taken when removing the lead from the atrium, due to the relatively thin atrial wall.

10. Discard the three externalized Heart Wires appropriately.

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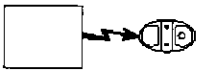
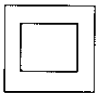
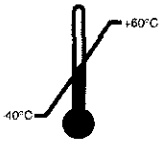
10.0 DEFINITION OF SYMBOLS

Below is a description of the symbols used in this manual and on the Guidant SYNCRUS™ System labels and packaging.

	WARNING: **Shock hazard**. Hazardous voltage may be present. Do not touch the paddle plates when the device is connected to the patient.
	WARNING: Read Instructions for Use.
	WARNING: Do not shock on T-wave. Synchronize shock with patient's R-wave.
	(Green indicator flashes): Energy has been transmitted from the external defibrillator to the SYNCRUS™ EDIM.
	(Red indicator flashes): Overvoltage condition in SYNCRUS™ EDIM. No energy was transmitted to patient. Refer to the Operator's Manual.
	Clean paddle plates before each use with a 70% isopropyl alcohol wipe.
	Type CF equipment.
	Class II equipment.
	Reference information; please read.
	Store at temperature between -40°C and 60°C.

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11.0 MAINTENANCE AND CALIBRATION

The SYNCRUS™ EDIM is a passive electrical device that relies on a user supplied external defibrillator for its power source. There are no user serviceable parts inside. This maintenance procedure is intended for the use of the hospital biomedical engineering department to verify proper function of the device and its safety features. If the device exhibits any discrepancies in any of these periodic checks, discontinue use of the device at once and contact Guidant Cardiac Surgery (Santa Clara, CA) for return instructions. **All maintenance procedures requiring an external defibrillator should be conducted with a compatible external defibrillator (see section on *Required User Supplied Components* for compatible defibrillators).**

11.1 Daily Maintenance

It is recommended that the following maintenance procedure be performed on a daily basis to ensure proper function of the SYNCRUS™ EDIM.

CAUTION: Perform all maintenance **BEFORE** connecting the SYNCRUS™ EDIM to the patient.

1. Clean the paddle plates and safety push button (see Figure 4) with a 70% isopropyl alcohol wipe before each use. A buildup of dirt on these conductive surfaces can cause degradation of electrical conduction and can prevent proper energy transmission.

2. Verify that the spring-loaded safety push button on the right side of the device can be depressed completely and that it returns to its extended position when the force is removed.

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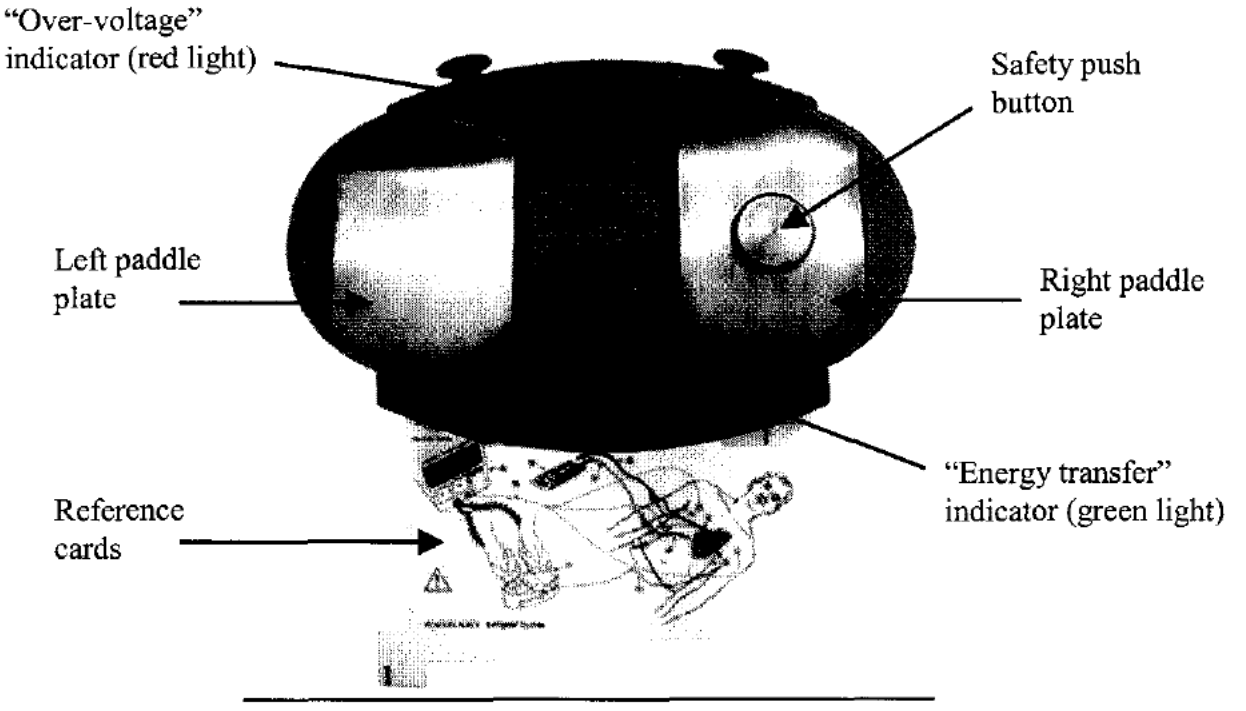
Figure 4. Top view of the SYNCRUS™ External Defibrillator Interface Module (EDIM)



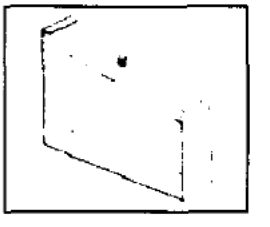
11.2 Full Maintenance

It is recommended that the following maintenance procedure be performed every 3 months to ensure proper function of the SYNCRUS™ EDIM. Also perform a full maintenance test if the EDIM has been dropped onto a hard surface prior to using the EDIM again.

11.2.1 Other Equipment

- External defibrillator (see section on *Required User Supplied Components* for compatible defibrillators)
- Ohmmeter
- Electrical safety analyzer or leakage current analyzer
- Defibrillator analyzer

- SYNCRUS™ EDIM maintenance test fixture (Guidant Cardiac Surgery order #TX-5200)



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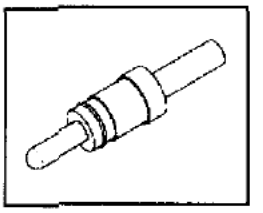
- SYNCRUS™ Cardioversion Cable test adapters – two required (Guidant Cardiac Surgery order #TX-5300). Hypertronics p/n YPN025-002G may also be used.



11.2.2 Full Maintenance Procedure

1. Check safety push button

   Verify that the spring-loaded safety push button on the right side of the SYNCRUS™ EDIM can be depressed completely and that it returns to its extended position when the force is removed.

2. Check safety switch isolation

   Equipment Used:
   - Ohmmeter
   - SYNCRUS™ Cardioversion Cable test adapters (2)

   Test Setup:
   2.1 Connect the SYNCRUS™ Cardioversion Extension Cable to the SYNCRUS™ EDIM.
   2.2 Connect the Cardioversion Cable test adapters to the output connectors on the SYNCRUS™ Cardioversion Extension Cable.
   2.3 Connect an ohmmeter lead to each of the test adapters.

   With the safety push button on the EDIM in its normal "up" position, the ohmmeter should read open (i.e. no continuity). With the safety push button depressed, the ohmmeter should read between 55 – 65 ohms.

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3. Check leakage current

Equipment Used:

- Electrical safety analyzer or leakage current analyzer
- SYNCRUS™ Cardioversion Cable test adapters (2)
- SYNCRUS™ EDIM maintenance test fixture

Note: the leakage current limits specified are for the SYNCRUS™ EDIM only. Any leakage current inherent in the leakage tester must be identified and deducted from the tester readout before applying the leakage current limits.

Patient Leakage Current (Mains on Paddle Plates)

Test Setup:

3.1 Connect the SYNCRUS™ Cardioversion Extension Cable to the SYNCRUS™ EDIM.

3.2 Connect the Cardioversion Cable test adapters to the output connectors on the SYNCRUS™ Cardioversion Extension Cable. Electrically short the two output terminals on the test adapters.

3.3 Connect the shorted test adapters to the ground terminal on the electrical safety or leakage current analyzer.

3.4 Attach the EDIM maintenance test fixture to the SYNCRUS™ EDIM. The test fixture should wrap around the right side of the EDIM and the latching mechanism should be located on the same side as the EDIM output terminals when properly installed for this test (see Figure 5).

3.5 Depress the SYNCRUS™ EDIM safety push button with the movable arm of the test fixture. Latch the movable arm and verify that the EDIM safety push button is fully depressed.

3.6 Make an electrical connection between the EDIM maintenance test fixture (via the lock nut) and an ECG terminal of the analyzer (i.e. RL connection).

3.7 Using the appropriate setting for the analyzer, apply either 120-volts or 240-volts (determined by the voltage powering the analyzer) to the EDIM. Descriptors for the analyzer test mode may include "Lead Isolation to Ground" or "Patient Lead Isolation Test".

The SYNCRUS™ EDIM shall not allow greater than 10μA leakage current when 240-volts are applied by the analyzer (or 5μA leakage current when 120-volts are applied) to the EDIM.

CAUTION: Do not depress the SYNCRUS™ EDIM safety push button with anything that is electrically common with your body. Serious injury may occur.

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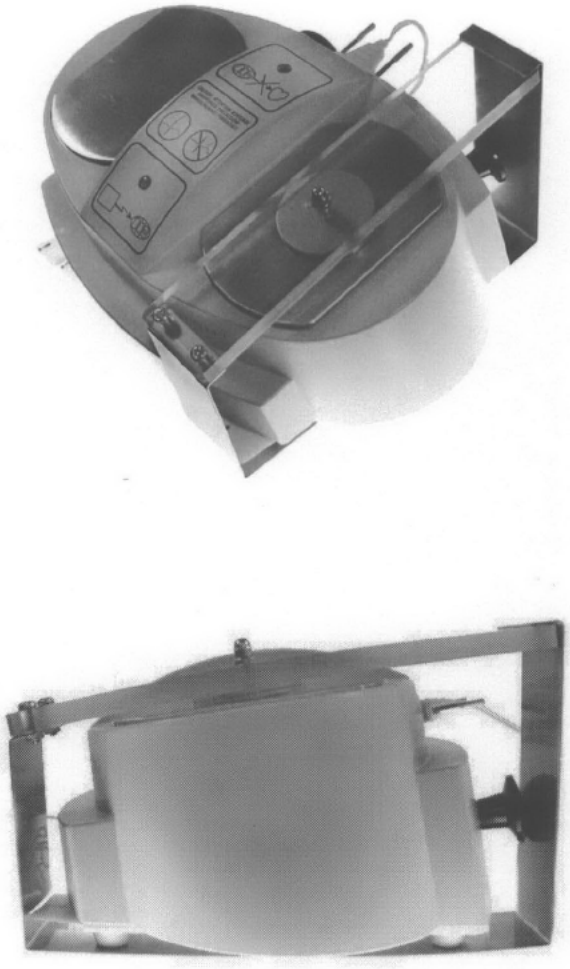
Figure 5. The EDIM maintenance test fixture shown properly installed on the right side of the SYNCRUS™ EDIM.



4. Check over-voltage protection

   Equipment Used:
   - External defibrillator

   Discharge a 360 joule shock from the external defibrillator into the SYNCRUS™ EDIM using the external paddles, but with no load connected to the output terminals.

   Note: This test verifies that the over-voltage protectors limit the output voltage from the EDIM to less than 800-volts. A monophasic external defibrillator needs to be

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used for this test in order to achieve a voltage greater than 800-volts at the voltage protectors when there is no load connected to the EDIM output.

The "over-voltage" indicator (red) on the top panel of the EDIM should flash momentarily. The "energy transfer" indicator (green) will also flash momentarily.

If the "energy transfer" indicator (green) does not flash, verify that the external defibrillator is delivering at least 360 joules by connecting a defibrillator analyzer directly to the defibrillator (remove the EDIM from the circuit). If the external defibrillator is delivering at least 360 joules, discontinue use of the EDIM. If the external defibrillator is not delivering at least 360 joules (and is set for 360 joules output), discontinue use of the external defibrillator.

5. Check "energy transfer" indicator

Equipment Used:
- External defibrillator
- Defibrillator analyzer
- SYNCRUS™ Cardioversion Cable test adapters (2)

Test Setup:
5.1 Connect the SYNCRUS™ Cardioversion Extension Cable to the SYNCRUS™ EDIM.
5.2 Connect the Cardioversion Cable test adapters to the output connectors on the SYNCRUS™ Cardioversion Extension Cable.
5.3 Connect the test adapters to the defibrillator analyzer.
5.4 Place the external defibrillator paddles on the SYNCRUS™ EDIM paddle plates. Assure that the right safety push button is fully depressed by the paddle.

Discharge a 100 joule shock from the external defibrillator into the SYNCRUS™ EDIM using the external paddles. The "energy transfer" indicator (green) will flash momentarily, while the "over-voltage" indicator (red) will not flash. Repeat the check with a 360 joule shock. The "energy transfer" indicator (green) will flash momentarily, while the "over-voltage" indicator (red) will not flash.

6. Check attenuation level

Equipment Used:
- External defibrillator
- Defibrillator analyzer
- SYNCRUS™ Cardioversion Cable test adapters (2)

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Test Setup:

6.1 Connect the SYNCRUS™ Cardioversion Extension Cable to the SYNCRUS™ EDIM.
6.2 Connect the Cardioversion Cable test adapters to the output connectors on the SYNCRUS™ Cardioversion Extension Cable.
6.3 Connect the test adapters to the defibrillator analyzer.
6.4 Place the external defibrillator paddles on the SYNCRUS™ EDIM paddle plates. Assure that the right safety push button is fully depressed by the paddle.

Use the defibrillator analyzer to verify the SYNCRUS™ EDIM attenuation level:

External defibrillator setting*	SYNCRUS™ EDIM output*
360 joule	10.4 - 11.1 joule

* If the external defibrillator does not deliver exactly 360 joules, the lower and upper SYNCRUS™ EDIM output energy limits may be calculated by multiplying the external defibrillator input energy by 0.0289 and 0.0309, respectively.

7. Check shock delivery delay

Equipment Used:

- External defibrillator
- Defibrillator analyzer
- SYNCRUS™ Cardioversion Cable test adapters (2)

Test Setup:

7.1 Connect the SYNCRUS™ Cardioversion Extension Cable to the SYNCRUS™ EDIM.
7.2 Connect the Cardioversion Cable test adapters to the output connectors on the SYNCRUS™ Cardioversion Extension Cable.
7.3 Connect the test adapters to the defibrillator analyzer.
7.4 Connect the defibrillator analyzer's normal sinus ECG output signal (60 bpm) to the synchronization input of the external defibrillator.
7.5 Place the external defibrillator paddles on the SYNCRUS™ EDIM paddle plates. Assure that the right safety push button is fully depressed by the paddle.

Using synchronized cardioversion mode, discharge a 200 joule shock from the external defibrillator into the SYNCRUS™ EDIM using the external paddles.

Use the defibrillator analyzer to measure actual delay time from the peak of the generated R-wave to the leading edge of the defibrillator discharge waveform, measured at the output of the SYNCRUS™ EDIM. The delay time must be less than 60 milliseconds.

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12.0 TROUBLESHOOTING

12.1 Internal Atrial Cardioversion

1. Recheck all electrical connections
2. If the atrial fibrillation episode was not terminated *and* no shock impulse was seen on the ECG monitor *and* the green indicator light on the SYNCRUS™ EDIM did not flash while the shock was delivered *and* the patient did not experience an involuntary thoracic muscle spasm, then it is likely that that the external defibrillator's energy did not reach the patient.
3. If the red indicator light on the SYNCRUS™ EDIM flashed during the cardioversion attempt, the internal voltage protection circuit prevented the shock from reaching the patient. Reduce the energy setting on the external defibrillator and attempt another cardioversion or substitute another external defibrillator and try another cardioversion.
4. Deliver another cardioversion shock, while watching the ECG monitor for a shock.
5. If a cardioversion shock was observed on the monitor and the atrial fibrillation episode does not terminate, even briefly, a Heart Wire electrode may be dislodged. Discontinue SYNCRUS™ atrial cardioversion therapy and revert to traditional therapy.
6. If no cardioversion shock is observed on the monitor and the atrial fibrillation episode is not terminated, the SYNCRUS™ EDIM or Cardioversion Extension Cable may be defective. If a spare unit is available, replace the SYNCRUS™ EDIM. If the same problem persists, replace the Cardioversion Extension Cable. Ask your Biomedical Engineering Department to test the SYNCRUS™ EDIM and Cardioversion Extension Cable per the maintenance procedure in the *Maintenance and Calibration* section.

12.2 Temporary Cardiac Pacing and ECG Sensing

1. Check the settings of the external pacemaker.
2. Recheck all electrical connections.
3. Check the batteries in the external pacemaker.
4. Check that the proper Heart Wire pacing connector pins are connected to the proper input(s) on the external pacemaker.
5. Check that the polarity of the pacing connector pins is correct and consistent to the external pacemaker. If incorrect, reverse the connectors between the Heart Wires and the patient cable.
6. Try using a different pacing cable.
7. Try connecting to a different (positive) electrode. If this corrects the situation, the problem lies either within the pacing wire or at the pacing electrode's connection to the heart. You can either continue pacing with this configuration, or install an indifferent electrode on the patient's skin.
8. Try connecting to a different stimulation (negative) electrode. If this corrects the situation, the problem lies either within the pacing wire or at the pacing electrode's connection to the heart. This situation cannot be corrected on this patient.

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13.0 WARRANTY AND SERVICE

The SYNCRUS™ External Defibrillator Interface Module (EDIM) is warranted for one (1) year from the date of purchase. If the device fails to perform as intended during the warranty period, return it to Guidant Cardiac Surgery (Santa Clara, CA) for a replacement unit.

The SYNCRUS™ EDIM is not user serviceable. Do not attempt to open the module case. Warranty is void if the tamper resistant seal on the EDIM is broken. Proper device function must be verified by your Biomedical Engineering or Equipment Maintenance Department. Refer to the section on *Maintenance and Calibration* for maintenance procedures.

Guidant Corporation
Cardiac Surgery
3200 Lakeside Drive
Santa Clara, CA 95054 USA
Toll-Free: (888) 880-2874 Fax: (888) 899-2874
Intl: (408) 845-3400 Intl: (408) 845-3568

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May be manufactured under one or more of the following patents: 5,674,253; 5,766,224; and RE 35,779.

P/N PPL2038200 Rev. A

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(b)(4) [redacted]

REPORT, REGRESSION DESIGN VERIFICATION TEST, BIPHASIC OPERATION, GRANITE

Drawing Number
(b)(4) [redacted]

Revision
A

Initial Approval	Date
Engineering	
Manufacturing Engineering	
Quality Assurance	
Customer	

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FORM: 914111, Rev D

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REVISION HISTORY

Rev	Change Number/Description	Date	Change Originator	Incorp by	Chkr
A	Initial release to Production	10/25/02	(b)(4)(b)(4)	(b)(4)	

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1. INTRODUCTION

1.1. Purpose

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[redacted]

1.2. Scope

(b)(4)

[redacted]

2. REFERENCE DOCUMENTS

(b)(4)

[redacted]

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3. SUMMARY OF TESTING

(b)(4)

[redacted]

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4. TEST RESULTS

4.1. Non-Compliances

(b)(4)

[redacted]

4.2. Summary of Results

Test	Result	Comment
(b)(4) [redacted]		

5. CONCLUSION

(b)(4)

[redacted]

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Appendix-A. Guidant Syncrus™ Product Specification Engineering Order

The following pages contain a copy of the Guidant Syncrus™ Product Specification change documentation.

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Appendix-C. Test Data Notebook

The following notebook (sheet 16) includes all test data obtained during the Design Verification Testing.

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4. [redacted] (b)(4)

WARNING! Cardiac defibrillators generate potentially dangerous voltages, which can be lethal if improperly handled by an untrained operator. Refer to the device manufacturer's operator or service manual for the specific device inspection requirements.

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GUIDANT *Syncrus™ System*

Post Cardiac Surgery Atrial Cardioversion and Temporary Cardiac Pacing

Atriale cardioversie en tijdelijke pacing na hartchirurgie

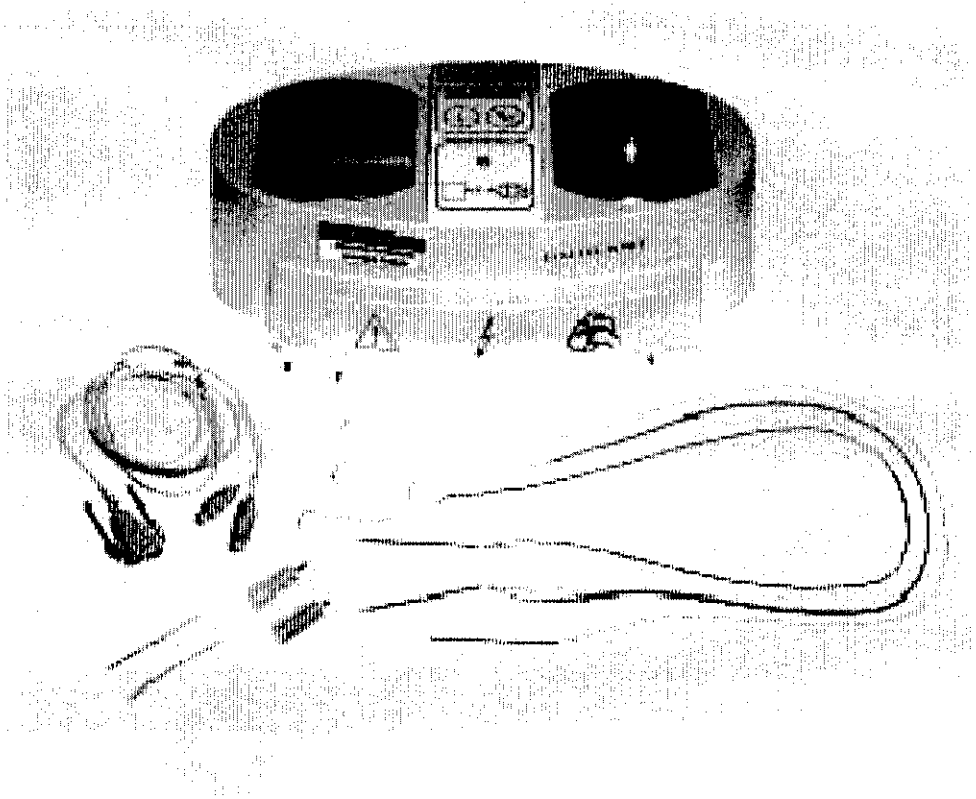
Cardioversion auriculaire en chirurgie postcardiaque et stimulation cardiaque temporaire

Atriale Elektrokonversion und temporäre Herzstimulation nach herzchirurgischen Eingriffen

Stimolazione cardiaca temporanea e cardioversione atriale post-intervento cardiochirurgico

心臓手術後の心房カルディオバージョンおよび一時的心臓ペーシング

Cardioversión auricular y estimulación cardiaca temporal tras cirugía cardiaca



INSTRUCTIONS FOR USE

ENGLISH / NEDERLANDS / FRANÇAIS / DEUTSCH / ITALIANO
日本語 / ESPAÑOL

GUIDANT

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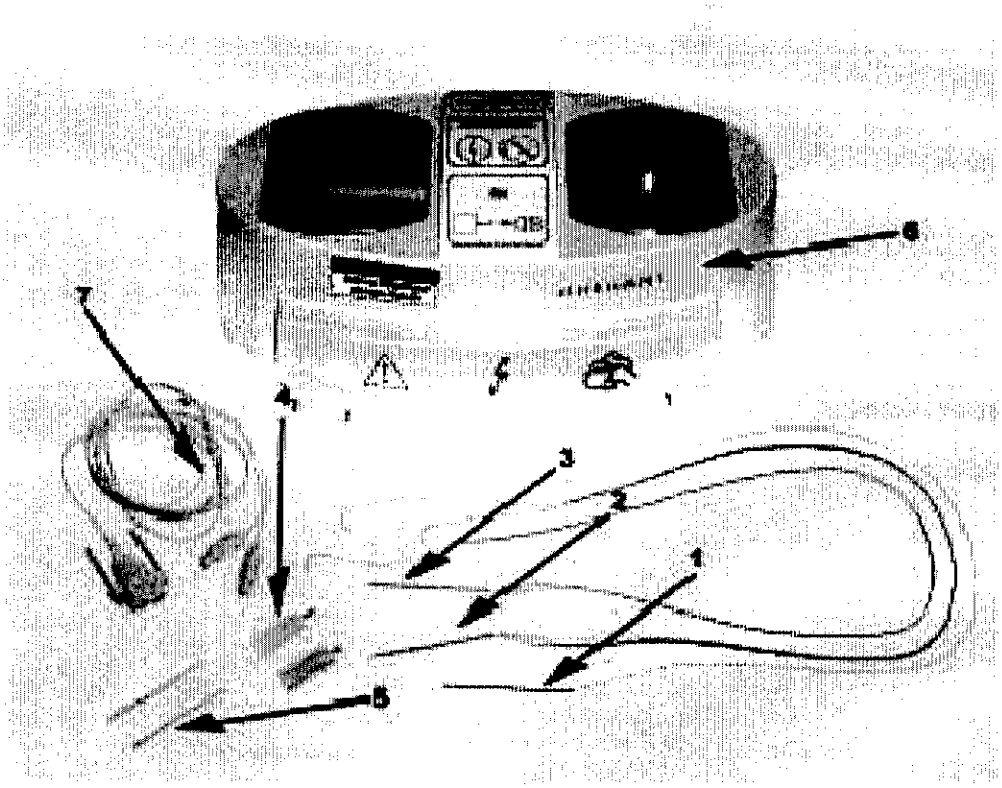

Figure 1.

Guidant Syncrus™ System

1. Left Atrial Heart Wire (unipolar)
2. Right Atrial Heart Wire (tripolar)
3. Ventricular Heart Wire (bipolar)
4. Yellow Cardioversion Connectors
5. Protective Tubings
6. External Defibrillator Interface Module (EDIM)
7. Cardioversion Extension Cable

Note: The Heart Wires (with yellow cardioversion connectors and protective tubings) are sold separately from the EDIM and Cardioversion Extension Cable.

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INSTRUCTIONS FOR USE

Carefully read all instructions prior to use. Observe all warnings and precautions noted throughout these instructions.

SYSTEM DESCRIPTION:
The Guidant Syncrus System provides low energy internal cardioversion therapy to treat postoperative atrial fibrillation via Syncrus Heart Wires placed directly on the patient's heart. The system functions also include temporary atrial and ventricular pacing and ECG sensing capabilities.

The Syncrus System consists of the following components:

- Three single use Heart Wires that are attached to the myocardial tissue of the left atrium, right atrium, and right or left ventricle during cardiac surgery. The Heart Wires transmit low energy shocks to the patient's heart for electrical atrial cardioversion. The Heart Wires also provide for temporary cardiac pacing and ECG sensing capabilities.
- A reusable External Defibrillator Interface Module (EDIM), which interfaces between a monophasic, low-energy, external defibrillator and the Heart Wires. The EDIM reduces the output energy from the defibrillator to a low energy shock delivered through the Heart Wires.
- A reusable Cardioversion Extension Cable that connects the Heart Wires to the EDIM.

The Syncrus System components must be used in conjunction with a monophasic, low energy external defibrillator, an external pacemaker, and pacing cables that connect the Heart Wires to the external pacemaker. The user supplies the external defibrillator, external pacemaker, and pacing cables.

INDICATIONS FOR USE:
The Guidant Syncrus™ Internal Cardioversion System is indicated for use in post-operative cardiac surgery patients who require temporary atrial or ventricular pacing/sensing and/or atrial cardioversion.

CONTRAINDICATIONS:
There are no known general contraindications for temporary post surgical heart wire leads. Patient anatomy and medical condition, however, should determine the use and implantation procedure.

WARNINGS:

- The Guidant Syncrus System is compatible with monophasic low energy external defibrillators only.
- Perform synchronized cardioversion only. Unsynchronized shocks may result in ventricular fibrillation, causing patient injury or death.
- The Syncrus Heart Wires provide a direct path for electrical current flow to the patient's heart. DO NOT touch the heart wire leads or the EDIM (when connected to the Heart Wires) with your bare hands or with anything that may deliver static (electrostatic discharge). Avoid the possibility of unintentional contact between the wire leads, including extension cable, and any equipment used as well as any conductive surface contact. Line powered equipment used in the vicinity of the patient must be properly grounded.
- The Syncrus EDIM and Cardioversion Extension Cable are designed solely for use with Syncrus Heart Wires.
- DO NOT connect the Heart Wires to any equipment other than that specified in these instructions and the Syncrus System Operator's Manual. Patient injury or death may result.

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- If the Syncrus System EDIM has been dropped onto a hard surface, perform a FULL maintenance test as described in the Syncrus System Operator's Manual (*Maintenance and Calibration* section) prior to using the EDIM again. Dropping the EDIM may damage internal components, possibly rendering the device inoperable or out of specification.
- Wire fracture, dislodgement, abrasion and/or an incomplete connection can cause a periodic or continual loss of pacing and sensing, possibly resulting in inappropriate delivery of conversion therapy. Connect the pacing connector pins for baseline measurements to a pacing system analyzer (PSA) and evaluate the placement by determining R-wave amplitude, pacing threshold, and pacing lead impedance. Secure the Syncrus Heart Wires by taping the cardioversion connectors and pacing pins to the patient's body until needed.
- Although pliable, the lead body is not designed to tolerate excessive flexing, bending, or tension. This could cause structural weakness, conductor discontinuity, and/or lead dislodgement. Secure the cardioversion connectors and pacing pins to the patient's body until needed. Minimize manipulation of the heart wires.
- Equipment and accessories connected to the Guidant Syncrus System shall comply with IEC-601-1, type CF.

PRECAUTIONS:

- Syncrus Heart Wires are for single use only. DO NOT RESTERILIZE. DO NOT REUSE.
- The Syncrus Heart Wires are gamma sterilized after packaging. When they are received, they are sterile and ready for use. Should the seal or package be wet, damaged, punctured, or if the seal is broken, do not use or attempt to resterilize. Contact the local Guidant representative.
- Pre-clinical testing supports the use of this device up to 7 cardioversion attempts. Cardioversion attempts ranged from 1 to 9 attempts in clinical trials. Physicians should treat patients in accordance with judgment and experience. Assessment of the patient's overall condition and physician discretion should dictate the number of attempts to treat.
- It is recommended that defibrillation equipment and a pacing sensor system analyzer (PSA) be readily available during lead placement and removal.

INSTRUCTIONS FOR USE:

1. Attach the Syncrus Heart Wires to the patient's myocardial surface during cardiac surgery in the following order and before the patient's chest is closed. The described fixation technique is furnished for informational purposes only. The physician may choose to vary the fixation technique in accordance with judgment and experience. The selected fixation technique of each Heart Wire placement should always allow for ease of extraction through gentle traction. Proper surgical procedures and techniques are the responsibility of the medical professional. Figures 2 through 4 illustrate heart wire placement as performed in clinical trials.

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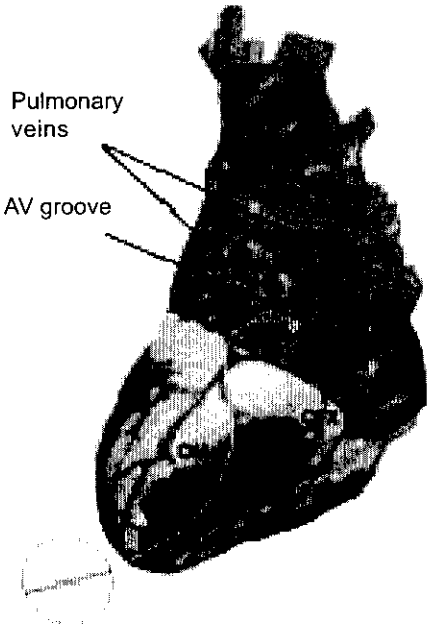

Figure 2.
Syncrus Left Atrial Heart Wire Placement

Left Atrial Heart Wire (unipolar)

- *Cardioversion Electrode (yellow wire):* Use the attached curved needle to affix the cardioversion electrode to the left atrial myocardium on the atrioventricular (AV) groove between the left and right pulmonary veins in an "S" pattern as illustrated in Figure 2 for optimal results. After the cardioversion electrode is affixed, cut off the curved needle and discard it. Place a slight bend or kink at the end of the electrode.

Anterior view

Figure 3.
Syncrus Right Atrial Heart Wire Placement

Right Atrial Heart Wire (tripolar)

- *Cardioversion Electrode (yellow wire):* Use the attached curved needle to affix the cardioversion electrode into the right atrial myocardium in an "S" pattern as shown in Figure 3 for optimal results. After the cardioversion electrode is affixed, cut off the curved needle and discard it. Place a slight bend or kink at the end of the electrode.
- Placement should be made to maximize the atrial muscle mass between the right atrial cardioversion electrode and the left atrial cardioversion electrode.
- *Pacing Electrode (black and blue wires):* Use the attached curved needle to affix the bipolar pacing electrodes into the right atrial myocardium. For optimal cardiac pacing, bury both the anode and cathode in the myocardium. After the pacing electrodes are affixed, cut off the needle and discard it. Place a slight bend or kink at the end of the anode electrode.

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Anterior view

Figure 4.
Syncrus Ventricular Heart Wire Placement

Ventricular Heart Wire (bipolar)

- *Pacing Electrodes (black and white wires):* Use the attached curved needle to affix the bipolar pacing electrodes into the myocardial tissue of either the right or left ventricle as illustrated in Figure 4 for optimal results. The positive pacing electrode (anode) is attached to the needle, while the negative electrode (cathode) is contained in the 4 mm long bullet. For optimal cardiac pacing, bury both the anode and cathode in the myocardium. After pacing electrodes are affixed, cut off the curved needle and discard it. Place a slight bend or kink at the end of the anode electrode.

2. Once the cardioversion and pacing electrodes have been affixed to the patient's heart, visualize the paths that the Heart Wires will travel as they are extracted.
3. Use the straight needle on the proximal end of each Syncrus Heart Wire to externalize the Heart Wires through the chest wall and skin. Once the Heart Wires are externalized, cut off the thoracic needles, maximizing the length of the exposed cardioversion leads. Discard the thoracic needles appropriately.
4. Attach a yellow cardioversion connector provided with the Syncrus Left and Right Atrial Heart Wires. This is done by threading the Heart Wire cardioversion lead through the pinhole on the backside of the connector and pushing the pin into the connector. Make sure there is good electrical contact between the Heart Wire cardioversion lead and the yellow cardioversion connector.
5. Connect the pacing connector pins for baseline measurements to a pacing system analyzer (PSA) and evaluate the placement by determining R-wave amplitude, pacing threshold, and pacing lead impedance.
6. Cover the pacing connector pins on the Right Atrial Heart Wire (black and blue wires) and Ventricular Heart Wire (black and white wires) with protective tubing provided with the Syncrus Heart Wires. Secure the Syncrus Heart Wires by taping the cardioversion connectors and pacing pins to the patient's body until needed.
7. When Syncrus atrial cardioversion therapy is needed, connect the yellow cardioversion connectors to the Syncrus Cardioversion Extension Cable. Ensure that the Cable is connected to the EDIM. Apply internal atrial cardioversion by placing external defibrillator paddles on the paddle plates of the Syncrus EDIM and deliver energy. The EDIM will attenuate the external defibrillator output energy by approximately 97% (for example, a 100-joule external shock will result in an approximate 3-joule internal cardioversion shock to the heart).
8. When temporary cardiac pacing and ECG sensing are needed, remove the protective tubing from the pacing connector pins. Connect the pacing connector pins into the appropriate pacing cables. Ensure that the pacing cables are connected to an external pacemaker. Administer cardiac pacing therapy.
9. To remove the Syncrus Heart Wires, remove any tape holding the Heart Wires in place. Apply gentle and continuous external traction to remove the Heart Wires from the patient. Special care should be taken when removing the lead from the atrium, due to the relatively thin atrial wall.
10. Discard the three externalized Heart Wires appropriately.

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ADVERSE EVENTS:
Two studies were conducted with the original Syncrus System (TADpole System) in Europe[1]. Results from both studies demonstrated that the Guidant Syncrus System was safe and effective for its intended use.

Table 1. Adverse Events Reported Across Studies

Complications	# of pts with AE's (n=538)	% of pts with AE's
Wire dislodgement	1	0.19%
Cardiac Arrest/VF	1	0.19%
Difficult wire extraction	2	0.37%
Infection	1	0.19%
Hypoventilation	1	0.19%
Death*	2	0.37%
Total Complications	**8**	**1.48%**

* Deaths were unrelated to therapy with Syncrus System.
[1] For clinical study details refer to *Clinical Trial* section.

POTENTIAL ADVERSE EVENTS:
Based on the literature and Syncrus heart wire implant experience, the possible physical effects from implantation are listed below.

- Allergic reaction
- Atrial wall rupture
- Bleeding
- Cardiac tamponade
- Difficult wire removal
- Displacement dislodgement
- Erosion/extrusion
- Fibrotic tissue formation
- Hematoma
- Histotoxic reaction
- Inappropriate therapy
- Incomplete connection with pulse generator
- Infection
- Lead abrasion
- Lead failure
- Lead fracture or insulation break
- Lead tip deformation and/or breakage
- Local tissue reaction
- Loss or under sensing
- Myocardial injury
- Myocardial irritability
- Over sensing
- Post-shock rhythm disturbances
- Random component failures
- Threshold elevation

CLINICAL TRIALS:
The Syncrus System was studied in the following (2) trials: Pilot Clinical Investigation for the InControl TADpole Heart Wires (Temporary Atrial Cardioversion Post-Op Low Energy) and The TADpole™ System for Post-Cardiac Surgery Atrial Cardioversion and Atrial/Ventricular Pacing and Sensing.

Pilot Clinical Investigation for the InControl TADpole Heart Wires (Temporary Atrial Cardioversion Post-Op Low Energy)
This investigation was designed as an observational non-randomized study to evaluate the features and functionality of the therapy. The final analysis covers 466 implanted patients. The mean implant duration of the study population was 7.1 days.

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Table 2. Description of the Study Population

Characteristic	
Number of patients	n=466
Gender	
Male	348
Female	116
Unknown	2
Age at Time of Implant	
Range (years)	23 – 83
Mean ± Standard Deviation	64.2 ± 9.2
Cardiovascular Procedures*	
CABG	420
Valve Replacement	43
Valve Repair	9

* Cardiovascular procedures are not mutually exclusive of one another.

Arrhythmia Treatment Success and Energy Delivered

Eighty-one patients experiencing a total of 95 AF episodes were treated with the therapy. A per patient cardioversion overall success rate of 74% and a per episode success rate of 78% were recorded. The mean number of joules delivered to the patient per successful attempt was 6.02 Joules. There were an average number of 2.54 cardioversion attempts per successful episode.

Table 3. Per Patient and Per Episode Therapy Success Summary

Cardioversion Success	n (%)
81 Patients with Arrhythmias	
Success No	21 (26%)
Success Yes	60 (74%)
95 Episodes	
Success No	21 (22%)
Success Yes	74 (78%)
Joules Delivered per Successful Attempt	
Mean	6.02
SD	2.50
Range	1.5 - 10.8
Average number of Attempts per Successful Episode	2.54

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Table 4. Per Attempt and Cumulative Therapy Success Summary

Attempts	Success Yes/No	Total # of Attempts	Success Rate per Attempt (%)	Cumulative Success Rate (%)*
1st Attempt	Success Yes	40	42.11	42.11
	Success No	55		
2nd Attempt	Success Yes	30	45.45	73.70
	Success No	36		
3rd Attempt	Success Yes	16	41.03	90.54
	Success No	23		
4th Attempt	Success Yes	6	37.50	96.85
	Success No	10		
5th Attempt	Success Yes	2	33.33	98.95
	Success No	4		
6th Attempt	Success Yes	1	33.33	100.00
	Success No	2		
7th Attempt	Success Yes	0	0.00	
	Success No	2		
8th Attempt	Success Yes	0	0.00	
	Success No	2		
9th Attempt	Success Yes	0	0.00	
	Success No	1		

* From the total of successful cardioversions attempts, the cumulative success rate is calculated as the percentage of successful cardioversions after the first, second, third, fourth etc. attempts using the total successful attempts as the denominator. For example, 42.11% of the total successful cardioversions resulted from a first cardioversion attempt. Data illustrates that over 90% of the total successful cardioversions occurred within the first three cardioversion attempts. Incremental cardioversion successes were observed as a result of additional attempts.

Summary of Adverse Events

A total of eight adverse events in seven patients were recorded throughout the duration of the study.

Table 5. Adverse Events

	# of pts with AE's (n=466)	% of pts with AE's
Complications (total)	8	1.71%
Wire dislodgement	1	0.21%
Cardiac Arrest/VF	1	0.21%
Difficult wire extraction	2	0.43%
Infection	1	0.21%
Hypoventilation	1	0.21%
Death*	2	0.43%

* Two deaths were not related to the TADpole System.

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The TADpole™ System for Post-Cardiac Surgery Atrial Cardioversion and Atrial/Ventricular Pacing and Sensing

This investigation was designed as a confirmatory observational non-randomized study intended to optimize the effectiveness of the therapy including heart wire placement. Heart wire placement is illustrated in Figures 2 through 4. The study is an analysis of 72 implanted patients. The mean implant duration of the study population was 6.2 days.

Table 6. Description of the Study Population

Characteristic	n (%)
Number of patients	72
Gender	
Male	50
Female	21
Unknown	1
Age at Time of Implant (years)	
Range	32 – 89
Mean ± Standard Deviation	65.26 ± 10.6
Mean Ejection Fraction ± Standard Deviation (%)	57.43 ± 16.96 (93%)
Cardiovascular Procedures	
CABG	71
Mitral Valve Replacement	1

Arrhythmia Treatment Success and Energy Delivered

Thirteen patients experiencing a total of 14 AF episodes were treated with the therapy. A per patient cardioversion overall success rate of 92.3% and a per episode success rate of 92.8% were recorded. The mean number of Joules delivered to the patient per successful attempt was 7.72 Joules. There were an average number of 1.54 cardioversion attempts per successful episode.

Table 7. Per Patient and Per Episode Therapy Success Summary

Cardioversion Success	n (%)
13 Patients with Arrhythmias	
Success No	1 (7.69%)
Success Yes	12 (92.3%)
14 Episodes	
Success No	1 (7.14%)
Success Yes	13 (92.8%)
Joules Delivered per Successful Attempt	
Mean	7.72
SD	1.73
Range	6 - 10.8
Average number of Attempts per Successful Episode	1.54

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Table 8. Per Attempt and Cumulative Therapy Success Summary

Attempts	Success Yes/No	Total # of Attempts	Success Rate per Attempt (%)	Cumulative Success Rate (%)*
1st Attempt	Success Yes	10	71.42	66.67*
	Success No	4		
2nd Attempt	Success Yes	4	66.66	93.33
	Success No	2		
3rd Attempt	Success Yes	0	0	93.33
	Success No	2		
4th Attempt	Success Yes	1	100.00	100.00
	Success No	0		

* From the total of successful cardioversions attempts, the cumulative success rate is calculated as the percentage of successful cardioversions after the first, second, third and fourth attempts. For example 66.67% of the total successful cardioversions resulted from a first cardioversion attempt using the total successful attempts as the denominator. Data illustrates that over 90% of the total successful cardioversions occurred within the first 3 cardioversion attempts. Incremental cardioversion successes were observed as a result of additional attempts.

Summary of Adverse Events
No adverse events were observed in this study.

ENERGY INPUT/OUT ATTENUATION:
The EDIM attenuates the energy output of a monophasic, low-energy external defibrillator down to 3% of its original joule output. The EDIM produces an energy transfer of 3% (+/- 1%) on the input energy from the defibrillator. Since the circuitry of the EDIM consists of a passive voltage divider network, the attenuation consists of a uniform reduction of input voltage, resulting in an output waveform identical to that of the defibrillators waveform, except reduced in magnitude (Figure 5).

Figure 5. EDIM Input Output Waveform

External Defibrillator Output Waveform **EDIM Output Waveform**

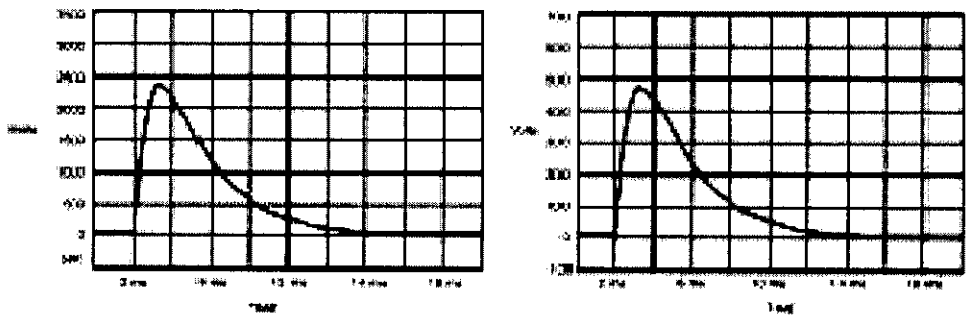

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Table 9. Minimum and Maximum Energy Output of the EDIM

Input from External Defibrillator (Joules)	Output Energy from EDIM (Joules) MIN	MAX
50	1.4	1.5
100	2.9	3.1
150	4.3	4.6
200	5.8	6.2
250	7.2	7.7
300	8.7	9.3
350	10.1	10.8
360	10.4	11.1

HOW SUPPLIED:
The Syncrus Heart Wires are supplied STERILE in an unopened and undamaged package. The Syncrus Heart Wires have been sterilized using gamma irradiation and are for single use only. DO NOT RESTERILIZE. DO NOT REUSE.

The Syncrus External Defibrillator Interface Module (EDIM) is supplied non-sterile and is reusable. One Syncrus Cardioversion Extension Cable, one maintenance test fixture, and two extension cable test adapters are also supplied with the EDIM.

To perform internal atrial cardioversion, the hospital must supply a low energy, external, monophasic defibrillator. To perform temporary cardiac pacing and ECG sensing, the hospital must supply an external pacemaker and appropriate pacing cables. A list of compatible external defibrillators, external pacemakers and pacing cables are provided in the Syncrus System Operator's Manual (*Required User Supplied Components* section) for your convenience.

CAUTION:
Federal (U.S.A.) law restricts this device to sale, distribution and use by or on the order of a physician.

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WARRANTY:
Guidant Corporation warrants that its Products substantially conform to Guidant Corporation published specifications for such Product for a period of twelve (12) months from the date of shipment, and will replace any Products confirmed by Guidant Corporation as defective Products, at Guidant Corporation's sole option, during said period. This warranty is contingent upon proper use of Products in the application for which they were intended as indicated in the Product label claims, and Guidant Corporation makes no warranty (express, implied, or statutory) for Products that are modified or subjected to unusual physical or electrical stress. With regard to Guidant Corporation Products which are labeled FOR SINGLE USE ONLY or DO NOT REUSE, this warranty is null and void following the single use of the Products. Guidant Corporation does not provide a warranty for those Products subjected to resterilization and/or reuse unless the Products are specifically designed and labeled for reuse.

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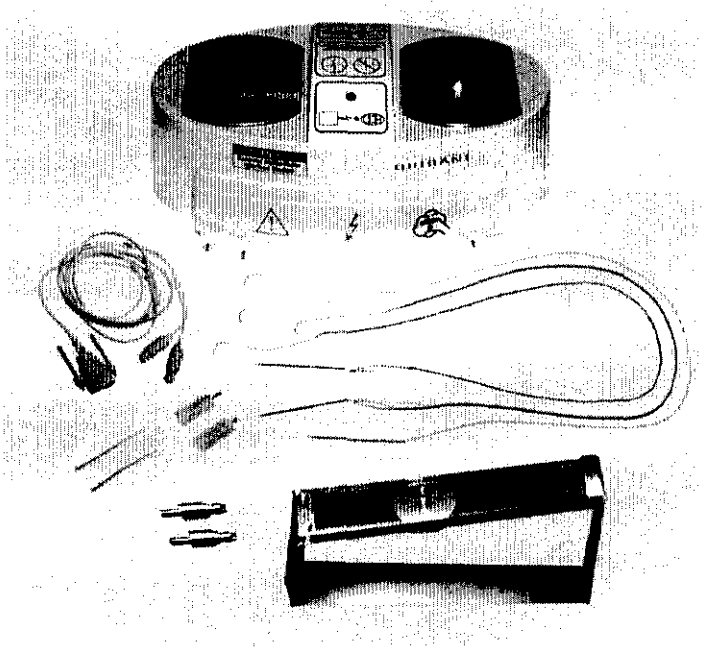
Guidant Syncrus™ System

Post Cardiac Surgery Atrial Cardioversion and Temporary Cardiac Pacing
Atriale cardioversie en tijdelijke pacing na hartchirurgie
Cardioversion auriculaire en chirurgie postcardiaque et stimulation cardiaque temporaire
Atriale Elektrokonversion und temporäre Herzstimulation nach herzchirurgischen Eingriffen
Stimolazione cardiaca temporanea e cardioversione atriale post-intervento cardiochirurgico
心臓手術後の心房カルディオバージョンと一時的心臓ペーシング
Cardioversión auricular y estimulación cardíaca temporal tras cirugía cardíaca



OPERATOR'S MANUAL

ENGLISH / NEDERLANDS / FRANÇAIS / DEUTSCH / ITALIANO
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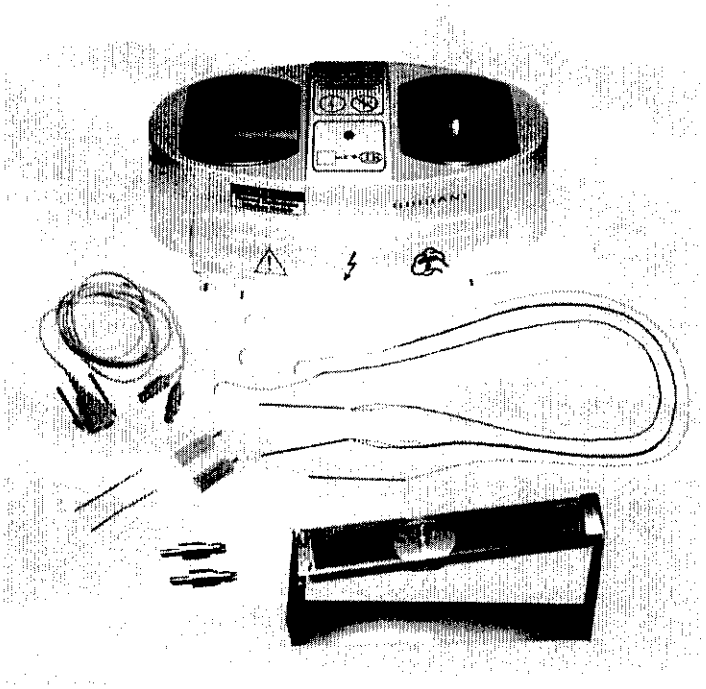
Guidant Syncrus™ System

Post Cardiac Surgery Atrial Cardioversion
And
Temporary Cardiac Pacing



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1.0 SYNCRUS™ ATRIAL CARDIOVERSION THERAPY

The Guidant Syncrus™ System provides low energy internal cardioversion therapy to treat postoperative atrial fibrillation in conjunction with temporary cardiac pacing and ECG sensing.

During cardiac surgery, Syncrus™ Heart Wires are attached to appropriate locations on the patient's myocardium using standard surgical technique. The proximal ends of the Syncrus™ Heart Wires are externalized through the patient's chest wall and connected to appropriate cables attached to the Syncrus™ External Defibrillator Interface Module (EDIM) and a temporary external pacemaker.

In the event of post cardiac surgery atrial fibrillation, the clinician performs a routine synchronized electrical cardioversion, except that the external defibrillator paddles rest on the paddle plates of the Syncrus™ EDIM, rather than on the patient's chest. The patient is sedated at the physician's discretion. The *maximum* energy level administered through the Syncrus™ EDIM to the Syncrus™ Heart Wires is approximately 11 joules directly to the patient's myocardium, compared to 360 joules if delivered transthoracically with external defibrillator paddles.

The Syncrus™ Heart Wires are designed to also provide temporary cardiac pacing and ECG sensing before and after internal atrial cardioversion without requiring the physician to rearrange cables and wires.

Carefully read all instructions prior to use. Observe all warnings and precautions noted throughout these instructions.

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2.0 SYSTEM DESCRIPTION

The Guidant Syncrus™ System provides low energy internal cardioversion therapy to treat postoperative atrial fibrillation via Syncrus™ Heart Wires placed directly on the patient's heart. The system functions also include temporary atrial and ventricular pacing and ECG sensing capabilities.

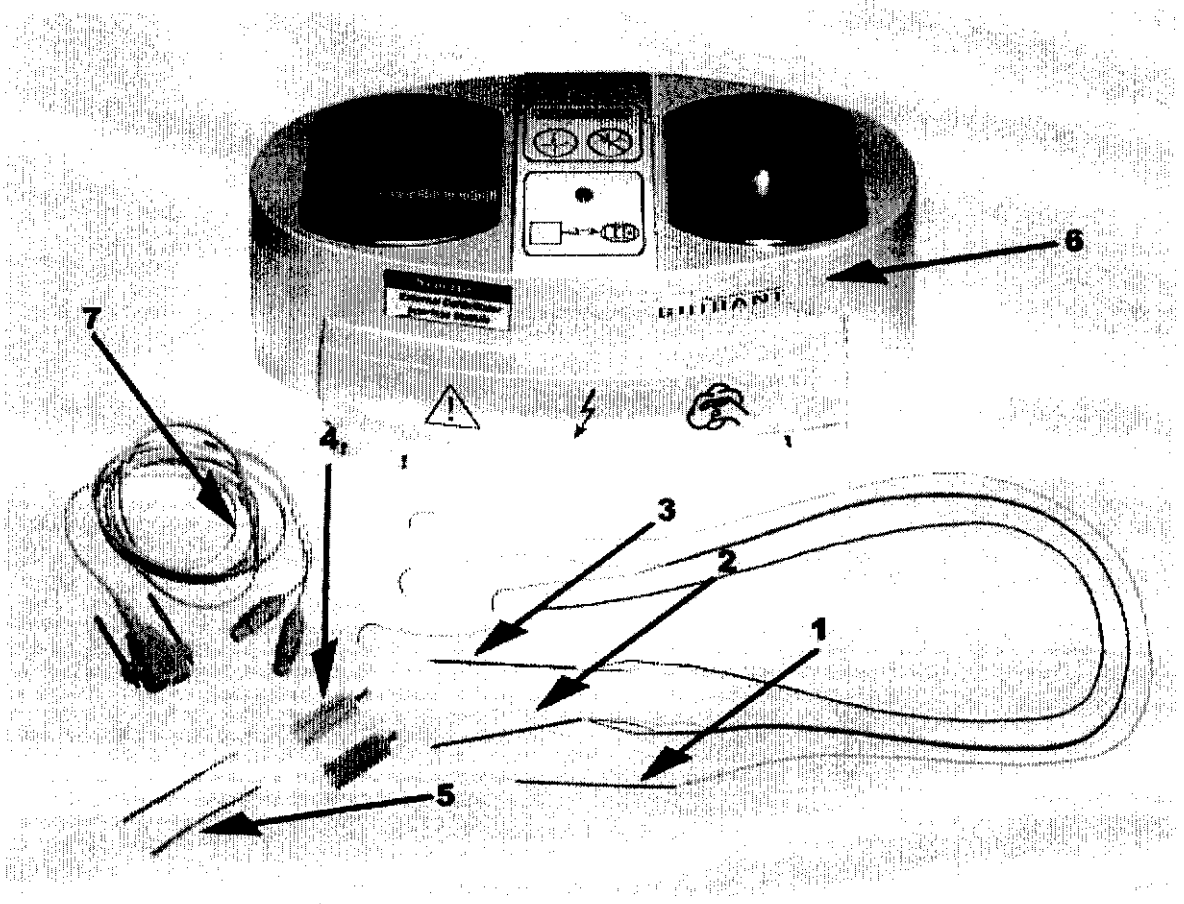

Figure 1. Guidant Syncrus™ System

1. Left Atrial Heart Wire (unipolar)
2. Right Atrial Heart Wire (tripolar)
3. Ventricular Heart Wire (bipolar)
4. Yellow Cardioversion Connectors
5. Protective Tubing
6. External Defibrillator Interface Module (EDIM)
7. Cardioversion Extension Cable

Note: The Heart Wires (with yellow cardioversion connectors and protective tubing) are sold separately from the EDIM and Cardioversion Extension Cable.

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The Syncrus™ System consists of the following components:

- Three single use Heart Wires that are attached to myocardial tissue of the left atrium, right atrium, and right or left ventricle during cardiac surgery. The Heart Wires transmit low energy shocks to the patient's heart for electrical atrial cardioversion. The Heart Wires also provide temporary cardiac pacing and ECG sensing capabilities.

- A reusable External Defibrillator Interface Module (EDIM), which interfaces between a monophasic, low-energy, external defibrillator and the Heart Wires. The EDIM reduces the output energy from the defibrillator to a low energy shock delivered through the Heart Wires.

- A reusable Cardioversion Extension Cable that connects the Heart Wires to the EDIM.

The Syncrus System components must be used in conjunction with a monophasic, low energy external defibrillator, an external pacemaker, and pacing cables that connect the Heart Wires to the external pacemaker. The user supplies the external defibrillator, external pacemaker, and pacing cables.

3.0 INDICATIONS FOR USE

The Guidant Syncrus™ Internal Cardioversion System is indicated for use in post-operative cardiac surgery patients who require temporary atrial or ventricular pacing/sensing and/or atrial cardioversion.

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4.0 COMPONENTS DESCRIPTION

4.1 Syncrus™ Heart Wires

The Syncrus™ Heart Wires consist of three myocardial wires: a unipolar Heart Wire for the left atrium, a tripolar Heart Wire for the right atrium, and a bipolar Heart Wire for the left or right ventricle. The Syncrus™ Heart Wires are for single use only and should not be reused or resterilized.

The Left Atrial Heart Wire is a unipolar lead with a cardioversion electrode for atrial cardioversion. The Right Atrial Heart Wire is tripolar with one electrode for atrial cardioversion (that is used in conjunction with the cardioversion electrode on the Left Atrial Heart Wire) and a bipolar pacing lead with one electrode for atrial pacing and ECG sensing and a second electrode for grounding. The Ventricular Heart Wire is a bipolar pacing lead with one electrode for ventricular pacing and ECG sensing and a second electrode for grounding.

The Syncrus™ Heart Wire electrodes are placed on appropriate locations in the myocardium and the proximal ends of the Heart Wires are passed through the chest wall and skin of the patient using a straight thoracic needle attached to each Heart Wire. The thoracic needles are cut off after externalization and yellow cardioversion connectors are attached to the cardioversion lead (yellow wire) on the Left and Right Atrial Heart Wires. The pacing connector pins on the Right Atrial Heart Wire (black and blue wires) and Ventricular Heart Wire (black and white wires) are covered with a protective tubing. The cardioversion and pacing connectors are usually taped to the patient's body until needed. After the Syncrus™ Heart Wires are no longer needed (usually just prior to patient discharge from the hospital), the Heart Wires are removed from the patient with gentle and continuous external traction.

To perform internal atrial cardioversion, the cardioversion connectors on the Left and Right Atrial Heart Wires must be connected to the Syncrus™ Cardioversion Extension Cable and EDIM. The hospital must supply a monophasic low energy external defibrillator.

To perform atrial and ventricular pacing and ECG sensing, the pacing connector pins on the Right Atrial Heart Wire and Ventricular Heart Wire must be connected to the appropriate pacing cables and an external pacemaker. The hospital must supply both the external pacemaker and pacing cables.

4.2 Syncrus™ External Defibrillator Interface Module (EDIM)

The Syncrus™ EDIM is a non-sterile and reusable device that allows the energy from an external defibrillator to be transmitted through the Left and Right Atrial Heart Wires directly to the patient's myocardium.

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To perform internal electrical cardioversion, external defibrillator paddles are placed on the paddle plates and safety push button of the Syncrus™ EDIM. The EDIM reduces the output energy from an external monophasic defibrillator by approximately 97% and delivers a low energy internal cardioversion shock to the left and right atrial myocardium. For every 100 joules input from the external defibrillator, approximately 3 joules are actually delivered to the patient's heart.

4.3 Syncrus™ Cardioversion Extension Cable

The Syncrus™ Cardioversion Extension Cable is a reusable cable that connects the cardioversion connectors on the Left and Right Atrial Heart Wires to the Syncrus™ EDIM.

4.4 EDIM Maintenance Test Fixture and Cardioversion Cable Test Adapters

The EDIM maintenance test fixture and Cardioversion Cable test adapters are used to perform the full maintenance test on the Guidant Syncrus™ System as described in the *Maintenance and Calibration* Section.

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5.0 MAINTAINING SYSTEM EFFECTIVENESS

5.1 Syncrus™ Heart Wires

≠# The Syncrus™ Heart Wires are for single use only. DO NOT RESTERILIZE. DO NOT REUSE.

5.2 Syncrus™ EDIM and Cardioversion Extension Cable

≠# The EDIM should only be used with a monophasic, low-energy external defibrillator.

≠# Perform functional checks on the Syncrus™ EDIM daily and monthly (see section on *Maintenance and Calibration*).

≠# Do not use conductive gel or paste on the external defibrillator paddles or Syncrus™ EDIM paddle plates.

≠# Do not immerse the Syncrus™ EDIM or Cardioversion Extension Cable in liquid.

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6.0 REQUIRED USER SUPPLIED COMPONENTS

To apply Syncrus™ atrial cardioversion therapy, the user must supply a monophasic low energy external defibrillator, an external pacemaker, and the appropriate pacing cables. Below is a list of compatible external defibrillators, pacemakers and pacing cables that have been tested with the Guidant Syncrus™ System.

External pacemaker:

- ≠# Medtronic Dual-Chamber Model 5388 External (Temporary) Pulse Generator
- ≠# Medtronic Single-Chamber Model 5348 External (Temporary) Pulse Generator

Pacing cables:

- ≠# Medtronic 5433A Reusable EPG atrial safety cables
- ≠# Medtronic 5433V Reusable EPG ventricular safety cables
- ≠# Medtronic 5487 6 ft. sterile disposable patient safety cables

Monophasic, low-energy external defibrillator with R-wave synchronization capability:

- ≠# Medtronic Physio-Control LifePak™ 9, 10, 11, 12 (excluding 3D Biphasic™ Technology) defibrillator
- ≠# Agilent (Hewlett Packard) Codemaster™ defibrillator
- ≠# Zoll Medical Corporation defibrillator

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7.0 WARNINGS

- ≠# The Guidant Syncrus System is compatible with monophasic low energy external defibrillators only.
- ≠# Perform synchronized cardioversion only. Unsynchronized shocks may result in ventricular fibrillation, causing patient injury or death.
- ≠# The Syncrus Heart Wires provide a direct path for electrical current flow to the patient's heart. DO NOT touch the heart wire leads or the EDIM (when connected to the Heart Wires) with your bare hands or with anything that may deliver static (electrostatic discharge). Avoid the possibility of unintentional contact between the wire leads, including extension cable, and any equipment used as well as any conductive surface contact. Line powered equipment used in the vicinity of the patient must be properly grounded.
- ≠# The Syncrus EDIM and Cardioversion Extension Cable are designed solely for use with Syncrus Heart Wires.
- ≠# DO NOT connect the Heart Wires to any equipment other than that specified in these instructions and the Syncrus System Operator's Manual. Patient injury or death may result.
- ≠# If the Syncrus System EDIM has been dropped onto a hard surface, perform a FULL maintenance test as described in the Syncrus System Operator's Manual (*Maintenance and Calibration* section) prior to using the EDIM again. Dropping the EDIM may damage internal components, possibly rendering the device inoperable or out of specification.
- ≠# Wire fracture, dislodgement, abrasion and/or an incomplete connection can cause a periodic or continual loss of pacing and sensing, possibly resulting in inappropriate delivery of conversion therapy. Connect the pacing connector pins for baseline measurements to a pacing system analyzer (PSA) and evaluate the placement by determining R-wave amplitude, pacing threshold, and pacing lead impedance. Secure the Syncrus Heart Wires by taping the cardioversion connectors and pacing pins to the patient's body until needed.
- ≠# Although pliable, the lead body is not designed to tolerate excessive flexing, bending, or tension. This could cause structural weakness, conductor discontinuity, and/or lead dislodgement. Secure the cardioversion connectors and pacing pins to the patient's body until needed. Minimize manipulation of the heart wires.
- ≠# Equipment and accessories connected to the Guidant Syncrus System shall comply with IEC-601-1, type CF.

8.0 PRECAUTIONS

- ≠# Syncrus Heart Wires are for single use only. DO NOT RESTERILIZE. DO NOT REUSE.

- ≠# The Syncrus Heart Wires are gamma sterilized after packaging. When they are received, they are sterile and ready for use. Should the seal or package be wet,

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damaged, punctured, or if the seal is broken, do not use or attempt to resterilize. Contact the local Guidant representative.

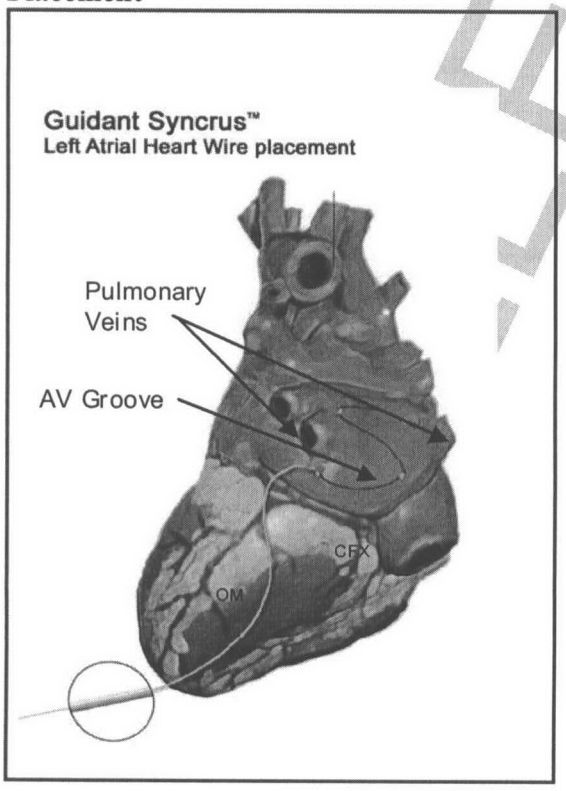
≠# Pre-clinical testing supports the use of this device up to 7 cardioversion attempts. Cardioversion attempts ranged from 1 to 9 attempts in clinical trials. Physicians should treat patients in accordance with judgment and experience. Assessment of the patient's overall condition and physician discretion should dictate the number of attempts to treat.

≠# It is recommended that defibrillation equipment and a pacing sensor system analyzer (PSA) be readily available during lead placement and removal.

9.0 ATTACHING THE SYNCRUS™ HEART WIRES TO THE MYOCARDIUM

1. Attach the Syncrus Heart Wires to the patient's myocardial surface during cardiac surgery in the following order and before the patient's chest is closed. The described fixation technique is furnished for informational purposes only. The physician may choose to vary the fixation technique in accordance with judgment and experience. The selected fixation technique of each Heart Wire placement should always allow for ease of extraction through gentle traction. Proper surgical procedures and techniques are the responsibility of the medical professional. Figures 2 through 4 illustrate heart wire placement as performed in clinical trials.

Figure 2. Syncrus Left Atrial Heart Wire Placement



Left Atrial Heart Wire (unipolar)

≠# *Cardioversion Electrode (yellow wire)*: Use the attached curved needle to affix the cardioversion electrode to the left atrial myocardium on the atrioventricular (AV) groove between the left and right pulmonary veins in an "S" pattern as illustrated in Figure 2 for optimal results. After the cardioversion electrode is affixed, cut off the curved needle and discard it. Place a slight bend or kink at the end of the electrode.

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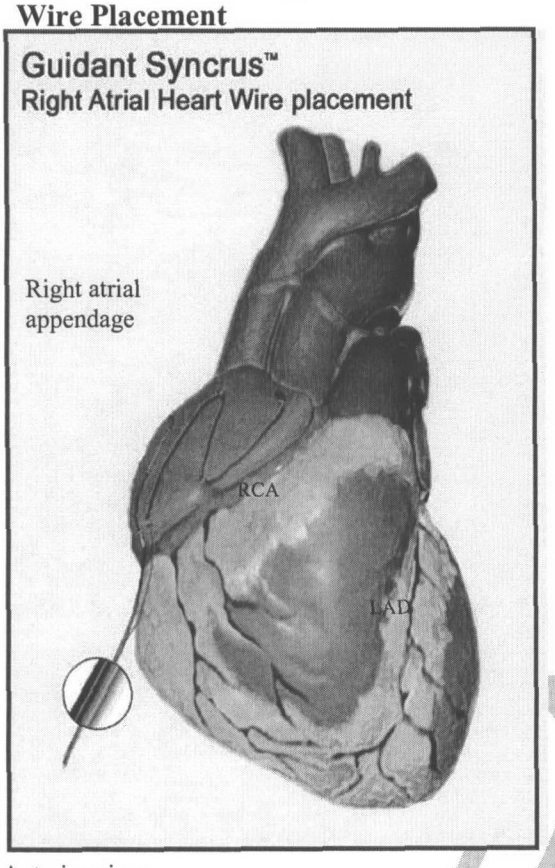
Figure 3. Syncrus Right Atrial Heart Wire Placement



Anterior view

Right Atrial Heart Wire (tripolar)

≠# *Cardioversion Electrode (yellow wire)*: Use the attached curved needle to affix the cardioversion electrode into the right atrial myocardium in an "S" pattern as shown in Figure 3 for optimal results. After the cardioversion electrode is affixed, cut off the curved needle and discard it. Place a slight bend or kink at the end of the electrode.

≠# Placement should be made to maximize the atrial muscle mass between the right atrial cardioversion electrode and the left atrial cardioversion electrode.

≠# *Pacing Electrode (black and blue wires):* Use the attached curved needle to affix the bipolar pacing electrodes into the right atrial myocardium. For optimal cardiac pacing, bury both the anode and cathode in the myocardium. After the pacing electrodes are affixed, cut off the needle and discard it. Place a slight bend or kink at the end of the anode electrode.

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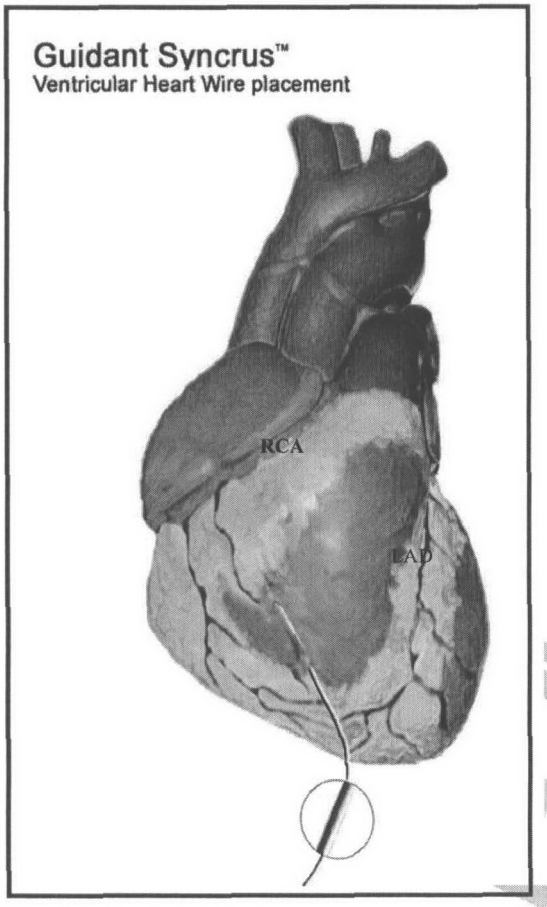
Figure 4. Syncrus Ventricular Heart Wire Placement



Anterior view

Ventricular Heart Wire (bipolar)

#\# *Pacing Electrodes (black and white wires)*: Use the attached curved needle to affix the bipolar pacing electrodes into the myocardial tissue of either the right or left ventricle as illustrated in Figure 4 for optimal results. The positive pacing electrode (anode) is attached to the needle, while the negative electrode (cathode) is contained in the 4 mm long bullet. For optimal cardiac pacing, bury both the anode and cathode in the myocardium. After pacing electrodes are affixed, cut off the curved needle and discard it. Place a slight bend or kink at the end of the anode electrode.

2. Once the cardioversion and pacing electrodes have been affixed to the patient's heart, visualize the paths that the Heart Wires will travel as they are extracted.

3. Use the straight thoracic needle on the proximal end of each Syncrus™ Heart Wire to externalize the Heart Wires through the chest wall and skin. Once the Heart Wires are externalized, cut off the thoracic needles, maximizing the exposed cardioversion leads. Discard the thoracic needles appropriately.

4. Attach a yellow cardioversion connector provided with the Syncrus Left and Right Atrial Heart Wires. This is done by threading the Heart Wire cardioversion lead through the pinhole on the backside of the connector and pushing the pin into the connector. Make sure there is good electrical contact between the Heart Wire cardioversion lead and the yellow cardioversion connector.

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5. Connect the pacing connector pins for baseline measurements to a pacing system analyzer (PSA) and evaluate the placement by determining R-wave amplitude, pacing threshold, and pacing lead impedance.

6. Cover the pacing connector pins on the Right Atrial Heart Wire (black and blue wires) and Ventricular Heart Wire (black and white wires) with protective tubing provided with the Syncrus Heart Wires. Secure the Syncrus Heart Wires by taping the cardioversion connectors and pacing pins to the patient's body until needed.

7. When Syncrus atrial cardioversion therapy is needed, connect the yellow cardioversion connectors to the Syncrus Cardioversion Extension Cable. Ensure that the Cable is connected to the EDIM. Apply internal atrial cardioversion by placing external defibrillator paddles on the paddle plates of the Syncrus EDIM and delivering energy. The EDIM will attenuate the external defibrillator output energy by approximately 97% (for example, a 100- joule external shock will result in an approximate 3-joule internal cardioversion shock to the heart).

8. When temporary cardiac pacing and ECG sensing are needed, remove the protective tubing from the pacing connector pins. Connect the pacing connector pins into the appropriate pacing cables. Ensure that the pacing cables are connected to an external pacemaker. Administer cardiac pacing therapy.

9. To remove the Syncrus Heart Wires, remove any tape holding the Heart Wires in place. Apply gentle and continuous external traction to remove the Heart Wires from the patient. Special care should be taken when removing the lead from the atrium, due to the relatively thin atrial wall.

10. Discard the three externalized Heart Wires appropriately.

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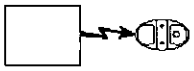
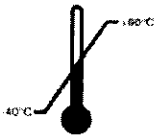
10.0 DEFINITION OF SYMBOLS

Below is a description of the symbols used in this manual and on the Guidant Syncrus™ System labels and packaging.

	WARNING: **Shock hazard**. Hazardous voltage may be present. Do not touch the paddle plates when the device is connected to the patient.
	WARNING: Read Instructions for Use.
	WARNING: Do not shock on T-wave. Synchronize shock with patient's R-wave.
	(Green indicator flashes): Energy has been transmitted from the external defibrillator to the Syncrus™ EDIM.
	(Red indicator flashes): Overvoltage condition in Syncrus™ EDIM. No energy was transmitted to patient. Refer to the Operator's Manual.
	Clean paddle plates before each use with a 70% isopropyl alcohol wipe.
	Type CF equipment.
	Class II equipment.
	Reference information; please read.
	Store at temperature between -40°C and 60°C.

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11.0 MAINTENANCE AND CALIBRATION

The Syncrus™ EDIM is a passive electrical device that relies on a user supplied external defibrillator for its power source. There are no user serviceable parts inside. This maintenance procedure is intended for the use of the hospital biomedical engineering department to verify proper function of the device and its safety features. If the device exhibits any discrepancies in any of these periodic checks, discontinue use of the device at once and contact Guidant Cardiac Surgery (Santa Clara, CA) for return instructions. **All maintenance procedures requiring an external defibrillator should be conducted with a compatible external defibrillator (see section on *Required User Supplied Components* for compatible defibrillators).**

11.1 Daily Maintenance

It is recommended that the following maintenance procedure be performed on a daily basis to ensure proper function of the Syncrus™ EDIM.

CAUTION: Perform all maintenance **BEFORE** connecting the Syncrus™ EDIM to the patient.

1. Clean the paddle plates and safety push button (right side) with a 70% isopropyl alcohol wipe before each use. A buildup of dirt on these conductive surfaces can cause degradation of electrical conduction and can prevent proper energy transmission.

2. Verify that the spring-loaded safety push button on the right side of the device can be depressed completely and that it returns to its extended position when the force is removed.

11.2 Full Maintenance (monthly)

It is recommended that the following maintenance procedure be performed on a monthly basis to ensure proper function of the Syncrus™ EDIM. Also perform a full maintenance test if the EDIM has been dropped onto a hard surface prior to using the EDIM again.

11.2.1 Other Equipment

- External defibrillator (see section on *Required User Supplied Components* for compatible defibrillators)
- Impulse 3000 or 4000 defibrillator analyzer (DNI Nevada, Inc., Carson City, NV, USA) or equivalent.
- Syncrus™ EDIM maintenance test fixture (Guidant Cardiac Surgery order #TX-5200)
- Syncrus™ Cardioversion Cable test adapter; two required (Guidant Cardiac Surgery order #TX-5300). Hypertronics p/n YPN025-002G may also be used.

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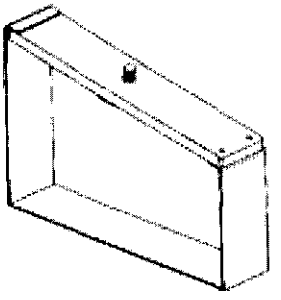
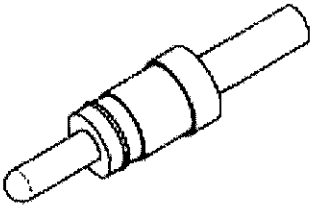
≠# Hi-pot tester capable of 4 kV AC output
≠# Oscilloscope with high voltage probe



Syncrus™ EDIM maintenance test fixture TX-5200



Syncrus™ Cardioversion Cable test adapter TX-5300 (2 required)

11.2.2 Full Maintenance Procedure

1 Check leakage current

Note: the leakage current limits specified are for the Syncrus™ EDIM only. Any leakage current inherent in the leakage tester must be identified and deducted from the tester readout before applying the leakage current limits.

Patient Leakage Current (Mains on Paddle Plates)

Test Setup:

1.1 Connect the Syncrus™ Cardioversion Extension Cable to the Syncrus™ EDIM.
1.2 Connect a Cardioversion Cable test adapter to each output connector on the Syncrus™ Cardioversion Extension Cable. Electrically short the two output terminals on the test adapters.
1.3 Connect a current measuring device to the shorted output terminals of the test adapters.
1.4 Attach the EDIM maintenance test fixture to the Syncrus™ EDIM. The test fixture should wrap around the right side of the EDIM and the latching mechanism should be located on the same side as the EDIM output terminals when properly installed for this test (see Figure 5).
1.5 Depress the Syncrus™ EDIM safety push button with the movable arm of the test fixture. Latch the movable arm and verify that the EDIM safety push button is fully depressed.

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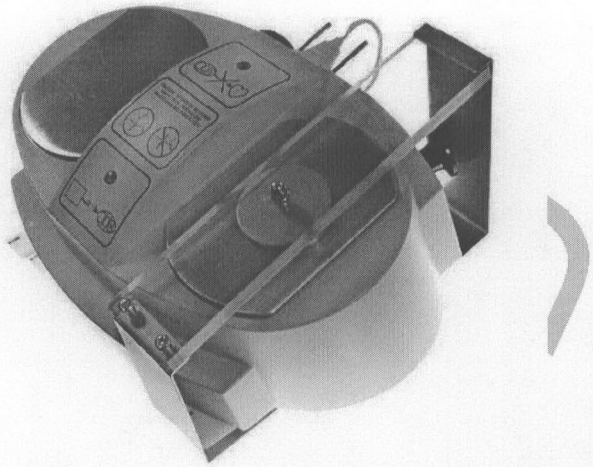

Figure 5. The EDIM maintenance test fixture shown properly installed to the Syncrus™ EDIM.

The Syncrus™ EDIM shall not allow greater than 10μA leakage current when a 240-volt source is connected (or 5μA leakage current when a 120 volt source is connected) to the left paddle plate and the current measuring device is attached to the output jacks electrically tied together and shorted to ground. The EDIM safety push button should be depressed for this check.

Patient Leakage Current (Mains on the Applied Part) - The Syncrus™ EDIM shall not allow greater than 10 μA leakage current when a 240 volt source is connected (or 5μA leakage current when a 120 volt source is connected) to the output jacks electrically tied together and the measuring device is attached to the left paddle plate and shorted to ground. The EDIM safety push button should be depressed for this check.

CAUTION: Do not depress the Syncrus™ EDIM safety push button with anything that is electrically common with your body. Serious injury may occur.

2. Check mechanical isolation

   Verify that the spring-loaded safety push button on the right side of the Syncrus™ EDIM can be depressed completely and that it returns to its extended position when the force is removed.

3. Check attenuation level

Test Setup:

3.1 Connect the Syncrus™ Cardioversion Extension Cable to the Syncrus™ EDIM.
3.2 Connect a Cardioversion Cable test adapter to each output connector on the Syncrus™ Cardioversion Extension Cable.

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3.3 Connect the test adapters to the defibrillator analyzer.
3.4 Place the external defibrillator paddles on the Syncrus™ EDIM paddle plates. Assure that the right safety push button is fully depressed by the paddle.

Use the defibrillator analyzer to verify the Syncrus™ EDIM attenuation level:

External defibrillator setting*	Syncrus™ EDIM output*
360 joule	10.4 - 11.1 joule

* If the external defibrillator does not deliver exactly 360 joules, the lower and upper Syncrus™ EDIM output energy limits may be calculated by multiplying the external defibrillator input energy by 0.0289 and 0.0309, respectively.

4. Check shock delivery delay

Test Setup:
4.1 Connect the Syncrus™ Cardioversion Extension Cable to the Syncrus™ EDIM.
4.2 Connect a Cardioversion Cable test adapter to each output connector on the Syncrus™ Cardioversion Extension Cable.
4.3 Connect the test adapters to the defibrillator analyzer.
4.4 Connect the defibrillator analyzer's normal sinus ECG output signal (60 bpm) to the synchronization input of the external defibrillator.
4.5 Place the external defibrillator paddles on the Syncrus™ EDIM paddle plates. Assure that the right safety push button is fully depressed by the paddle.
4.6 Discharge the external defibrillator at 360 joules, using synchronized cardioversion mode.

Use the defibrillator analyzer to measure actual delay time from the peak of the generated R-wave to the leading edge of the defibrillator discharge waveform, measured at the output of the Syncrus™ EDIM. The delay time must be less than 60 milliseconds.

5. Check over-voltage protection

Discharge a 360 joule shock from the external defibrillator into the Syncrus™ EDIM using the external paddles, but with no load connected to the output terminals. The "over-voltage" indicator on the top panel of the EDIM should flash momentarily (red color). The "energy transfer" indicator (green) will also flash momentarily.

If the "energy transfer" indicator does not flash, verify that the external defibrillator is delivering at least 360 joules by connecting the defibrillator analyzer directly to the defibrillator (remove the EDIM from the circuit). If the external defibrillator is delivering at least 360 joules, discontinue use of the EDIM. If the external defibrillator is not delivering at least 360 joules (and is set for 360 joules output), discontinue use of the external defibrillator.

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6. Check "energy transfer" indicator
   Test Setup:
   6.1 Connect the Syncrus™ Cardioversion Extension Cable to the Syncrus™ EDIM.
   6.2 Connect a Cardioversion Cable test adapter to each output connector on the Syncrus™ Cardioversion Extension Cable.
   6.3 Connect a 60 ohm, 100 watt resistor across the terminals of the test adapters.
   6.4 Place the external defibrillator paddles on the Syncrus™ EDIM paddle plates. Assure that the right safety push button is fully depressed by the paddle.

   Discharge a 100 joule shock from the external defibrillator into the Syncrus™ EDIM using the external paddles. The "energy transfer" indicator (green) will flash momentarily, while the "over-voltage" indicator (red) will not flash. Repeat the check with a 360 joule shock. The "energy transfer" indicator will flash momentarily, while the "over-voltage" indicator will not flash.

7. Dielectric withstand

   Test Setup:
   7.1 Connect the Syncrus™ Cardioversion Extension Cable to the Syncrus™ EDIM.
   7.2 Connect the Cardioversion Cable test adapters to the Syncrus™ Cardioversion Extension Cable.
   7.3 Electrically short the output terminals on the test adapters.
   7.4 Attach the EDIM maintenance test fixture to the Syncrus™ EDIM. The test fixture should wrap around the **left** side of the EDIM and the latching mechanism should be located on the same side as the EDIM output terminals when properly installed for this test (see Figure 6).
   7.5 Connect the positive hi-pot output lead to the Syncrus™ EDIM left paddle plate via the electrical connector on the EDIM maintenance test fixture.
   7.6 Connect the negative hi-pot lead to the shorted output terminals on the Cardioversion Cable test adapters.

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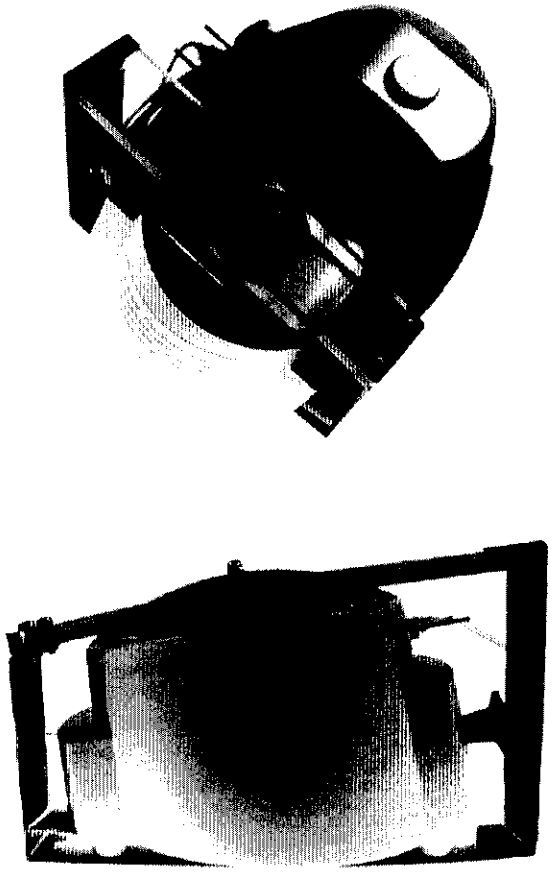

Figure 6. The EDIM maintenance test fixture shown properly installed to the Syncrus™ EDIM.

Set the hi-pot tester to output 4000 Volts AC. The EDIM right safety push button should not be depressed for this check.

Slowly raise the voltage to 4000 Volts AC and remain at that voltage for 1 minute. There should be no arcing or tripping of the hi-pot's limit detector and the current flow should be less than 33 mA.

8. Waveform verification

Test Setup – Part 1:

1. Connect the external defibrillator paddles to the defibrillator analyzer.
2. Connect the oscilloscope to the oscilloscope output jack on the defibrillator analyzer.
3. Set the defibrillator to 10 joules output.

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Use the oscilloscope to capture the waveform of the external defibrillator discharging directly into the defibrillator analyzer. Label this waveform "External Defibrillator Waveform".

Test Setup – Part 2:

1. Connect the Syncrus™ Cardioversion Extension Cable to the Syncrus™ EDIM.
2. Connect the Cardioversion Cable test adapters to the Syncrus™ Cardioversion Extension Cable.
3. Connect the test adapters to the defibrillator analyzer.
4. Connect the oscilloscope to the oscilloscope output jack on the defibrillator analyzer.
5. Set the external defibrillator to 360 joules output.

Discharge the external defibrillator into the Syncrus™ EDIM. Capture the output waveform of the EDIM with the oscilloscope. Label this waveform "Syncrus™ EDIM Waveform". Compare the two waveforms from Part 1 and 2 of this test. They should be very similar in shape, maximum voltage, and duration. If any voltage spikes or "noise" are present on the EDIM waveform that are not present on the external defibrillator waveform after the initial discharge of the external defibrillator, discontinue use of the Syncrus™ EDIM and contact Guidant Cardiac Surgery (Santa Clara, CA) for further instructions.

NOTE: There may be some voltage spikes or "noise" present in the external defibrillator waveform that are not present on the Syncrus™ EDIM output waveform. This is a normal condition.

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12.0 TROUBLESHOOTING

12.1 Internal Atrial Cardioversion

1. Recheck all electrical connections
2. If the atrial fibrillation episode was not terminated *and* no shock impulse was seen on the ECG monitor *and* the green indicator light on the Syncrus™ EDIM did not flash while the shock was delivered *and* the patient did not experience an involuntary thoracic muscle spasm, then it is likely that that the external defibrillator's energy did not reach the patient.
3. If the red indicator light on the Syncrus™ EDIM flashed during the cardioversion attempt, the internal voltage protection circuit prevented the shock from reaching the patient. Reduce the energy setting on the external defibrillator and attempt another cardioversion or substitute another external defibrillator and try another cardioversion.
4. Deliver another cardioversion shock, while watching the ECG monitor for a shock.
5. If a cardioversion shock was observed on the monitor and the atrial fibrillation episode does not terminate, even briefly, a Heart Wire electrode may be dislodged. Discontinue Syncrus™ atrial cardioversion therapy and revert to traditional therapy.
6. If no cardioversion shock is observed on the monitor and the atrial fibrillation episode is not terminated, the Syncrus™ EDIM or Cardioversion Extension Cable may be defective. If a spare unit is available, replace the Syncrus™ EDIM. If the same problem persists, replace the Cardioversion Extension Cable. Ask your Biomedical Engineering Department to test the Syncrus™ EDIM and Cardioversion Extension Cable per the maintenance procedure in the *Maintenance and Calibration* section.

12.2 Temporary Cardiac Pacing and ECG Sensing

1. Check the settings of the external pacemaker.
2. Recheck all electrical connections.
3. Check the batteries in the external pacemaker.
4. Check that the proper Heart Wire pacing connector pins are connected to the proper input(s) on the external pacemaker.
5. Check that the polarity of the pacing connector pins is correct and consistent to the external pacemaker. If incorrect, reverse the connectors between the Heart Wires and the patient cable.
6. Try using a different pacing cable.
7. Try connecting to a different (positive) electrode. If this corrects the situation, the problem lies either within the pacing wire or at the pacing electrode's connection to the heart. You can either continue pacing with this configuration, or install an indifferent electrode on the patient's skin.

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8. Try connecting to a different stimulation (negative) electrode. If this corrects the situation, the problem lies either within the pacing wire or at the pacing electrode's connection to the heart. This situation cannot be corrected on this patient.

13.0 WARRANTY AND SERVICE

The Syncrus™ External Defibrillator Interface Module (EDIM) is warranted for one (1) year from the date of purchase. If the device fails to perform as intended during the warranty period, return it to Guidant Cardiac Surgery (Santa Clara, CA) for a replacement unit.

The Syncrus™ EDIM is not user serviceable. Do not attempt to open the module case. Warranty is void if the tamper resistant seal on the EDIM is broken. Proper device function must be verified monthly by your Biomedical Engineering or Equipment Maintenance Department. Refer to the section on *Maintenance and Calibration* for maintenance procedures.

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Intl: (650) 617-5400
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May be manufactured under one or more of the following patents: 5,674,253; 5,766,224; and RE 35,779.

P/N PPL2036625 Rev. A

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Guidant Syncrus™ System

Heart Wires, 3-Wire Kit
Cardioconversiedraden, 3-dradige kit
Electrodes cardiaques, kit trifilaire
Hertzleitungen, Kit mit 3 Leitungen
Cavi cardiaci, kit di 3 cavi
心臓ワイヤ、3ワイヤキット
Cables cardiacos,juego de 3 cables

	Inhalt: 10-Syncrus-Herzleitung-Kits
Contents: 10-Syncrus Heart Wire Kits	Contenuto: Kit di 10 cavi cardiaci Syncrus
Inhoud: 10-Syncrus kits met cardioversie-/pacingdraden	内容 10-Syncrus心臓ワイヤキット
Contenu: 10-Kits d'electrodes cardiaques Syncrus	Contenido: 10-Juegos de cables cardíacos Syncrus

REF TX-3000

LOT 2120581

2002-12

2003-11

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Santa Clara, CA 95054 USA
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GUIDANT

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Federal Law (USA) restricts this device to sale by or on the order of a physician.

WPL2035635-01 (04/14/02)

Guidant Syncrus™ System

Heart Wires, 3-Wire Kit
Cardioconversiedraden, 3-dradige kit
Electrodes cardiaques, kit trifilaire
Hertzleitungen, Kit mit 3 Leitungen
Cavi cardiaci, kit di 3 cavi
心臓ワイヤ、3ワイヤキット
Cables cardiacos,juego de 3 cables

See Instructions for Use.

Single use only.
Do not resterilize.

STERILE R STERILE unless package is opened or damaged.

REF TX-3000

(01) 2 0802526 27230 5

(17) 031130 (10) 2120581 (91) 3000

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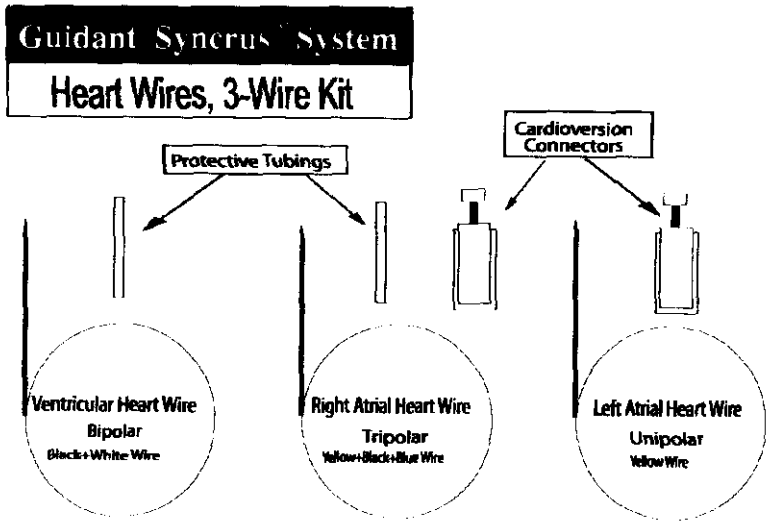

WPL2035886-01(04/17/02)

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Guidant Syncrus™ System

Heart Wires, 3-Wire Kit
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Electrodes cardiaques, kit trifilaire
Hertzleitungen, Kit mit 3 Leitungen
Cavi cardiaci, kit di 3 cavi
心臓ワイヤ、3ワイヤキット
Cables cardíacos,juego de 3 cables

REF TX-3000

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2002-12

2003-11

See Instructions for Use.

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Federal Law (USA) restricts this device to sale by or on the order of a physician.

WPL2035634-01 (4/14/02)

Contents:
1- Syncrus Right Atrial Heart Wire (tripolar)
1- Syncrus Left Atrial Heart Wire (unipolar)
1- Syncrus Ventricular Heart wire (bipolar)
2- Cardioversion Connectors
2- Protective Tubings

Inhalt:
1- Syncrus-Rechtsatrial-Herzleitung (tripolar)
1- Syncrus-Linksatrial-Herzleitung (unipolar)
1- Syncrus-Ventrikel-Herzleitung (bipolar)
2- Defibrillator-Anschlüsse
2- Schutzröhren

Inhoud:
1- Syncrus recher atriale draad (driepolig)
1- Syncrus linker atriale draad (eenpolig)
1- Syncrus ventriculaire draad (bipolair)
2- Cardioversieconnectoren
2- Beveiligingsslangen

Contenuto:
1- Cavo cardiaco Syncrus, atrio destro (tripolare)
1- Cavo cardiaco Syncrus, atrio sinistro (unipolare)
1- Cavo cardiaco Syncrus, ventricolo (bipolare)
2- Connettori per cardioversione
2- Tubazioni protettive

Conteau:
1- Electrode auriculair droite Syncrus (tripolaire)
1- Electrode auriculaire guache Syncrus (unipolaire)
1- Electrode ventriclaire Syncrus (bipolaire)
2- Connecteures de cardioversion
2- Tubulure protectrice

内容
1- Syncrus右心房用心臓ワイヤ（三極）
1- Syncrus左心房用心臓ワイヤ（単極）
1- Syncrus心室用心臓ワイヤ（双極）
2- 選択的除細動コネクタ
2- 保護チューブ

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(01) 0 0802526 27230 1

(17) 031130 (10) 2120581 (91) 3001

Contenido:
1- Cable cardiaco tripolar de la aurícula derecha Syncrus
1- Cable cardiaco unipolar de la aurícula izquierda Syncrus
1- Cable cardiaco bipolar ventricular Syncrus
2- Conectores de cardioversión
2- Tubos protectores

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GUIDANT

Memorandum

To: Syncrus DHF

From: Robert Quan

Date: December 5, 2002

Re: FMEA/Risk Analysis Review

The Syncrus FMEA and Risk Analysis documents were reviewed to identify potential hazards / failure modes that may be associated in using biphasic defibrillators with the Syncrus Internal Cardioversion System.

The documents reviewed include:

Guidant Cardiac Surgery (CS) Documents:

HA0564 Rev. B	Risk Analysis, Syncrus System
FMEA0557 Rev. B	FMEA, Syncrus Extension Cable
FMEA0558 Rev. B	FMEA, Syncrus Heart Wires

(b)(4) [redacted]
(b)(4) [redacted] (b)(4) [redacted]

During the review of (b)(4) Document No. (b)(4) [redacted] multiple references to 'waveform testing' in the 'Remarks/Comments' section should be revised for clarification. A number of tests identified in the Full Maintenance section of the Operator's Manual serves as verification testing of the waveform. A revision request will be submitted to (b)(4) to revise the document for this minor modification.

Results of the review identified no new hazards or failure modes associated in using biphasic defibrillators with the Syncrus Internal Cardioversion System.

CONCURRENCE

Department	Name	Signature	Date
Product Development	(b)(4) [redacted]	(b)(4) [redacted]	12-5-02.
Manufacturing Engineering	[redacted]	[redacted]	12-5-02
Regulatory Affairs	[redacted]	[redacted]	12-5-02
Quality Assurance (Originator)	[redacted]	[redacted]	12-5-02
Clinical	[redacted]	[redacted]	12/5/02

Guidant Corporation
Cardiac Surgery
3200 Lakeside Drive, Santa Clara, CA 95054
www.guidant.com

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

(b)(4)

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

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STATEMENT OF INDICATIONS FOR USE

510(k) Number (if known): K_____

Device Name: Guidant Syncrus™ Internal Cardioversion System

Indications For Use: The Guidant SYNCRUS™ Internal Cardioversion System is indicated for use in post-operative cardiac surgery patients who require temporary atrial or ventricular pacing/sensing and/or atrial cardioversion.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use_____ OR (Per 21 CFR 801.109) Over-The-Counter Use_____

(Optional Format 1-2-96)

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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SPECIAL 510(k): Device Modification

ODE Review Memorandum (Decision Making Document is Attached)

To: THE FILE **RE:** DOCUMENT NUMBER K024071

This 510(k) submission contains information/data on modifications made to the SUBMITTER'S own Class II, Class III or Class I devices requiring 510(k). The following items are present and acceptable (delete/add items as necessary): ✓ = Present and acceptable

1. The name and 510(k) number of the SUBMITTER'S previously cleared device. (For a preamendments device, a statement to this effect has been provided.)
   - ✓ The predicate device is the Guidant Syncrus Internal Cardioversion System, K020701, cleared May 24, 2002.
2. Submitter's statement that the **INDICATION/INTENDED USE** of the modified device as described in its labeling **HAS NOT CHANGED** along with the proposed labeling which includes instructions for use, package labeling, and, if available, advertisements or promotional materials.
   - ✓ The intended use has not changed. It reads, "The Guidant Syncrus Internal Cardioversion System is indicated for use in post-operative cardiac surgery patients who require temporary atrial or ventricular pacing/sensing and/or atrial cardioversion."
   - ✓ Labeling has been provided. It has been modified to account for the changes, noted below, and is acceptable.
3. A description of the device **MODIFICATIONS,** including clearly labeled diagrams, engineering drawings, photographs, user's and/or service manuals in sufficient detail to demonstrate that the **FUNDAMENTAL SCIENTIFIC TECHNOLOGY** of the modified device **has not changed**.

   The modifications include:
   - ✓ Qualifying the device to be used with certain biphasic defibrillators, and modifying the labeling accordingly. Using their same verification and validation activities, the sponsor has demonstrated that the device will perform as intended with the Medtronic Physio-Control LIFEPAK 12 and LIFEPAK 20 biphasic defibrillators, and the Agilent (Philips Medical) Heartstream or Heartstream XL and XLT defibrillators. *The device is not compatible with the Zoll M Series biphasic or monophasic defibrillators*, as these devices will not discharge energy into the EDIM. **Labeling includes appropriate warnings.**
   - ✓ Modifying the maintenance procedures (requiring changes to the service manual); and
   - ✓ Adding an alternative method for heart wire placement to the Instructions for Use manual.
4. **Comparison Information** (similarities and differences) to applicant's legally marketed predicate device including, labeling, intended use, physical characteristics.
   - ✓ The sponsor has provided a detailed comparison in Section 7 of the file.
5. A **Design Control Activities Summary** which includes:
   a) Identification of Risk Analysis method(s) used to assess the impact of the modification on the device and its components, and the results of the analysis
   b) Based on the Risk Analysis, an identification of the verification and/or validation activities required, including methods or tests used and acceptance criteria to be applied
   c) ✓ A declaration of conformity with design controls. The declaration of conformity should include:
      i) ✓ A statement signed by the individual responsible, that, as required by the risk analysis, all verification and validation activities were performed by the designated individual(s) and the results demonstrated that the predetermined acceptance criteria were met, and
      ii) ✓ A statement signed by the individual responsible, that the manufacturing facility is in conformance with design control procedure requirements as specified in 21 CFR 820.30 and the records are available for review.

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6. A **Truthful and Accurate Statement (✓)**, a **510(k) Summary (✓) or Statement** and the **Indications for Use Enclosure (✓).**

The labeling for this modified subject device has been reviewed to verify that the indication/intended use for the device is unaffected by the modification. In addition, the submitter's description of the particular modification(s) and the comparative information between the modified and unmodified devices demonstrate that the fundamental scientific technology has not changed. The submitter has provided the design control information as specified in The New 510(k) Paradigm and on this basis, I recommend the device be determined substantially equivalent to the previously cleared (or their preamendment) device.

Please see the notes from conference call with Guidant on February 7, 2003.

(Reviewer's Signature) (Date) 2/9/03

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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THE 510(K) DOCUMENTATION FORMS ARE AVAILABLE ON THE LAN UNDER 510(K) BOILERPLATES TITLED "DOCUMENTATION" AND MUST BE FILLED OUT WITH EVERY FINAL DECISION (SE, NSE, NOT A DEVICE, ETC.).

"SUBSTANTIAL EQUIVALENCE" (SE) DECISION MAKING DOCUMENTATION

K020701

Reviewer:_____Megan Moynahan_____

Division/Branch:__DCD/PDLB_____

Device Name:____Guidant Syncrus System_____

Product To Which Compared (510(K) Number If Known):_____K020701_____

		YES	NO	
1.	Is Product A Device	✓		If **NO** = Stop
2.	Is Device Subject To 510(k)?	✓		If **NO** = Stop
3.	Same Indication Statement?	✓		If **YES** = Go To 5
4.	Do Differences Alter The Effect Or Raise New Issues of Safety Or Effectiveness?			If **YES** = Stop **NE**
5.	Same Technological Characteristics?	✓		If **YES** = Go To 7
6.	Could The New Characteristics Affect Safety Or Effectiveness?			If **YES** = Go To 8
7.	Descriptive Characteristics Precise Enough?		✓	If **NO** = Go To 10 If **YES** = Stop **SE**
8.	New Types Of Safety Or Effectiveness Questions?			If **YES** = Stop **NE**
9.	Accepted Scientific Methods Exist?			If **NO** = Stop **NE**
10.	Performance Data Available?	✓		If **NO** = Request Data
11.	Data Demonstrate Equivalence?	✓		Final Decision: **Substantially Equivalent**

Note: In addition to completing the form on the LAN, "yes" responses to questions 4, 6, 8, and 11, and every "no" response requires an explanation. ***See Notes in Special 510(k) Summary***

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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GUIDANT

Cardiac Surgery

REGULATORY PHONE LOG

REGULATORY AGENCY: FDA/CDRH/ODE (Pacemakers, Defibrillators and Leads branch)

SUBMISSION: Syncrus System – Special 510(K) K024071/S001

DATE: 2/76/03 TIME: 12:00 PM PT

GUIDANT CONTACT: Ziad Rouag, Debbie Cogan, Kobby Danwah,

AGENCY CONTACT: Megan Moynahan (Branch Chief)

PHONE NUMBER: NA

CARDIAC INITIATED: YES: ☒ NO: ☐

REASON FOR CALL: Real Time review of Syncrus System – Special 510(K) K024071/S001

Per FDA request, Guidant agreed to conduct a teleconference, real-time review of the above note special 510(k) submission amendment, intended to qualify the Syncrus System for usage with biphasic defibrillators. Participating in the meeting were Ms. Megan Moynahan, FDA Branch Chief, Pacing, Defibrillator and Leads Branch; Ziad Rouag, Director Clinical and Regulatory Affairs; Kobby Dankwah, Director of Product Development; and Debbie Cogan, Regulatory Affairs Associate.

The review was conducted with Guidant responding to FDA questions previously submitted in response the Special 510(k) submitted December 9, 2002. Ziad Rouag addressed the questions in the same manner and order as they appeared in the submission amendment dated January 10, 2003. The full text of the response may be found in the amendment K024071/S001.

Ms. Moynahan requested additional clarification regarding (b)(4) [redacted]

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4) [redacted]

(b)(4) [redacted].

Ms. Moynahan requested additional clarification (b)(4) [redacted]

Ms. Moynahan considered the need for a cautionary label on the EDIM requesting to user to check for defibrillator compatibility. Guidant felt this was not necessary since the Syncrus EDIM initially undergoes screening testing prior to introduction to the floor by biomedical engineers at hospitals. The screening would be documented and the EDIM would be specially marked (e.g. using color coded stickers) prior to introduction to the floor. The biomedical staff would detect any defibrillator compatibility issues. In addition instructions for use list tested compatible defibrillators. To illustrate the robustness of this process, a complaint of this nature concerning the Zoll M series monophonic defibrillator was received from a hospital biomedical group during its initial device screening. As discussed above an appropriate warning will be added to the IFU.

On a separate matter, Guidant requested clarification regarding a seperate 510k, the ESSeX Aspiration/Irrigation Instrument with Positioning Guide (K023630). As Branch Chief of the Pacing, Defibrillator and Leads Branch, Ms. Moynahan had been consulted on this 510(k) premarket application that had been submitted to the general surgical group, through third party review. Guidant wished to understand the reason why the Pacing, Defibrillator and Leads Branch had recommended non-substantial equivalency against the Medtronic Myocardial Implant Tool. Ms. Moynahan stated that the problem was in the Indication for Use statement that included reference to the removal of cardiac leads and heart wires. The removal function was not compatible with the Medtronic tool's cleared indication. Guidant noted it was willing to re-submit a premarket application predicating off of the Medtronic Implant Tool with an appropriate indication for use statement that would exclude the removal of cardiac leads and heart wires. Guidant inquired as to whether such a tool would have to be specialized for use with a specific cardiac lead or heart wire. Ms. Moynahan indicated it would not have to specify a specific device but it would have to indicate that it is for use with devices of a certain size and dimension. Guidant indicated it intended to submit a 510(k) premarket notification for the ESSeX Aspiration/Irrigation Instrument with Positioning Guide to the Pacing, Defibrillator and Leads Branch with an appropriate indication within the near future. Ms. Moynahan acknowledged that intention.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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At the conclusion of the meeting Guidant agreed to forward meeting minutes via email to Ms. Moynahan.

I concur -

Signature: [illegible] Date 2/9/03

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Moynahan, Megan

From: Moynahan, Megan
nt: Sunday, February 09, 2003 8:54 PM
: 'Rouag, Ziad A. (SC)'
c: Cogan, Debbie (SC)
Subject: RE: Syncrus System - Special 510(K) K024071/A001

Thanks. Per our phone conversation, are you going to be modifying your labeling to further indicate the Syncrus' incompatibility with the Zoll M Series monophasic as well? If so, you should send a copy of the revised labeling (electronically, and as an amendment to the file sent through Document Mail Center). Once I get the electronic copy, I can close out the file.

Thanks,
Megan

-----Original Message-----
From: Rouag, Ziad A. (SC) [mailto:zrouag@guidant.com]
Sent: Friday, February 07, 2003 2:00 PM
To: moynahan Megan (E-mail)
Cc: Cogan, Debbie (SC)
Subject: Syncrus System - Special 510(K) K024071/A001

Dear Ms. Moynahan,

As discussed please find attached final minutes from yesterday's conference call.

<<Moynahan020603-Final.doc>>

ad Rouag
.rector or Regulatory & Clinical Affairs
3200 Lakeside Drive
Santa Clara, CA 95054-2807
email:zrouag@guidant.com
tel: 408-845-1847
pager: 877-506-5469
fax:408-845-1855
cell: 408-425-8052

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Guidant SYNCRUS™ System

Post Cardiac Surgery Atrial Cardioversion and Temporary Cardiac Pacing

INSTRUCTIONS FOR USE

Excerpt - see warning

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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CONTRAINDICATIONS:

There are no known general contraindications for temporary post surgical heart wire leads. Patient anatomy and medical condition, however, should determine the use and implantation procedure.

WARNINGS:

The SYNCRUS™ System is not compatible with all low energy external defibrillators. Zoll M Series defibrillators, both monophasic and biphasic, will not discharge energy into the EDIM and are incompatible with the SYNCRUS™ System. Refer to the SYNCRUS™ System Operator's Manual (see section 6.0, *Required User Supplied Components*) for a list of compatible external defibrillators.

- Perform synchronized cardioversion only. Unsynchronized shocks may result in ventricular fibrillation, causing patient injury or death.

- The SYNCRUS™ Heart Wires provide a direct path for electrical current flow to the patient's heart. DO NOT touch the Heart Wire leads or the EDIM (when connected to the Heart Wires) with your bare hands or with anything that may deliver static (electrostatic discharge). Avoid the possibility of unintentional contact between the wire leads, including extension cable, and any equipment used as well as any conductive surface contact. Line powered equipment used in the vicinity of the patient must be properly grounded.

- The SYNCRUS™ EDIM and Cardioversion Extension Cable are designed solely for use with the SYNCRUS™ Heart Wires.

- DO NOT connect the Heart Wires to any equipment other than that specified in these instructions and the SYNCRUS™ System Operator's Manual. Patient injury or death may result.

- If the SYNCRUS™ EDIM has been dropped, perform a FULL maintenance test as described in the SYNCRUS™ System Operator's Manual (see section 11.0, *Maintenance and Calibration*) prior to using the EDIM again. Dropping the EDIM may damage internal components, possibly rendering the device inoperable or out of specification.

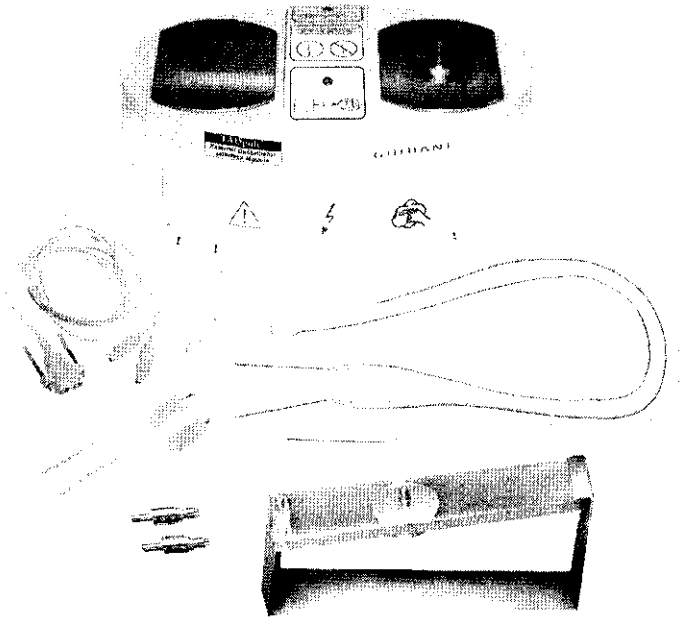
- Wire fracture, dislodgement, abrasion and/or an incomplete connection can cause a periodic or continual loss of pacing and sensing, possibly resulting in inappropriate delivery of conversion therapy. Connect the pacing connector pins for baseline measurements to a pacing system analyzer (PSA) or temporary pacemaker and evaluate the placement by determining R-wave amplitude, pacing threshold, and pacing lead impedance. Secure the SYNCRUS™ Heart Wires by taping the cardioversion connectors and pacing pins to the patient's body until needed.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2014-7272; Released 10/23/14

Guidant SYNCRUS™ System

Post Cardiac Surgery Atrial Cardioversion
And
Temporary Cardiac Pacing



OPERATOR'S MANUAL

Excerpt - see warning

CE
0344

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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7.0 WARNINGS

- The SYNCRUS™ System is not compatible with all low energy external defibrillators. The Zoll M Series defibrillators will not discharge energy into the EDIM and are incompatible with the SYNCRUS™ System. See section 6.0 on *Required User Supplied Components* for a list of compatible external defibrillators.
- Perform synchronized cardioversion only. Unsynchronized shocks may result in ventricular fibrillation, causing patient injury or death.
- The SYNCRUS™ Heart Wires provide a direct path for electrical current flow to the patient's heart. DO NOT touch the heart wire leads or the EDIM (when connected to the Heart Wires) with your bare hands or with anything that may deliver static (electrostatic discharge). Avoid the possibility of unintentional contact between the wire leads, including extension cable, and any equipment used as well as any conductive surface contact. Line powered equipment used in the vicinity of the patient must be properly grounded.
- The SYNCRUS™ EDIM and Cardioversion Extension Cable are designed solely for use with the SYNCRUS™ Heart Wires.
- DO NOT connect the Heart Wires to any equipment other than that specified in these instructions and the SYNCRUS™ System Operator's Manual. Patient injury or death may result.
- If the SYNCRUS™ EDIM has been dropped, perform a FULL maintenance test as described in the SYNCRUS™ System Operator's Manual (see section 11.0, *Maintenance and Calibration*) prior to using the EDIM again. Dropping the EDIM may damage internal components, possibly rendering the device inoperable or out of specification.
- Wire fracture, dislodgement, abrasion and/or an incomplete connection can cause a periodic or continual loss of pacing and sensing, possibly resulting in inappropriate delivery of conversion therapy. Connect the pacing connector pins for baseline measurements to a pacing system analyzer (PSA) or temporary pacemaker and evaluate the placement by determining R-wave amplitude, pacing threshold, and pacing lead impedance. Secure the SYNCRUS™ Heart Wires by taping the cardioversion connectors and pacing pins to the patient's body until needed.
- Although pliable, the lead body is not designed to tolerate excessive flexing, bending, or tension. This could cause structural weakness, conductor discontinuity, and/or lead dislodgement. Secure the cardioversion connectors and pacing pins to the patient's body until needed. Minimize manipulation of the Heart Wires.
- Equipment and accessories connected to the Guidant SYNCRUS™ System shall comply with IEC-601-1, type CF.

8.0 PRECAUTIONS

- SYNCRUS™ Heart Wires are for single use only. DO NOT RESTERILIZE. DO NOT REUSE.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

Memorandum

From: Reviewer(s) - Name(s) Megan Maynard

Subject: 510(k) Number K024071

To: The Record - It is my recommendation that the subject 510(k) Notification:

- ☐ Refused to accept.
- ☑ Requires additional information (other than refuse to accept). Phone hold questions faxed 12/23
- ☐ Is substantially equivalent to marketed devices.
- ☐ NOT substantially equivalent to marketed devices.
  - Dc Novo Classification Candidate? ☐ YES ☐ NO
- ☐ Other (e.g., exempt by regulation, not a device, duplicate, etc.)

Is this device subject to Postmarket Surveillance?	☐ YES	☐ NO
Is this device subject to the Tracking Regulation?	☐ YES	☐ NO
Was clinical data necessary to support the review of this 510(k)?	☐ YES	☐ NO
Is this a prescription device?	☐ YES	☐ NO
Was this 510(k) reviewed by a Third Party?	☐ YES	☐ NO
Special 510(k)?	☐ YES	☐ NO
Abbreviated 510(k)? Please fill out form on H Drive 510k/boilers	☐ YES	☐ NO

This 510(k) contains:

Truthful and Accurate Statement ☐ Requested ☐ Enclosed
(required for originals received 3-14-95 and after)

☐ A 510(k) summary OR ☐ A 510(k) statement

☐ The required certification and summary for class III devices

☐ The indication for use form (required for originals received 1-1-96 and after)

Animal Tissue Source ☐ YES ☐ NO

The submitter requests under 21 CFR 807.95 (doesn't apply for SEs):

☐ No Confidentiality ☐ Confidentiality for 90 days ☐ Continued Confidentiality exceeding 90 da

Predicate Product Code with class: Additional Product Code(s) with panel (optional):

Review: [signature] PDLB 12/23
(Branch Chief) (Branch Code) (Date)

Final Review: _____
(Division Director) (Date)

Revised:8/17/99

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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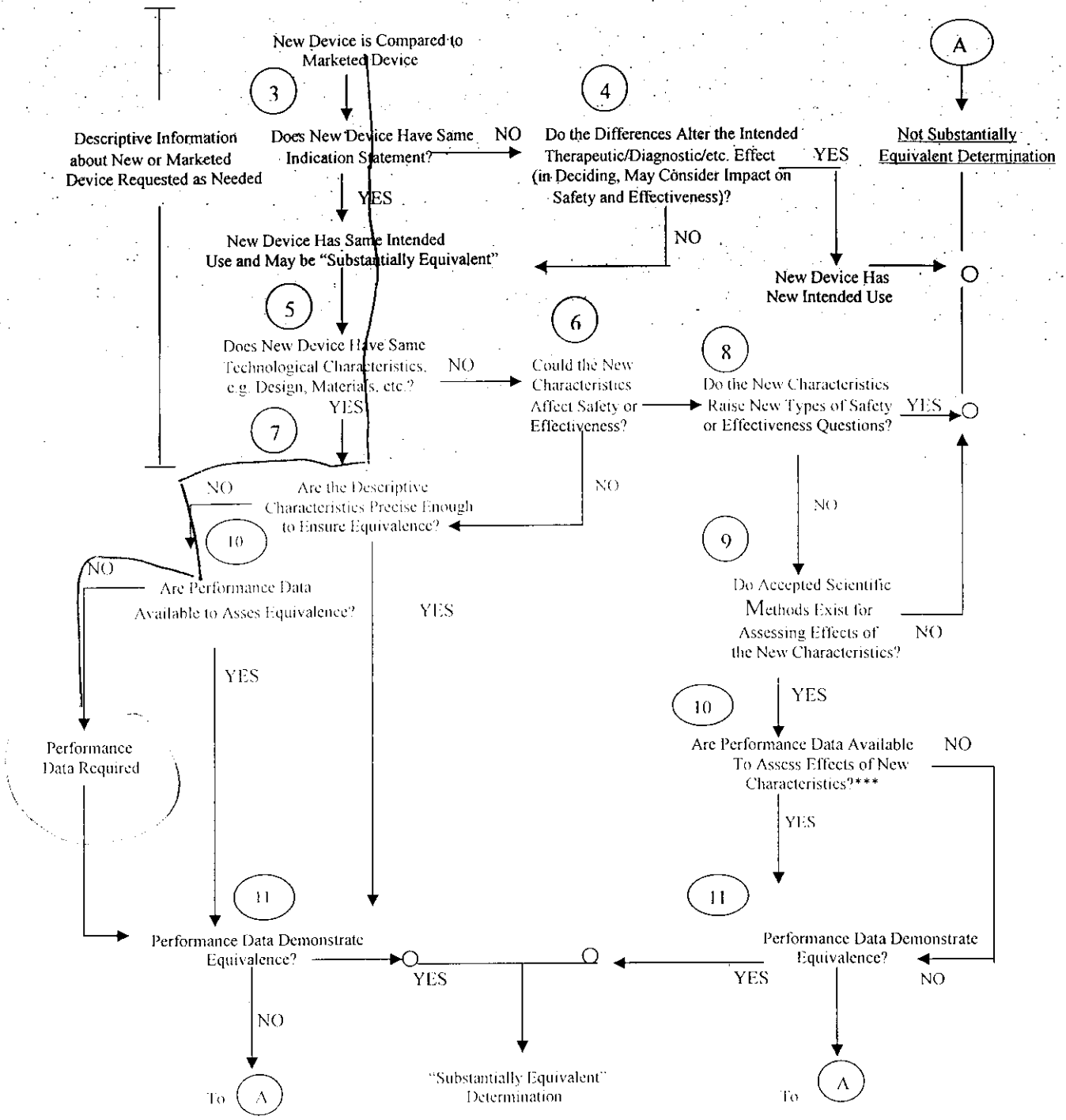
510(k) "SUBSTANTIAL EQUIVALENCE" DECISION-MAKING PROCESS



❖ 510(k) Submissions compare new devices to marketed devices. FDA requests additional information if the relationship between marketed and "predicate" (pre-Amendments or reclassified post-Amendments) devices is unclear

❖❖ This decision is normally based on descriptive information alone, but limited testing information is sometimes required

❖❖❖ Data may be in the 510(k), other 510(k)s, the Center's classification files, or the literature

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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FAX COVER SHEET

U.S. FOOD AND DRUG ADMINISTRATION
CENTER FOR DEVICES AND RADIOLOGICAL HEALTH
OFFICE OF DEVICE EVALUATION

DIVISION OF CARDIOVASCULAR DEVICES
9200 CORPORATE BOULEVARD HFZ-450
ROCKVILLE, MARYLAND 20850

NO. OF PAGES: 2 (including cover sheet) DATE: 12/23/02

TO: Debbie Cogan FAX#: (408) 845-1855

COMMENTS:

Per my voicemail, I am placing this file on phone hold pending your responses to the following questions. Please give me a call if you have any questions.

SENDER'S NAME: Megan Moynahan

SENDER'S FAX # ☑ (301) 594-3076 ☐ (301) 480-4204 ☐ (301) 827-4351

SENDER'S PHONE # ☐ (301) 443-8320 ☑ (301) 443-8517 ☐ (301) 443-8262 ☐ (301) 443-8609 ☐ (301) 443-8243
x180

FROM:
- ☐ Office of the Director
- ☐ Cardiac Electrophysiology & Monitoring Devices (CEMB)
- ☑ Pacing, Defibrillator & Leads Branch (PDLB)
- ☐ Circulatory Support & Prosthetics (CSPB)
- ☐ Interventional Cardiology Devices (ICDB)
- ☐ Peripheral Vascular Devices Branch (PVDB)

****

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PLEASE ADVISE IF TRANSMISSION IS ILLEGIBLE

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(b)(4) Deficiencies Raised by FDA's Reviewers

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INTEROFFICE MEMORANDUM

TO: K024071

FROM: MEGAN MOYNAHAN, BRANCH CHIEF, PDLB

SUBJECT: GUIDANT SYNCRUS INTERNAL CARDIOVERSION SYSTEM

DATE: 12/23/02

CC: DEFICIENCIES FOR THE SPONSOR – PHONE HOLD

SUMMARY

The sponsor has submitted this Special 510(k) to request market clearance for modifications to the labeling of the Syncrus Internal Cardioversion System. In my review, I came across the following issues that require a response by the sponsor:

(b)(4), (b)(5) Issues Raised by FDA's Reviewers, FDA Internal opinions/recommendations

[redacted]

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(b)(4), (b)(5) Issues Raised by FDA's Reviewers, FDA Internal opinions/recommendations

[redacted]

RECOMMENDATION

These deficiencies were forwarded to the sponsor via fax on 12/23/02. The file should be placed on Phone Hold.

Megan Moynahan, Branch Chief, PDLB

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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SCREENING CHECKLIST
FOR ALL PREMARKET NOTIFICATION [510(k)] SUBMISSIONS

510(k) Number: _____

The cover letter clearly identifies the type of 510(k) submission as (Check the appropriate box):

☐ Special 510(k) - Do Sections 1 and 2

☐ Abbreviated 510(k) - Do Sections 1; 3 and 4

☐ Traditional 510(k) or no identification provided - Do Sections 1 and 4

Section 1: Required Elements for All Types of 510(k) submissions:

	Present or Adequate	Missing or Inadequate
Cover letter, containing the elements listed on page 3-2 of the Premarket Notification [510)] Manual.		
Table of Contents.		
Truthful and Accurate Statement.		
Device's Trade Name, Device's Classification Name and Establishment Registration Number.		
Device Classification Regulation Number and Regulatory Status (Class I, Class II, Class III or Unclassified).		
Proposed Labeling including the material listed on page 3-4 of the Premarket Notification [510)] Manual.		
Statement of Indications for Use that is on a separate page in the premarket submission.		
Substantial Equivalence Comparison, including comparisons of the new device with the predicate in areas that are listed on page 3-4 of the Premarket Notification [510)] Manual.		
510(k) Summary or 510(k) Statement.		
Description of the device (or modification of the device) including diagrams, engineering drawings, photographs or service manuals.		
Identification of legally marketed predicate device. *		
Compliance with performance standards. * [See Section 514 of the Act and 21 CFR 807.87 (d).]		
Class III Certification and Summary. **		
Financial Certification or Disclosure Statement for 510(k) notifications with a clinical study. * [See 21 CFR 807.87 (i)]		
510(k) Kit Certification ***		

* - May not be applicable for Special 510(k)s.

** - Required for Class III devices, only.

*** - See pages 3-12 and 3-13 in the Premarket Notification [510)] Manual and the Convenience Kits Interim Regulatory Guidance.

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Section 2: Required Elements for a SPECIAL 510(k) submission:

	Present	Inadequate or Missing
Name and 510(k) number of the submitter's own, unmodified predicate device.		
A description of the modified device and a comparison to the sponsor's predicate device.		
A statement that the intended use(s) and indications of the modified device, as described in its labeling are the same as the intended uses and indications for the submitter's unmodified predicate device.		
Reviewer's confirmation that the modification has not altered the fundamental scientific technology of the submitter's predicate device.		
A Design Control Activities Summary that includes the following elements (a-c):		
a. Identification of Risk Analysis method(s) used to assess the impact of the modification on the device and its components, and the results of the analysis.		
b. Based on the Risk Analysis, an identification of the required verification and validation activities, including the methods or tests used and the acceptance criteria to be applied.		
c. A Declaration of Conformity with design controls that includes the following statements:		
A statement that, as required by the risk analysis, all verification and validation activities were performed by the designated individual(s) and the results of the activities demonstrated that the predetermined acceptance criteria were met. This statement is signed by the individual responsible for those particular activities.		
A statement that the manufacturing facility is in conformance with the design control procedure requirements as specified in 21 CFR 820.30 and the records are available for review. This statement is signed by the individual responsible for those particular activities.		

Section 3: Required Elements for an ABBREVIATED 510(k)* submission:

	Present	Inadequate or Missing
For a submission, which relies on a guidance document and/or special control(s), a summary report that describes how the guidance and/or special control(s) was used to address the risks associated with the particular device type. (If a manufacturer elects to use an alternate approach to address a particular risk, sufficient detail should be provided to justify that approach.)		
For a submission, which relies on a recognized standard, a declaration of conformity [For a listing of the required elements of a declaration of conformity, SEE **Required Elements for a Declaration of Conformity to a Recognized Standard,** which		

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is posted with the 510(k) boilers on the H drive.]		
For a submission, which relies on a recognized standard without a declaration of conformity, a statement that the manufacturer intends to conform to a recognized standard and that supporting data will be available before marketing the device.		
For a submission, which relies on a non-recognized standard that has been historically accepted by FDA, a statement that the manufacturer intends to conform to a recognized standard and that supporting data will be available before marketing the device.		
For a submission, which relies on a non-recognized standard that has not been historically accepted by FDA, a statement that the manufacturer intends to conform to a recognized standard and that supporting data will be available before marketing the device and any additional information requested by the reviewer in order to determine substantial equivalence.		
Any additional information, which is not covered by the guidance document, special control, recognized standard and/or non-recognized standard, in order to determine substantial equivalence.		

* - When completing the review of an abbreviated 510(k), please fill out an Abbreviated Standards Data Form (located on the H drive) and list all the guidance documents, special controls, recognized standards and/or non-recognized standards, which were noted by the sponsor.

Section 4: Additional Requirements for ABBREVIATED and TRADITIONAL 510(k) submissions (If Applicable):

	Present	Inadequate or Missing
a) Biocompatibility data for all patient-contacting materials, OR certification of identical material/formulation:		
b) Sterilization and expiration dating information:		
i) sterilization process		
ii) validation method of sterilization process		
iii) SAL		
iv) packaging		
v) specify pyrogen free		
vi) ETO residues		
vii) radiation dose		
viii) Traditional Method or Non-Traditional Method		
c) Software Documentation:		

Items with checks in the "Present or Adequate" column do not require e additional information from the sponsor. Items with checks in the " Missing or Inadequate" column must be submitted before substantive review of the document.

Passed Screening _____Yes _____No
Reviewer: _____
Concurrence by Review Branch: _____

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Date:

The deficiencies identified above represent the issues that we believe need to be resolved before our review of your 510(k) submission can be successfully completed. In developing the deficiencies, we carefully considered the statutory criteria as defined in Section 513(i) of the Federal Food, Drug, and Cosmetic Act for determining substantial equivalence of your device. We also considered the burden that may be incurred in your attempt to respond to the deficiencies. We believe that we have considered the least burdensome approach to resolving these issues. If, however, you believe that information is being requested that is not relevant to the regulatory decision or that there is a less burdensome way to resolve the issues, you should follow the procedures outlined in the "A Suggested Approach to Resolving Least Burdensome Issues" document. It is available on our Center web page at: http://www.fda.gov/cdrh/modact/leastburdensome.html

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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REVISED:3/14/95

THE 510(K) DOCUMENTATION FORMS ARE AVAILABLE ON THE LAN UNDER 510(K) BOILERPLATES TITLED "DOCUMENTATION" AND MUST BE FILLED OUT WITH EVERY FINAL DECISION (SE, NSE, NOT A DEVICE, ETC.).

"SUBSTANTIAL EQUIVALENCE" (SE) DECISION MAKING DOCUMENTATION

K_____

Reviewer: _____

Division/Branch: _____

Device Name: _____

Product To Which Compared (510(K) Number If Known): _____

	YES	NO	
1. Is Product A Device			If NO = Stop
2. Is Device Subject To 510(k)?			If NO = Stop
3. Same Indication Statement?			If YES = Go To 5
4. Do Differences Alter The Effect Or Raise New Issues of Safety Or Effectiveness?			If YES = Stop NE
5. Same Technological Characteristics?			If YES = Go To 7
6. Could The New Characteristics Affect Safety Or Effectiveness?			If YES = Go To 8
7. Descriptive Characteristics Precise Enough?			If NO = Go To 10 If YES = Stop SE
8. New Types Of Safety Or Effectiveness Questions?			If YES = Stop NE
9. Accepted Scientific Methods Exist?			If NO = Stop NE
10. Performance Data Available?			If NO = Request Data
11. Data Demonstrate Equivalence?			Final Decision:

Note: In addition to completing the form on the LAN, "yes" responses to questions 4, 6, 8, and 11, and every "no" response requires an explanation.

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1. Intended Use:

2. Device Description: Provide a statement of how the device is either similar to and/or different from other marketed devices, plus data (if necessary) to support the statement. Is the device life-supporting or life sustaining? Is the device implanted (short-term or long-term)? Does the device design use software? Is the device sterile? Is the device for single use? Is the device over-the-counter or prescription use? Does the device contain drug or biological product as a component? Is this device a kit? Provide a summary about the devices design, materials, physical properties and toxicology profile if important.

EXPLANATIONS TO "YES" AND "NO" ANSWERS TO QUESTIONS ON PAGE 1 AS NEEDED

1. Explain why not a device:

2. Explain why not subject to 510(k):

3. How does the new indication differ from the predicate device's indication:

4. Explain why there is or is not a new effect or safety or effectiveness issue:

5. Describe the new technological characteristics:

6. Explain how new characteristics could or could not affect safety or effectiveness:

7. Explain how descriptive characteristics are not precise enough:

8. Explain new types of safety or effectiveness questions raised or why the questions are not new:

9. Explain why existing scientific methods can not be used:

10. Explain what performance data is needed:

11. Explain how the performance data demonstrates that the device is or is not substantially equivalent:

ATTACH ADDITIONAL SUPPORTING INFORMATION

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Internal Administrative Form

	YES	NO
1. Did the firm request expedited review? 2. Did we grant expedited review?		
3. Have you verified that the Document is labeled Class III for GMP purposes? 4. If, not, has POS been notified?		
5. Is the product a device? 6. Is the device exempt from 510(k) by regulation or policy? 7. Is the device subject to review by CDRH?		
8. Are you aware that this device has been the subject of a previous NSE decision? 9. If yes, does this new 510(k) address the NSE issue(s), (e.g., performance data)?		
10. Are you aware of the submitter being the subject of an integrity investigation? 11. If, yes, consult the ODE Integrity Officer. 12. Has the ODE Integrity Officer given permission to proceed with the review? (Blue Book Memo #I91-2 and Federal Register 90N0332, September 10, 1991.		

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

Memorandum

From: Reviewer(s) - Name(s) Megan Mayrah

Subject: 510(k) Number K024071/S1

To: The Record - It is my recommendation that the subject 510(k) Notification:

☐ Refused to accept.

☐ Requires additional information (other than refuse to accept).

☑ Is substantially equivalent to marketed devices.

☐ NOT substantially equivalent to marketed devices.

De Novo Classification Candidate? ☐ YES ☐ NO

☐ Other (e.g., exempt by regulation, not a device, duplicate, etc.)

Is this device subject to Postmarket Surveillance?	☐ YES	☑ NO
Is this device subject to the Tracking Regulation?	☐ YES	☑ NO
Was clinical data necessary to support the review of this 510(k)?	☐ YES	☑ NO
Is this a prescription device?	☑ YES	☐ NO
Was this 510(k) reviewed by a Third Party?	☐ YES	☑ NO
Special 510(k)?	☑ YES	☐ NO
Abbreviated 510(k)? Please fill out form on H Drive 510k/boilers	☐ YES	☑ NO

This 510(k) contains:

Truthful and Accurate Statement ☐ Requested ☑ Enclosed
(required for originals received 3-14-95 and after)

☑ A 510(k) summary OR ☐ A 510(k) statement

☐ The required certification and summary for class III devices N/A

☑ The indication for use form (required for originals received 1-1-96 and after)

Animal Tissue Source ☐ YES ☐ NO

The submitter requests under 21 CFR 807.95 (doesn't apply for SEs):

☐ No Confidentiality ☐ Confidentiality for 90 days ☐ Continued Confidentiality exceeding 90 day

Predicate Product Code with class: NHW (II)

Additional Product Code(s) with panel (optional):

Review: (Branch Chief) [signature] (Branch Code) PDUB (Date) 2/14/03

Final Review: (Division Director) Ashley B. Brown for BDZ (Date) 2/14/03

Revised 8/17/99

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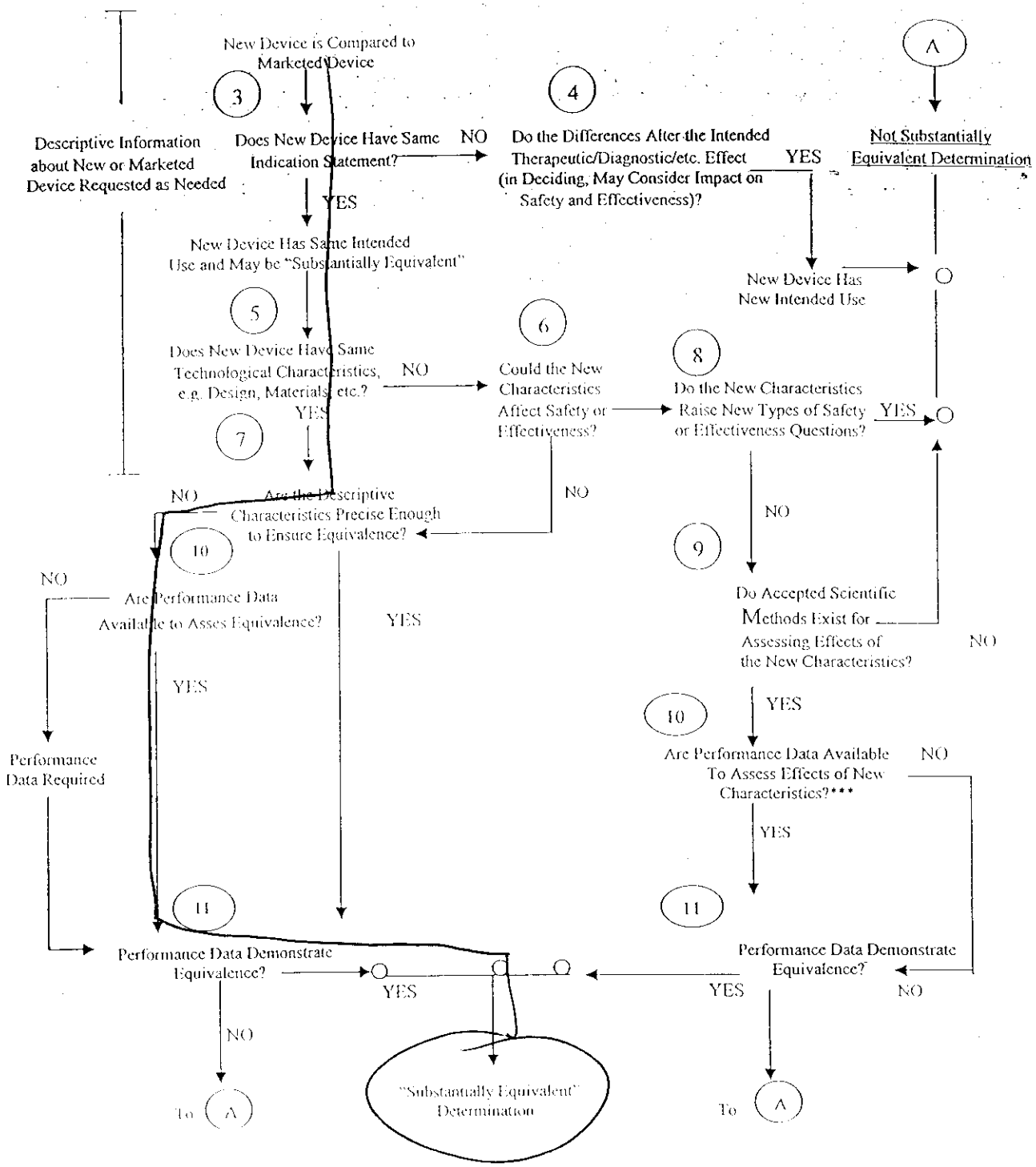
510(k) "SUBSTANTIAL EQUIVALENCE" DECISION-MAKING PROCESS



- 510(k) Submissions compare new devices to marketed devices. FDA requests additional information if the relationship between marketed and "predicate" (pre-Amendments or reclassified post-Amendments) devices is unclear.
- This decision is normally based on descriptive information alone, but limited testing information is sometimes required
- Data maybe in the 510(k), other 510(k)s, the Center's classification files, or the literature

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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DEPARTMENT OF HEALTH AND HUMAN SERVICES Public Health Service

Food and Drug Administration
Center for Devices and
Radiological Health
Office of Device Evaluation
Document Mail Center (HFZ-401)
9200 Corporate Blvd.
Rockville, Maryland 20850

January 15, 2003

GUIDANT CARDIAC SURGERY
3200 LAKESIDE DR.
SANTA CLARA, CA 95054
ATTN: DEBBIE COGAN

510(k) Number: K024071
Product: GUIDANT SYNCRUS INTERNAL CARDIOVERSION SYSTEM

The additional information you have submitted has been received.

We will notify you when the processing of this submission has been completed or if any additional information is required. Please remember that all correspondence concerning your submission MUST be sent to the Document Mail Center (HFZ-401) at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification submission. Also, please note the new Blue Book Memorandum regarding Fax and E-mail Policy entitled, "Fax and E-Mail Communication with Industry about Premarket Files Under Review. Please refer to this guidance for information on current fax and e-mail practices at www.fda.gov/cdrh/ode/a02-01.html.

The Safe Medical Devices Act of 1990, signed on November 28, states that you may not place this device into commercial distribution until you receive a letter from FDA allowing you to do so. As in the past, we intend to complete our review as quickly as possible. Generally we do so 90 days. However, the complexity of a submission or a requirement for additional information may occasionally cause the review to extend beyond 90 days. Thus, if you have not received a written decision or been contacted within 90 days of our receipt date you may want to check with FDA to determine the status of your submission.

If you have procedural or policy questions, please contact the Division of Small Manufacturers International and Consumer Assistance (DSMICA) at (301) 443-6597 or at their toll-free number (800) 638-2041, or contact me at (301) 594-1190.

Sincerely yours,

Marjorie Shulman
Supervisory Consumer Safety Officer
Premarket Notification Section
Office of Device Evaluation
Center for Devices and
Radiological Health

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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K024071/S1

GUIDANT

January 10, 2003

Document Mail Center (HFZ-401)
Center for Devices and Radiological Health
Food and Drug Administration
9200 Corporate Boulevard
Rockville, Maryland 20850

FDA/CDRH/OCE/DID
2003 JAN 15 A 8: 17
RECEIVED

RE: Amendment K024071/A001: Special 510(k) Notification for the Guidant Syncrus™ System

Dear Ms. Moynahan,

Thank you for your prompt response to our above referenced application. This amendment is in response to questions received via fax on December 23, 2002. Our response as noted below includes (b)(4) [redacted]

(b)(4) [redacted]

(b)(4) [redacted]

Guidant Corporation
3200 Lakeside Drive, Santa Clara, CA 95054-2807
Tel 408.845.3100 Fax 408.845.1800
www.guidant.com

SK 1 18

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4) [redacted]

(b)(4) [redacted] (b)(4) [redacted]

(b)(4) [redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4)

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(b)(4)

[redacted]

Guidant Cardiac Surgery has taken precautions to protect the confidentiality of this information, and requests FDA to hold the contents of this submission as confidential, under the maximum protection provided by the law. Furthermore, Guidant understands

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that the submission to the government of false information is prohibited by 18 USC 1001 and 21 USC 331(q).

If you have any questions, please contact Debbie Cogan, Regulatory Affairs Associate, by phone at (408) 845-1910 or by e-mail at dcogan@guidant.com.

Sincerely,

Debbie Cogan
Regulatory Affairs Associate

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Test Numb	Test Name	Pass/Fail	Comments
(b)(4)	[redacted]		

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Guidant ~~Synerus~~SYNCRUS™ System

Post Cardiac Surgery Atrial Cardioversion and Temporary Cardiac Pacing

INSTRUCTIONS FOR USE

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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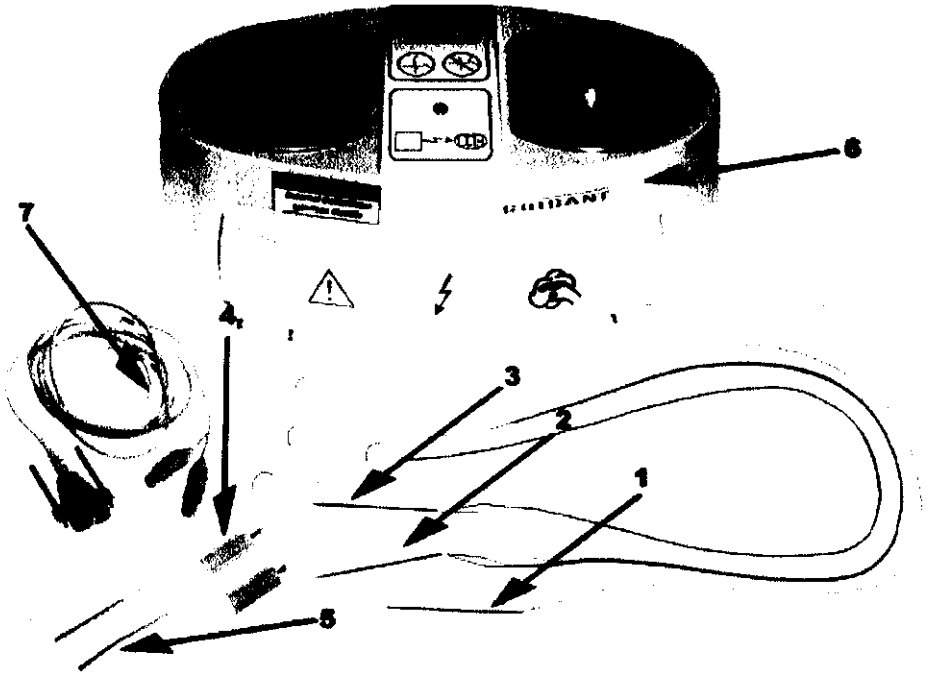

Figure 1.

Guidant ~~Syncrus~~SYNCRUS™ System

1. Left Atrial Heart Wire (unipolar)
2. Right Atrial Heart Wire (tripolar)
3. Ventricular Heart Wire (bipolar)
4. Yellow Cardioversion Connectors
5. Protective Tubings
6. External Defibrillator Interface Module (EDIM)
7. Cardioversion Extension Cable

Note: The Heart Wires (with yellow cardioversion connectors and protective tubings) are sold separately from the EDIM and Cardioversion Extension Cable.

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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INSTRUCTIONS FOR USE

Carefully read all instructions prior to use. Observe all warnings and precautions noted throughout these instructions.

SYSTEM DESCRIPTION:

The Guidant ~~Syncrus~~SYNCRUS™ System provides low energy internal cardioversion therapy to treat postoperative atrial fibrillation via ~~Syncrus~~SYNCRUS™ Heart Wires placed directly on the patient's heart. The ~~system~~ System's functions also include temporary atrial and ventricular pacing and ECG sensing capabilities.

The ~~Syncrus~~SYNCRUS™ System consists of the following components:

- Three single use Heart Wires that are attached to the myocardial tissue of the left atrium, right atrium, and right or left ventricle during cardiac surgery. The Heart Wires transmit low energy shocks to the patient's heart for electrical atrial cardioversion. The Heart Wires also provide for temporary cardiac pacing and ECG sensing capabilities.

- A reusable External Defibrillator Interface Module (EDIM), which interfaces between a ~~monophasic,~~ compatible low- energy~~,~~ external defibrillator and the Heart Wires. The EDIM reduces the output energy from the defibrillator to a low energy shock delivered through the Heart Wires.

- A reusable Cardioversion Extension Cable that connects the Heart Wires to the EDIM.

The ~~Syncrus~~SYNCRUS™ System components must be used in conjunction with a ~~monophasic,~~ compatible low energy external defibrillator, an external pacemaker, and pacing cables that connect the Heart Wires to the external pacemaker. The user supplies the external defibrillator, external pacemaker, and pacing cables.

Refer to the SYNCRUS™ System Operator's Manual (*Required User Supplied Components* section) for a list of compatible external defibrillators, external pacemakers and pacing cables that have been tested with the Guidant SYNCRUS™ System.

INDICATIONS FOR USE:

The Guidant ~~Syncrus~~SYNCRUS™ Internal Cardioversion System is indicated for use in post-operative cardiac surgery patients who require temporary atrial or ventricular pacing/sensing and/or atrial cardioversion.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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CONTRAINDICATIONS:

There are no known general contraindications for temporary post surgical heart wire leads. Patient anatomy and medical condition, however, should determine the use and implantation procedure.

WARNINGS:

- The ~~Guidant Syncrus~~SYNCRUS™ System is not compatible with ~~monophasic~~ all low energy external defibrillators ~~only~~. Refer to the SYNCRUS™ System Operator's Manual (*Required User Supplied Components* section) for a list of compatible external defibrillators.

- Perform synchronized cardioversion only. Unsynchronized shocks may result in ventricular fibrillation, causing patient injury or death.

- The ~~Syncrus~~SYNCRUS™ Heart Wires provide a direct path for electrical current flow to the patient's heart. DO NOT touch the ~~heart wire~~Heart Wire leads or the EDIM (when connected to the Heart Wires) with your bare hands or with anything that may deliver static (electrostatic discharge). Avoid the possibility of unintentional contact between the wire leads, including extension cable, and any equipment used as well as any conductive surface contact. Line powered equipment used in the vicinity of the patient must be properly grounded.

- The ~~Syncrus~~SYNCRUS™ EDIM and Cardioversion Extension Cable are designed solely for use with ~~Syncrus~~the SYNCRUS™ Heart Wires.

- DO NOT connect the Heart Wires to any equipment other than that specified in these instructions and the ~~Syncrus~~SYNCRUS™ System Operator's Manual. Patient injury or death may result.

- If the ~~Syncrus~~SYNCRUS™ ~~System~~ EDIM has been dropped ~~onto a hard surface~~, perform a FULL maintenance test as described in the ~~Syncrus~~SYNCRUS™ System Operator's Manual (*Maintenance and Calibration* section) prior to using the EDIM again. Dropping the EDIM may damage internal components, possibly rendering the device inoperable or out of specification.

- Wire fracture, dislodgement, abrasion and/or an incomplete connection can cause a periodic or continual loss of pacing and sensing, possibly resulting in inappropriate delivery of conversion therapy. Connect the pacing connector pins for baseline measurements to a pacing system analyzer (PSA) or temporary pacemaker and evaluate the placement by determining R-wave amplitude, pacing threshold, and pacing lead impedance. Secure the ~~Syncrus~~SYNCRUS™ Heart Wires by taping the cardioversion connectors and pacing pins to the patient's body until needed.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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- Although pliable, the lead body is not designed to tolerate excessive flexing, bending, or tension. This could cause structural weakness, conductor discontinuity, and/or lead dislodgement. Secure the cardioversion connectors and pacing pins to the patient's body until needed. Minimize manipulation of the ~~heart wires~~Heart Wires.

- Equipment and accessories connected to the Guidant ~~Synerus~~SYNCRUS™ System shall comply with IEC-601-1, type CF.

PRECAUTIONS:

- ~~Synerus~~SYNCRUS™ Heart Wires are for single use only. DO NOT RESTERILIZE. DO NOT REUSE.

- The ~~Synerus~~SYNCRUS™ Heart Wires are gamma sterilized after packaging. When they are received, they are sterile and ready for use. Should the seal or package be wet, damaged, punctured, or if the seal is broken, do not use or attempt to resterilize. Contact the local Guidant representative.

- Pre-clinical testing supports the use of this device up to 7 cardioversion attempts. Cardioversion attempts ranged from 1 to 9 attempts in clinical trials. Physicians should treat patients in accordance with judgment and experience. Assessment of the patient's overall condition and physician discretion should dictate the number of attempts to treat.

- It is recommended that defibrillation equipment and a pacing sensor system analyzer (PSA) or temporary pacemaker be readily available during lead placement and removal.

INSTRUCTIONS FOR USE:

1. Attach the ~~Synerus~~SYNCRUS™ Heart Wires to the patient's myocardial surface during cardiac surgery in the following order and before the patient's chest is closed. The described fixation techniques ~~is~~are furnished for informational purposes only. The physician may choose to vary the fixation technique in accordance with judgment and experience. The selected fixation technique of each Heart Wire placement should always allow for ease of extraction through gentle traction. Proper surgical procedures and techniques are the responsibility of the medical professional~~. Figures 2 through 3 illustrate heart wire placement as performed in clinical trials~~.

   Left Atrial Heart Wire (unipolar)

   - *Cardioversion Electrode (yellow wire)*: Use the attached curved needle to affix the cardioversion electrode to the left atrial myocardium. After the cardioversion electrode is affixed (see Figures 2a and 3a), cut off the curved needle and discard it. Place a slight bend or kink at the end of the electrode.

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Right Atrial Heart Wire (tripolar)

- *Cardioversion Electrode (yellow wire)*: Use the attached curved needle to affix the cardioversion electrode to the right atrial myocardium. After the cardioversion electrode is affixed (see Figures 2b and 3b), cut off the curved needle and discard it. Place a slight bend or kink at the end of the electrode.

  Placement should be made to maximize the atrial muscle mass between the right atrial cardioversion electrode and the left atrial cardioversion electrode.

- *Pacing Electrodes (black and blue wires)*: Use the attached curved needle to affix the bipolar pacing electrodes to the right atrial myocardium. For optimal cardiac pacing, bury both the pacing electrode and bullet in the myocardium. After the pacing electrodes are affixed (see Figures 2b and 3b), cut off the needle and discard it. Place a slight bend or kink at the end of the pacing electrode.

Ventricular Heart Wire (bipolar)

- *Pacing Electrodes (black and white wires)*: Use the attached curved needle to affix the bipolar pacing electrodes into the myocardial tissue of either the right or left ventricle. For optimal cardiac pacing, bury both the pacing electrode and bullet in the myocardium. After the pacing electrodes are affixed (see Figures 2c and 3c), cut off the curved needle and discard it. Place a slight bend or kink at the end of the pacing electrode.

Figures 2 through 3 illustrate two examples of Heart Wire placement techniques as used in clinical practice.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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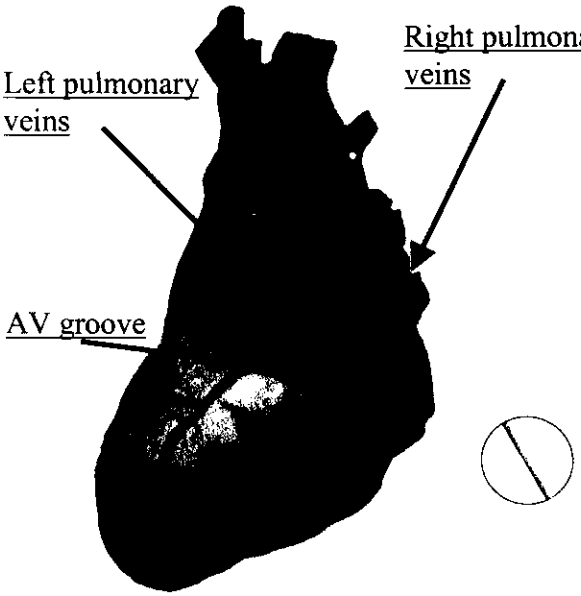
Figure 2. SYNCRUS™ Heart Wire Placement Technique A (used in clinical trials in Europe)



2a. Left Atrial Wire Placement
Figure shows the cardioversion electrode placed in an "S" pattern between the atrioventricular (AV) groove and the left and right pulmonary veins.

(Lateral-posterior view)

2b. Right Atrial Wire Placement
Figure shows the cardioversion electrode placed in an "S" pattern on the right atrial appendage.

The pacing electrode and bullet are shown placed on the right atrial myocardium.

(Anterior view)

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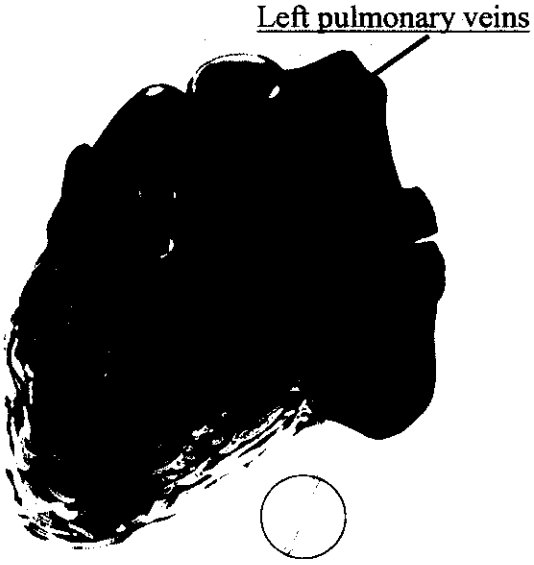
2c. Ventricular Wire Placement
Figure shows the pacing electrode and bullet placed on the right ventricle.

(Anterior view)

Figure 3. SYNCRUS™ Heart Wire Placement Technique B



3a. Left Atrial Wire Placement
Figure shows the cardioversion electrode placed within 5 mm anterior of the left pulmonary veins.

(Lateral-posterior view)

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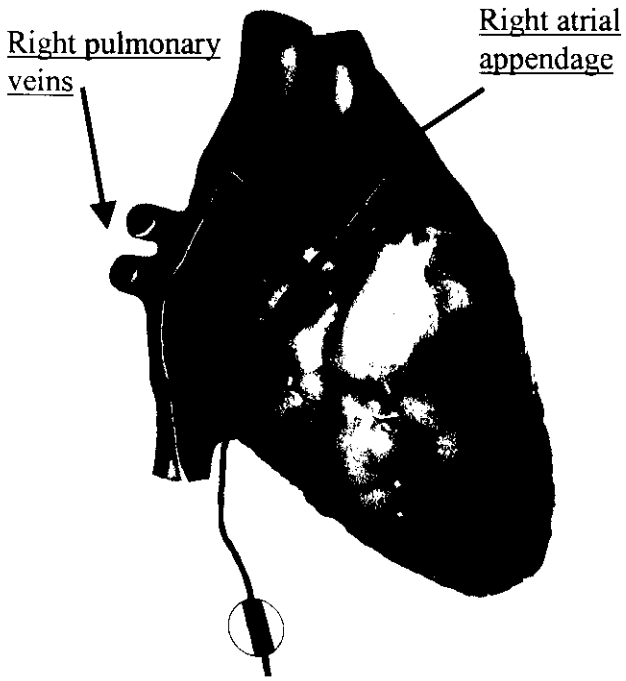

3b. Right Atrial Wire Placement
Figure shows the cardioversion electrode placed by the inferior vena cava and up towards the right pulmonary veins within 5 mm of the SA node.

The pacing electrode and bullet are shown placed on the right atrial appendage.

(Lateral view)

3c. Ventricular Wire Placement
Figure shows the pacing electrode and bullet placed on the right ventricle.

(Anterior view)

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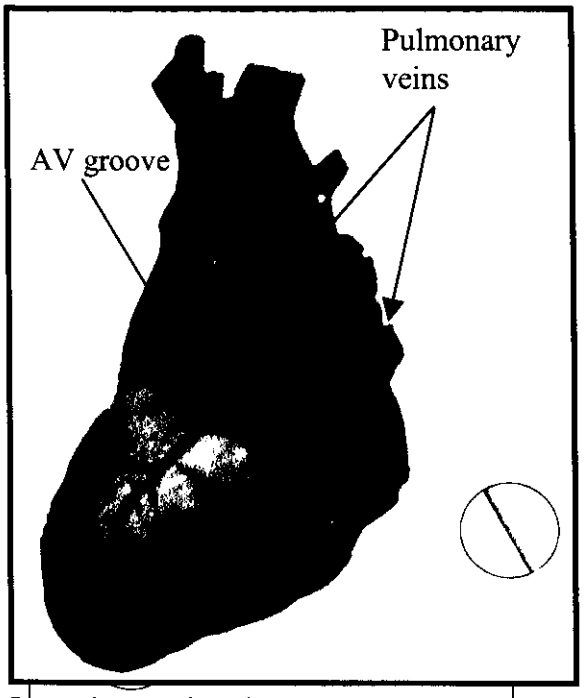

Lateral-posterior view

~~Left Atrial Heart Wire (unipolar)~~

- ~~*Cardioversion Electrode (yellow wire):* Use the attached curved needle to affix the cardioversion electrode to the left atrial myocardium on the atrioventricular (AV) groove between the left and right pulmonary veins in an "S" pattern as illustrated in Figure 2 for optimal results. After the cardioversion electrode is affixed, cut off the curved needle and discard it. Place a slight bend or kink at the end of the electrode.~~

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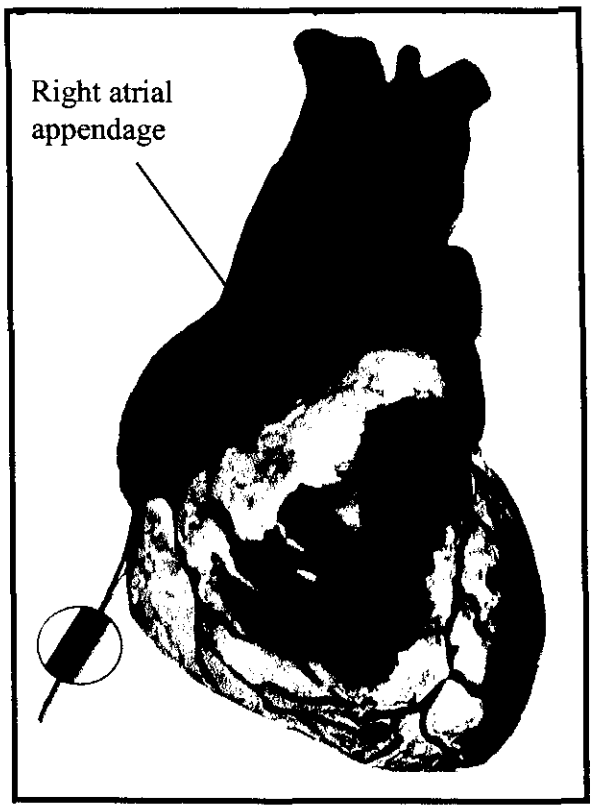

Anterior view

~~Right Atrial Heart Wire (tripolar)~~

- ~~*Cardioversion Electrode (yellow wire):* Use the attached curved needle to affix the cardioversion electrode into the right atrial myocardium in an "S" pattern as shown in Figure 3 for optimal results. After the cardioversion electrode is affixed, cut off the curved needle and discard it. Place a slight bend or kink at the end of the electrode.~~

- ~~Placement should be made to maximize the atrial muscle mass between the right atrial cardioversion electrode and the left atrial cardioversion electrode.~~

- ~~*Pacing Electrodes (black and blue wires):* Use the attached curved needle to affix the bipolar pacing electrodes into the right atrial myocardium. For optimal cardiac pacing, bury both the anode and cathode in the myocardium. After the pacing electrodes are affixed, cut off the needle and discard it. Place a slight bend or kink at the end of the anode electrode.~~

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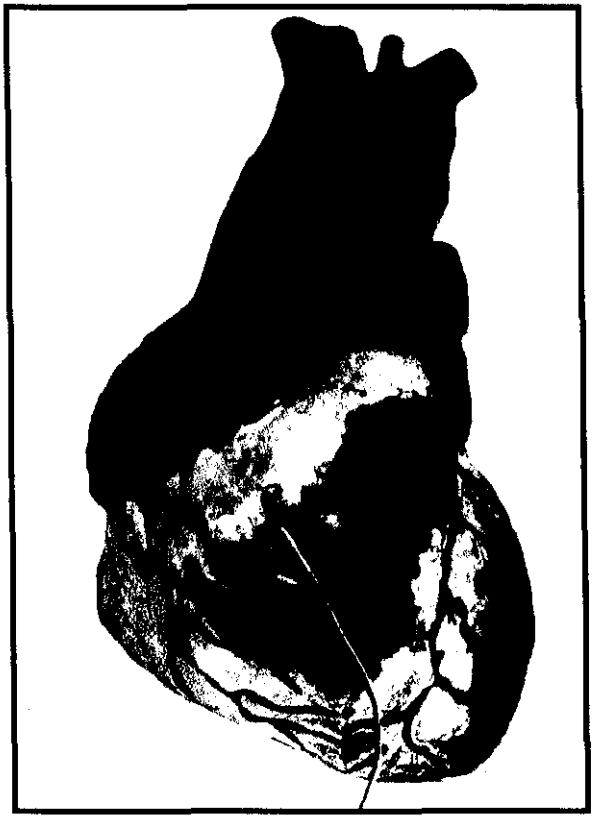
~~**Figure 4. SYNCRUS Ventricular Heart Wire Placement**~~



Anterior view

~~Ventricular Heart Wire (bipolar)~~

~~*Pacing Electrodes (black and white wires):* Use the attached curved needle to affix the bipolar pacing electrodes into the myocardial tissue of either the right or left ventricle as illustrated in Figure 4 for optimal results. The positive pacing electrode (anode) is attached to the needle, while the negative electrode (cathode) is contained in the 4 mm long bullet. For optimal cardiac pacing, bury both the anode and cathode in the myocardium. After pacing electrodes are affixed, cut off the curved needle and discard it. Place a slight bend or kink at the end of the anode electrode.~~

2. Once the cardioversion and pacing electrodes have been affixed to the patient's heart, visualize the paths that the Heart Wires will travel as they are extracted.

3. Use the straight needle on the proximal end of each ~~Syncrus~~SYNCRUS™ Heart Wire to externalize the Heart Wires through the chest wall and skin. Once the Heart Wires are externalized, cut off the thoracic needles, maximizing the length of the exposed cardioversion leads. Discard the thoracic needles appropriately.

4. Attach the yellow cardioversion connectors provided with the SYNCRUS™ Heart Wires to the yellow cardioversion wires on the Left and Right Atrial Heart Wires. ~~Attach a yellow cardioversion connector provided with the Syncrus Left and Right Atrial Heart Wires.~~ This is done by threading the Heart Wire cardioversion lead through the pinhole on the backside of the connector and pushing the pin into the connector. Make sure there is good electrical contact between the Heart Wire cardioversion lead and the yellow cardioversion connector.

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5. Connect the pacing connector pins for baseline measurements to a pacing system analyzer (PSA) or temporary pacemaker and evaluate the placement by determining R-wave amplitude, pacing threshold, and pacing lead impedance.

6. Cover the pacing connector pins on the Right Atrial Heart Wire (black and blue wires) and Ventricular Heart Wire (black and white wires) with the protective tubings provided with the ~~Syncrus~~ SYNCRUS™ Heart Wires~~.~~. Secure the ~~Syncrus~~ SYNCRUS™ Heart Wires by taping the cardioversion connectors and pacing pins to the patient's body until needed.

7. When ~~Syncrus~~ SYNCRUS™ atrial cardioversion therapy is needed, connect the yellow cardioversion connectors to the ~~Syncrus~~ SYNCRUS™ Cardioversion Extension Cable. Ensure that the Cable is connected to the EDIM. Apply internal atrial cardioversion by placing external defibrillator paddles on the paddle plates of the ~~Syncrus~~ SYNCRUS™ EDIM and deliver~~ing~~ energy. The EDIM will attenuate the external defibrillator output energy by approximately 97% (for example, a 100–joule external shock will result in an approximate 3-joule internal cardioversion shock to the heart).

8. When temporary cardiac pacing and ECG sensing are needed, remove the protective tubing from the pacing connector pins. Connect the pacing connector pins into the appropriate pacing cables. Ensure that the pacing cables are connected to an external pacemaker. Administer cardiac pacing therapy.

9. To remove the ~~Syncrus~~ SYNCRUS™ Heart Wires, remove any tape holding the Heart Wires in place. Apply gentle and continuous external traction to remove the Heart Wires from the patient~~.~~. Special care should be taken when removing the ~~lead~~ wires from the— ~~atrium~~atria, due to the relatively thin atrial wall.

10. Discard the three externalized Heart Wires appropriately.

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ADVERSE EVENTS:

Two studies were conducted with the original ~~Syncrus~~ SYNCRUS™ System (TADpole System) in Europe[1]. Results from both studies demonstrated that the Guidant ~~Syncrus~~ SYNCRUS™ System was safe and effective for its intended use.

Table 1. Adverse Events Reported Across Studies

Complications	# of pts with AE's (n=538)	% of pts with AE's
Wire dislodgement	1	0.19%
Cardiac Arrest/VF	1	0.19%
Difficult wire extraction	2	0.37%
Infection	1	0.19%
Hypoventilation	1	0.19%
Death*	2	0.37%
Total Complications	**8**	**1.48%**

POTENTIAL ADVERSE EVENTS:

Based on the literature and ~~Syncrus~~ SYNCRUS™ ~~heart wire~~Heart Wire implant experience, the possible physical effects from implantation are listed below.

- Allergic reaction
- Atrial wall rupture
- Bleeding
- Cardiac tamponade
- Difficult wire removal
- Displacement dislodgement
- Erosion/extrusion
- Fibrotic tissue formation
- Hematoma
- Histotoxic reaction
- Inappropriate therapy
- Incomplete connection with pulse generator
- Infection
- Lead abrasion
- Lead failure
- Lead fracture or insulation break
- Lead tip deformation and/or breakage
- Local tissue reaction
- Loss of sensing or under sensing
- Myocardial injury
- Myocardial irritability
- Over sensing
- Post-shock rhythm disturbances
- Random component failures
- Threshold elevation

CLINICAL TRIALS:

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* Deaths were unrelated to therapy with the ~~Syncrus~~SYNCRUS™ System.

[1] For clinical study details refer to *Clinical Trial* section.

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The ~~Syncrus~~ SYNCRUS™ System was studied in the following (2) trials: Pilot Clinical Investigation for the InControl TADpole Heart Wires (Temporary Atrial Cardioversion Post-Op Low Energy) and The TADpole™ System for Post-Cardiac Surgery Atrial Cardioversion and Atrial/Ventricular Pacing and Sensing.

Pilot Clinical Investigation for the InControl TADpole Heart Wires (Temporary Atrial Cardioversion Post-Op Low Energy)

This investigation was designed as an observational non-randomized study to evaluate the features and functionality of the therapy. The final analysis covers 466 implanted patients. The mean implant duration of the study population was 7.1 days.

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Table 2. Description of the Study Population

Characteristic	
Number of patients	n=466
Gender	
Male	348
Female	116
Unknown	2
Age at Time of Implant	
Range (years)	23 – 83
Mean ± Standard Deviation	64.2 ± 9.2
Cardiovascular Procedures*	
CABG	420
Valve Replacement	43
Valve Repair	9

*Cardiovascular procedures are not mutually exclusive of one another.

Arrhythmia Treatment Success and Energy Delivered

Eighty-one patients experiencing a total of 95 AF episodes were treated with the therapy. A per patient cardioversion overall success rate of 74% and a per episode success rate of 78% were recorded. The mean number of joules delivered to the patient per successful attempt was 6.02 Joules. There were an average number of 2.54 cardioversion attempts per successful episode.

Table 3. Per Patient and Per Episode Therapy Success Summary

Cardioversion Success	n (%)
81 Patients with Arrhythmias	
Success No	21 (26%)
Success Yes	60 (74%)
95 Episodes	
Success No	21 (22%)
Success Yes	74 (78%)
Joules Delivered per Successful Attempt	
Mean	6.02
SD	2.50
Range	1.5 - 10.8
Average number of Attempts per Successful Episode	2.54

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Table 4. Per Attempt and Cumulative Therapy Success Summary

Attempts	Success Yes/No	Total # of Attempts	Success Rate per Attempt (%)	Cumulative Success Rate (%)*
1st Attempt	Success Yes	40	42.11	42.11
	Success No	55		
2nd Attempt	Success Yes	30	45.45	73.70
	Success No	36		
3rd Attempt	Success Yes	16	41.03	90.54
	Success No	23		
4th Attempt	Success Yes	6	37.50	96.85
	Success No	10		
5th Attempt	Success Yes	2	33.33	98.95
	Success No	4		
6th Attempt	Success Yes	1	33.33	100.00
	Success No	2		
7th Attempt	Success Yes	0	0.00	
	Success No	2		
8th Attempt	Success Yes	0	0.00	
	Success No	2		
9th Attempt	Success Yes	0	0.00	
	Success No	1		

- From the total of successful cardioversions attempts, the cumulative success rate is calculated as the percentage of successful cardioversions after the first, second, third, fourth etc... attempts using the total successful attempts as the denominator. For example, 42.10 % of the total successful cardioversions resulted from a first cardioversion attempt. Data illustrates that over 90 % of the total successful cardioversions occurred within the first three cardioversion attempts. Incremental cardioversion successes were observed as a result of additional attempts.

Summary of Adverse Events

A total of eight adverse events in seven patients were recorded throughout the duration of the study.

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Table 5. Adverse Events

	# of pts with AE's (n=466)	% of pts with AE's
Complications (total)	8	1.71%
Wire dislodgement	1	0.21%
Cardiac Arrest/VF	1	0.21%
Difficult wire extraction	2	0.43%
Infection	1	0.21%
Hypoventilation	1	0.21%
Death*	2	0.43%

* Two deaths were not related to the TADpole System.

The TADpole™ System for Post-Cardiac Surgery Atrial Cardioversion and Atrial/Ventricular Pacing and Sensing

This investigation was designed as a confirmatory observational non-randomized study intended to optimize the effectiveness of the therapy including ~~heart wire~~Heart Wire placement. Heart wire placement is illustrated in Figures 1 through 3. The study is an analysis of 72 implanted patients. The mean implant duration of the study population was 6.2 days.

Table 6. Description of the Study Population

Characteristic	n (%)
Number of patients	72
Gender	
Male	50
Female	21
Unknown	1
Age at Time of Implant (years)	
Range	32 – 89
Mean ± Standard Deviation	65.26 ± 10.6
Mean Ejection Fraction ± Standard Deviation (%)	57.43 ± 16.96 (93%)
Cardiovascular Procedures	
CABG	71
Mitral Valve Replacement	1

Arrhythmia Treatment Success and Energy Delivered

Thirteen patients experiencing a total of 14 AF episodes were treated with the therapy. A per patient cardioversion overall success rate of 92.3% and a per episode success rate of 92.8% were recorded. The mean number of Joules delivered to the patient per successful attempt

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was 7.72 Joules. There were an average number of 1.54 cardioversion attempts per successful episode.

Table 7. Per Patient and Per Episode Therapy Success Summary

Cardioversion Success	n (%)
13 Patients with Arrhythmias	
Success No	1(7.69%)
Success Yes	12 (92.3%)
14 Episodes	
Success No	1 (7.14%)
Success Yes	13 (92.8%)
Joules Delivered per Successful Attempt	
Mean	7.72
SD	1.73
Range	6 - 10.8
Average number of Attempts per Successful Episode	1.54

Table 8. Per Attempt and Cumulative Therapy Success Summary

Attempts	Success Yes/No	Total # of Attempts	Success Rate per Attempt (%)	Cumulative Success Rate (%)*
1st Attempt	Success Yes	10	71.42	66.67*
	Success No	4		
2nd Attempt	Success Yes	4	66.66	93.33
	Success No	2		
3rd Attempt	Success Yes	0	0	93.33
	Success No	2		
4th Attempt	Success Yes	1	100.00	100.00
	Success No	0		

- From the total of successful cardioversions attempts, the cumulative success rate is calculated as the percentage of successful cardioversions after the first, second, third and fourth attempts. For example 66.67% of the total successful cardioversions resulted from a first cardioversion attempt using the total successful attempts as the denominator. Data illustrates that over 90 % of the total successful cardioversions occurred within the first 3 cardioversion attempts. Incremental cardioversion successes were observed as a result of additional attempts.

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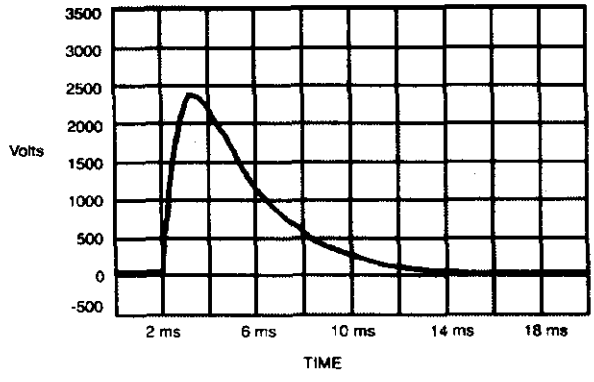
Summary of Adverse Events
No adverse events were observed in this study.

ENERGY INPUT/OUT ATTENUATION:

The EDIM attenuates the energy output of a ~~monophasic,~~compatible low-_energy external defibrillator down to 3% of its original joule output. ~~The EDIM produces an energy transfer of 3% (+/- 1%) on the input energy from the defibrillator.~~ Since the circuitry of the EDIM consists of a passive voltage divider network, the attenuation consists of a uniform reduction of input voltage, resulting in an output waveform identical to that of the defibrillators waveform, except reduced in magnitude (Figure 5).

Figure 5. EDIM Input Output Waveform

External Defibrillator Output Waveform **EDIM Output Waveform**



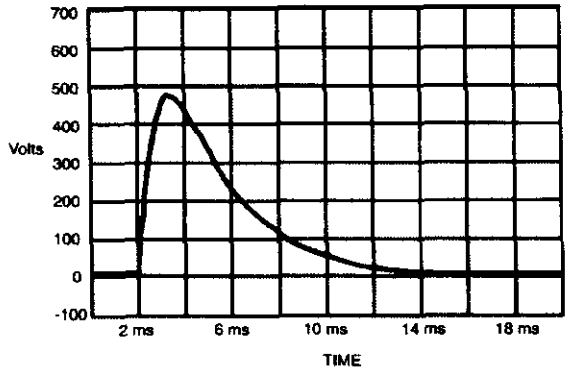


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Table 9. Minimum and Maximum Energy Output of the EDIM

Input from External Defibrillator (Joules)	Output Energy from EDIM (Joules)	
	MIN	MAX
50	1.4~~2~~3	1.~~5~~6
100	2.~~9~~6	3.~~1~~2
150	~~4.3~~3.9	4.~~6~~8
200	~~5.8~~5.2	6.~~2~~4
250	~~7.2~~6.5	~~7.7~~8.0
300	~~8.7~~7.8	9.~~3~~6
350	~~10~~9.1	~~10.8~~11.2
360	~~10~~9.4	11.~~1~~5

HOW SUPPLIED:
The ~~Synerus~~ SYNCRUS™ Heart Wires are supplied STERILE in an unopened and undamaged package. The ~~Synerus~~ SYNCRUS™ Heart Wires have been sterilized using gamma irradiation and are for single use only. DO NOT RESTERILIZE. DO NOT REUSE.

The ~~Synerus~~ SYNCRUS™ External Defibrillator Interface Module (EDIM) is supplied non-sterile and is reusable. One ~~Synerus~~ SYNCRUS™ Cardioversion ~~External~~ Extension Cable, one maintenance test fixture, and two extension cable test adapters are also supplied with the EDIM.

To perform internal atrial cardioversion, the hospital must supply a compatible low energy~~,~~ external~~, monophasic~~ defibrillator. To perform temporary cardiac pacing and ECG sensing, the hospital must supply an external pacemaker and appropriate pacing cables. A list of compatible external defibrillators, external pacemakers and pacing cables are provided in the ~~Synerus~~ SYNCRUS™ System Operator's Manual (*Required User Supplied Components* section) for your convenience.

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

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WARRANTY:
Guidant Corporation warrants that its Products substantially conform to Guidant Corporation published specifications for such Product for a period of twelve (12) months from the date of shipment, and will replace ~~and~~ any ~~p~~Products confirmed by Guidant Corporation as defective Products, at Guidant Corporation's sole option, during said period. This warranty is contingent upon proper use of Products in the application for which they ~~are~~ were intended as indicated in the ~~product~~ Product label claims, and Guidant Corporation makes no warranty (express, implied, or statutory) for Products that are modified or subjected to unusual physical or electrical stress. With regard to Guidant Corporation Products which are labeled ~~for~~ FOR SINGLE USE ONLY or DO NOT REUSE~~. This~~, this warranty is null and void following the single use of the Products. Guidant Corporation doe not provide a warranty for those Products subject to resterilization and/or reuse unless the Products are specifically designed and labeled for reuse.

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May be manufactured under one or more of the following patents: 5,674,253; 5,766,224; and RE 35,779.

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Guidant SYNCRUS™ System

Post Cardiac Surgery Atrial Cardioversion and Temporary Cardiac Pacing

INSTRUCTIONS FOR USE

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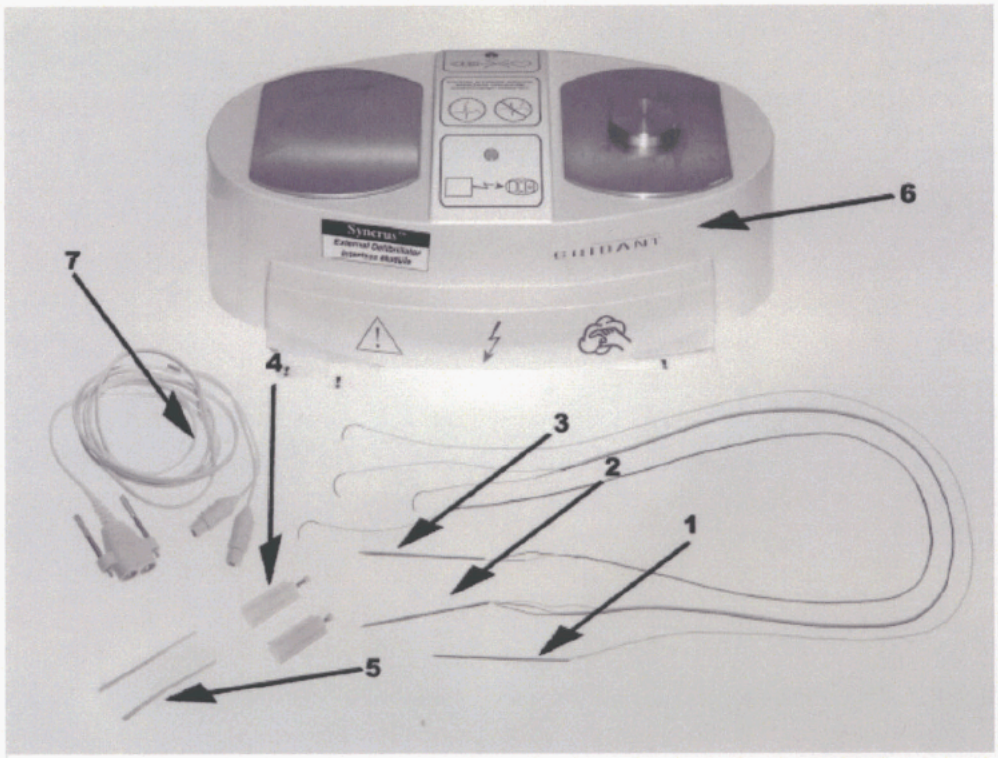

Figure 1.

Guidant SYNCRUS™ System

1. Left Atrial Heart Wire (unipolar)
2. Right Atrial Heart Wire (tripolar)
3. Ventricular Heart Wire (bipolar)
4. Yellow Cardioversion Connectors
5. Protective Tubings
6. External Defibrillator Interface Module (EDIM)
7. Cardioversion Extension Cable

Note: The Heart Wires (with yellow cardioversion connectors and protective tubings) are sold separately from the EDIM and Cardioversion Extension Cable.

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INSTRUCTIONS FOR USE

Carefully read all instructions prior to use. Observe all warnings and precautions noted throughout these instructions.

SYSTEM DESCRIPTION:

The Guidant SYNCRUS™ System provides low energy internal cardioversion therapy to treat postoperative atrial fibrillation via SYNCRUS™ Heart Wires placed directly on the patient's heart. The System's functions also include temporary atrial and ventricular pacing and ECG sensing capabilities.

The SYNCRUS™ System consists of the following components:

- Three single use Heart Wires that are attached to the myocardial tissue of the left atrium, right atrium, and right or left ventricle during cardiac surgery. The Heart Wires transmit low energy shocks to the patient's heart for electrical atrial cardioversion. The Heart Wires also provide for temporary cardiac pacing and ECG sensing capabilities.

- A reusable External Defibrillator Interface Module (EDIM), which interfaces between a compatible low energy external defibrillator and the Heart Wires. The EDIM reduces the output energy from the defibrillator to a low energy shock delivered through the Heart Wires.

- A reusable Cardioversion Extension Cable that connects the Heart Wires to the EDIM.

The SYNCRUS™ System components must be used in conjunction with a compatible low energy external defibrillator, an external pacemaker, and pacing cables that connect the Heart Wires to the external pacemaker. The user supplies the external defibrillator, external pacemaker, and pacing cables.

Refer to the SYNCRUS™ System Operator's Manual (see section 6.0, *Required User Supplied Components*) for a list of compatible external defibrillators, external pacemakers and pacing cables that have been tested with the Guidant SYNCRUS™ System.

INDICATIONS FOR USE:

The Guidant SYNCRUS™ Internal Cardioversion System is indicated for use in post-operative cardiac surgery patients who require temporary atrial or ventricular pacing/sensing and/or atrial cardioversion.

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CONTRAINDICATIONS:

There are no known general contraindications for temporary post surgical heart wire leads. Patient anatomy and medical condition, however, should determine the use and implantation procedure.

WARNINGS:

- The SYNCRUS™ System is not compatible with all low energy external defibrillators. Refer to the SYNCRUS™ System Operator's Manual (see section 6.0, *Required User Supplied Components*) for a list of compatible external defibrillators. The Zoll M Series biphasic defibrillator will not discharge energy into the EDIM and is incompatible with the SYNCRUS System.

- Perform synchronized cardioversion only. Unsynchronized shocks may result in ventricular fibrillation, causing patient injury or death.

- The SYNCRUS™ Heart Wires provide a direct path for electrical current flow to the patient's heart. DO NOT touch the Heart Wire leads or the EDIM (when connected to the Heart Wires) with your bare hands or with anything that may deliver static (electrostatic discharge). Avoid the possibility of unintentional contact between the wire leads, including extension cable, and any equipment used as well as any conductive surface contact. Line powered equipment used in the vicinity of the patient must be properly grounded.

- The SYNCRUS™ EDIM and Cardioversion Extension Cable are designed solely for use with the SYNCRUS™ Heart Wires.

- DO NOT connect the Heart Wires to any equipment other than that specified in these instructions and the SYNCRUS™ System Operator's Manual. Patient injury or death may result.

- If the SYNCRUS™ EDIM has been dropped, perform a FULL maintenance test as described in the SYNCRUS™ System Operator's Manual (see section 11.0, *Maintenance and Calibration*) prior to using the EDIM again. Dropping the EDIM may damage internal components, possibly rendering the device inoperable or out of specification.

- Wire fracture, dislodgement, abrasion and/or an incomplete connection can cause a periodic or continual loss of pacing and sensing, possibly resulting in inappropriate delivery of conversion therapy. Connect the pacing connector pins for baseline measurements to a pacing system analyzer (PSA) or temporary pacemaker and evaluate the placement by determining R-wave amplitude, pacing threshold, and pacing lead impedance. Secure the SYNCRUS™ Heart Wires by taping the cardioversion connectors and pacing pins to the patient's body until needed.

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- Although pliable, the lead body is not designed to tolerate excessive flexing, bending, or tension. This could cause structural weakness, conductor discontinuity, and/or lead dislodgement. Secure the cardioversion connectors and pacing pins to the patient's body until needed. Minimize manipulation of the Heart Wires.

- Equipment and accessories connected to the Guidant SYNCRUS™ System shall comply with IEC-601-1, type CF.

PRECAUTIONS:

- SYNCRUS™ Heart Wires are for single use only. DO NOT RESTERILIZE. DO NOT REUSE.

- The SYNCRUS™ Heart Wires are gamma sterilized after packaging. When they are received, they are sterile and ready for use. Should the seal or package be wet, damaged, punctured, or if the seal is broken, do not use or attempt to resterilize. Contact the local Guidant representative.

- Pre-clinical testing supports the use of this device up to 7 cardioversion attempts. Cardioversion attempts ranged from 1 to 9 attempts in clinical trials. Physicians should treat patients in accordance with judgment and experience. Assessment of the patient's overall condition and physician discretion should dictate the number of attempts to treat.

- It is recommended that defibrillation equipment and a pacing sensor system analyzer (PSA) or temporary pacemaker be readily available during lead placement and removal.

INSTRUCTIONS FOR USE:

1. Attach the SYNCRUS™ Heart Wires to the patient's myocardial surface during cardiac surgery in the following order and before the patient's chest is closed. The described fixation techniques are furnished for informational purposes only. The physician may choose to vary the fixation technique in accordance with judgment and experience. The selected fixation technique of each Heart Wire placement should always allow for ease of extraction through gentle traction. Proper surgical procedures and techniques are the responsibility of the medical professional.

   Left Atrial Heart Wire (unipolar)

   - *Cardioversion Electrode (yellow wire)*: Use the attached curved needle to affix the cardioversion electrode to the left atrial myocardium. After the cardioversion electrode is affixed (see Figures 2a and 3a), cut off the curved needle and discard it. Place a slight bend or kink at the end of the electrode.

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Right Atrial Heart Wire (tripolar)

- *Cardioversion Electrode (yellow wire)*: Use the attached curved needle to affix the cardioversion electrode to the right atrial myocardium. After the cardioversion electrode is affixed (see Figures 2b and 3b), cut off the curved needle and discard it. Place a slight bend or kink at the end of the electrode.

  Placement should be made to maximize the atrial muscle mass between the right atrial cardioversion electrode and the left atrial cardioversion electrode.

- *Pacing Electrodes (black and blue wires)*: Use the attached curved needle to affix the bipolar pacing electrodes to the right atrial myocardium. For optimal cardiac pacing, bury both the pacing electrode and bullet in the myocardium. After the pacing electrodes are affixed (see Figures 2b and 3b), cut off the needle and discard it. Place a slight bend or kink at the end of the pacing electrode.

Ventricular Heart Wire (bipolar)

- *Pacing Electrodes (black and white wires)*: Use the attached curved needle to affix the bipolar pacing electrodes into the myocardial tissue of either the right or left ventricle. For optimal cardiac pacing, bury both the pacing electrode and bullet in the myocardium. After the pacing electrodes are affixed (see Figures 2c and 3c), cut off the curved needle and discard it. Place a slight bend or kink at the end of the pacing electrode.

Figures 2 through 3 illustrate two examples of Heart Wire placement techniques as used in clinical practice.

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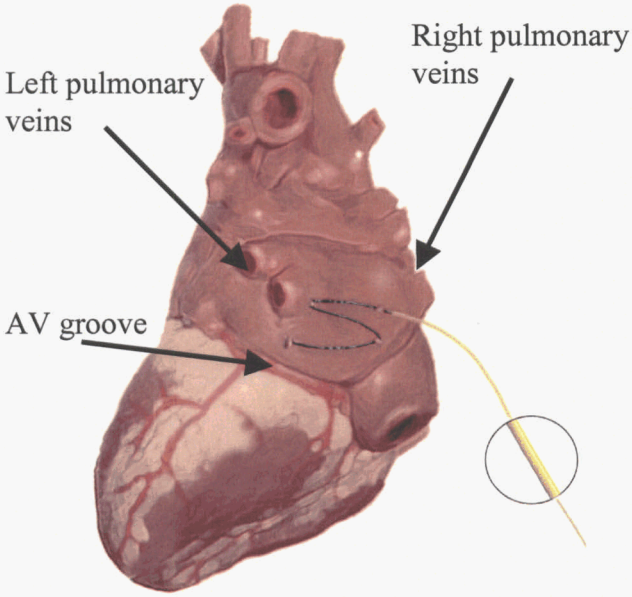
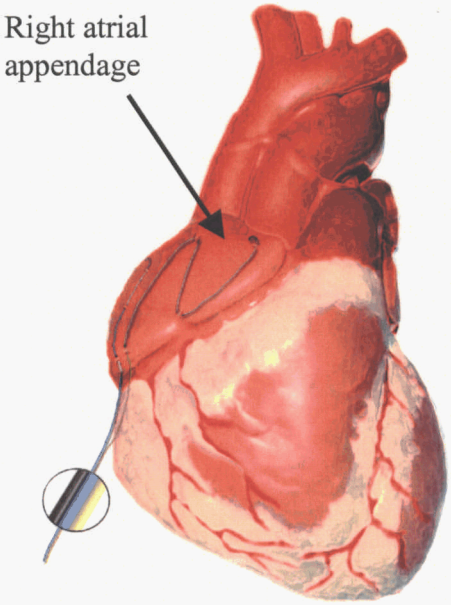
Figure 2. SYNCRUS™ Heart Wire Placement Technique A (used in clinical trials in Europe)



2a. Left Atrial Wire Placement
Figure shows the cardioversion electrode placed in an "S" pattern between the atrioventricular (AV) groove and the left and right pulmonary veins.

(Lateral-posterior view)



2b. Right Atrial Wire Placement
Figure shows the cardioversion electrode placed in an "S" pattern on the right atrial appendage.

The pacing electrode and bullet are shown placed on the right atrial myocardium.

(Anterior view)

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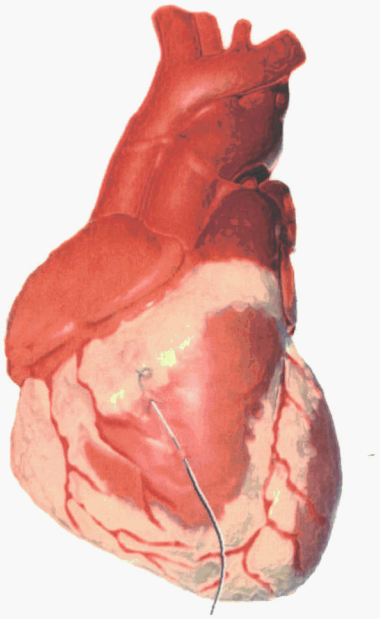
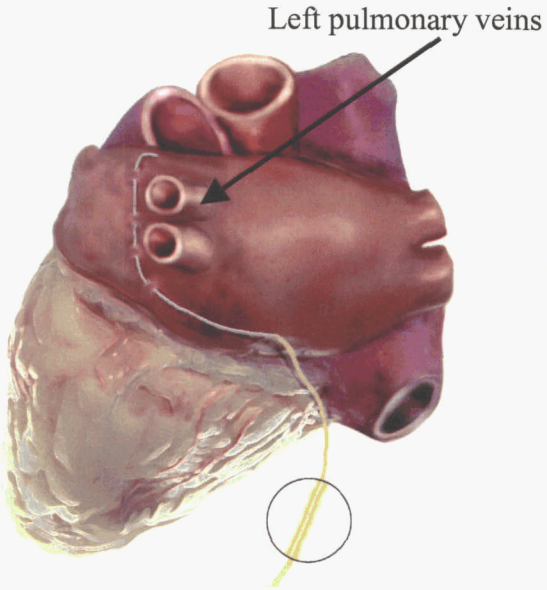


2c. Ventricular Wire Placement
Figure shows the pacing electrode and bullet placed on the right ventricle.

(Anterior view)

Figure 3. SYNCRUS™ Heart Wire Placement Technique B



3a. Left Atrial Wire Placement
Figure shows the cardioversion electrode placed within 5 mm anterior of the left pulmonary veins.

(Lateral-posterior view)

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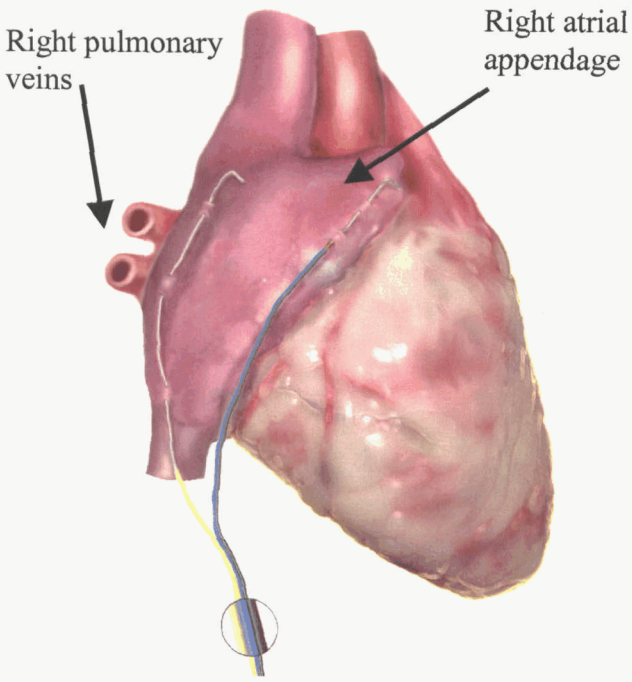
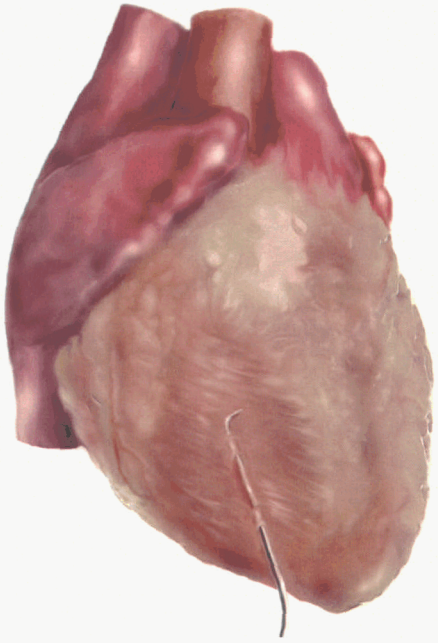


3b. Right Atrial Wire Placement
Figure shows the cardioversion electrode placed by the inferior vena cava and up towards the right pulmonary veins within 5 mm of the SA node.

The pacing electrode and bullet are shown placed on the right atrial appendage.

(Lateral view)



3c. Ventricular Wire Placement
Figure shows the pacing electrode and bullet placed on the right ventricle.

(Anterior view)

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2. Once the cardioversion and pacing electrodes have been affixed to the patient's heart, visualize the paths that the Heart Wires will travel as they are extracted.

3. Use the straight needle on the proximal end of each SYNCRUS™ Heart Wire to externalize the Heart Wires through the chest wall and skin. Once the Heart Wires are externalized, cut off the thoracic needles, maximizing the length of the exposed cardioversion leads. Discard the thoracic needles appropriately.

4. Attach the yellow cardioversion connectors provided with the SYNCRUS™ Heart Wires to the yellow cardioversion wires on the Left and Right Atrial Heart Wires. This is done by threading the Heart Wire cardioversion lead through the pinhole on the backside of the connector and pushing the pin into the connector. Make sure there is good electrical contact between the Heart Wire cardioversion lead and the yellow cardioversion connector.

5. Connect the pacing connector pins for baseline measurements to a pacing system analyzer (PSA) or temporary pacemaker and evaluate the placement by determining R-wave amplitude, pacing threshold, and pacing lead impedance.

6. Cover the pacing connector pins on the Right Atrial Heart Wire (black and blue wires) and Ventricular Heart Wire (black and white wires) with the protective tubings provided with the SYNCRUS™ Heart Wires. Secure the SYNCRUS™ Heart Wires by taping the cardioversion connectors and pacing pins to the patient's body until needed.

7. When SYNCRUS™ atrial cardioversion therapy is needed, connect the yellow cardioversion connectors to the SYNCRUS™ Cardioversion Extension Cable. Ensure that the Cable is connected to the EDIM. Apply internal atrial cardioversion by placing external defibrillator paddles on the paddle plates of the SYNCRUS™ EDIM and deliver energy. The EDIM will attenuate the external defibrillator output energy by approximately 97% (for example, a 100-joule external shock will result in an approximate 3-joule internal cardioversion shock to the heart).

8. When temporary cardiac pacing and ECG sensing are needed, remove the protective tubing from the pacing connector pins. Connect the pacing connector pins into the appropriate pacing cables. Ensure that the pacing cables are connected to an external pacemaker. Administer cardiac pacing therapy.

9. To remove the SYNCRUS™ Heart Wires, remove any tape holding the Heart Wires in place. Apply gentle and continuous external traction to remove the Heart Wires from the patient. Special care should be taken when removing the wires from the atria, due to the relatively thin atrial wall.

10. Discard the three externalized Heart Wires appropriately.

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ADVERSE EVENTS:
Two studies were conducted with the original SYNCRUS™ System (TADpole System) in Europe[1]. Results from both studies demonstrated that the Guidant SYNCRUS™ System was safe and effective for its intended use.

Table 1. Adverse Events Reported Across Studies

Complications	# of pts with AE's (n=538)	% of pts with AE's
Wire dislodgement	1	0.19%
Cardiac Arrest/VF	1	0.19%
Difficult wire extraction	2	0.37%
Infection	1	0.19%
Hypoventilation	1	0.19%
Death*	2	0.37%
Total Complications	**8**	**1.48%**

POTENTIAL ADVERSE EVENTS:
Based on the literature and SYNCRUS™ Heart Wire implant experience, the possible physical effects from implantation are listed below.

- Allergic reaction
- Atrial wall rupture
- Bleeding
- Cardiac tamponade
- Difficult wire removal
- Displacement dislodgement
- Erosion/extrusion
- Fibrotic tissue formation
- Hematoma
- Histotoxic reaction
- Inappropriate therapy
- Incomplete connection with pulse generator
- Infection
- Lead abrasion
- Lead failure
- Lead fracture or insulation break
- Lead tip deformation and/or breakage
- Local tissue reaction
- Loss of sensing or under sensing
- Myocardial injury
- Myocardial irritability
- Over sensing
- Post-shock rhythm disturbances
- Random component failures
- Threshold elevation

CLINICAL TRIALS:
The SYNCRUS™ System was studied in the following (2) trials: Pilot Clinical Investigation for the InControl TADpole Heart Wires (Temporary Atrial Cardioversion Post-Op Low

* Deaths were unrelated to therapy with the SYNCRUS™ System.
[1] For clinical study details refer to *Clinical Trial* section.

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Energy) and The TADpole™ System for Post-Cardiac Surgery Atrial Cardioversion and Atrial/Ventricular Pacing and Sensing.

Pilot Clinical Investigation for the InControl TADpole Heart Wires (Temporary Atrial Cardioversion Post-Op Low Energy)

This investigation was designed as an observational non-randomized study to evaluate the features and functionality of the therapy. The final analysis covers 466 implanted patients. The mean implant duration of the study population was 7.1 days.

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Table 2. Description of the Study Population

Characteristic	
Number of patients	n=466
Gender	
Male	348
Female	116
Unknown	2
Age at Time of Implant	
Range (years)	23 – 83
Mean ± Standard Deviation	64.2 ± 9.2
Cardiovascular Procedures*	
CABG	420
Valve Replacement	43
Valve Repair	9

*Cardiovascular procedures are not mutually exclusive of one another.

Arrhythmia Treatment Success and Energy Delivered

Eighty-one patients experiencing a total of 95 AF episodes were treated with the therapy. A per patient cardioversion overall success rate of 74% and a per episode success rate of 78% were recorded. The mean number of joules delivered to the patient per successful attempt was 6.02 Joules. There were an average number of 2.54 cardioversion attempts per successful episode.

Note: Clinical results were achieved using monophasic external defibrillators. Use with biphasic defibrillators was not studied.

Table 3. Per Patient and Per Episode Therapy Success Summary

Cardioversion Success	n (%)
81 Patients with Arrhythmias	
Success No	21 (26%)
Success Yes	60 (74%)
95 Episodes	
Success No	21 (22%)
Success Yes	74 (78%)
Joules Delivered per Successful Attempt	
Mean	6.02
SD	2.50
Range	1.5 - 10.8
Average number of Attempts per Successful Episode	2.54

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Table 4. Per Attempt and Cumulative Therapy Success Summary

Attempts	Success Yes/No	Total # of Attempts	Success Rate per Attempt (%)	Cumulative Success Rate (%)*
1st Attempt	Success Yes	40	42.11	42.11
	Success No	55		
2nd Attempt	Success Yes	30	45.45	73.70
	Success No	36		
3rd Attempt	Success Yes	16	41.03	90.54
	Success No	23		
4th Attempt	Success Yes	6	37.50	96.85
	Success No	10		
5th Attempt	Success Yes	2	33.33	98.95
	Success No	4		
6th Attempt	Success Yes	1	33.33	100.00
	Success No	2		
7th Attempt	Success Yes	0	0.00	
	Success No	2		
8th Attempt	Success Yes	0	0.00	
	Success No	2		
9th Attempt	Success Yes	0	0.00	
	Success No	1		

- From the total of successful cardioversions attempts, the cumulative success rate is calculated as the percentage of successful cardioversions after the first, second, third, fourth etc... attempts using the total successful attempts as the denominator. For example, 42.10 % of the total successful cardioversions resulted from a first cardioversion attempt. Data illustrates that over 90 % of the total successful cardioversions occurred within the first three cardioversion attempts. Incremental cardioversion successes were observed as a result of additional attempts.

Summary of Adverse Events

A total of eight adverse events in seven patients were recorded throughout the duration of the study.

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Table 5. Adverse Events

	# of pts with AE's (n=466)	% of pts with AE's
Complications (total)	8	1.71%
Wire dislodgement	1	0.21%
Cardiac Arrest/VF	1	0.21%
Difficult wire extraction	2	0.43%
Infection	1	0.21%
Hypoventilation	1	0.21%
Death*	2	0.43%

* Two deaths were not related to the TADpole System.

The TADpole™ System for Post-Cardiac Surgery Atrial Cardioversion and Atrial/Ventricular Pacing and Sensing

This investigation was designed as a confirmatory observational non-randomized study intended to optimize the effectiveness of the therapy including Heart Wire placement. Heart wire placement is illustrated in Figures 1 through 3. The study is an analysis of 72 implanted patients. The mean implant duration of the study population was 6.2 days.

Table 6. Description of the Study Population

Characteristic	**n (%)**
Number of patients	72
Gender	
Male	50
Female	21
Unknown	1
Age at Time of Implant (years)	
Range	32 – 89
Mean ± Standard Deviation	65.26 ± 10.6
Mean Ejection Fraction ± Standard Deviation (%)	57.43 ± 16.96 (93%)
Cardiovascular Procedures	
CABG	71
Mitral Valve Replacement	1

Arrhythmia Treatment Success and Energy Delivered

Thirteen patients experiencing a total of 14 AF episodes were treated with the therapy. A per patient cardioversion overall success rate of 92.3% and a per episode success rate of 92.8% were recorded. The mean number of Joules delivered to the patient per successful attempt

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was 7.72 Joules. There were an average number of 1.54 cardioversion attempts per successful episode.

Note: Clinical results were achieved using monophasic external defibrillators. Use with biphasic defibrillators was not studied.

Table 7. Per Patient and Per Episode Therapy Success Summary

Cardioversion Success	n (%)
13 Patients with Arrhythmias	
Success No	1(7.69%)
Success Yes	12 (92.3%)
14 Episodes	
Success No	1 (7.14%)
Success Yes	13 (92.8%)
Joules Delivered per Successful Attempt	
Mean	7.72
SD	1.73
Range	6 - 10.8
Average number of Attempts per Successful Episode	1.54

Table 8. Per Attempt and Cumulative Therapy Success Summary

Attempts	Success Yes/No	Total # of Attempts	Success Rate per Attempt (%)	Cumulative Success Rate (%)*
1st Attempt	Success Yes	10	71.42	66.67*
	Success No	4		
2nd Attempt	Success Yes	4	66.66	93.33
	Success No	2		
3rd Attempt	Success Yes	0	0	93.33
	Success No	2		
4th Attempt	Success Yes	1	100.00	100.00
	Success No	0		

- From the total of successful cardioversions attempts, the cumulative success rate is calculated as the percentage of successful cardioversions after the first, second, third and fourth attempts. For example 66.67% of the total successful cardioversions resulted from a first cardioversion attempt using the total successful attempts as the denominator. Data illustrates that over 90 % of the total successful cardioversions occurred within the first 3

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cardioversion attempts. Incremental cardioversion successes were observed as a result of additional attempts.

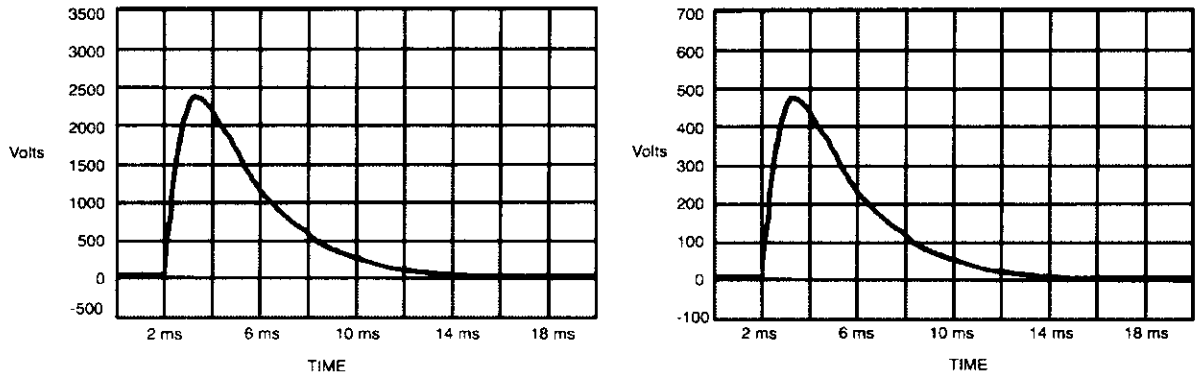
Summary of Adverse Events
No adverse events were observed in this study.

ENERGY INPUT/OUT ATTENUATION:
The EDIM attenuates the energy output of a compatible low energy external defibrillator down to 3% of its original joule output. Since the circuitry of the EDIM consists of a passive voltage divider network, the attenuation consists of a uniform reduction of input voltage, resulting in an output waveform identical to that of the defibrillators waveform, except reduced in magnitude (Figure 5).

Figure 5. EDIM Input/Output Waveform

Monophasic Waveform

External Defibrillator Output Waveform **EDIM Output Waveform**



Biphasic Waveform (Truncated Exponential)

External Defibrillator Output Waveform **EDIM Output Waveform**

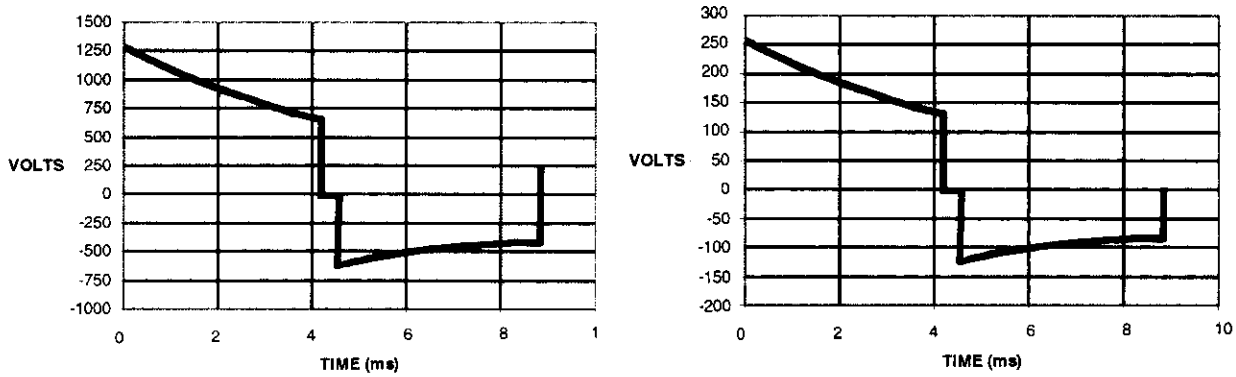


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Table 9. Minimum and Maximum Energy Output of the EDIM

Input from External Defibrillator (Joules)	Output Energy from EDIM (Joules)	
	MIN	MAX
50	1.3	1.6
100	2.6	3.2
150	3.9	4.8
200	5.2	6.4
250	6.5	8.0
300	7.8	9.6
350	9.1	11.2
360	9.4	11.5

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HOW SUPPLIED:
The SYNCRUS™ Heart Wires are supplied STERILE in an unopened and undamaged package. The SYNCRUS™ Heart Wires have been sterilized using gamma irradiation and are for single use only. DO NOT RESTERILIZE. DO NOT REUSE.

The SYNCRUS™ External Defibrillator Interface Module (EDIM) is supplied non-sterile and is reusable. One SYNCRUS™ Cardioversion Extension Cable, one maintenance test fixture, and two extension cable test adapters are also supplied with the EDIM.

To perform internal atrial cardioversion, the hospital must supply a compatible low energy external defibrillator. To perform temporary cardiac pacing and ECG sensing, the hospital must supply an external pacemaker and appropriate pacing cables. A list of compatible external defibrillators, external pacemakers and pacing cables are provided in the SYNCRUS™ System Operator's Manual (see section 6.0, *Required User Supplied Components*) for your convenience.

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

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WARRANTY:
Guidant Corporation warrants that its Products substantially conform to Guidant Corporation published specifications for such Product for a period of twelve (12) months from the date of shipment, and will replace any Products confirmed by Guidant Corporation as defective Products, at Guidant Corporation's sole option, during said period. This warranty is contingent upon proper use of Products in the application for which they were intended as indicated in the Product label claims, and Guidant Corporation makes no warranty (express, implied, or statutory) for Products that are modified or subjected to unusual physical or electrical stress. With regard to Guidant Corporation Products which are labeled FOR SINGLE USE ONLY or DO NOT REUSE, this warranty is null and void following the single use of the Products. Guidant Corporation doe not provide a warranty for those Products subject to resterilization and/or reuse unless the Products are specifically designed and labeled for reuse.

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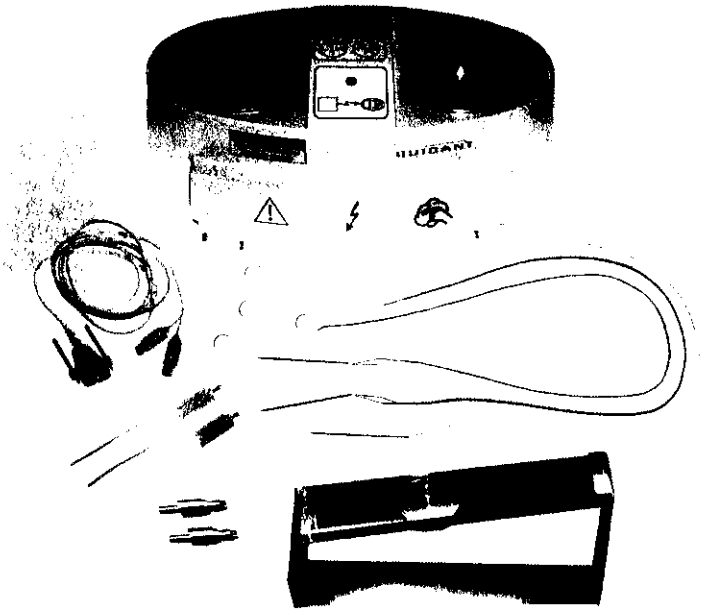
Post Cardiac Surgery Atrial Cardioversion
And
Temporary Cardiac Pacing



OPERATOR'S MANUAL

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1.0 ~~SYNCRUS~~SYNCRUS™ ATRIAL CARDIOVERSION THERAPY

The Guidant ~~Syncrus~~SYNCRUS™ System provides low energy internal cardioversion therapy to treat postoperative atrial fibrillation in conjunction with temporary cardiac pacing and ECG sensing.

During cardiac surgery, ~~Syncrus~~SYNCRUS™ Heart Wires are attached to appropriate locations on the patient's myocardium using standard surgical technique. The proximal ends of the ~~Syncrus~~SYNCRUS™ Heart Wires are externalized through the patient's chest wall and connected to appropriate cables attached to the ~~Syncrus~~SYNCRUS™ External Defibrillator Interface Module (EDIM) and a temporary external pacemaker.

In the event of post cardiac surgery atrial fibrillation, the clinician performs a routine synchronized electrical cardioversion, except that the external defibrillator paddles rest on the paddle plates of the ~~Syncrus~~SYNCRUS™ EDIM, rather than on the patient's chest. The patient is sedated at the physician's discretion. The *maximum* energy level administered through the ~~Syncrus~~SYNCRUS™ EDIM to the ~~Syncrus~~SYNCRUS™ Heart Wires is approximately 11 joules directly to the patient's myocardium, compared to 360 joules if delivered transthoracically with external defibrillator paddles.

The ~~Syncrus~~SYNCRUS™ Heart Wires are designed to also provide temporary cardiac pacing and ECG sensing before and after internal atrial cardioversion without requiring the physician to rearrange cables and wires.

Carefully read all instructions prior to use. Observe all warnings and precautions noted throughout these instructions.

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2.0 SYSTEM DESCRIPTION

The Guidant ~~Synerus~~SYNCRUS™ System provides low energy internal cardioversion therapy to treat postoperative atrial fibrillation via ~~Synerus~~SYNCRUS™ Heart Wires placed directly on the patient's heart. The Ssystem's functions also include temporary atrial and ventricular pacing and ECG sensing capabilities.

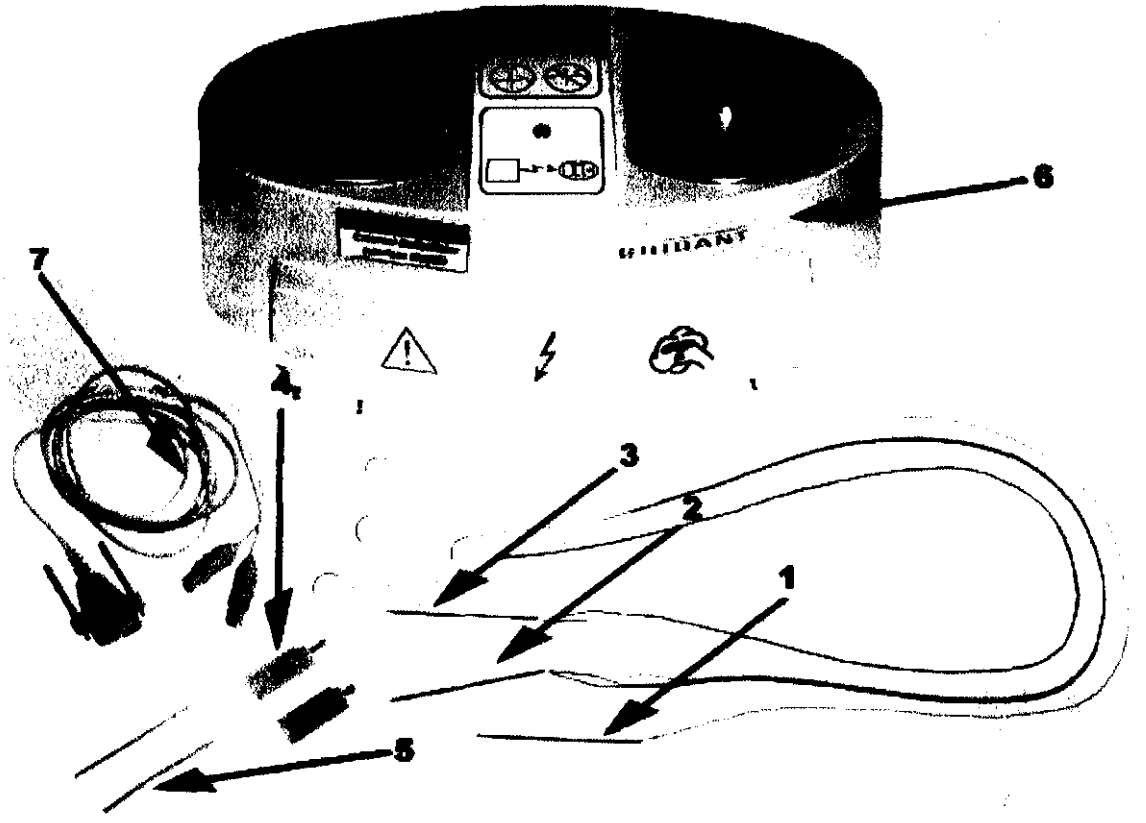

Figure 1. Guidant ~~Synerus~~SYNCRUS™ System

1. Left Atrial Heart Wire (unipolar)
2. Right Atrial Heart Wire (tripolar)
3. Ventricular Heart Wire (bipolar)
4. Yellow Cardioversion Connectors
5. Protective Tubings
6. External Defibrillator Interface Module (EDIM)
7. Cardioversion Extension Cable

Note: The Heart Wires (with yellow cardioversion connectors and protective tubings) are sold separately from the EDIM and Cardioversion Extension Cable.

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The ~~Syncrus~~SYNCRUS™ System consists of the following components:

- Three single use Heart Wires that are attached to myocardial tissue of the left atrium, right atrium, and right or left ventricle during cardiac surgery. The Heart Wires transmit low energy shocks to the patient's heart for electrical atrial cardioversion. The Heart Wires also provide temporary cardiac pacing and ECG sensing capabilities.

- A reusable External Defibrillator Interface Module (EDIM), which interfaces between a compatible ~~monophasic,~~ low- energy~~,~~ external defibrillator and the Heart Wires. The EDIM reduces the output energy from the defibrillator to a low energy shock delivered through the Heart Wires.

- A reusable Cardioversion Extension Cable that connects the Heart Wires to the EDIM.

The ~~Syncrus~~SYNCRUS™ System components must be used in conjunction with a compatible ~~monophasic,~~ low energy external defibrillator, an external pacemaker, and pacing cables that connect the Heart Wires to the external pacemaker. The user supplies the external defibrillator, external pacemaker, and pacing cables.

Refer to section on *Required User Supplied Components* for a list of compatible external defibrillators, external pacemakers and pacing cables that have been tested with the Guidant SYNCRUS™ System.

3.0 INDICATIONS FOR USE

The Guidant ~~Syncrus~~SYNCRUS™ Internal Cardioversion System is indicated for use in post-operative cardiac surgery patients who require temporary atrial or ventricular pacing/sensing and/or atrial cardioversion.

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4.0 COMPONENTS DESCRIPTION

4.1 ~~Syncrus~~SYNCRUS™ Heart Wires

The ~~Syncrus~~SYNCRUS™ Heart Wires consist of three myocardial wires: a unipolar Heart Wire for the left atrium, a tripolar Heart Wire for the right atrium, and a bipolar Heart Wire for the left or right ventricle. The ~~Syncrus~~SYNCRUS™ Heart Wires are for single use only and should not be reused or resterilized.

The Left Atrial Heart Wire is a unipolar ~~lead~~ wire with a cardioversion electrode for atrial cardioversion. The Right Atrial Heart Wire is tripolar with one electrode for atrial cardioversion (that is used in conjunction with the cardioversion electrode on the Left Atrial Heart Wire) and a bipolar pacing lead with one electrode for atrial pacing and ECG sensing and a second electrode for grounding. The Ventricular Heart Wire is a bipolar pacing lead with one electrode for ventricular pacing and ECG sensing and a second electrode for grounding.

The ~~Syncrus~~SYNCRUS™ Heart Wire electrodes are placed on appropriate locations in the myocardium and the proximal ends of the Heart Wires are passed through the patient's chest wall and skin ~~of the patient~~ using a straight thoracic needle attached to each Heart Wire. The thoracic needles are cut off after externalization and yellow cardioversion connectors are attached to the cardioversion lead (yellow wire) on the Left and Right Atrial Heart Wires. The pacing connector pins on the Right Atrial Heart Wire (black and blue wires) and Ventricular Heart Wire (black and white wires) are covered with a protective tubing. The cardioversion and pacing connectors are usually taped to the patient's body until needed. After the ~~Syncrus~~SYNCRUS™ Heart Wires are no longer needed (usually just prior to patient discharge from the hospital), the Heart Wires are removed from the patient with gentle and continuous external traction.

To perform internal atrial cardioversion, the cardioversion ~~connectors~~ wires on the Left and Right Atrial Heart Wires must be connected to the ~~Syncrus~~SYNCRUS™ Cardioversion Extension Cable and EDIM. The hospital must supply a ~~monophasic~~ compatible low energy external defibrillator.

To perform atrial and ventricular pacing and ECG sensing, the pacing connector pins on the Right Atrial Heart Wire and Ventricular Heart Wire must be connected to the appropriate pacing cables and an external pacemaker. The hospital must supply both the external pacemaker and pacing cables.

4.2 ~~Syncrus~~SYNCRUS™ External Defibrillator Interface Module (EDIM)

The ~~Syncrus~~SYNCRUS™ EDIM is a non-sterile and reusable device that allows the energy from ~~an~~ compatible external defibrillator to be transmitted through the Left and Right Atrial Heart Wires directly to the patient's myocardium.

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To perform internal electrical cardioversion, external defibrillator paddles are placed on the paddle plates and safety push button of the ~~Syncrus~~SYNCRUS™ EDIM. The EDIM reduces the output energy from an external ~~monophasic~~ defibrillator by approximately 97% and delivers a low energy internal cardioversion shock to the left and right atrial myocardium. For every 100 joules input from the external defibrillator, approximately 3 joules are actually delivered to the patient's heart.

4.3 ~~Syncrus~~SYNCRUS™ Cardioversion Extension Cable

The ~~Syncrus~~SYNCRUS™ Cardioversion Extension Cable is a reusable cable that connects the cardioversion connectors on the Left and Right Atrial Heart Wires to the ~~Syncrus~~SYNCRUS™ EDIM.

4.4 EDIM Maintenance Test Fixture and Cardioversion Cable Test Adapters

The EDIM maintenance test fixture and Cardioversion Cable test adapters are used to perform the full maintenance test on the Guidant ~~Syncrus~~SYNCRUS™ System as described in the *Maintenance and Calibration* ~~Section~~section.

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5.0 MAINTAINING SYSTEM EFFECTIVENESS

5.1 ~~Synerus~~SYNCRUS™ Heart Wires

- The ~~Synerus~~SYNCRUS™ Heart Wires are for single use only. DO NOT RESTERILIZE. DO NOT REUSE.

5.2 ~~Synerus~~SYNCRUS™ EDIM and Cardioversion Extension Cable

- The EDIM should only be used with a ~~monophasic,~~compatible low-energy external defibrillator (see section on *Required User Supplied Components*).

- Perform functional checks on the ~~Synerus~~SYNCRUS™ EDIM ~~daily and monthly (see section on *Maintenance and Calibration*).~~as described in the *Maintenance and Calibration* section.

- Do not use conductive gel or paste on the external defibrillator paddles or ~~Synerus~~SYNCRUS™ EDIM paddle plates.

- Do not immerse the ~~Synerus~~SYNCRUS™ EDIM or Cardioversion Extension Cable in liquid.

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6.0 REQUIRED USER SUPPLIED COMPONENTS

To apply ~~Syncrus~~SYNCRUS™ atrial cardioversion therapy, the user must supply a compatible ~~monophasic~~ low energy external defibrillator, an external pacemaker, and the appropriate pacing cables. Below is a list of compatible external defibrillators, pacemakers and pacing cables that have been tested with the Guidant ~~Syncrus~~SYNCRUS™ System.

External pacemaker:

- Medtronic Dual-Chamber Model 5388 External (Temporary) Pulse Generator
- Medtronic Single-Chamber Model 5348 External (Temporary) Pulse Generator

Pacing cables:

- Medtronic 5433A Reusable EPG atrial safety cables
- Medtronic 5433V Reusable EPG ventricular safety cables
- Medtronic 5487 6 ft. sterile disposable patient safety cables

Biphasic, low energy external defibrillator with R-wave synchronization capability and external paddles:

- Medtronic Physio-Control LIFEPAK® 12 and LIFEPAK® 20 defibrillators
- Agilent (Philips Medical) Heartstream™ or HeartStart XL and XLT defibrillators

Note: The Zoll M Series biphasic defibrillator will not discharge energy into the SYNCRUS™ EDIM.

Monophasic, low-energy external defibrillator with R-wave synchronization capability:

- Medtronic Physio-Control ~~LifePak™~~ LIFEPAK® 9, 10, 11, 12 ~~(excluding 3D Biphasic™ Technology)~~ defibrillators
- Agilent (Philips Medical)~~(Hewlett Packard)~~ ~~Codemaster~~CodeMaster™ defibrillator
- Zoll ~~Medical Corporation~~M Series defibrillator with monophasic capability

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7.0 WARNINGS

- The ~~Guidant Syncrus~~SYNCRUS™ System is not compatible with ~~monophasic~~all low energy external defibrillators ~~only~~. See section on *Required User Supplied Components* for a list of compatible external defibrillators.
- Perform synchronized cardioversion only. Unsynchronized shocks may result in ventricular fibrillation, causing patient injury or death.
- The ~~Syncrus~~SYNCRUS™ Heart Wires provide a direct path for electrical current flow to the patient's heart. DO NOT touch the heart wire leads or the EDIM (when connected to the Heart Wires) with your bare hands or with anything that may deliver static (electrostatic discharge). Avoid the possibility of unintentional contact between the wire leads, including extension cable, and any equipment used as well as any conductive surface contact. Line powered equipment used in the vicinity of the patient must be properly grounded.
- The ~~Syncrus~~SYNCRUS™ EDIM and Cardioversion Extension Cable are designed solely for use with the ~~Syncrus~~SYNCRUS™ Heart Wires.
- DO NOT connect the Heart Wires to any equipment other than that specified in these instructions and the ~~Syncrus~~SYNCRUS™ System Operator's Manual. Patient injury or death may result.
- If the ~~Syncrus~~SYNCRUS™ ~~System~~ EDIM has been dropped ~~onto a hard surface~~, perform a FULL maintenance test as described in the ~~Syncrus~~SYNCRUS™ System Operator's Manual (*Maintenance and Calibration* section) prior to using the EDIM again. Dropping the EDIM may damage internal components, possibly rendering the device inoperable or out of specification.
- Wire fracture, dislodgement, abrasion and/or an incomplete connection can cause a periodic or continual loss of pacing and sensing, possibly resulting in inappropriate delivery of conversion therapy. Connect the pacing connector pins for baseline measurements to a pacing system analyzer (PSA) or temporary pacemaker and evaluate the placement by determining R-wave amplitude, pacing threshold, and pacing lead impedance. Secure the ~~Syncrus~~SYNCRUS™ Heart Wires by taping the cardioversion connectors and pacing pins to the patient's body until needed.
- Although pliable, the lead body is not designed to tolerate excessive flexing, bending, or tension. This could cause structural weakness, conductor discontinuity, and/or lead dislodgement. Secure the cardioversion connectors and pacing pins to the patient's body until needed. Minimize manipulation of the ~~heart wires~~Heart Wires.
- Equipment and accessories connected to the Guidant ~~Syncrus~~SYNCRUS™ System shall comply with IEC-601-1, type CF.

8.0 PRECAUTIONS

- ~~Syncrus~~SYNCRUS™ Heart Wires are for single use only. DO NOT RESTERILIZE. DO NOT REUSE.

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- The ~~Synerus~~SYNCRUS™ Heart Wires are gamma sterilized after packaging. When they are received, they are sterile and ready for use. Should the seal or package be wet, damaged, punctured, or if the seal is broken, do not use or attempt to resterilize. Contact the local Guidant representative.
- Pre-clinical testing supports the use of this device up to 7 cardioversion attempts. Cardioversion attempts ranged from 1 to 9 attempts in clinical trials. Physicians should treat patients in accordance with judgment and experience. Assessment of the patient's overall condition and physician discretion should dictate the number of attempts to treat.
- It is recommended that defibrillation equipment and a pacing sensor system analyzer (PSA) or temporary pacemaker be readily available during lead placement and removal.

9.0 ATTACHING THE ~~SYNCRUS~~SYNCRUS™ HEART WIRES TO THE MYOCARDIUM

1. -Attach the ~~Synerus~~SYNCRUS™ Heart Wires to the patient's myocardial surface during cardiac surgery in the following order and before the patient's chest is closed. The described fixation techniques ~~is~~are furnished for informational purposes only. The physician may choose to vary the fixation technique in accordance with judgment and experience. The selected fixation technique of each Heart Wire placement should always allow for ease of extraction through gentle traction. Proper surgical procedures and techniques are the responsibility of the medical professional. ~~Figures 2 through 4 illustrate heart wire placement as performed in clinical trials.~~

Left Atrial Heart Wire (unipolar)

- *Cardioversion Electrode (yellow wire)*: Use the attached curved needle to affix the cardioversion electrode to the left atrial myocardium. After the cardioversion electrode is affixed (see Figures 2a and 3a), cut off the curved needle and discard it. Place a slight bend or kink at the end of the electrode.

Right Atrial Heart Wire (tripolar)

- *Cardioversion Electrode (yellow wire)*: Use the attached curved needle to affix the cardioversion electrode to the right atrial myocardium. After the cardioversion electrode is affixed (see Figures 2b and 3b), cut off the curved needle and discard it. Place a slight bend or kink at the end of the electrode.

  Placement should be made to maximize the atrial muscle mass between the right atrial cardioversion electrode and the left atrial cardioversion electrode.

- *Pacing Electrodes (black and blue wires)*: Use the attached curved needle to affix the bipolar pacing electrodes to the right atrial myocardium. For optimal cardiac pacing, bury both the pacing electrode and bullet in the myocardium. After the

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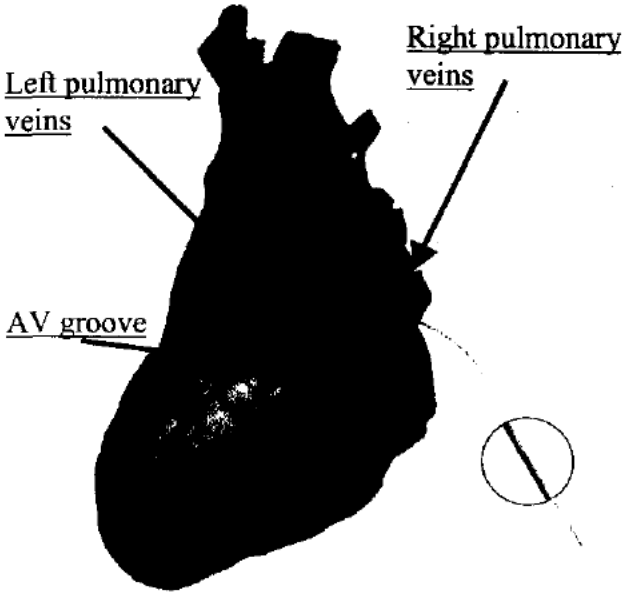
pacing electrodes are affixed (see Figures 2b and 3b), cut off the needle and discard it. Place a slight bend or kink at the end of the pacing electrode.

- Ventricular Heart Wire (bipolar)
  Pacing Electrodes (black and white wires): Use the attached curved needle to affix the bipolar pacing electrodes into the myocardial tissue of either the right or left ventricle. For optimal cardiac pacing, bury both the pacing electrode and bullet in the myocardium. After the pacing electrodes are affixed (see Figures 2c and 3c), cut off the curved needle and discard it. Place a slight bend or kink at the end of the pacing electrode.

Figures 2 through 3 illustrate two examples of Heart Wire placement techniques as used in clinical practice.

Figure 2. SYNCRUS™ Heart Wire Placement Technique A (used in clinical trials in Europe)



2a. Left Atrial Wire Placement
Figure shows the cardioversion electrode placed in an "S" pattern between the atrioventricular (AV) groove and the left and right pulmonary veins.

(Lateral-posterior view)

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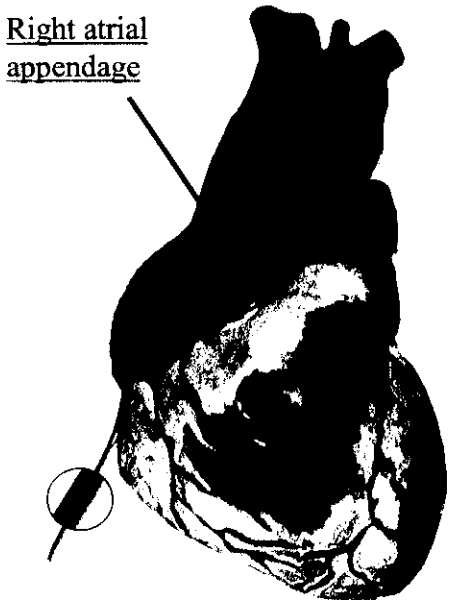

2b. Right Atrial Wire Placement
Figure shows the cardioversion electrode placed in an "S" pattern on the right atrial appendage.

The pacing electrode and bullet are shown placed on the right atrial myocardium.

(Anterior view)

2c. Ventricular Wire Placement
Figure shows the pacing electrode and bullet placed on the right ventricle.

(Anterior view)

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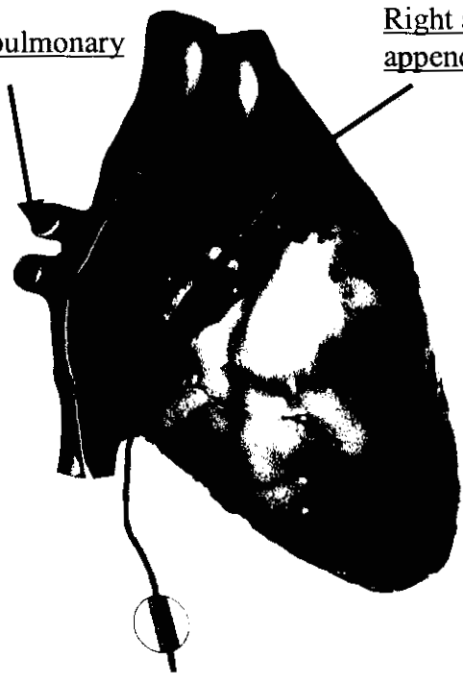
Figure 3. SYNCRUS™ Heart Wire Placement Technique B

3a. Left Atrial Wire Placement
Figure shows the cardioversion electrode placed within 5 mm anterior of the left pulmonary veins.

(Lateral-posterior view)



3b. Right Atrial Wire Placement
Figure shows the cardioversion electrode placed by the inferior vena cava and up towards the right pulmonary veins within 5 mm of the SA node.

The pacing electrode and bullet are shown placed on the right atrial appendage.

(Lateral view)

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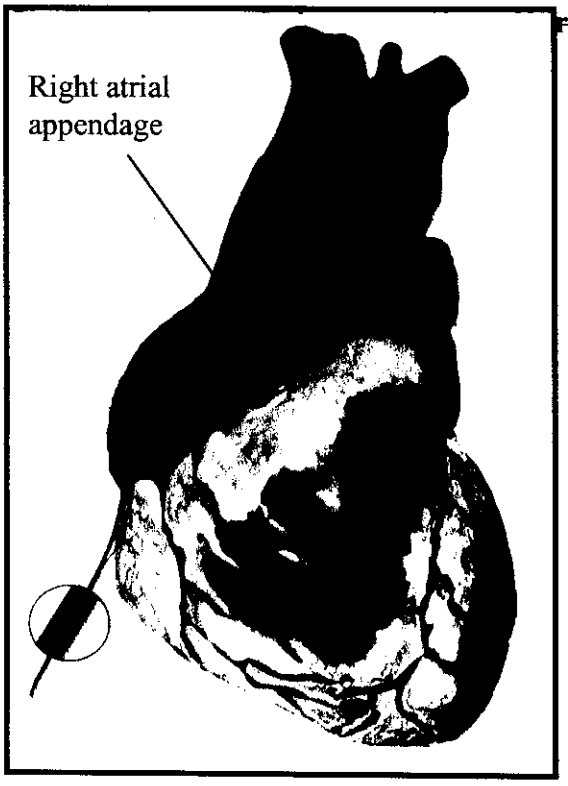
3c. Ventricular Wire Placement
Figure shows the pacing electrode and bullet placed on the right ventricle.

(Anterior view)



Anterior view

~~Right Atrial Heart Wire (tripolar)~~

- ~~*Cardioversion Electrode (yellow wire):* Use the attached curved needle to affix the cardioversion electrode into the right atrial myocardium in an "S" pattern as shown in Figure 3 for optimal results. After the cardioversion electrode is affixed, cut off the curved needle and discard it. Place a slight bend or kink at the end of the electrode.~~

~~*Pacing Electrode (black and blue wires):* Use the attached curved needle to affix the bipolar pacing electrodes into the right atrial myocardium. For optimal cardiac pacing, bury both the anode and cathode in the myocardium. After the pacing electrodes are affixed, cut off the needle and discard it. Place a slight bend or kink at the end of the anode electrode.~~

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~~Figure 4. Syncrus Ventricular Heart Wire Placement~~

Anterior view

~~Ventricular Heart Wire (bipolar)~~

- ~~*Pacing Electrodes (black and white wires)*: Use the attached curved needle to affix the bipolar pacing electrodes into the myocardial tissue of either the right or left ventricle as illustrated in Figure 4 for optimal results. The positive pacing electrode (anode) is attached to the needle, while the negative electrode (cathode) is contained in the 4 mm long bullet. For optimal cardiac pacing, bury both the anode and cathode in the myocardium. After pacing electrodes are affixed, cut off the curved needle and discard it. Place a slight bend or kink at the end of the anode electrode.~~

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2. Right atrial appendage

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ximal end of each ~~Syncrus~~SYNCRUS™
through the chest wall and skin. Once the
ıoracic needles, maximizing the exposed
ıeedles appropriately.

's provided with the SYNCRUS™ Heart
ı the Left and Right Atrial Heart Wires.
~~rovided with the Syncrus Left and Right~~
ing the Heart Wire cardioversion lead
connector and pushing the pin into the
cal contact between the Heart Wire
ersion connector.

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5. _Connect the pacing connector pins for baseline measurements to a pacing system analyzer (PSA) or temporary pacemaker and evaluate the placement by determining R-wave amplitude, pacing threshold, and pacing lead impedance.

6. _Cover the pacing connector pins on the Right Atrial Heart Wire (black and blue wires) and Ventricular Heart Wire (black and white wires) with the protective tubings provided with the ~~Synerus~~ SYNCRUS™ Heart Wires. Secure the ~~Synerus~~ SYNCRUS™ Heart Wires by taping the cardioversion connectors and pacing pins to the patient's body until needed.

7. _When ~~Synerus~~ SYNCRUS™ atrial cardioversion therapy is needed, connect the yellow cardioversion connectors to the ~~Synerus~~ SYNCRUS™ Cardioversion Extension Cable. Ensure that the Cable is connected to the EDIM. Apply internal atrial cardioversion by placing external defibrillator paddles on the paddle plates of the ~~Synerus~~ SYNCRUS™ EDIM and deliver~~ing~~ energy. The EDIM will attenuate the external defibrillator output energy by approximately 97% (for example, a 100--joule external shock will result in an approximate 3-joule internal cardioversion shock to the heart).

8. _When temporary cardiac pacing and ECG sensing are needed, remove the protective tubing from the pacing connector pins. Connect the pacing connector pins into the appropriate pacing cables. Ensure that the pacing cables are connected to an external pacemaker. Administer cardiac pacing therapy.

9. _To remove the ~~Synerus~~ SYNCRUS™ Heart Wires, remove any tape holding the Heart Wires in place. Apply gentle and continuous external traction to remove the Heart Wires from the patient. Special care should be taken when removing the lead from the atrium, due to the relatively thin atrial wall.

10. Discard the three externalized Heart Wires appropriately.

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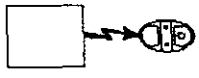
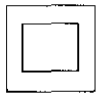
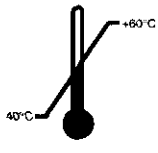
10.0 DEFINITION OF SYMBOLS

Below is a description of the symbols used in this manual and on the Guidant ~~Synerus~~SYNCRUS™ System labels and packaging.

	WARNING: **Shock hazard**. Hazardous voltage may be present. Do not touch the paddle plates when the device is connected to the patient.
	WARNING: Read Instructions for Use.
	WARNING: Do not shock on T-wave. Synchronize shock with patient's R-wave.
	(Green indicator flashes): Energy has been transmitted from the external defibrillator to the ~~Synerus~~SYNCRUS™ EDIM.
	(Red indicator flashes): Overvoltage condition in ~~Synerus~~SYNCRUS™ EDIM. No energy was transmitted to patient. Refer to the Operator's Manual.
	Clean paddle plates before each use with a 70% isopropyl alcohol wipe.
	Type CF equipment.
	Class II equipment.
	Reference information; please read.
	Store at temperature between -40°C and 60°C.

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11.0 MAINTENANCE AND CALIBRATION

The ~~Syncrus~~SYNCRUS™ EDIM is a passive electrical device that relies on a user supplied external defibrillator for its power source. There are no user serviceable parts inside. This maintenance procedure is intended for the use of the hospital biomedical engineering department to verify proper function of the device and its safety features. If the device exhibits any discrepancies in any of these periodic checks, discontinue use of the device at once and contact Guidant Cardiac Surgery (Santa Clara, CA) for return instructions. **All maintenance procedures requiring an external defibrillator should be conducted with a compatible external defibrillator (see section on *Required User Supplied Components* for compatible defibrillators).**

11.1 Daily Maintenance

It is recommended that the following maintenance procedure be performed on a daily basis to ensure proper function of the ~~Syncrus~~SYNCRUS™ EDIM.

CAUTION: Perform all maintenance **BEFORE** connecting the ~~Syncrus~~SYNCRUS™ EDIM to the patient.

1. Clean the paddle plates and safety push button ~~(right side)~~ (see Figure 4) with a 70% isopropyl alcohol wipe before each use. A buildup of dirt on these conductive surfaces can cause degradation of electrical conduction and can prevent proper energy transmission.

2. Verify that the spring-loaded safety push button on the right side of the device can be depressed completely and that it returns to its extended position when the force is removed.

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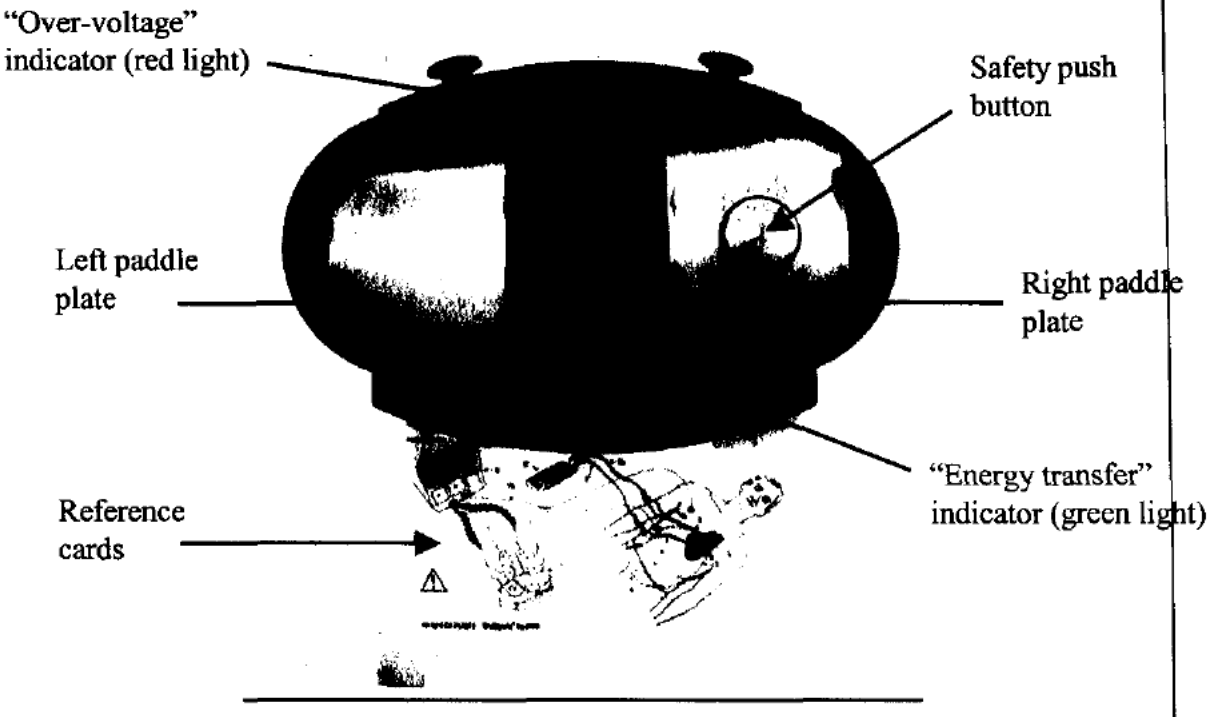
Figure 4. Top view of the SYNCRUS™ External Defibrillator Interface Module (EDIM)



11.2 Full Maintenance ~~(monthly)~~

It is recommended that the following maintenance procedure be performed ~~on a monthly basis~~every 3 months to ensure proper function of the ~~Synerus~~SYNCRUS™ EDIM. Also perform a full maintenance test if the EDIM has been dropped onto a hard surface prior to using the EDIM again.

11.2.1 Other Equipment

- External defibrillator (see section on *Required User Supplied Components* for compatible defibrillators)
- Ohmmeter
- Electrical safety analyzer or leakage current analyzer
- Defibrillator analyzer

~~Impulse 3000 or 4000 defibrillator analyzer (DNI Nevada, Inc., Carson City, NV, USA) or equivalent.~~

~~Synerus™ EDIM maintenance test fixture (Guidant Cardiac Surgery order #TX-5200)~~

~~□Synerus™ Cardioversion Cable test adapter; two required (Guidant Cardiac Surgery order #TX-5300). Hypertronics p/n YPN025-002G may also be used.~~

~~□Hi-pot tester capable of 4 kV AC output~~

~~□Oscilloscope with high voltage probe~~

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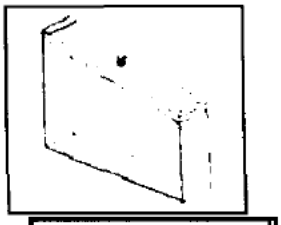
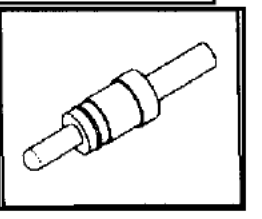
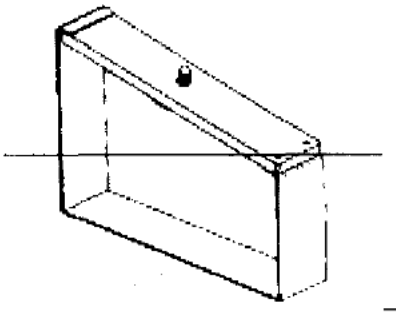
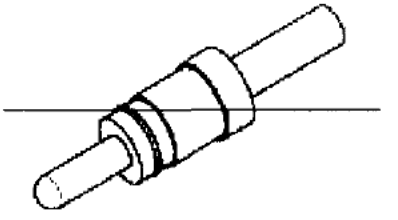
- SYNCRUS™ EDIM maintenance test fixture (Guidant Cardiac Surgery order #TX-5200)



- SYNCRUS™ Cardioversion Cable test adapters – two required (Guidant Cardiac Surgery order #TX-5300). Hypertronics p/n YPN025-002G may also be used.







~~Syncrus™ EDIM maintenance test fixture TX-5200~~

~~Syncrus™ Cardioversion Cable test adapter TX-5300 (2 required)~~

11.2.2 Full Maintenance Procedure

1. Check safety push button

Verify that the spring-loaded safety push button on the right side of the SYNCRUS™ EDIM can be depressed completely and that it returns to its extended position when the force is removed.

2. Check safety switch isolation

Equipment Used:
- Ohmmeter
- SYNCRUS™ Cardioversion Cable test adapters (2)

Test Setup:

2.1 Connect the SYNCRUS™ Cardioversion Extension Cable to the SYNCRUS™ EDIM.

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2.2 Connect the Cardioversion Cable test adapters to the output connectors on the SYNCRUS™ Cardioversion Extension Cable.

2.3 Connect an ohmmeter lead to each of the test adapters.

With the safety push button on the EDIM in its normal "up" position, the ohmmeter should read open (i.e. no continuity). With the safety push button depressed, the ohmmeter should read between 55 – 65 ohms.

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~~1.~~ Check leakage current
3.

Equipment Used:

- Electrical safety analyzer or leakage current analyzer
- SYNCRUS™ Cardioversion Cable test adapters (2)
- SYNCRUS™ EDIM maintenance test fixture

Note: the leakage current limits specified are for the ~~Syncrus~~SYNCRUS™ EDIM only. Any leakage current inherent in the leakage tester must be identified and deducted from the tester readout before applying the leakage current limits.

Patient Leakage Current (Mains on Paddle Plates)

Test Setup:

~~1.1~~3.1 Connect the ~~Syncrus~~SYNCRUS™ Cardioversion Extension Cable to the ~~Syncrus~~SYNCRUS™ EDIM.

3.2 Connect the Cardioversion Cable test adapters to the output connectors on the SYNCRUS™ Cardioversion Extension Cable. Electrically short the two output terminals on the test adapters.

3.3 ~~1.2~~ Connect the shorted test adapters to the ground terminal on the electrical safety or leakage current analyzer.~~a Cardioversion Cable test adapter to each output connector on the Syncrus™ Cardioversion Extension Cable. Electrically short the two output terminals on the test adapters~~

3.4 Attach the EDIM maintenance test fixture to the SYNCRUS™ EDIM. The test fixture should wrap around the right side of the EDIM and the latching mechanism should be located on the same side as the EDIM output terminals when properly installed for this test (see Figure 5).

3.5 Depress the SYNCRUS™ EDIM safety push button with the movable arm of the test fixture. Latch the movable arm and verify that the EDIM safety push button is fully depressed.

3.6 Make an electrical connection between the EDIM maintenance test fixture (via the lock nut) and an ECG terminal of the analyzer (i.e. RL connection).

3.7 Using the appropriate setting for the analyzer, apply either 120-volts or 240-volts (determined by the voltage powering the analyzer) to the EDIM. Descriptors for the analyzer test mode may include "Lead Isolation to Ground" or "Patient Lead Isolation Test".

~~1.3Connect a current measuring device to the shorted output terminals of the test adapters.~~

~~Attach the EDIM maintenance test fixture to the Syncrus™ EDIM. The test fixture should wrap around the right side of the EDIM and the latching mechanism should be located on the same side as the EDIM output terminals when properly installed for this test (see Figure 5).~~

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~~1.5Depress the Syncrus™ EDIM safety push button with the movable arm of the test fixture. Latch the movable arm and verify that the EDIM safety push button is fully depressed.~~

The SYNCRUS™ EDIM shall not allow greater than 10μA leakage current when 240-volts are applied by the analyzer (or 5μA leakage current when 120-volts are applied) to the EDIM.

CAUTION: Do not depress the SYNCRUS™ EDIM safety push button with anything that is electrically common with your body. Serious injury may occur.

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Figure 5. The EDIM maintenance test fixture shown properly installed on the right side of the SYNCRUS™ EDIM.

~~**Figure 5.** The EDIM maintenance test fixture shown properly installed to the Syncrus™ EDIM.~~

~~The Syncrus™ EDIM shall not allow greater than 10μA leakage current when a 240-volt source is connected (or 5μA leakage current when a 120 volt source is connected) to the left paddle plate and the current measuring device is attached to the output jacks electrically tied together and shorted to ground. The EDIM safety push button should be depressed for this check.~~

~~Patient Leakage Current (Mains on the Applied Part) - The Syncrus™ EDIM shall not allow greater than 10 μA leakage current when a 240 volt source is connected (or 5μA leakage current when a 120 volt source is connected) to the output jacks electrically tied~~

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~~together and the measuring device is attached to the left paddle plate and shorted to ground. The EDIM safety push button should be depressed for this check.~~

~~**CAUTION:** Do not depress the Syncrus™ EDIM safety push button with anything that is electrically common with your body. Serious injury may occur.~~

4. Check over-voltage protection

Equipment Used:
- External defibrillator

Discharge a 360 joule shock from the external defibrillator into the SYNCRUS™ EDIM using the external paddles, but with no load connected to the output terminals.

Note: This test verifies that the over-voltage protectors limit the output voltage from the EDIM to less than 800-volts. A monophasic external defibrillator needs to be used for this test in order to achieve a voltage greater than 800-volts at the voltage protectors when there is no load connected to the EDIM output.

The "over-voltage" indicator (red) on the top panel of the EDIM should flash momentarily. The "energy transfer" indicator (green) will also flash momentarily.

If the "energy transfer" indicator (green) does not flash, verify that the external defibrillator is delivering at least 360 joules by connecting a defibrillator analyzer directly to the defibrillator (remove the EDIM from the circuit). If the external defibrillator is delivering at least 360 joules, discontinue use of the EDIM. If the external defibrillator is not delivering at least 360 joules (and is set for 360 joules output), discontinue use of the external defibrillator.~~2. Check mechanical isolation~~

~~Verify that the spring-loaded safety push button on the right side of the Syncrus™ EDIM can be depressed completely and that it returns to its extended position when the force is removed.~~

5. Check "energy transfer" indicator

Equipment Used:
- External defibrillator
- Defibrillator analyzer
- SYNCRUS™ Cardioversion Cable test adapters (2)

Test Setup:

5.1 Connect the SYNCRUS™ Cardioversion Extension Cable to the SYNCRUS™ EDIM.

5.2 Connect the Cardioversion Cable test adapters to the output connectors on the SYNCRUS™ Cardioversion Extension Cable.

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5.3 Connect the test adapters to the defibrillator analyzer.
5.4 Place the external defibrillator paddles on the SYNCRUS™ EDIM paddle plates. Assure that the right safety push button is fully depressed by the paddle.

Discharge a 100 joule shock from the external defibrillator into the SYNCRUS™ EDIM using the external paddles. The "energy transfer" indicator (green) will flash momentarily, while the "over-voltage" indicator (red) will not flash. Repeat the check with a 360 joule shock. The "energy transfer" indicator (green) will flash momentarily, while the "over-voltage" indicator (red) will not flash.

6. ~~3.~~ Check attenuation level

Equipment Used:

- External defibrillator
- Defibrillator analyzer
- SYNCRUS™ Cardioversion Cable test adapters (2)

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Test Setup:

~~3.1~~6.1 Connect the ~~Syncrus~~SYNCRUS™ Cardioversion Extension Cable to the ~~Syncrus~~SYNCRUS™ EDIM.

~~3.2~~6.2 Connect the Cardioversion Cable test adapters to the output connectors on the SYNCRUS™ Cardioversion Extension Cable. ~~Connect a Cardioversion Cable test adapter to each output connector on the Syncrus™ Cardioversion Extension Cable.~~

~~3.3~~6.3 Connect the test adapters to the defibrillator analyzer.

~~3.4~~6.4 Place the external defibrillator paddles on the ~~Syncrus~~SYNCRUS™ EDIM paddle plates. Assure that the right safety push button is fully depressed by the paddle.

Use the defibrillator analyzer to verify the ~~Syncrus~~SYNCRUS™ EDIM attenuation level:

External defibrillator setting*	~~Syncrus~~SYNCRUS™ EDIM output*
360 joule	10.4 - 11.1 joule

* If the external defibrillator does not deliver exactly 360 joules, the lower and upper ~~Syncrus~~SYNCRUS™ EDIM output energy limits may be calculated by multiplying the external defibrillator input energy by 0.0289 and 0.0309, respectively.

7. Check shock delivery delay

Equipment Used:

- External defibrillator
- Defibrillator analyzer
- SYNCRUS™ Cardioversion Cable test adapters (2)

Test Setup:

7.1 Connect the SYNCRUS™ Cardioversion Extension Cable to the SYNCRUS™ EDIM.

7.2 Connect the Cardioversion Cable test adapters to the output connectors on the SYNCRUS™ Cardioversion Extension Cable.

7.3 Connect the test adapters to the defibrillator analyzer.

7.4 Connect the defibrillator analyzer's normal sinus ECG output signal (60 bpm) to the synchronization input of the external defibrillator.

7.5 Place the external defibrillator paddles on the SYNCRUS™ EDIM paddle plates. Assure that the right safety push button is fully depressed by the paddle.

Using synchronized cardioversion mode, discharge a 200 joule shock from the external defibrillator into the SYNCRUS™ EDIM using the external paddles.

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Use the defibrillator analyzer to measure actual delay time from the peak of the generated R-wave to the leading edge of the defibrillator discharge waveform, measured at the output of the SYNCRUS™ EDIM. The delay time must be less than 60 milliseconds.~~4. Check shock delivery delay~~

~~Test Setup:~~

~~4.1Connect the Syncrus™ Cardioversion Extension Cable to the Syncrus™ EDIM.~~

~~Connect a Cardioversion Cable test adapter to each output connector on the Syncrus™ Cardioversion Extension Cable.~~

~~4.3 Connect the test adapters to the defibrillator analyzer.~~

~~4.4Connect the defibrillator analyzer's normal sinus ECG output signal (60 bpm) to the synchronization input of the external defibrillator.~~

~~Place the external defibrillator paddles on the Syncrus™ EDIM paddle plates. Assure that the right safety push button is fully depressed by the paddle.~~

~~4.6 Discharge the external defibrillator at 360 joules, using synchronized cardioversion mode.~~

~~Use the defibrillator analyzer to measure actual delay time from the peak of the generated R-wave to the leading edge of the defibrillator discharge waveform, measured at the output of the Syncrus™ EDIM. The delay time must be less than 60 milliseconds.~~

~~5. Check over-voltage protection~~

~~Discharge a 360 joule shock from the external defibrillator into the Syncrus™ EDIM using the external paddles, but with no load connected to the output terminals. The "over-voltage" indicator on the top panel of the EDIM should flash momentarily (red color). The "energy transfer" indicator (green) will also flash momentarily.~~

~~If the "energy transfer" indicator does not flash, verify that the external defibrillator is delivering at least 360 joules by connecting the defibrillator analyzer directly to the defibrillator (remove the EDIM from the circuit). If the external defibrillator is delivering at least 360 joules, discontinue use of the EDIM. If the external defibrillator is not delivering at least 360 joules (and is set for 360 joules output), discontinue use of the external defibrillator.~~

~~6. Check "energy transfer" indicator~~

~~Test Setup:~~

~~6.1Connect the Syncrus™ Cardioversion Extension Cable to the Syncrus™ EDIM.~~

~~6.2Connect a Cardioversion Cable test adapter to each output connector on the Syncrus™ Cardioversion Extension Cable.~~

~~6.3 Connect a 60 ohm, 100 watt resistor across the terminals of the test adapters.~~

~~6.4 Place the external defibrillator paddles on the Syncrus™ EDIM paddle plates. Assure that the right safety push button is fully depressed by the paddle.~~

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~~Discharge a 100 joule shock from the external defibrillator into the Syncrus™ EDIM using the external paddles. The "energy transfer" indicator (green) will flash momentarily, while the "over-voltage" indicator (red) will not flash. Repeat the check with a 360 joule shock. The "energy transfer" indicator will flash momentarily, while the "over-voltage" indicator will not flash.~~

~~7.Dielectric withstand~~

~~Test Setup:~~

~~7.1 Connect the Syncrus™ Cardioversion Extension Cable to the Syncrus™ EDIM.~~

~~7.2 Connect the Cardioversion Cable test adapters to the Syncrus™ Cardioversion Extension Cable.~~

~~7.3 Electrically short the output terminals on the test adapters.~~

~~7.4Attach the EDIM maintenance test fixture to the Syncrus™ EDIM. The test fixture should wrap around the **left** side of the EDIM and the latching mechanism should be located on the same side as the EDIM output terminals when properly installed for this test (see Figure 6).~~

~~7.5Connect the positive hi-pot output lead to the Syncrus™ EDIM left paddle plate via the electrical connector on the EDIM maintenance test fixture.~~

~~7.6Connect the negative hi-pot lead to the shorted output terminals on the Cardioversion Cable test adapters.~~

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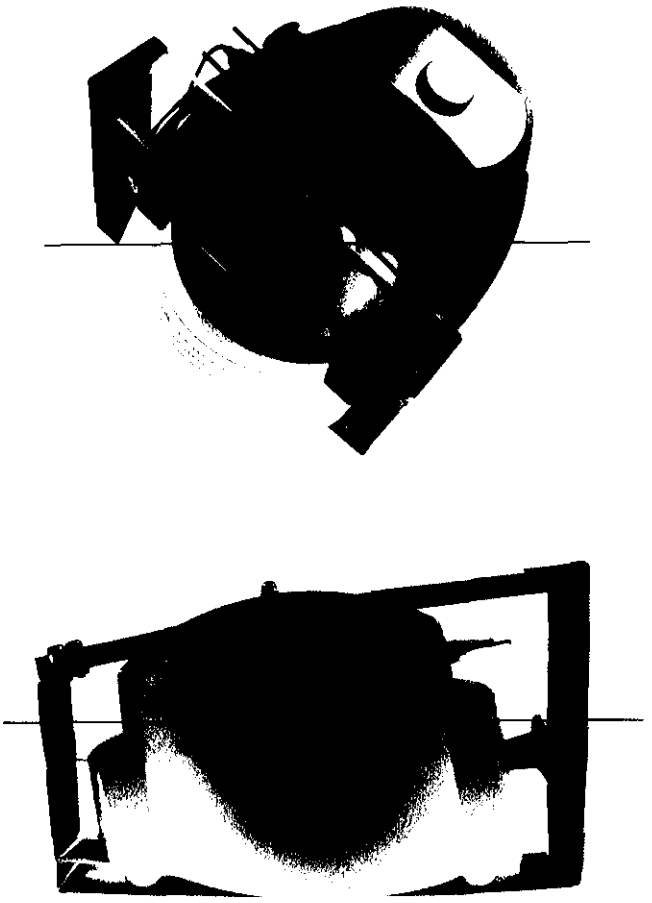

~~**Figure 6.** The EDIM maintenance test fixture shown properly installed to the Syncrus™ EDIM.~~

~~Set the hi-pot tester to output 4000 Volts AC. The EDIM right safety push button should not be depressed for this check.~~

~~Slowly raise the voltage to 4000 Volts AC and remain at that voltage for 1 minute. There should be no arcing or tripping of the hi-pot's limit detector and the current flow should be less than 33 mA.~~

~~8.Waveform verification~~

~~Test Setup – Part 1:~~

~~1. Connect the external defibrillator paddles to the defibrillator analyzer.~~
~~2. Connect the oscilloscope to the oscilloscope output jack on the defibrillator analyzer.~~
~~3. Set the defibrillator to 10 joules output.~~

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~~Use the oscilloscope to capture the waveform of the external defibrillator discharging directly into the defibrillator analyzer. Label this waveform "External Defibrillator Waveform".~~

~~Test Setup – Part 2:~~

~~1.Connect the Syncrus™ Cardioversion Extension Cable to the Syncrus™ EDIM.~~

~~2. Connect the Cardioversion Cable test adapters to the Syncrus™ Cardioversion Extension Cable.~~

~~3. Connect the test adapters to the defibrillator analyzer.~~

~~4. Connect the oscilloscope to the oscilloscope output jack on the defibrillator analyzer.~~

~~5. Set the external defibrillator to 360 joules output.~~

~~Discharge the external defibrillator into the Syncrus™ EDIM. Capture the output waveform of the EDIM with the oscilloscope. Label this waveform "Syncrus™ EDIM Waveform". Compare the two waveforms from Part 1 and 2 of this test. They should be very similar in shape, maximum voltage, and duration. If any voltage spikes or "noise" are present on the EDIM waveform that are not present on the external defibrillator waveform after the initial discharge of the external defibrillator, discontinue use of the Syncrus™ EDIM and contact Guidant Cardiac Surgery (Santa Clara, CA) for further instructions.~~

~~NOTE: There may be some voltage spikes or "noise" present in the external defibrillator waveform that are not present on the Syncrus™ EDIM output waveform. This is a normal condition.~~

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12.0 TROUBLESHOOTING

12.1 Internal Atrial Cardioversion

1. Recheck all electrical connections
2. If the atrial fibrillation episode was not terminated *and* no shock impulse was seen on the ECG monitor *and* the green indicator light on the ~~Syncrus~~SYNCRUS™ EDIM did not flash while the shock was delivered *and* the patient did not experience an involuntary thoracic muscle spasm, then it is likely that that the external defibrillator's energy did not reach the patient.
3. If the red indicator light on the ~~Syncrus~~SYNCRUS™ EDIM flashed during the cardioversion attempt, the internal voltage protection circuit prevented the shock from reaching the patient. Reduce the energy setting on the external defibrillator and attempt another cardioversion or substitute another external defibrillator and try another cardioversion.
4. Deliver another cardioversion shock, while watching the ECG monitor for a shock.
5. If a cardioversion shock was observed on the monitor and the atrial fibrillation episode does not terminate, even briefly, a Heart Wire electrode may be dislodged. Discontinue ~~Syncrus~~SYNCRUS™ atrial cardioversion therapy and revert to traditional therapy.
6. If no cardioversion shock is observed on the monitor and the atrial fibrillation episode is not terminated, the ~~Syncrus~~SYNCRUS™ EDIM or Cardioversion Extension Cable may be defective. If a spare unit is available, replace the ~~Syncrus~~SYNCRUS™ EDIM. If the same problem persists, replace the Cardioversion Extension Cable. Ask your Biomedical Engineering Department to test the ~~Syncrus~~SYNCRUS™ EDIM and Cardioversion Extension Cable per the maintenance procedure in the *Maintenance and Calibration* section.

12.2 Temporary Cardiac Pacing and ECG Sensing

1. Check the settings of the external pacemaker.
2. Recheck all electrical connections.
3. Check the batteries in the external pacemaker.
4. Check that the proper Heart Wire pacing connector pins are connected to the proper input(s) on the external pacemaker.
5. Check that the polarity of the pacing connector pins is correct and consistent to the external pacemaker. If incorrect, reverse the connectors between the Heart Wires and the patient cable.
6. Try using a different pacing cable.
7. Try connecting to a different (positive) electrode. If this corrects the situation, the problem lies either within the pacing wire or at the pacing electrode's connection to the heart. You can either continue pacing with this configuration, or install an indifferent electrode on the patient's skin.

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8. Try connecting to a different stimulation (negative) electrode. If this corrects the situation, the problem lies either within the pacing wire or at the pacing electrode's connection to the heart. This situation cannot be corrected on this patient.

13.0 WARRANTY AND SERVICE

The ~~Syncrus~~SYNCRUS™ External Defibrillator Interface Module (EDIM) is warranted for one (1) year from the date of purchase. If the device fails to perform as intended during the warranty period, return it to Guidant Cardiac Surgery (Santa Clara, CA) for a replacement unit.

The ~~Syncrus~~SYNCRUS™ EDIM is not user serviceable. Do not attempt to open the module case. Warranty is void if the tamper resistant seal on the EDIM is broken. Proper device function must be verified ~~monthly~~ by your Biomedical Engineering or Equipment Maintenance Department. Refer to the section on *Maintenance and Calibration* for maintenance procedures.

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May be manufactured under one or more of the following patents: 5,674,253; 5,766,224; and RE 35,779.

P/N ~~PPL2036625 Rev. A~~PPL2038200 Rev. A

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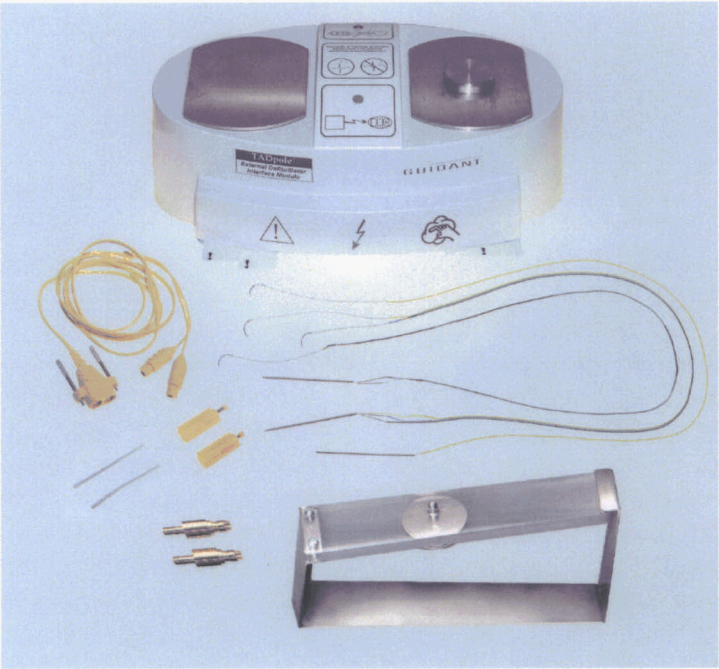
Guidant SYNCRUS™ System

Post Cardiac Surgery Atrial Cardioversion
And
Temporary Cardiac Pacing



OPERATOR'S MANUAL

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1.0 SYNCRUS™ ATRIAL CARDIOVERSION THERAPY

The Guidant SYNCRUS™ System provides low energy internal cardioversion therapy to treat postoperative atrial fibrillation in conjunction with temporary cardiac pacing and ECG sensing.

During cardiac surgery, SYNCRUS™ Heart Wires are attached to appropriate locations on the patient's myocardium using standard surgical technique. The proximal ends of the SYNCRUS™ Heart Wires are externalized through the patient's chest wall and connected to appropriate cables attached to the SYNCRUS™ External Defibrillator Interface Module (EDIM) and a temporary external pacemaker.

In the event of post cardiac surgery atrial fibrillation, the clinician performs a routine synchronized electrical cardioversion, except that the external defibrillator paddles rest on the paddle plates of the SYNCRUS™ EDIM, rather than on the patient's chest. The patient is sedated at the physician's discretion. The *maximum* energy level administered through the SYNCRUS™ EDIM to the SYNCRUS™ Heart Wires is approximately 11 joules directly to the patient's myocardium, compared to 360 joules if delivered transthoracically with external defibrillator paddles.

The SYNCRUS™ Heart Wires are designed to also provide temporary cardiac pacing and ECG sensing before and after internal atrial cardioversion without requiring the physician to rearrange cables and wires.

Carefully read all instructions prior to use. Observe all warnings and precautions noted throughout these instructions.

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2.0 SYSTEM DESCRIPTION

The Guidant SYNCRUS™ System provides low energy internal cardioversion therapy to treat postoperative atrial fibrillation via SYNCRUS™ Heart Wires placed directly on the patient's heart. The System's functions also include temporary atrial and ventricular pacing and ECG sensing capabilities.

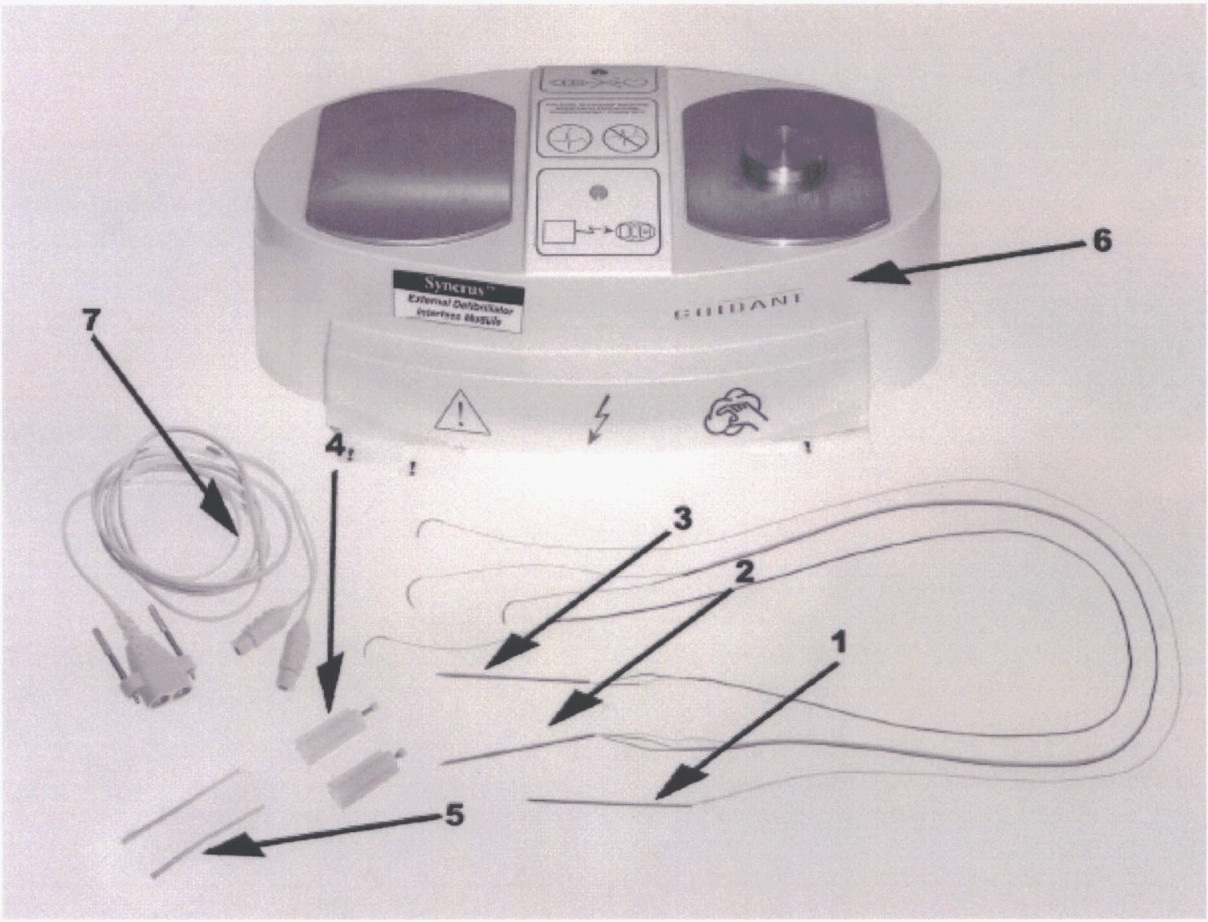

Figure 1. Guidant SYNCRUS™ System

1. Left Atrial Heart Wire (unipolar)
2. Right Atrial Heart Wire (tripolar)
3. Ventricular Heart Wire (bipolar)
4. Yellow Cardioversion Connectors
5. Protective Tubings
6. External Defibrillator Interface Module (EDIM)
7. Cardioversion Extension Cable

Note: The Heart Wires (with yellow cardioversion connectors and protective tubings) are sold separately from the EDIM and Cardioversion Extension Cable.

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The SYNCRUS™ System consists of the following components:

- Three single use Heart Wires that are attached to myocardial tissue of the left atrium, right atrium, and right or left ventricle during cardiac surgery. The Heart Wires transmit low energy shocks to the patient's heart for electrical atrial cardioversion. The Heart Wires also provide temporary cardiac pacing and ECG sensing capabilities.

- A reusable External Defibrillator Interface Module (EDIM), which interfaces between a compatible low energy external defibrillator and the Heart Wires. The EDIM reduces the output energy from the defibrillator to a low energy shock delivered through the Heart Wires.

- A reusable Cardioversion Extension Cable that connects the Heart Wires to the EDIM.

The SYNCRUS™ System components must be used in conjunction with a compatible low energy external defibrillator, an external pacemaker, and pacing cables that connect the Heart Wires to the external pacemaker. The user supplies the external defibrillator, external pacemaker, and pacing cables.

Refer to section 6.0 on *Required User Supplied Components* for a list of compatible external defibrillators, external pacemakers and pacing cables that have been tested with the Guidant SYNCRUS™ System.

3.0 INDICATIONS FOR USE

The Guidant SYNCRUS™ Internal Cardioversion System is indicated for use in post-operative cardiac surgery patients who require temporary atrial or ventricular pacing/sensing and/or atrial cardioversion.

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4.0 COMPONENTS DESCRIPTION

4.1 SYNCRUS™ Heart Wires

The SYNCRUS™ Heart Wires consist of three myocardial wires: a unipolar Heart Wire for the left atrium, a tripolar Heart Wire for the right atrium, and a bipolar Heart Wire for the left or right ventricle. The SYNCRUS™ Heart Wires are for single use only and should not be reused or resterilized.

The Left Atrial Heart Wire is a unipolar wire with a cardioversion electrode for atrial cardioversion. The Right Atrial Heart Wire is tripolar with one electrode for atrial cardioversion (that is used in conjunction with the cardioversion electrode on the Left Atrial Heart Wire) and a bipolar pacing lead with one electrode for atrial pacing and ECG sensing and a second electrode for grounding. The Ventricular Heart Wire is a bipolar pacing lead with one electrode for ventricular pacing and ECG sensing and a second electrode for grounding.

The SYNCRUS™ Heart Wire electrodes are placed on appropriate locations in the myocardium and the proximal ends of the Heart Wires are passed through the patient's chest wall and skin using a straight thoracic needle attached to each Heart Wire. The thoracic needles are cut off after externalization and yellow cardioversion connectors are attached to the cardioversion lead (yellow wire) on the Left and Right Atrial Heart Wires. The pacing connector pins on the Right Atrial Heart Wire (black and blue wires) and Ventricular Heart Wire (black and white wires) are covered with a protective tubing. The cardioversion and pacing connectors are usually taped to the patient's body until needed. After the SYNCRUS™ Heart Wires are no longer needed (usually just prior to patient discharge from the hospital), the Heart Wires are removed from the patient with gentle and continuous external traction.

To perform internal atrial cardioversion, the cardioversion wires on the Left and Right Atrial Heart Wires must be connected to the SYNCRUS™ Cardioversion Extension Cable and EDIM. The hospital must supply a compatible low energy external defibrillator.

To perform atrial and ventricular pacing and ECG sensing, the pacing connector pins on the Right Atrial Heart Wire and Ventricular Heart Wire must be connected to the appropriate pacing cables and an external pacemaker. The hospital must supply both the external pacemaker and pacing cables.

4.2 SYNCRUS™ External Defibrillator Interface Module (EDIM)

The SYNCRUS™ EDIM is a non-sterile and reusable device that allows the energy from a compatible external defibrillator to be transmitted through the Left and Right Atrial Heart Wires directly to the patient's myocardium.

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To perform internal electrical cardioversion, external defibrillator paddles are placed on the paddle plates and safety push button of the SYNCRUS™ EDIM. The EDIM reduces the output energy from an external defibrillator by approximately 97% and delivers a low energy internal cardioversion shock to the left and right atrial myocardium. For every 100 joules input from the external defibrillator, approximately 3 joules are actually delivered to the patient's heart.

4.3 SYNCRUS™ Cardioversion Extension Cable

The SYNCRUS™ Cardioversion Extension Cable is a reusable cable that connects the cardioversion connectors on the Left and Right Atrial Heart Wires to the SYNCRUS™ EDIM.

4.4 EDIM Maintenance Test Fixture and Cardioversion Cable Test Adapters

The EDIM maintenance test fixture and Cardioversion Cable test adapters are used to perform the full maintenance test on the Guidant SYNCRUS™ System as described in section 11.0, *Maintenance and Calibration*.

5.0 MAINTAINING SYSTEM EFFECTIVENESS

5.1 SYNCRUS™ Heart Wires

- The SYNCRUS™ Heart Wires are for single use only. DO NOT RESTERILIZE. DO NOT REUSE.

5.2 SYNCRUS™ EDIM and Cardioversion Extension Cable

- The EDIM should only be used with a compatible low energy external defibrillator (see section 6.0 on *Required User Supplied Components*).
- Perform functional checks on the SYNCRUS™ EDIM as described in section 11.0, *Maintenance and Calibration*.
- Do not use conductive gel or paste on the external defibrillator paddles or SYNCRUS™ EDIM paddle plates.
- Do not immerse the SYNCRUS™ EDIM or Cardioversion Extension Cable in liquid.

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6.0 REQUIRED USER SUPPLIED COMPONENTS

To apply SYNCRUS™ atrial cardioversion therapy, the user must supply a compatible low energy external defibrillator, an external pacemaker, and the appropriate pacing cables. Below is a list of compatible external defibrillators, pacemakers and pacing cables that have been tested with the Guidant SYNCRUS™ System.

External pacemaker:

- Medtronic Dual-Chamber Model 5388 External (Temporary) Pulse Generator
- Medtronic Single-Chamber Model 5348 External (Temporary) Pulse Generator

Pacing cables:

- Medtronic 5433A Reusable EPG atrial safety cables
- Medtronic 5433V Reusable EPG ventricular safety cables
- Medtronic 5487 6 ft. sterile disposable patient safety cables

Biphasic, low energy external defibrillator with R-wave synchronization capability and external paddles:

- Medtronic Physio-Control LIFEPAK® 12 and LIFEPAK® 20 defibrillators
- Agilent (Philips Medical) Heartstream™ or HeartStart XL and XLT defibrillators

Note: The Zoll M Series biphasic defibrillator will not discharge energy into the SYNCRUS™ EDIM and is incompatible with the SYNCRUS System.

Monophasic, low energy external defibrillator with R-wave synchronization capability:

- Medtronic Physio-Control LIFEPAK® 9, 10, 11, 12 defibrillators
- Agilent (Philips Medical) CodeMaster™ defibrillator
- Zoll M Series defibrillator with monophasic capability

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7.0 WARNINGS

- The SYNCRUS™ System is not compatible with all low energy external defibrillators. See section 6.0 on *Required User Supplied Components* for a list of compatible external defibrillators. The Zoll M Series biphasic defibrillator will not discharge energy into the EDIM and is incompatible with the SYNCRUS System.
- Perform synchronized cardioversion only. Unsynchronized shocks may result in ventricular fibrillation, causing patient injury or death.
- The SYNCRUS™ Heart Wires provide a direct path for electrical current flow to the patient's heart. DO NOT touch the heart wire leads or the EDIM (when connected to the Heart Wires) with your bare hands or with anything that may deliver static (electrostatic discharge). Avoid the possibility of unintentional contact between the wire leads, including extension cable, and any equipment used as well as any conductive surface contact. Line powered equipment used in the vicinity of the patient must be properly grounded.
- The SYNCRUS™ EDIM and Cardioversion Extension Cable are designed solely for use with the SYNCRUS™ Heart Wires.
- DO NOT connect the Heart Wires to any equipment other than that specified in these instructions and the SYNCRUS™ System Operator's Manual. Patient injury or death may result.
- If the SYNCRUS™ EDIM has been dropped, perform a FULL maintenance test as described in the SYNCRUS™ System Operator's Manual (see section 11.0, *Maintenance and Calibration*) prior to using the EDIM again. Dropping the EDIM may damage internal components, possibly rendering the device inoperable or out of specification.
- Wire fracture, dislodgement, abrasion and/or an incomplete connection can cause a periodic or continual loss of pacing and sensing, possibly resulting in inappropriate delivery of conversion therapy. Connect the pacing connector pins for baseline measurements to a pacing system analyzer (PSA) or temporary pacemaker and evaluate the placement by determining R-wave amplitude, pacing threshold, and pacing lead impedance. Secure the SYNCRUS™ Heart Wires by taping the cardioversion connectors and pacing pins to the patient's body until needed.
- Although pliable, the lead body is not designed to tolerate excessive flexing, bending, or tension. This could cause structural weakness, conductor discontinuity, and/or lead dislodgement. Secure the cardioversion connectors and pacing pins to the patient's body until needed. Minimize manipulation of the Heart Wires.
- Equipment and accessories connected to the Guidant SYNCRUS™ System shall comply with IEC-601-1, type CF.

8.0 PRECAUTIONS

- SYNCRUS™ Heart Wires are for single use only. DO NOT RESTERILIZE. DO NOT REUSE.

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- The SYNCRUS™ Heart Wires are gamma sterilized after packaging. When they are received, they are sterile and ready for use. Should the seal or package be wet, damaged, punctured, or if the seal is broken, do not use or attempt to resterilize. Contact the local Guidant representative.
- Pre-clinical testing supports the use of this device up to 7 cardioversion attempts. Cardioversion attempts ranged from 1 to 9 attempts in clinical trials. Physicians should treat patients in accordance with judgment and experience. Assessment of the patient's overall condition and physician discretion should dictate the number of attempts to treat.
- It is recommended that defibrillation equipment and a pacing sensor system analyzer (PSA) or temporary pacemaker be readily available during lead placement and removal.

9.0 ATTACHING THE SYNCRUS™ HEART WIRES TO THE MYOCARDIUM

1. Attach the SYNCRUS™ Heart Wires to the patient's myocardial surface during cardiac surgery in the following order and before the patient's chest is closed. The described fixation techniques are furnished for informational purposes only. The physician may choose to vary the fixation technique in accordance with judgment and experience. The selected fixation technique of each Heart Wire placement should always allow for ease of extraction through gentle traction. Proper surgical procedures and techniques are the responsibility of the medical professional.

   Left Atrial Heart Wire (unipolar)

   - *Cardioversion Electrode (yellow wire)*: Use the attached curved needle to affix the cardioversion electrode to the left atrial myocardium. After the cardioversion electrode is affixed (see Figures 2a and 3a), cut off the curved needle and discard it. Place a slight bend or kink at the end of the electrode.

   Right Atrial Heart Wire (tripolar)

   - *Cardioversion Electrode (yellow wire)*: Use the attached curved needle to affix the cardioversion electrode to the right atrial myocardium. After the cardioversion electrode is affixed (see Figures 2b and 3b), cut off the curved needle and discard it. Place a slight bend or kink at the end of the electrode.

     Placement should be made to maximize the atrial muscle mass between the right atrial cardioversion electrode and the left atrial cardioversion electrode.

   - *Pacing Electrodes (black and blue wires):* Use the attached curved needle to affix the bipolar pacing electrodes to the right atrial myocardium. For optimal cardiac pacing, bury both the pacing electrode and bullet in the myocardium. After the

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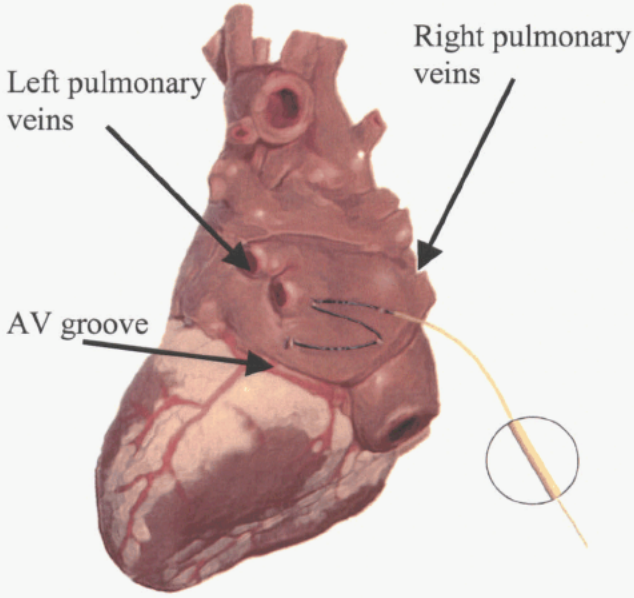
pacing electrodes are affixed (see Figures 2b and 3b), cut off the needle and discard it. Place a slight bend or kink at the end of the pacing electrode.

- Ventricular Heart Wire (bipolar)
  Pacing Electrodes (black and white wires): Use the attached curved needle to affix the bipolar pacing electrodes into the myocardial tissue of either the right or left ventricle. For optimal cardiac pacing, bury both the pacing electrode and bullet in the myocardium. After the pacing electrodes are affixed (see Figures 2c and 3c), cut off the curved needle and discard it. Place a slight bend or kink at the end of the pacing electrode.

Figures 2 through 3 illustrate two examples of Heart Wire placement techniques as used in clinical practice.

Figure 2. SYNCRUS™ Heart Wire Placement Technique A (used in clinical trials in Europe)



2a. Left Atrial Wire Placement
Figure shows the cardioversion electrode placed in an "S" pattern between the atrioventricular (AV) groove and the left and right pulmonary veins.

(Lateral-posterior view)

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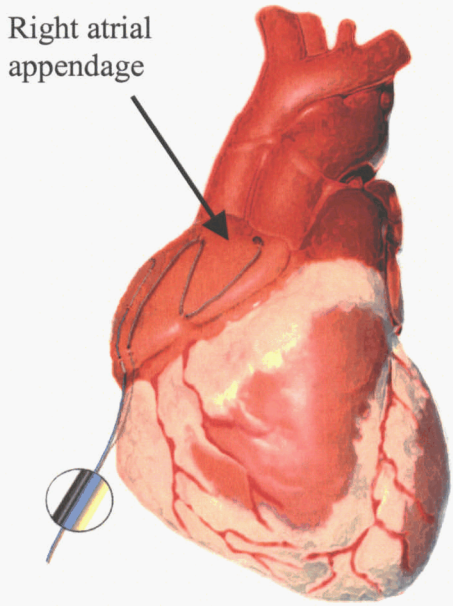
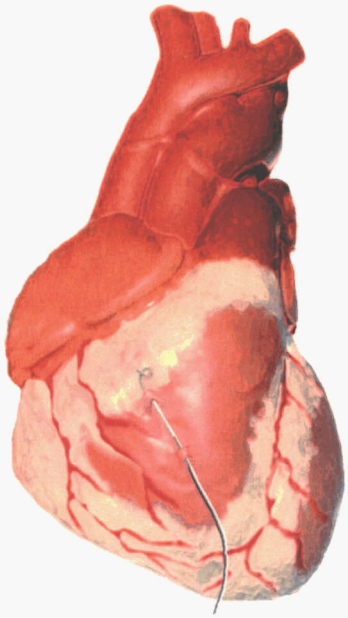


2b. Right Atrial Wire Placement
Figure shows the cardioversion electrode placed in an "S" pattern on the right atrial appendage.

The pacing electrode and bullet are shown placed on the right atrial myocardium.

(Anterior view)



2c. Ventricular Wire Placement
Figure shows the pacing electrode and bullet placed on the right ventricle.

(Anterior view)

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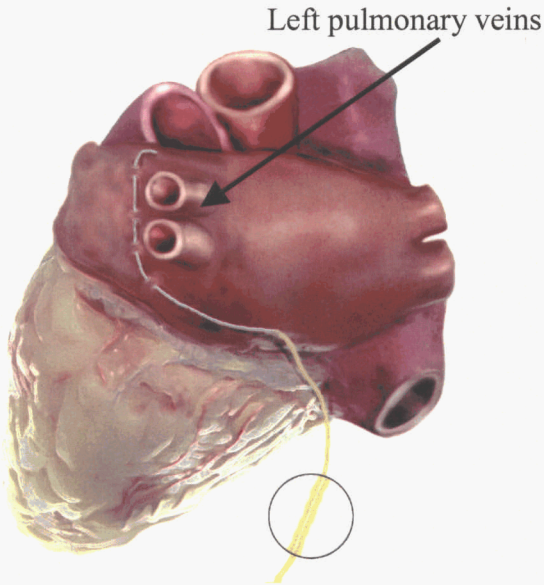
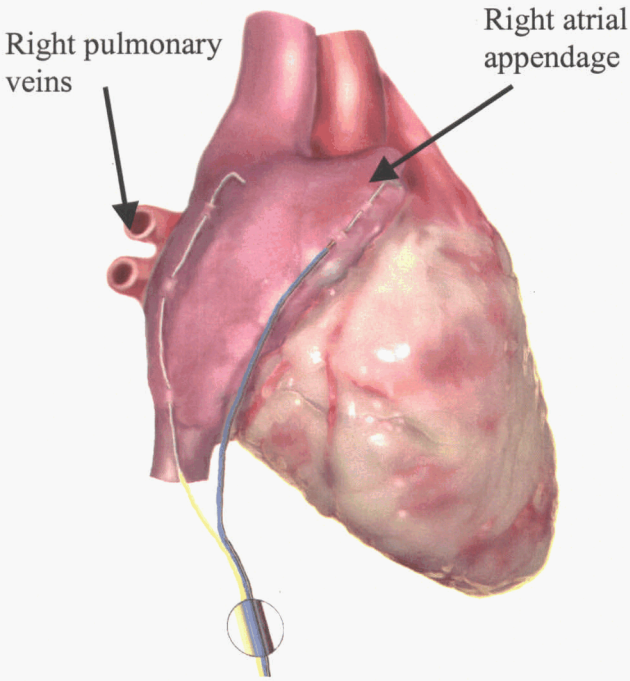
Figure 3. SYNCRUS™ Heart Wire Placement Technique B



3a. Left Atrial Wire Placement
Figure shows the cardioversion electrode placed within 5 mm anterior of the left pulmonary veins.

(Lateral-posterior view)



3b. Right Atrial Wire Placement
Figure shows the cardioversion electrode placed by the inferior vena cava and up towards the right pulmonary veins within 5 mm of the SA node.

The pacing electrode and bullet are shown placed on the right atrial appendage.

(Lateral view)

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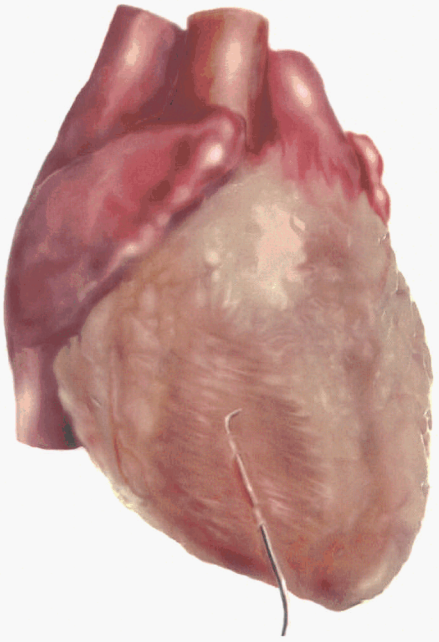

3c. Ventricular Wire Placement
Figure shows the pacing electrode and bullet placed on the right ventricle.

(Anterior view)

2. Once the cardioversion and pacing electrodes have been affixed to the patient's heart, visualize the paths that the Heart Wires will travel as they are extracted.

3. Use the straight thoracic needle on the proximal end of each SYNCRUS™ Heart Wire to externalize the Heart Wires through the chest wall and skin. Once the Heart Wires are externalized, cut off the thoracic needles, maximizing the exposed cardioversion leads. Discard the thoracic needles appropriately.

4. Attach the yellow cardioversion connectors provided with the SYNCRUS™ Heart Wires to the yellow cardioversion wires on the Left and Right Atrial Heart Wires. This is done by threading the Heart Wire cardioversion lead through the pinhole on the backside of the connector and pushing the pin into the connector. Make sure there is good electrical contact between the Heart Wire cardioversion lead and the yellow cardioversion connector.

5. Connect the pacing connector pins for baseline measurements to a pacing system analyzer (PSA) or temporary pacemaker and evaluate the placement by determining R-wave amplitude, pacing threshold, and pacing lead impedance.

6. Cover the pacing connector pins on the Right Atrial Heart Wire (black and blue wires) and Ventricular Heart Wire (black and white wires) with the protective tubings provided with the SYNCRUS™ Heart Wires. Secure the SYNCRUS™ Heart Wires by taping the cardioversion connectors and pacing pins to the patient's body until needed.

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7. When SYNCRUS™ atrial cardioversion therapy is needed, connect the yellow cardioversion connectors to the SYNCRUS™ Cardioversion Extension Cable. Ensure that the Cable is connected to the EDIM. Apply internal atrial cardioversion by placing external defibrillator paddles on the paddle plates of the SYNCRUS™ EDIM and deliver energy. The EDIM will attenuate the external defibrillator output energy by approximately 97% (for example, a 100-joule external shock will result in an approximate 3-joule internal cardioversion shock to the heart).

8. When temporary cardiac pacing and ECG sensing are needed, remove the protective tubing from the pacing connector pins. Connect the pacing connector pins into the appropriate pacing cables. Ensure that the pacing cables are connected to an external pacemaker. Administer cardiac pacing therapy.

9. To remove the SYNCRUS™ Heart Wires, remove any tape holding the Heart Wires in place. Apply gentle and continuous external traction to remove the Heart Wires from the patient. Special care should be taken when removing the lead from the atrium, due to the relatively thin atrial wall.

10. Discard the three externalized Heart Wires appropriately.

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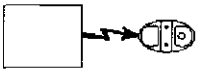
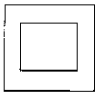
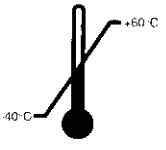
10.0 DEFINITION OF SYMBOLS

Below is a description of the symbols used in this manual and on the Guidant SYNCRUS™ System labels and packaging.

	WARNING: **Shock hazard**. Hazardous voltage may be present. Do not touch the paddle plates when the device is connected to the patient.
	WARNING: Read Instructions for Use.
	WARNING: Do not shock on T-wave. Synchronize shock with patient's R-wave.
	(Green indicator flashes): Energy has been transmitted from the external defibrillator to the SYNCRUS™ EDIM.
	(Red indicator flashes): Overvoltage condition in SYNCRUS™ EDIM. No energy was transmitted to patient. Refer to the Operator's Manual.
	Clean paddle plates before each use with a 70% isopropyl alcohol wipe.
	Type CF equipment.
	Class II equipment.
	Reference information; please read.
	Store at temperature between -40°C and 60°C.

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11.0 MAINTENANCE AND CALIBRATION

The SYNCRUS™ EDIM is a passive electrical device that relies on a user supplied external defibrillator for its power source. There are no user serviceable parts inside. This maintenance procedure is intended for the use of the hospital biomedical engineering department to verify proper function of the device and its safety features. If the device exhibits any discrepancies in any of these periodic checks, discontinue use of the device at once and contact Guidant Cardiac Surgery (Santa Clara, CA) for return instructions. **All maintenance procedures requiring an external defibrillator should be conducted with a compatible external defibrillator (see section 6.0 on *Required User Supplied Components* for compatible defibrillators).**

11.1 Daily Maintenance

It is recommended that the following maintenance procedure be performed on a daily basis to ensure proper function of the SYNCRUS™ EDIM.

CAUTION: Perform all maintenance **BEFORE** connecting the SYNCRUS™ EDIM to the patient.

1. Clean the paddle plates and safety push button (see Figure 4) with a 70% isopropyl alcohol wipe before each use. A buildup of dirt on these conductive surfaces can cause degradation of electrical conduction and can prevent proper energy transmission.

2. Verify that the spring-loaded safety push button on the right side of the device can be depressed completely and that it returns to its extended position when the force is removed.

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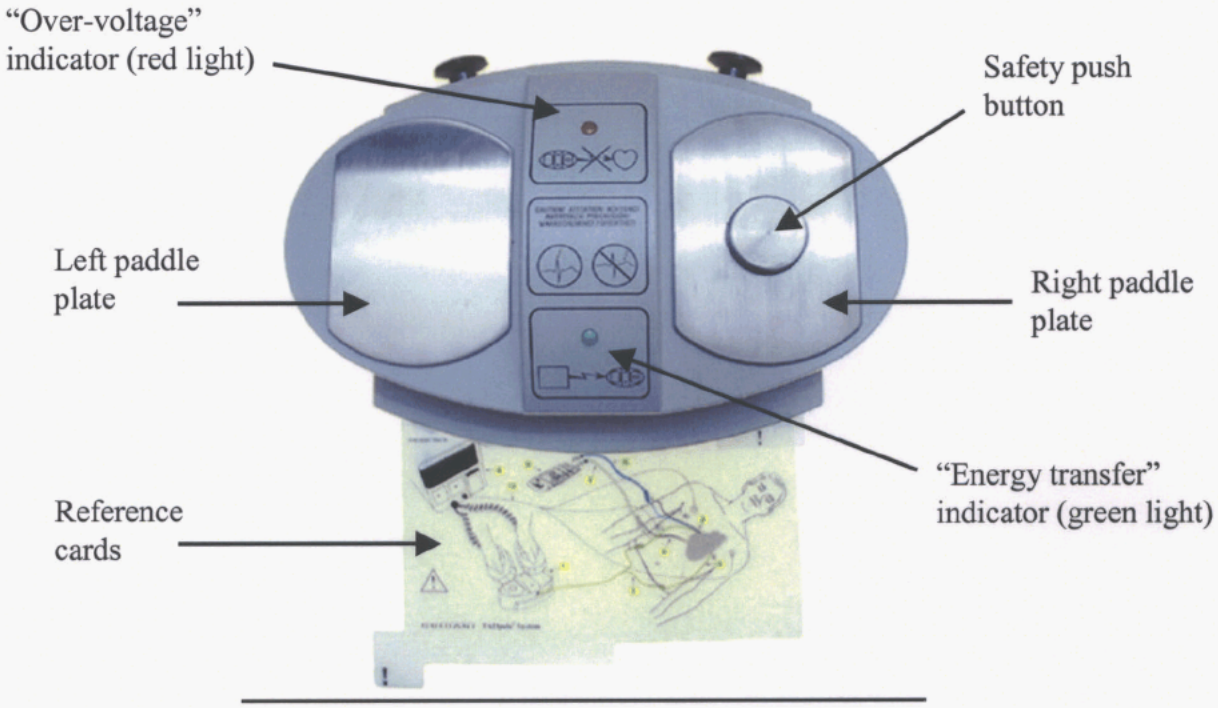
Figure 4. Top view of the SYNCRUS™ External Defibrillator Interface Module (EDIM)



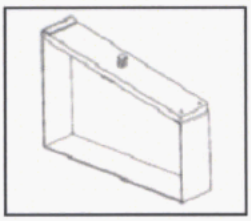
11.2 Full Maintenance

It is recommended that the following maintenance procedure be performed every 3 months to ensure proper function of the SYNCRUS™ EDIM. Also perform a full maintenance test if the EDIM has been dropped onto a hard surface prior to using the EDIM again.

11.2.1 Other Equipment

- External defibrillator (see section 6.0 on *Required User Supplied Components* for compatible defibrillators)
- Ohmmeter
- Electrical safety analyzer or leakage current analyzer
- Defibrillator analyzer

- SYNCRUS™ EDIM maintenance test fixture (Guidant Cardiac Surgery order #TX-5200)



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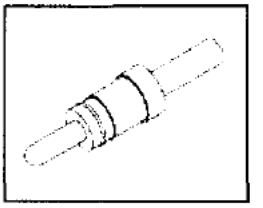
- SYNCRUS™ Cardioversion Cable test adapters – two required (Guidant Cardiac Surgery order #TX-5300). Hypertronics p/n YPN025-002G may also be used.



11.2.2 Full Maintenance Procedure

1. Check safety push button

   Verify that the spring-loaded safety push button on the right side of the SYNCRUS™ EDIM can be depressed completely and that it returns to its extended position when the force is removed.

2. Check safety switch isolation

   Equipment Used:
   - Ohmmeter
   - SYNCRUS™ Cardioversion Cable test adapters (2)

   Test Setup:
   2.1 Connect the SYNCRUS™ Cardioversion Extension Cable to the SYNCRUS™ EDIM.
   2.2 Connect the Cardioversion Cable test adapters to the output connectors on the SYNCRUS™ Cardioversion Extension Cable.
   2.3 Connect an ohmmeter lead to each of the test adapters.

   With the safety push button on the EDIM in its normal "up" position, the ohmmeter should read open (i.e. no continuity). With the safety push button depressed, the ohmmeter should read between 55 – 65 ohms.

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3. Check leakage current

Equipment Used:

- Electrical safety analyzer or leakage current analyzer
- SYNCRUS™ Cardioversion Cable test adapters (2)
- SYNCRUS™ EDIM maintenance test fixture

Note: the leakage current limits specified are for the SYNCRUS™ EDIM only. Any leakage current inherent in the leakage tester must be identified and deducted from the tester readout before applying the leakage current limits.

Patient Leakage Current (Mains on Paddle Plates)

Test Setup:

3.1 Connect the SYNCRUS™ Cardioversion Extension Cable to the SYNCRUS™ EDIM.

3.2 Connect the Cardioversion Cable test adapters to the output connectors on the SYNCRUS™ Cardioversion Extension Cable. Electrically short the two output terminals on the test adapters.

3.3 Connect the shorted test adapters to the ground terminal on the electrical safety or leakage current analyzer.

3.4 Attach the EDIM maintenance test fixture to the SYNCRUS™ EDIM. The test fixture should wrap around the right side of the EDIM and the latching mechanism should be located on the same side as the EDIM output terminals when properly installed for this test (see Figure 5).

3.5 Depress the SYNCRUS™ EDIM safety push button with the movable arm of the test fixture. Latch the movable arm and verify that the EDIM safety push button is fully depressed.

3.6 Make an electrical connection between the EDIM maintenance test fixture (via the lock nut) and an ECG terminal of the analyzer (i.e. RL connection).

3.7 Using the appropriate setting for the analyzer, apply either 120-volts or 240-volts (determined by the voltage powering the analyzer) to the EDIM. Descriptors for the analyzer test mode may include "Lead Isolation to Ground" or "Patient Lead Isolation Test".

The SYNCRUS™ EDIM shall not allow greater than 10μA leakage current when 240-volts are applied by the analyzer (or 5μA leakage current when 120-volts are applied) to the EDIM.

CAUTION: Do not depress the SYNCRUS™ EDIM safety push button with anything that is electrically common with your body. Serious injury may occur.

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Figure 5. The EDIM maintenance test fixture shown properly installed on the right side of the SYNCRUS™ EDIM.

4. Check over-voltage protection

   Equipment Used:
   - External defibrillator

   Discharge a 360 joule shock from the external defibrillator into the SYNCRUS™ EDIM using the external paddles, but with no load connected to the output terminals.

   Note: This test verifies that the over-voltage protectors limit the output voltage from the EDIM to less than 800-volts. A monophasic external defibrillator needs to be

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used for this test in order to achieve a voltage greater than 800-volts at the voltage protectors when there is no load connected to the EDIM output.

The "over-voltage" indicator (red) on the top panel of the EDIM should flash momentarily. The "energy transfer" indicator (green) will also flash momentarily.

If the "energy transfer" indicator (green) does not flash, verify that the external defibrillator is delivering at least 360 joules by connecting a defibrillator analyzer directly to the defibrillator (remove the EDIM from the circuit). If the external defibrillator is delivering at least 360 joules, discontinue use of the EDIM. If the external defibrillator is not delivering at least 360 joules (and is set for 360 joules output), discontinue use of the external defibrillator.

5. Check "energy transfer" indicator

Equipment Used:
- External defibrillator
- Defibrillator analyzer
- SYNCRUS™ Cardioversion Cable test adapters (2)

Test Setup:
5.1 Connect the SYNCRUS™ Cardioversion Extension Cable to the SYNCRUS™ EDIM.
5.2 Connect the Cardioversion Cable test adapters to the output connectors on the SYNCRUS™ Cardioversion Extension Cable.
5.3 Connect the test adapters to the defibrillator analyzer.
5.4 Place the external defibrillator paddles on the SYNCRUS™ EDIM paddle plates. Assure that the right safety push button is fully depressed by the paddle.

Discharge a 100 joule shock from the external defibrillator into the SYNCRUS™ EDIM using the external paddles. The "energy transfer" indicator (green) will flash momentarily, while the "over-voltage" indicator (red) will not flash. Repeat the check with a 360 joule shock. The "energy transfer" indicator (green) will flash momentarily, while the "over-voltage" indicator (red) will not flash.

6. Check attenuation level

Equipment Used:
- External defibrillator
- Defibrillator analyzer
- SYNCRUS™ Cardioversion Cable test adapters (2)

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Test Setup:

6.1 Connect the SYNCRUS™ Cardioversion Extension Cable to the SYNCRUS™ EDIM.

6.2 Connect the Cardioversion Cable test adapters to the output connectors on the SYNCRUS™ Cardioversion Extension Cable.

6.3 Connect the test adapters to the defibrillator analyzer.

6.4 Place the external defibrillator paddles on the SYNCRUS™ EDIM paddle plates. Assure that the right safety push button is fully depressed by the paddle.

Use the defibrillator analyzer to verify the SYNCRUS™ EDIM attenuation level:

External defibrillator setting*	SYNCRUS™ EDIM output*
360 joules	9.4 - 11.5 joules

* If the external defibrillator does not deliver exactly 360 joules, the lower and upper SYNCRUS™ EDIM output energy limits may be calculated by multiplying the external defibrillator input energy by 0.026 and 0.032, respectively.

7. Check shock delivery delay

Equipment Used:

- External defibrillator
- Defibrillator analyzer
- SYNCRUS™ Cardioversion Cable test adapters (2)

Test Setup:

7.1 Connect the SYNCRUS™ Cardioversion Extension Cable to the SYNCRUS™ EDIM.

7.2 Connect the Cardioversion Cable test adapters to the output connectors on the SYNCRUS™ Cardioversion Extension Cable.

7.3 Connect the test adapters to the defibrillator analyzer.

7.4 Connect the defibrillator analyzer's normal sinus ECG output signal (60 bpm) to the synchronization input of the external defibrillator.

7.5 Place the external defibrillator paddles on the SYNCRUS™ EDIM paddle plates. Assure that the right safety push button is fully depressed by the paddle.

Using synchronized cardioversion mode, discharge a 200 joule shock from the external defibrillator into the SYNCRUS™ EDIM using the external paddles.

Use the defibrillator analyzer to measure actual delay time from the peak of the generated R-wave to the leading edge of the defibrillator discharge waveform, measured at the output of the SYNCRUS™ EDIM. The delay time must be less than 60 milliseconds.

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12.0 TROUBLESHOOTING

12.1 Internal Atrial Cardioversion

1. Recheck all electrical connections
2. If the atrial fibrillation episode was not terminated *and* no shock impulse was seen on the ECG monitor *and* the green indicator light on the SYNCRUS™ EDIM did not flash while the shock was delivered *and* the patient did not experience an involuntary thoracic muscle spasm, then it is likely that that the external defibrillator's energy did not reach the patient.
3. If the red indicator light on the SYNCRUS™ EDIM flashed during the cardioversion attempt, the internal voltage protection circuit prevented the shock from reaching the patient. Reduce the energy setting on the external defibrillator and attempt another cardioversion or substitute another external defibrillator and try another cardioversion.
4. Deliver another cardioversion shock, while watching the ECG monitor for a shock.
5. If a cardioversion shock was observed on the monitor and the atrial fibrillation episode does not terminate, even briefly, a Heart Wire electrode may be dislodged. Discontinue SYNCRUS™ atrial cardioversion therapy and revert to traditional therapy.
6. If no cardioversion shock is observed on the monitor and the atrial fibrillation episode is not terminated, the SYNCRUS™ EDIM or Cardioversion Extension Cable may be defective. If a spare unit is available, replace the SYNCRUS™ EDIM. If the same problem persists, replace the Cardioversion Extension Cable. Ask your Biomedical Engineering Department to test the SYNCRUS™ EDIM and Cardioversion Extension Cable per the maintenance procedure in section 11.0, *Maintenance and Calibration*.

12.2 Temporary Cardiac Pacing and ECG Sensing

1. Check the settings of the external pacemaker.
2. Recheck all electrical connections.
3. Check the batteries in the external pacemaker.
4. Check that the proper Heart Wire pacing connector pins are connected to the proper input(s) on the external pacemaker.
5. Check that the polarity of the pacing connector pins is correct and consistent to the external pacemaker. If incorrect, reverse the connectors between the Heart Wires and the patient cable.
6. Try using a different pacing cable.
7. Try connecting to a different (positive) electrode. If this corrects the situation, the problem lies either within the pacing wire or at the pacing electrode's connection to the heart. You can either continue pacing with this configuration, or install an indifferent electrode on the patient's skin.
8. Try connecting to a different stimulation (negative) electrode. If this corrects the situation, the problem lies either within the pacing wire or at the pacing electrode's connection to the heart. This situation cannot be corrected on this patient.

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13.0 WARRANTY AND SERVICE

The SYNCRUS™ External Defibrillator Interface Module (EDIM) is warranted for one (1) year from the date of purchase. If the device fails to perform as intended during the warranty period, return it to Guidant Cardiac Surgery (Santa Clara, CA) for a replacement unit.

The SYNCRUS™ EDIM is not user serviceable. Do not attempt to open the module case. Warranty is void if the tamper resistant seal on the EDIM is broken. Proper device function must be verified by your Biomedical Engineering or Equipment Maintenance Department. Refer to section 11.0 on *Maintenance and Calibration* for maintenance procedures.

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May be manufactured under one or more of the following patents: 5,674,253; 5,766,224; and RE 35,779.

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