U.S. Department of Health & Human Services

Food and Drug Administration

SAVE REQUEST

USER:	(kml)
FOLDER:	K991786 - 1256 pages
COMPANY:	GENERAL ELECTRIC MEDICAL SYSTEMS INFORMATION TECHN (GENEELECMEDISYSB)
PRODUCT:	ELECTROCARDIOGRAPH (DPS)
SUMMARY:	Product: MARS UNITY WORKSTATION WITH HEART RATE VARIABILITY (HRV) OPTION
DATE REQUESTED:	Sep 29, 2016
DATE PRINTED:	Sep 29, 2016
Note:	Printed

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 18 1999

Ms. Laura L. McCornis
Regulatory Affairs Specialist
GE Marquette Medical Systems
8200 W. Tower Avenue
Milwaukee, WI 53223

Re: K991786
MARS Unity Workstation with Heart Rate Variability
Regulatory Class: II (two)
Product Code: DPS
Dated: September 17, 1999
Received: September 20, 1999

Dear Ms. McCornis:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we 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). 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Nancy C. Brogdon for

Celia M. Witten, Ph.D., M.D.
Acting Director
Division of Cardiovascular,
Respiratory, and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Section 11 Indications for Use Statement

510(k) Number (if known): Unknown - 510(k) filed: May 24, 1999

Device Name: MARS Unity Workstation with Heart Rate Variability (HRV) Option

Indications For Use:

The MARS Unity Workstation is intended to acquire, analyze, edit, review, report and store ambulatory and monitoring network ECG and multiparameter data. The MARS Unity Workstation is intended to be used by trained operators under the direct supervision of a licensed health care practitioner in a hospital or clinic environment. Patient population includes both adult and pediatric.

The Heart Rate Variability (HRV) Option is intended to be used for the analysis of the variability in RR intervals (heart rate) and to report measurements of the variability heart rate data.

Heart Rate Variability (HRV) Option is intended to provide only HRV measurements and is not intended to produce any interpretation of those measurements or any kind of diagnosis.

The HRV measurements produced by Heart Rate Variability (HRV) Option are intended to be used by qualified personnel in evaluating the patient in conjunction with patient's clinical history, symptoms, other diagnostic tests, as well as the professional's clinical judgement.

The HRV feature of this device has not been shown to be safe and effective for a specific clinical diagnosis.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter Use____
(Optional Format 1-2-96)

Nancy C Brogdon
(Division Sign-Off)
Division of Cardiovascular, Respiratory, and Neurological Devices
510(k) Number K991786

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

Memorandum

From: Reviewer(s) - Name(s) Donna-Bea Tillman

Subject: 510(k) Number K991786/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 NA
- ☒ The indication for use form (required for originals received 1-1-96 and after)
- Material of Biological Origin ☐ YES ☒ NO NA

The submitter requests under 21 CFR 807.95 (doesn't apply for SEs):

☐ No Confidentiality ☐ Confidentiality for 90 days ☐ Continued Confidentiality exceeding 90 days

Predicate Product Code with class: 74 DPS Class III

Additional Product Code(s) with panel (optional):

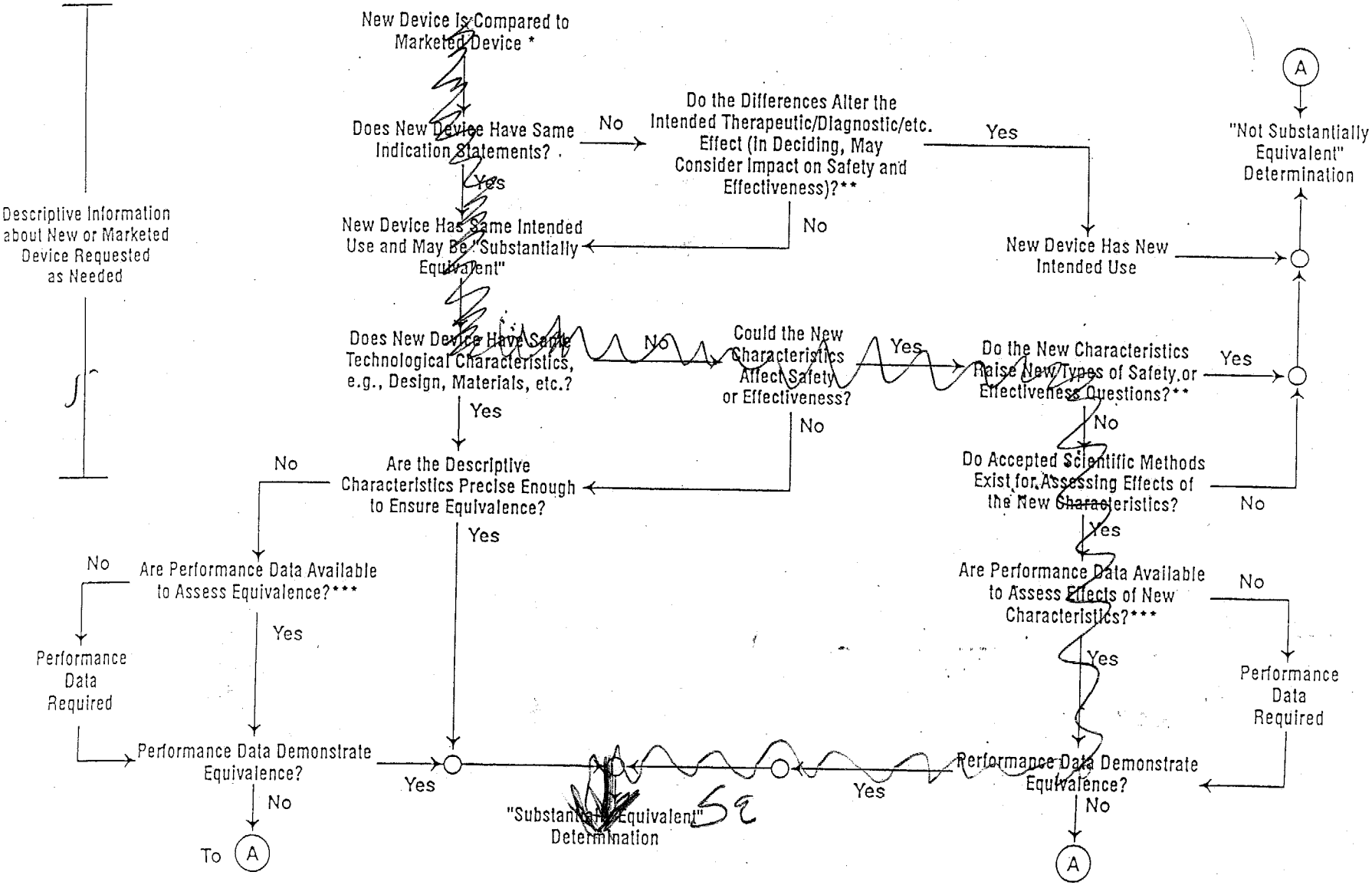
Review: [signature] (Branch Chief) PEDD (Branch Code) 11/12/99 (Date)

Final Review: Nancy C Brogdon for CMW (Division Director) 11-16-99 (Date)

Revised:8/17//99

4

510(k) "Substantial Equivalence" Decision-Making Process (Detailed)



* 510(k) Su s Compare New Devices to Marketed Devices. FDA Requests Additiona ion If the Relationship Between Marketed and "Predicate" (Pre-Amendments or Reclassified Post-Amendments) Devices Is Unclear.

** This Decisi mally Based on Descriptive Information Alone, But Limited Tes rmation Is Sometimes Required.

*** Data May Be in the 510(k), Other 510(k)s, The Center's Classification Files, or the Literature.

K 991786/S1

Reviewer: Donna-Bea Tillman
Biomedical Engineer

Division/Branch: DCRND/PEDG
(HFZ-450)

Trade Name: Mars Unity Workstation (v4.1) with Heart Rate Variability
Common Name: Holter Analysis System
Predicate Device: Spacelabs Heart Rate Variability Option (K950779)

Applicant: GE Marquette
Contact: Laura McComis

Phone: (414) 362-2688
Fax: (414) 355-3790

INTENDED USE:

(see attached Indications for use page)

	YES	NO
Life-supporting or life-sustaining?		✓
Implanted (long-term or short-term)?		✓
Uses software?	✓	
Sterile?		✓
Single use?		✓
Home use?		✓
For prescription?	✓	
Contains drug or biologic?		✓
Kit?		✓

Reason for Submission of 510(k)

- New device
- New indications
- Changes in technology
- Other: ✓

Substantial Equivalence (SE) Decision Making Documentation

		YES	NO	
1.	Is product a device?	✓	–	IF NO, STOP
2.	Device subject to 510(k)?	–	–	IF NO, STOP
3.	Same indication statement?	✓	–	IF YES, GOTO 5
4.	Do differences alter the effect or raise new issues of safety or effectiveness?	–	–	IF YES,STOP->NSE
5.	Same technological characteristics?	–	✓	IF YES, GOTO 7
6.	Could the new characteristics Affect safety or effectiveness?	✓	–	IF YES, GOTO 8
7.	Descriptive characteristics precise enough?	–	–	IF YES, STOP->SE
8.	New types of safety and effectiveness questions?	–	✓	IF YES, STOP->NSE
9.	Accepted scientific methods exist?	✓	–	IF NO,STOP->NSE
10.	Performance data available?	✓	–	IF NO,REQ. DATA
11.	Data demonstrate equivalence	✓	–	**IF YES, STOP->SE**

5. **Describe the new technological characteristics.**
The device includes an algorithm to measure heart rate variability.

*6. **Explain how the new characteristics could or could not effect safety or effectiveness.**
The indications clearly state that this feature is intended to be used as an adjunct to other diagnostic tools.

7. **Explain how descriptive characteristics are not precise enough.**
Test data is needed to validate the performance of the algorithm

*8. **Explain new types of safety or effectiveness questions raised or why the question are not new.**
There are many examples of interpretive ECG algorithms currently on the market –

Fax

To:	Donna-Bea Tillman	**From:**	Laura L McComis
Fax:	1-301-594-3076	**Pages:**	4 including this sheet
Phone:	1-414-362-2688	**Date:**	11/05/99
Re:	MARS w/HRV K991786	**CC:**	

☐ **Urgent** X **For Review** ☐ **Please Comment** ☐ **Please Reply** ☐ **Please Recycle**

Attached is GE Marquette Medical System's response to your questions dated 11/3/99. I will forward a hard copy to DMC is these are acceptable.

Please contact me at 1-414-362-2688 if you need any further clarification.

Laura L McComis

GE Marquette Medical Systems

marquette

GE Marquette Medical Systems
A GE Medical Systems Company
8200 W Tower Ave., Milwaukee, WI 53223

November 5, 1999

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

Subject: K991786
MARS Unity Workstation with Heart Rate Variability (HRV)
Amendment: Additional Information Request

To Whom It May Concern:

Please route the following information to Donna-Bea Tillman, Ph. D. at (301) 443-8517 Ext-177. This information has been requested by the reviewer as additional information required for the review of the referenced 510(k) submitted by GE Marquette Medical Systems.

CONFIDENTIALITY

GE Marquette Medical Systems regards the information and data provided in this Premarket Notification to be confidential and proprietary in nature. This particularly applies to information related to and performance of the GE Marquette MARS Unity Workstation with Heart Rate Variability (HRV) including, but not limited to, the identification of system or circuit architecture, assembly details, performance test results, and technical specifications. Accordingly, this information must be protected from disclosure with the Freedom of Information (FOI) Act, as well as 21 CFR 20.

GE Marquette appreciates the administrative and scientific considerations relevant to this submission, and we look forward to receiving a timely decision by the FDA regarding the information presented. Should you have any questions regarding the contents of this amendment to the Premarket Notification, please contact me by telephone at (414) 362-2688 or by fax at (414) 355-3790.

Sincerely,

GE MARQUETTE MEDICAL SYSTEMS, INC.

Laura L. McComis

Laura L McComis
Regulatory Affairs Specialist.

13

The following is being provided in response to a request for additional information received on November 4, 1999 from Donna-Bea Tillman, Ph. D.

(b)(4)Proprietary Information

[redacted]

****
*** TX REPORT ***
****

TRANSMISSION OK

TX/RX NO	1635
CONNECTION TEL	914143553790
SUBADDRESS	
CONNECTION ID	
ST. TIME	11/03 16:28
USAGE T	00'51
PGS.	2
RESULT	OK

Donna-Bea Tillman
9200 Corporate Blvd, HFZ-450
Rockville, MD 20850 USA
(301) 443-8517 (phone)
(301) 594-3076 (fax)
dbt@cdrh.fda.gov

FDA/CDRH/ODE/DCRD/PEDG

Fax

To:	Laura McComis	**From:**	Donna-Bea Tillman
Fax:	414 355-3790	**Pages:**	2
Phone:		**Date:**	11/03/99
Re:	K991786	**CC:**	

☐ **Urgent** ☐ **For Review** ☐ **Please Comment** x **Please Reply** ☐ **Please Recycle**

• **Comments:**

Please call me at (301) 443-8517 if you need any clarification. You can fax the response to me at (301) 594-3076, but please send a hard copy to the DMC as well.

16

Additional questions

1. The databases that you have used to validate your HRV algorithm can be used to assess your device's ability to detect QRS complexes and ectopic beats. Please discuss how you have validated your process for dealing with missing or noisy beats. The User's Guide notes that when an interval is excluded (due to a missed beat or noisy beat), a cubic spline process is used to interpolate between the surrounding intervals (original submission, p.183). Please explain how this algorithm was validated.

2. You have noted that the expected results for the error "*Section 3.4: BB50 exceeds max difference allowed*" were wrong – they did not take into account the fact that the algorithm can only process data that is acquired in increments of whole minutes. When the test was re-run taking this into account, the results were as expected. Please explain how the device handles data that is not acquired in whole minutes.

3. Your description of the decision process that is used to classify SPRs appears to be appropriate. However, there is one SPR that was classified as "catastrophic" (page 741, MMSmk16656). Please provide further information.

Please call me at (301) 443-8517 if you need any clarification. You can fax the respone to me at (301) 594-3076, but please send a hard copy to the DMC as well.

Donna-Bea Tillman

K991786/S

marquette

GE Marquette Medical Systems
A GE Medical Systems Company
8200 W. Tower Ave., Milwaukee, WI 53223

September 17, 1999

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

SK-42

Subject: K991786
MARS Unity Workstation with Heart Rate Variability (HRV)
Amendment: Additional Information Request

To Whom It May Concern:

Please route the following information to Donna-Bea Tillman, Ph. D. at (301) 443-8517 Ext-177. This information has been requested by the reviewer as additional information required for the review of the referenced 510(k) submitted by GE Marquette Medical Systems.

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Sincerely,

GE MARQUETTE MEDICAL SYSTEMS, INC.

Laura L McComis
Regulatory Affairs Specialist

19

Safety Information

Definitions

⚠ DANGER — Indicates an imminently hazardous situation which, if not avoided, WILL result in death or serious injury.

⚠ WARNING — Indicates a potentially hazardous situation which, if not avoided, COULD result in death or serious injury.

⚠ CAUTION — Indicates a potentially hazardous situation which, if not avoided may result in minor or moderate injury.

Messages

Additional safety messages may be found throughout this manual that provide appropriate safe operation information.

⚠ DANGER

Do NOT use in the presence of flammable anesthetics.

M15287-1B

⚠ WARNING

This is Class I equipment. The mains plug must be connected to an appropriate power supply.

M15287-5C

⚠ CAUTION

To reduce the risk of electric shock, do NOT remove cover (or back). Refer servicing to qualified personnel.

M15287-16A

⚠ CAUTION

Federal law restricts this device to sale by or on the order of a physician.

M15287-17A

000067

Safety Information

Intended Use

The MARS Unity Workstation is intended to acquire, analyze, edit, review, report and store ambulatory and monitoring network ECG and multiparameter data. The MARS Unity Workstation is intended to be used by trained operators under the direct supervision of a licensed healthcare practitioner in a hospital or clinic environment. Patient population includes both adult and pediatric.

Heart Rate Variability Option

The Heart Rate Variability (HRV) Option is intended to be used for the analysis of the variability in RR intervals (heart rate) and to report measurements of the variability heart rate data.

Heart Rate Variability (HRV) Option is intended to provide only HRV measurements and is not intended to produce any interpretation of those measurements or any kind of diagnosis.

The HRV measurements produced by Heart Rate Variability (HRV) Option are intended to be used by qualified personnel in evaluating the patient in conjunction with patient's clinical history, symptoms, other diagnostic tests, as well as the professional's clinical judgement.

The Heart Rate Variability (HRV) option is a purchasable option that requires the user to use a software activator before its use.

The HRV feature of this device has not been shown to be safe and effective for a specific clinical diagnosis.

Definitions

⚠ DANGER	Indicates an imminently hazardous situation which, if not avoided, WILL result in death or serious injury.
⚠ WARNING	Indicates a potentially hazardous situation which, if not avoided, COULD result in death or serious injury.
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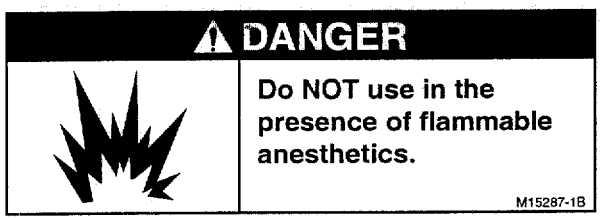

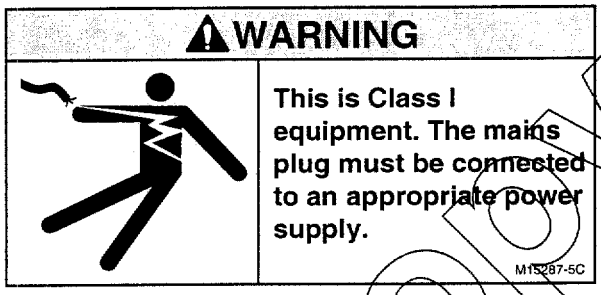

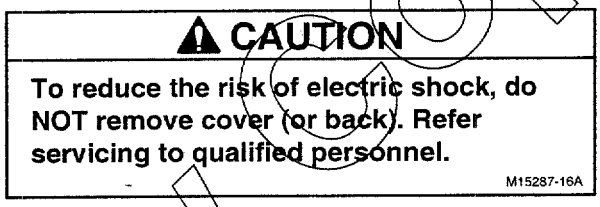

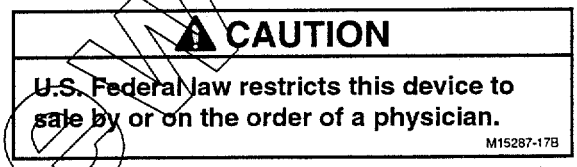

Responsibility of the Manufacturer

GE Marquette Medical Systems, Inc. is responsible for the effects of safety, reliability, and performance only if:

- Assembly operations, extensions, readjustments, modifications, or repairs are carried out by persons authorized by GE Marquette.
- The electrical installation of the relevant room complies with the requirements of the appropriate regulations.
- The equipment is used in accordance with the instructions for use.

General

This device is intended for use under the direct supervision of a licensed health care practitioner.

To ensure patient safety, use only parts and accessories manufactured or recommended by GE Marquette Medical Systems.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 2 3 1999

Ms. Laura L. McComis
Regulatory Affairs Specialist
GE Marquette Medical Systems
8200 W. Tower Avenue
Milwaukee, WI 53223

Re: K991786
MARS Unity Workstation with Heart Rate Variability (HRV)
Dated: May 25, 1999
Received: May 28, 1999

Dear Ms. McComis:

We have reviewed your Section 510(k) notification of intent to market the device referenced above. We cannot determine if the device is substantially equivalent to a legally marketed predicate device based solely on the information you provided. To complete the review of your submission, we require the following additional information:

(b)(4)Proprietary Information

27

(b)(4)Proprietary Information

We believe that this information is necessary for us to determine whether or not this device is substantially equivalent to a legally marketed predicate device with regard to its safety and effectiveness.

You may not market this device until you have provided adequate information described above and required by 21 CFR 807.87(l), and you have received a letter from FDA allowing you to do so. If you market the device without conforming to these requirements, you will be in violation of the Federal Food, Drug, and Cosmetic Act (Act). You may, however, distribute this device for investigational purposes to obtain clinical data if needed to establish substantial equivalence. Clinical investigations of this device must be conducted in accordance with the investigational device exemption (IDE) regulations.

If the information, or a request for an extension of time, is not received within 30 days, we will consider your premarket notification to be withdrawn and your submission will be deleted from our system. If you submit the requested information after 30 days it will be considered and processed as a new 510(k); therefore, all information previously submitted must be resubmitted so that your new 510(k) is complete.

The requested information, or a request for an extension of time, should reference your above 510(k) number and should be submitted in duplicate to:

Food and Drug Administration
Center for Devices and
Radiological Health
Document Mail Center (HFZ-401)
9200 Corporate Boulevard
Rockville, Maryland 20850

If you have any questions concerning the contents of this letter, please contact Donna-Bea Tillman, Ph.D., at (301) 443-8517 Ext-177. If you need information or assistance concerning the IDE regulations, please contact the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597, or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Thomas J. Callahan, Ph.D.
Director
Division of Cardiovascular,
Respiratory and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

DEPARTMENT OF HEALTH & HUMAN SERVICES

cc: HFZ-401 (DMC)
HFZ-404 510(k) Staff
HFZ-450 (DCNRD)
D.O.

Prepared by:DTillman:mlm:8/19/99

FILE COPY

OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE
Z-450		8/19						
+50		8/23						

U.S. GPO 1986-169-089

AUG 2 3 1999

Ms. Laura L. McComis
Regulatory Affairs Specialist
GE Marquette Medical Systems
8200 W. Tower Avenue
Milwaukee, WI 53223

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Dated: May 25, 1999
Received: May 28, 1999

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(b)(4)Proprietary Information

31

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9200 Corporate Boulevard
Rockville, Maryland 20850

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Sincerely yours,

Thomas J. Callahan, Ph.D.
Director
Division of Cardiovascular,
Respiratory and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food And Drug Administration

Memorandum

om: Reviewer(s) - Name(s) Donna-Bea Tillman

Subject: 510(k) Number K991786

To: The Record - It is my recommendation that the subject 510(k) Notification:

☐ Refused to accept.

☒ Requires additional information (other than refuse to accept).

☐ Accepted for review_____.

☐ 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	☐ 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)

Material of Biological Origin ☐ 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 days

Predicate Product Code with class: Additional Product Code(s) with panel (optional):

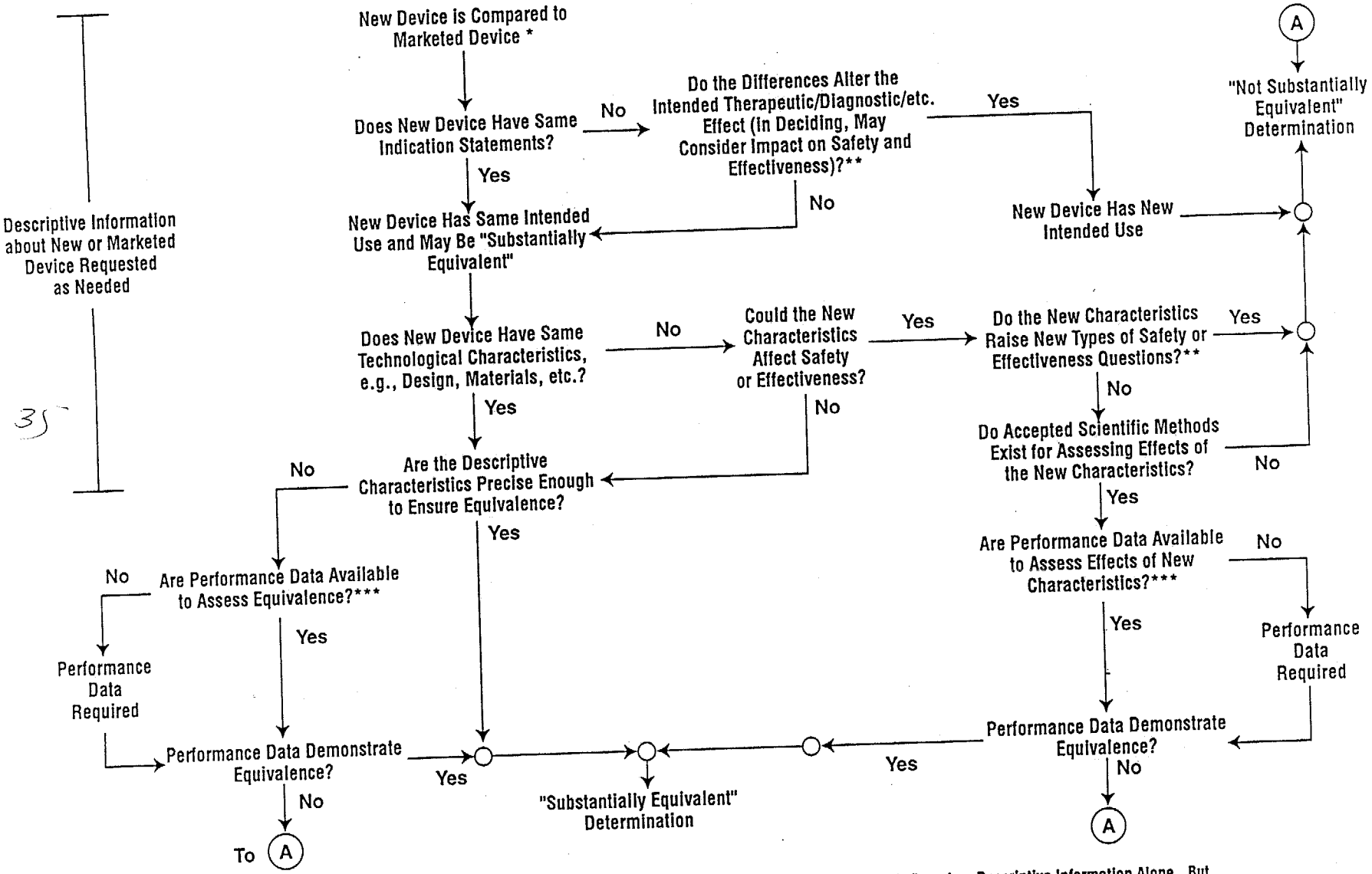
Review: _____ (Branch Chief) PCDo (Branch Code) 8/19/99 (Date)

Final Review: _____ (Division Director) 8/20 (Date)

34

Revised:6/2//98

510(k) "Substantial Equivalence" Decision-Making Process (Detailed)



* 510(k) Submissions Compare New Devices to Marketed Devices. FDA Requests Additional Information if the Relationship Between Marketed and "Predicate" (Previously Amendments or Reclassified Post-Amendments) Devices is Unclear.

** This Decision is Normally Based on Descriptive Information Alone, But Limiting Information is Sometimes Required.

*** Data in the 510(k), Other 510(k)s, The Center's Classification Files, or the Literature.

K 991786

Reviewer: Donna-Bea Tillman
Biomedical Engineer

Division/Branch: DCRND/PEDG
(HFZ-450)

Trade Name: Mars Unity Workstation (v4.1) with Heart Rate Variability
Common Name: Holter Analysis System
Predicate Device: Spacelabs Heart Rate Variability Option (K950779)

Applicant: GE Marquette
Contact: Laura McComis

Phone: (414) 362-2688
Fax: (414) 355-3790

INTENDED USE:

(see attached Indications for use page)

	YES	NO
Life-supporting or life-sustaining?		✓
Implanted (long-term or short-term)?		✓
Uses software?	✓	
Sterile?		✓
Single use?		✓
Home use?		✓
For prescription?	✓	
Contains drug or biologic?		✓
Kit?		✓

Reason for Submission of 510(k)

- New device
- New indications
- Changes in technology
- Other: ✓

Section 11 Indications for Use Statement

510(k) Number (if known): Unknown - 510(k) filed: May 24, 1999

Device Name: MARS Unity Workstation with Heart Rate Variability (HRV) Option

Indications For Use:

The MARS Unity Workstation is intended to acquire, analyze, edit, review, report and store ambulatory and monitoring network ECG and multiparameter data. The MARS Unity Workstation is intended to be used by trained operators under the direct supervision of a licensed health care practitioner in a hospital or clinic environment. Patient population includes both adult and pediatric.

The Heart Rate Variability (HRV) Option is intended to be used for the analysis of the variability in RR intervals (heart rate) and to report measurements of the variability heart rate data.

Heart Rate Variability (HRV) Option is intended to provide only HRV measurements and is not intended to produce any interpretation of those measurements or any kind of diagnosis.

The HRV measurements produced by Heart Rate Variability (HRV) Option are intended to be used by qualified personnel in evaluating the patient in conjunction with patient's clinical history, symptoms, other diagnostic tests, as well as the professional's clinical judgement.

The HRV feature of this device has not been shown to be safe and effective for a specific clinical diagnosis.

(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)

Screening Checklist
For all Premarket Notification 510(k) Submissions

Device Name:	K
Submitter (Company):	

Items which should be included *(circle missing & needed information)*	SPECIAL YES	SPECIAL NO	ABBREVIATED YES	ABBREVIATED NO	TRADITIONAL YES	TRADITIONAL NO	✓ IF ITEM IS NEEDED AND IS MISSING
1. Cover Letter clearly identifies Submission as: a) "Special 510(k): Device Modification" b) "Abbreviated 510(k)" c) Traditional 510(k)	GO TO # 2,3		GO TO # 2,4,5		GO TO #2 4,5		

2. GENERAL INFORMATION: REQUIRED IN ALL 510(K) SUBMISSIONS	NA SPECIALS YES	NA SPECIALS NO	YES ABBREVIATED YES	YES ABBREVIATED NO	NO TRADITIONAL YES	NO TRADITIONAL NO	✓ IF ITEM IS NEEDED AND IS MISSING
Financial Certification or Disclosure Statement for 510(k)s with a Clinical Study 807.87(i)							
a) trade name, classification name, establishment registration number, device class					✓		
b) OR a statement that the device is not yet classified	FDA-may be a classification request; see coordinator						
c) identification of legally marketed equivalent device	NA				✓		
d) compliance with Section 514 - performance standards	NA				✓		
e) address of manufacturer					✓		
f) Truthful and Accurate Statement					✓		
g) Indications for Use enclosure					✓		
h) SMDA Summary or Statement *(FOR ALL DEVICE CLASSES)*					✓		
i) Class III Certification & Summary *(FOR ALL CLASS III DEVICES)*					N/A		
j) Description of device (or modification) including diagrams, engineering drawings, photographs, service manuals					✓		
k) Proposed Labeling:					✓		
i) package labeling (user info)					✓		
ii) statement of intended use					✓		
iii) advertisements or promotional materials					✓		
i) MRI compatibility (if claimed)					✓		
l) Comparison Information (similarities and differences) to named legally marketed equivalent device (table preferred) should include:					✓		
i) Labeling					✓		
ii) intended use					✓		
iii) physical characteristics					✓		
iv) anatomical sites of use					✓		
v) performance (bench, animal, clinical) testing	NA				✓		
vi) safety characteristics	NA				✓		
m) If kit, kit certification					✓		

3. "SPECIALS" - ONLY FOR MODIFICATIONS TO MANUFACTURER'S OWN CLASS II , III OR RESERVED CLASS I DEVICE				
a) Name & 510(k) number of legally marketed (unmodified) predicate device				
b) *STATEMENT - INTENDED USE AND INDICATIONS FOR*			* If no - STOP not a special	46

	USE OF MODIFIED DEVICE AS DESCRIBED IN ITS LABELING HAVE NOT CHANGED*			
c)	***STATEMENT - FUNDAMENTAL SCIENTIFIC TECHNOLOGY OF THE MODIFIED DEVICE HAS NOT CHANGED****		* If no - STOP not a special	
d)	Design Control Activities Summary			
	i) 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			
	ii) 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			
	iii) A declaration of conformity with design controls. The declaration of conformity should include:			
	1) 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			
	2) A statement signed by the individual responsible, that manufacturing facility is in conformance with design control procedure Requirements as specified in 21 CFR 820.30 and the records are available for review.			

	SPECIALS		ABBREVIATED		TRADITIONAL		✓ IF ITEM IS NEEDED AND IS MISSING
	YES	NO	YES	NO	YES	NO	
4.	**ABBREVIATED 510(K): SPECIAL CONTROLS/CONFORMANCE TO RECOGNIZED STANDARDS - PLEASE FILL OUT THE STANDARDS ABBREVIATED FORM ON THE H DRIVE**						
a)	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						
b)	If a manufacturer elects to use an alternate approach to address a particular risk, sufficient detail should be provided to justify that approach.						
c)	For a submission, which relies on a recognized standard, a declaration of conformity to the standard. The declaration should include the following:						
	i) An identification of the applicable recognized consensus standards that were met						
	ii) A specification, for each consensus standard, that all requirements were met, except for						

inapplicable requirements or deviations noted below						
iii) An identification, for each consensus standard, of any way(s) in which the standard may have been adapted for application to the device under review, e.g., an identification of an alternative series of tests that were performed						
iv) An identification, for each consensus standard, of any requirements that were not applicable to the device						
v) A specification of any deviations from each applicable standard that were applied						
vi) A specification of the differences that may exist, if any, between the tested device and the device to be marketed and a justification of the test results in these areas of difference						
vii) Name/address of test laboratory/certification body involved in determining the conformance of the device with applicable consensus standards and a reference to any accreditations for those organizations						
d) Data/information to address issues not covered by guidance documents, special controls, and/or recognized standards						

5. Additional Considerations: (may be covered by Design Controls)							
a) Biocompatibility data for all patient-contacting materials, OR certification of identical material/formulation:					✓		
i) component & material					✓		
ii) identify patient-contacting materials							
iii) biocompatibility of final sterilized product					✓		
b) Sterilization and expiration dating information:					✓		
i) sterilization method					✓		
ii) SAL					✓		
iii) packaging					✓		
iv) specify pyrogen free					✓		
v) ETO residues					✓		
vi) radiation dose					✓		
c) Software validation & verification:					✓		
i) hazard analysis					✓		
ii) level of concern					✓		
iii) development documentation					✓		
iv) certification					✓		

Items shaded under "NO" are necessary for that type of submission. Circled items and items with checks in the "Needed & Missing" column must be submitted before acceptance of the document.

Passed Screening ✓ **Yes** ____ **No** **Reviewer:** Wallace E. Upton Jr

Date: ____ **Concurrence by Review Branch:** ____

48

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.

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 for home use 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

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.		

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

May 25, 1999

GE MARQUETTE MEDICAL SYSTEMS, INC.
8200 WEST TOWER AVE.
MILWAUKEE, WI 53223
ATTN: LAURA L. MCCOMIS

510(k) Number: K991786
Received: 25-MAY-1999
Product: MARS UNITY WORKSTATION WITH HEART RATE VARIABILITY (HRV)

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.

On January 1, 1996, FDA began requiring that all 510(k) submitters provide on a separate page and clearly marked "Indication For Use" the indication for use of their device. If you have not included this information on a separate page in your submission, please complete the attached and amend your 510(k) as soon as possible. Also if you have not included your 510(k) Summary or 510(k) Statement, or your Truthful and Accurate Statement, please do so as soon as possible. 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 Assistance (DSMA) 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 (HFZ-401) at the above letterhead address. Correspondence sent to any address other than the Document Mail Center will not be considered as part of your official premarket notification submission. Because of equipment and personnel limitations, we cannot accept telefaxed material as part of your official premarket notification submission, unless specifically requested of you by an FDA official. Any telefaxed material must be followed by a hard copy to the Document Mail Center (HFZ-401).

You should be familiar with the manual entitled, "Premarket Notification 510(k) Regulatory Requirements for Medical Devices" available from DSMA. 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 DSMA 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

SV

K991786

marquette

GE Marquette Medical Systems
A GE Medical Systems Company
8200 W Tower Ave., Milwaukee, WI 53223

May 24, 1999

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

Subject: 510(k) Premarket Notification Submission
MARS Unity Workstation with HRV (Heart Rate Variability) Option

To Whom It May Concern:

In accordance with section 510(k) of the Federal Food, Drug and Cosmetic Act, and in conformance with 21CFR 807, this pre-market notification is being submitted at least 90 days prior to the date upon which GE Marquette Medical Systems, Inc. proposes to introduce into interstate commerce for commercial distribution a modified device, MARS Unity Workstation with HRV (Heart Rate Variability) Option.

GE Marquette Medical Systems is a recent name change for our company, formerly Marquette Medical Systems. Either name is currently acceptable, as paperwork and documentation may still be in transition.

This submission is being filed as a modification to an existing device. It is being filed in support of the position that the proposed modified device, the MARS Unity Workstation with HRV (Heart Rate Variability) Option, is substantially equivalent to devices already in legal commercial distribution: CENTRA II Analysis System K922171 and Spacelabs Heart Rate Variability Software Option K950779. Changes were made to take advantage of technology changes and to improve system performance and functionality.

A table of the submitted information according to the agency's "DCRND Screening Checklist for Pre-market Notification 510(k)" is provided in Section 1.

The pre-market notification is submitted in duplicate (including this cover letter).

CONFIDENTIALITY

GE Marquette Medical Systems regards the information and data provided in this Premarket Notification to be confidential and proprietary in nature. This particularly applies to information related to and performance of the GE Marquette MARS Unity Workstation with HRV including, but not limited to, the identification of system or circuit architecture, assembly details, performance test results, and technical specifications. Accordingly, this information must be protected from disclosure with the Freedom of Information (FOI) Act, as well as 21 CFR 20.

GE Marquette Medical Systems appreciates the administrative and scientific considerations relevant to this submission, and we look forward to receiving a timely decision by the FDA regarding the information presented. Should you have any questions regarding the contents of this submission, please contact me by telephone at (414) 362-2688 or by fax at (414) 355-3790.

Sincerely,

GE MARQUETTE MEDICAL SYSTEMS

Laura L. McComis

Laura L McComis

Regulatory Affairs Specialist

5k21

CV
53 II

marquette

A GE Medical Systems Company

PREMARKET NOTIFICATION 510(K)

MARS Unity Workstation w/HRV Option

Volume I of III

Submitted: May 24, 1999

GE Marquette Medical Systems, Inc.
8200 West Tower Avenue
Milwaukee, Wisconsin 53223 USA
(414) 355-5000

Table of Contents

APPENDICES

Section 1 General Information

1.1 Submitter/Manufacturing Information:

GE Marquette Medical Systems
8200 W. Tower Ave.
Milwaukee, WI 53223 USA

1.2 Establishment Registration Number:

2124823

1.3 Contact Person:

Primary:

Laura L McComis
Corporate Regulatory Affairs
GE Marquette Medical Systems
Phone: (414) 362-2688
Fax: (414) 355-3790

Secondary:

Kristin Pabst
Regulatory Affairs Manager
GE Marquette Medical Systems
Phone: (414) 362-2793

Gerry Buss
Director, Regulatory Affairs
GE Marquette Medical Systems
Phone: (414) 362-2520

1.4 Manufacturing Site:

GE Marquette Medical Systems
8200 W. Tower Ave.
Milwaukee, WI 53223 USA

1.5 Device:

Subject of this premarket notification is a modified device.

Proprietary Name: MARS Unity Workstation with Heart Rate Variability (HRV) Option

Common/Usual Name: Holter Analysis System

1.6 Classification Names/Numbers:

21 CFR 870.1425 Programmable diagnostic computer — Class II — 74DQK

1.7 Device Classification:

Class II

1.8 Predicate Devices:

K922171 CENTRA II Analysis System
K950779 Spacelabs Heart Rate Variability Software Option

1.9 Performance Standards:

Performance standards (Section 514 of the Act) have not yet been established for the device that is the subject of this premarket notification submission.

1.10 Modified Device:

The CENTRA II Analysis System has been available since 1992. Since then the device name has been changed to MARS Unity Workstation. Through time, software and hardware technology updates have been incorporated to leverage available data source access and processing capabilities. Clinical review software module and Heart Rate Variability option module have been added to enhance the functionality of the system.

An overview of significant software and hardware modifications is provided in Appendix **S**.
A comparison between the proposed device and the predicate devices is provided in 5.1 Product Comparison Matrix.

1.11 Screening Checklist for Premarket Notification 510(k)

Reference DCRND DRAFT Guidance for Format and Content for Premarket Notification 510(k) - July 19, 1995

Device: MARS Unity Workstation with HRV Option			510(k)
Submitter: GE Marquette Medical Systems			
Items which should be addressed	✔		Refer to submission section:
	Yes	No	
1) General information: a) trade name, b) common name, c) establishment registration #, d) address of manufacturer, e) device class, f) new device or modification, g) predicate device identified, h) 513 / 514 compliance (none yet available)	✔		Section 1 General Information Page 5
2) a) SMDA requirements: 510(k) summary or statement (any class device) b) Class III Certification & Summary (if Class III)	✔		Section 2 Summary and Certification Page 9
3) Proposed Labeling: a)package labels, b) statement of intended use, c) advertisements or promotional materials, d) MRI compatibility (if claimed)	✔		Section 3 Proposed Labeling Page 11
4) Description of device (or modification) including diagrams, engineering drawings, photographs, service manuals	✔		Section 4 Device Description Page 13
5) Comparison Information (similarities and differences) to named legally marketed equivalent device (table preferred) should include: a)labeling, b) intended use, c) physical characteristics, d) anatomical sites, e)performance (bench, animal, clinical) testing, f) safety characteristics	✔		Section 5 Comparative Information Page 23
6) Biocompatibility data for all patient contacting materials, OR, certification of identical material / formulation: a) component & material, b) identify patient contacting materials, c) biocompatibility of final sterilized product	✔		Section 6 Biocompatibility Assessment Page 35
7) Sterilization and expiration dating information: a)sterilization method, b)SAL, c)packaging, d) specify if pyrogen free, e) ETO residues, f) radiation dose	✔		Section 7 Sterilization Information Page 36

8) Software validation & verification: a)hazard analysis, b)level of concern, c)development documentation, d) certification	✔		Section 8 Software Validation & Verification (includes hardware information) Page 37
9) Meets current (FDA) guidelines and applicable standards for this device: a)specify guidance and/or standards, b)comply with content	✔		Section 9 Specific Standards and Guidances Page 44
10) Premarket Notification Truthful and Accurate Statement	✔		Section 10 Premarket Notification Truthful and Accurate Statement Page 47
11) "Indications For Use" page	✔		Section 11 Indications for Use Statement Page 48

Passed 510(k) Screen:
Date:

Failed 510(k) Screen:
Date:

Section 2 Summary and Certification

2.1 510(k) Summary of Safety and Effectiveness

Date:	May 24, 1999
Submitter:	GE Marquette Medical Systems 8200 West Tower Avenue Milwaukee, WI 53223 USA
Contact Person:	Laura L McComis Corporate Regulatory Affairs GE Marquette Medical Systems Phone: (414) 362-2688 Fax: (414) 355-3790
Device: Trade Name:	MARS Unity Workstation with Heart Rate Variability (HRV) Option
Common/Usual Name:	Holter Analysis System
Classification Names:	Classification Name: Computer, Diagnostic, Programmable Classification Number: 74DQK
Predicate Devices:	K922171 CENTRA II Analysis System K950779 Spacelabs Heart Rate Variability Software Option
Device Description:	The Multi-Parameter Analysis and Review System (MARS) unity workstation (b)(4)Proprietary Information (b)(4)Proprietary Information number of software applications including Holter analysis and editing system software and full disclosure clinical review software. 1) The Holter analysis software performs acquisition, analysis, editing, review, reporting and storage of ambulatory ECG and multiparameter data acquired from solid-state electronic ECG recorders, tape recorders and the monitoring real-time network. 2) The clinical review software (CRS) is a full disclosure system that acquires ECG and mixed parameter waveform data from Marquette's Unity monitoring network for display and reporting. (b)(4)Proprietary Information [redacted]

Intended Use:	The MARS Unity Workstation is intended to acquire, analyze, edit, review, report and store ambulatory and monitoring network ECG and multiparameter data. The MARS Unity Workstation is intended to be used by trained operators under the direct supervision of a licensed health care practitioner in a hospital or clinic environment. Patient population includes both adult and pediatric. The Heart Rate Variability (HRV) Option is intended to be used for the analysis of the variability in RR intervals (heart rate) and to report measurements of the variability heart rate data. Heart Rate Variability (HRV) Option is intended to provide only HRV measurements and is not intended to produce any interpretation of those measurements or any kind of diagnosis. The HRV measurements produced by Heart Rate Variability (HRV) Option are intended to be used by qualified personnel in evaluating the patient in conjunction with patient's clinical history, symptoms, other diagnostic tests, as well as the professional's clinical judgement. The HRV feature of this device has not been shown to be safe and effective for a specific clinical diagnosis.
Technology:	MARS Unity Workstation with Heart Rate Variability (HRV) Option employs the same technology as the predicate devices.
Test Summary:	The MARS Unity Workstation with Heart Rate Variability (HRV) Option complies with voluntary standards as detailed in *Section 9 Specific Standards and Guidances* of this submission. The following quality assurance measures were applied to the development of MARS Unity Workstation with Heart Rate Variability (HRV) Option: • Risk analysis • Requirements specification reviews • Code inspections • Software and Hardware Testing • Safety testing • Environmental testing • Final validation
Conclusion:	The results of these measures demonstrate MARS Unity Workstation with Heart Rate Variability (HRV) Option is as safe, as effective, and performs as well as the predicate devices, CENTRA II Analysis System and Spacelabs Heart Rate Variability Software Option.

Section 3 Proposed Labeling

3.1 Intended Use

The MARS Unity Workstation is intended to acquire, analyze, edit, review, report and store ambulatory and monitoring network ECG and multiparameter data. The MARS Unity Workstation is intended to be used by trained operators under the direct supervision of a licensed health care practitioner in a hospital or clinic environment. Patient population includes both adult and pediatric.

The Heart Rate Variability (HRV) Option is intended to be used for the analysis of the variability in RR intervals (heart rate) and to report measurements of the variability heart rate data.

Heart Rate Variability (HRV) Option is intended to provide only HRV measurements and is not intended to produce any interpretation of those measurements or any kind of diagnosis.

The HRV measurements produced by Heart Rate Variability (HRV) Option are intended to be used by qualified personnel in evaluating the patient in conjunction with patient's clinical history, symptoms, other diagnostic tests, as well as the professional's clinical judgement.
The HRV feature of this device has not been shown to be safe and effective for a specific clinical diagnosis.

3.2 Proposed Operating Instructions (includes Prescription Device Statement)

The MARS Unity Workstation Operator Manual is provided in Appendix **A**.

The MARS Unity Workstation Heart Rate Variability Physician's Guide is provided in Appendix **B**.

The "Prescription Device Statement" can be found on the device and on page 1-5 of the Operator Manual.

3.3 Promotional Material (Device Claims)

Promotional brochures for MARS Unity Workstation can be found in Appendix **C**.

Promotional brochures for Marquette's Heart Rate Variability (HRV) Option and predicate device Spacelabs' Heart Rate Variability Software Option, can be found in Appendix **C**.

3.4 Device and Package Labeling

Device label drawings are provided in Appendix **O**.

3.5 Reports

After acquiring, editing and reviewing each patient's data, the Report Review application is used to print out a final report. The MARS system comes with default report formats. These reports can be customized to meet user needs. A description of default MARS system reports follows.

Report	Description
8000 Report	A Holter report. Contents include patient demographics, summary, interpretation, heart rates and a place for free-form text.

Report	Description
CRS Report	This is a report specifically chosen for customers who have purchased the CRS option. Contents include patient demographics, interpretation, table of contents, and full disclosure.
Holter Report	This is a condensed Holter report designed to provide cover page and sample strips. Contents include patient demographics, expanded summary, interpretation and free-form text.
Holter FD Report	This is a Holter report that has been expanded to include full disclosure data. Contents include patient demographics, expanded summary, interpretation, free-form text, and full disclosure printout.
CRS #2 Report	This is a report specifically chosen for customers who have purchased the CRS option. Contents include patient demographics, diary of events, and full disclosure printout.
HRV Report	The HRV report contains patient demographics, interpretation, free-form text, HRV summary and a table of contents.

A sample of MARS Unity Workstation reports is provided in Appendix **D**.

Section 4 Device Description

4.1 Purpose and Function of Device

The Multi-Parameter Analysis and Review System (MARS) unity workstation is an off-the-shelf computer hardware platform that supports a number of software applications including Holter analysis and editing system software and full disclosure clinical review software.

The MARS Unity Workstation is a system designed for acquisition, analysis, editing, review, and storage of ambulatory and monitoring network ECG and multiparameter data.

The Holter analysis software performs acquisition, analysis, editing, review, and storage of ambulatory ECG and multiparameter data acquired from solid-state electronic ECG recorders, tape recorders and the monitoring real-time network.

The clinical review software (CRS) is a full disclosure system that acquires ECG and mixed parameter waveform data from Marquette's Unity monitoring network for review and display.

(b)(4)Proprietary Information

The Heart Rate Variability (HRV) Option does not alter the ECG data or beat annotations in any way. The user may either use the tool to perform measurements using system defaults based on common definitions in the field of HRV or may configure the system to compute HRV based on their individual needs.

The Heart Rate Variability (HRV) Option was integrated into MARS System software version 3.0a and is released in subsequent versions as an option requiring a software activation key. The HRV option will be introduced to the U.S. market with release of version 4.1. Heart Rate Variability

(HRV) Option is intended to be used in a hospital or clinic environment by competent health professionals.

(b)(4)Proprietary Information

[redacted]

4.3 Physical Description

MARS workstation consists of custom application software, custom hardware, off-the-shelf (OTS) software and OEM hardware. Basic components of the system are:

Main CPU	CRT	Laser Printer	X-terminal
SEER Acquisition Unit	Mouse	Keyboard	Speakers
Tape Acquisition Unit	Modem	Uninterruptable Power Supply	DAT Tape Drive

It is packaged in three basic hardware configurations:

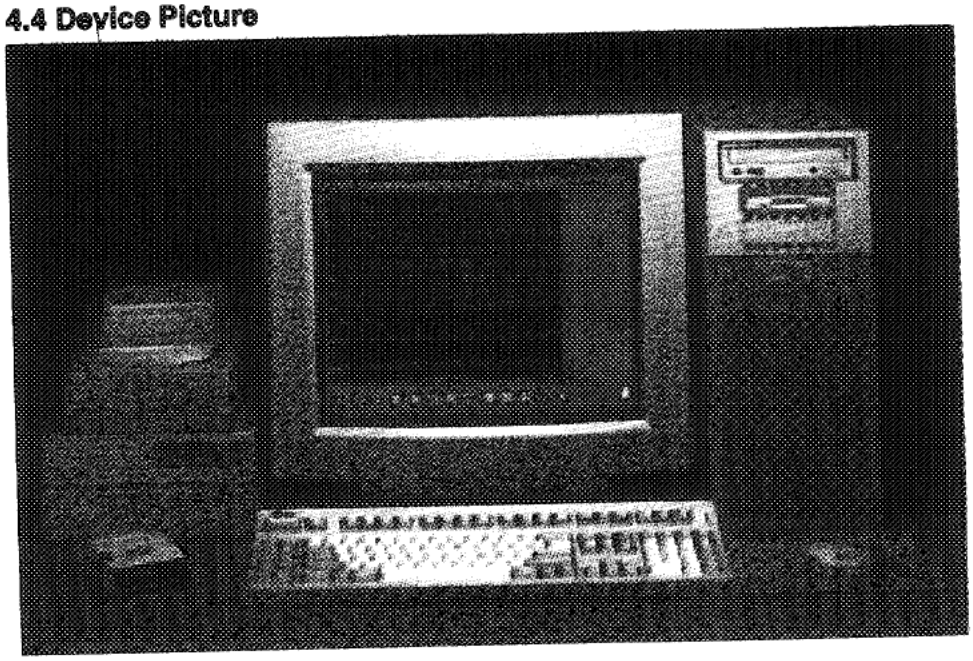
- MARS 3000 - Sun Ultra 5, 17" Monitor, CG3 Graphic Accelerator, 4 GB drive, 128MB Ram, Internal CD-ROM, Internal 3.5" Floppy, Additional Combined SCSI/Network Card
- MARS 5000 - Sun Ultra 10, 19" Monitor, Creator Graphics Accelerator, 1-4GB drive, 128MB Ram, Internal CD-ROM, 3.5" floppy, Additional combined SCSI/Network Card
- MARS 8000 - Sun Ultra 60, 21" Monitor, Creator 3D Graphics Accelerator, 9GB drive, 128MB Ram, Internal CD-ROM, Internal 3.5" Floppy, Additional Network Interface

Additional details regarding the device description, including a labeled diagram of the device addressing the name and function of all parts, are found on pages 2-3 through 2-12 of the operator manual. Refer to the following appendices:

- Appendix **A** Operating Instructions
- Appendix **M** Physical Specifications
- Appendix **N** Assembly Drawings
- Appendix **T** OEM Data

The above configurations represent the minimum hardware requirements.

4.4 Device Picture



4.5 Software Requirements and Design

- System requirements are defined in the *System Requirements Specification.*
- Software specifications are defined in the *System Requirements Specifications* and *Software Detailed Requirements.*
- HRV software design is detailed in *Software Design Documentation: HRV.*
- Safety requirements are defined in *Hazard Analysis: MARS 4.1* and *Hazard Analysis: HRV.*

Reference the documents listed below.

Document Title	Document Number	Appendix	Page Number
System Requirements Specification: MARS 4.1	421592-201	E	277
Software Detailed Requirements: MARS 4.1	421592-203	E	304
Software Detailed Requirements: HRV	418570-206	E	327
Software Design Documentation: HRV	418570-410	P	919
Hazard Analysis: MARS 4.1	421592-433	F	371
Hazard Analysis: HRV	418570-409	F	426

Security Measures

Security measures are discussed in the *System Requirements Specification.*

4.6 Software Description

(b)(4)Proprietary Information

[redacted]

(b)(4)Proprietary Information

4.9 Hardware Requirements and Design

The MARS Unity Workstations is built around a SUN workstation platform. The following subsystems are implemented primarily in hardware.

- Display
- Keyboard
- Host Processing Subsystem
- Power Supply

Hardware requirements are defined in the *System Requirements Specifications* document. Detailed requirements are defined in the *Electrical Detailed Requirements* document. Reference the documents listed below.

Document Title	Document Number	Appendix	Page Number
System Requirements Specification: MARS 4.1	421592-201	E	277
Electrical Detailed Requirements: MARS 4.1	421592-202	E	334

4.9.1 OEM Hardware

Specifications are provided on the MARS Unity Workstation specification sheet. Reference Appendix **M**.

OEM unit information is provided in the MARS Unity Workstation Service Manual. Appendix B of the MARS Unity Workstation Service Manual is provided in Appendix **T**.

4.9.2 Hardware Architecture

Additional details regarding the device description, including a labeled diagram of the device addressing the name and function of all parts, are found on pages 2-3 through 2-12 of the operator manual. Refer to the following appendices:

- Appendix **A** Operating Instructions
- Appendix **M** Physical Specifications
- Appendix **N** Assembly Drawings

4.9.3 Accessories

Accessory supplies for the MARS Unity Workstation with Heart Rate Variability (HRV) Option are consistent with those available with the predicate devices.

A list of accessory supplies is provided in Appendix **U**.

Section 6 Biocompatibility Assessment

Biocompatibility information is not applicable with respect to the device that is the subject of this submission. This device is not patient connected. Refer to Section 4 Device Description for additional information.

88

Section 7 Sterilization Information

Sterilization information is not applicable with respect to the device that is the subject of this submission. This device is not sterilized. Refer to Section 4 Device Description for additional information.

Product maintenance activities are defined in the document titled *Recommended Course of Action*.

Product discontinuance activities are defined in the document titled *Product Sales and Discontinuance*.

Reference the documents listed below.

Document Title	Document Number	Appendix	Page Number
(b)(4)Proprietary Information			

8.2 Risk Analysis

(b)(4)Proprietary Information

Document Title	Document Number	Appendix	Page Number
(b)(4)Proprietary Information			

8.3 Traceability Analysis

(b)(4)Proprietary Information

Document Title	Document Number	Appendix	Page Number
(b)(4)Proprietary Information			

8.4 MARS w/HRV Level of Concern

(b)(4)Proprietary Information

(b)(4)Proprietary Information

[redacted]

8.5 Software Verification and Validation Activities

(b)(4)Proprietary Information

[redacted]

Reference the documents listed below.

Document Title	Document Number	Appendix	Page Number

(b)(4)Proprietary Information

[redacted]

acceptable for release.

8.6 Software Version Level

The MARS Unity Workstation with HRV Option will release under MARS V4.1.

8.7 Software Certification

Software certification is provided on the following page.

93

Software Certification

I certify that the established procedures were adhered to, and that the described process was completed with the indicated (acceptable) results that demonstrate that the MARS Unity Workstation with Heart Rate Variability (HRV) Option meets its required specifications.

Randy Spaulding

Randy Spaulding
Engineering Project Leader
GE Marquette Medical Systems

5-24-99
Date

(b)(4)Proprietary Information

[redacted]

Reference the documents listed below.

Document Title	Document Number	Appendix Page Number
(b)(4)Proprietary Information		

[redacted]

Document Title	Document Number	Appendix Page Number
(b)(4)Proprietary Information		

96

(b)(4)Proprietary Information

[redacted]

9.4 Published Scientific Literature on HRV Techniques / Methods

There are no mandatory standards for performing HRV analysis. However, there is published material in scientific (technical and medical) literature that describes the guidelines and accepted techniques for properly performing HRV analysis.

The following is a list and summary of representative publications providing guidelines for HRV analysis. Copies of the following articles are contained in Appendix **L**.

1. "Heart Rate Variability, Standards of Measurement, Physiological Interpretation, and Clinical Use", Task Force of the European Society of Cardiology and the North American Society of Pacing and Electrophysiology, Circulation, vol. 93, no 5, March 1, 1996.

   Summary: The specific goals of this task force were to (1) standardize nomenclature and develop definitions of terms, (2) specify standard methods of measurements, (3) define physiological and pathophysiological correlates, (4) describe currently appropriate clinical applications, and (5) identify areas for future research.

2. Appel, Marvin L. MS, et al. "Beat to Beat Variability in Cardiovascular Variables: Noise or Music?", JACC Vol. 14, No. 5 November 1, 1989:1139-48.

   Summary: Cardiovascular variables such as heart rate, arterial blood pressure, stroke volume and the shape of electrocardiographic complexes all fluctuate on a beat-to-beat basis. These fluctuations have traditionally been ignored or, at best, treated as noise to be averaged out. The variability in cardiovascular signals reflects the hemodynamic interplay between perturbations to cardiovascular function and the dynamic response of the cardiovascular regulatory systems. Modern signal processing techniques provide a mean of analyzing beat to beat fluctuations in cardiovascular signals, so as to permit a quantitative, noninvasive or minimally invasive method of assessing closed loop hemodynamic regulation and cardiac electrical stability. This method promises to provide a new approach to the clinical diagnosis and management of alterations in cardiovascular regulation and stability.

3. Bigger, J Thomas Jr., MD, et. Al. "Frequency Domain Measures of Heart Period Variability and Mortality After Myocardial Infarction", Circulation Vol 85, No 1 January 1992.

   Summary: A large series of papers using data from the Multicenter Post Infarction Program (MPIP) demonstrating that many time domain and frequency domain measures of HRV derived from Holter studies can predict mortality after infarction.

4. Huikuri, Heikki V. MD, et. Al. "Frequency Domain Measures of Heart Rate Variability Before the Onset of Nonsustained and Sustained Ventricular Tachycardia in Patients With Coronary Artery Disease", Circulation Vol 87, No 4 April 1993.

   Summary: The purpose of this study was to examine whether there is a temporal relation between changes in HRV and the onset of spontaneous episodes of VT in patients at high risk of life-threatening arrhythmias.

5. Malliani, Alberto MD, et. Al. "Cardiovascular Neural Regulation Explored in the Frequency Domain", Circulation Vol 84, No 2 August 1991.

   Summary: Review of the general field of heart rate and blood pressure variability, with emphasis on clinical applications. Interpretation is that of using variability parameters to assess "sympathovagal balance". Includes description of autoregressive measurement technique.

6. Sands, Kenneth E. F., MD, et al. "Power Spectrum Analysis of Heart Rate Variability in Human Cardiac Transplant Recipients", Circulation Vol 79, No 1, January 1989.

   Summary: First report of HRV in cardiac transplant patients demonstrates first that short-term HRV is extremely reduced in these patients. Secondly, it demonstrates that changes in HRV might quantify rejection level in some patients.

7. Saul, J. Philip, "Beat-to-Beat Variations of Heart Rate Reflect Modulation of Cardiac Autonomic Outflow", NIPS, Volume 5/February 1990.

   Summary: A brief review of the history of the field of heart rate variability (HRV). The review includes 1) a brief discourse on the physiologic mediators of HRV, 2) the factors which influence different frequencies of variability, such as respiration and the arterial baroreflex, 3) brief discussions of the clinical utility of HRV, and 4) introduction to the use of broad band stimuli and transfer function analysis.

8. Sloan, Richard P., Ph.D., et al. "Cardiac Autonomic Control and Hostility in Healthy Subjects" The American Journal of Cardiology Volume 74, August 1, 1994.

   Summary: Use of HRV parameters to assess psychophysiologic control in normal subjects. A possible effect and role in cardiac disease is discussed.

9. Woo, Mary A., et. Al. "Complex Heart Rate Variability and Serum Norepinephrine Levels in Patients With Advanced Heart Failure", JACC, Vol. 23, No. 3 March 1, 1994:565-9

   Summary: This study examines the relation of a Poincaré plot of RR intervals to sympathetic nervous system activity in patients with severe congestive heart failure. Although the plots are qualitatively examined, it is an early report of use of this technique in human patients.

9.5 Conclusion

Marquette has followed the current practices and guidelines for implementing the Heart Rate Variability (HRV) Option software. It is important to note that the purpose of testing is to verify the reproducibility and accuracy of the HRV option, and not to support any clinical claims.

Section 10 Premarket Notification Truthful and Accurate Statement

Premarket Notification
Truthful and Accurate Statement

I certify, in my capacity as a Regulatory Affairs Specialist, that I believe to the best of my knowledge, that all data and information submitted in this premarket notification are truthful and accurate and that no material fact has been omitted.

Laura L. McComis

Laura L McComis
Regulatory Affairs Specialist
GE Marquette Medical Systems

24-MAY-1999
Date

100

Section 11 Indications for Use Statement

510(k) Number (if known): Unknown - 510(k) filed: May 24, 1999

Device Name: MARS Unity Workstation with Heart Rate Variability (HRV) Option

Indications For Use:

The MARS Unity Workstation is intended to acquire, analyze, edit, review, report and store ambulatory and monitoring network ECG and multiparameter data. The MARS Unity Workstation is intended to be used by trained operators under the direct supervision of a licensed health care practitioner in a hospital or clinic environment. Patient population includes both adult and pediatric.

The Heart Rate Variability (HRV) Option is intended to be used for the analysis of the variability in RR intervals (heart rate) and to report measurements of the variability heart rate data.

Heart Rate Variability (HRV) Option is intended to provide only HRV measurements and is not intended to produce any interpretation of those measurements or any kind of diagnosis.

The HRV measurements produced by Heart Rate Variability (HRV) Option are intended to be used by qualified personnel in evaluating the patient in conjunction with patient's clinical history, symptoms, other diagnostic tests, as well as the professional's clinical judgement.

The HRV feature of this device has not been shown to be safe and effective for a specific clinical diagnosis.

(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)

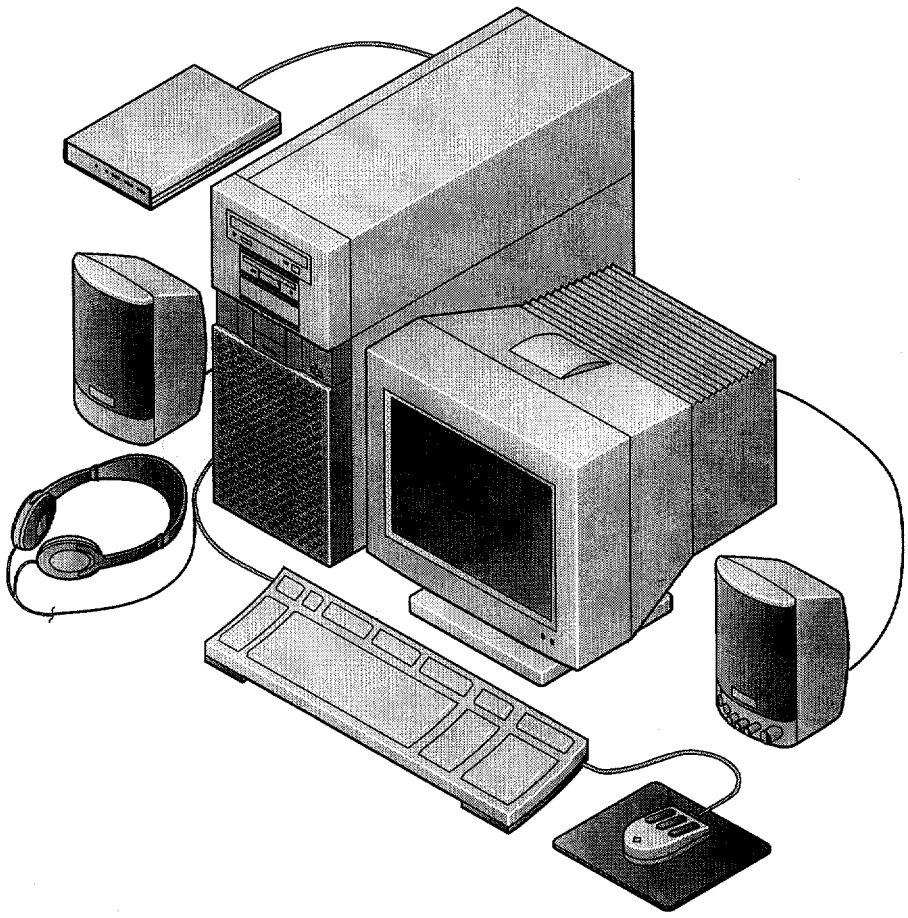
(Optional Format 1-2-96)

Appendix A
MARS Unity Workstation Operator Manual

MARS® unity workstation

user's guide

Software Versions 4.0a and 4.1
PN 410608-059 Revision B



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000050

103

NOTE

This manual reflects software versions 4.0 a. and 4.1

MD1144-412A

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CE Marking Information

Compliance

The MARS unity workstation bears CE mark CE-0366 or CE-0459 indicating its conformity with the provisions of the Council Directive 93/42/EEC concerning medical devices and fulfills the essential requirements of Annex I of this directive. The product is in radio-interference protection class A in accordance with EN 55011.

For devices manufactured in the United States, the CE mark is applied under the authority of Notified Body GMED (0459).
For devices manufactured in Germany, the CE mark is applied under the authority of Notified Body VDE (0366).

The country of manufacture and appropriate Notified Body can be found on the equipment labeling.

The product complies with the requirements of standard EN 60601-1-2 "Electromagnetic Compatibility - Medical Electrical Equipment".

The CE marking prescribed above is only found on the equipment labeling of the 230V European equipment. Only applicable equipment will bear the CE marking.

The safety and effectiveness of this device has been verified against previously distributed devices. Although all standards applicable to presently marketed devices may not be appropriate for prior devices (i.e. electromagnetic compatibility standards), this device will not impair the safe and effective use of those previously distributed devices. See user's information.

Exceptions

The MARS unity workstation EMC: Immunity Performance

The MARS unity workstation having a SEER Acquisition Unit was subjected to overvoltage/current surges per clause 36.202.3.2 of EN 60601-1-2. Collateral Standard: Electromagnetic compatibility—Requirements and tests (1993). The SEER Acquisition Unit may experience a loss of function that can be corrected by a manual reset.

Users should be aware of known RF sources, such as radio or TV stations and hand-held or mobile two-way radios, and consider them when installing a medical device or system.

Be aware that adding accessories or components, or modifying the medical device or system may degrade the EMI performance. Consult with qualified personnel regarding changes to the system configuration.

000052

000053

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(b)(4)Proprietary Information

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000054

10

Contents

000055

000056

000057

000058

7

Using the Clinical Review Station 7-1

8

Setting Up the Workstation 8-1

000059

112

000060

000061

1 Introduction

000063

Manual Information

Revision History

Each page of the document has the document part number followed by a revision letter at the bottom of the page. The revision letter identifies the documents update level.

Table 1-1. Revision History PN 410608-059

Revision	Date	Comment
A	23 October 1998	Initial release of: ■ New hardware platform information [MARS 8000 unity workstation (RU), MARS 5000 unity workstation (RT), MARS 3000 unity workstation (RS)] ■ 4.1 software
B	4 December 1998	The following changed: ■ Revised information about setting SVE criteria ■ Revised information about demixing ■ Tape acquisition unit checkout procedures

Manual Purpose

This manual contains the instructions necessary to operate the equipment safely in accordance with its function and intended use. These instructions include but are not limited to:

- an explanation of the function of controls and indicators
- the sequence of operation
- connection and disconnection of detachable parts and accessories
- instructions for operator cleaning, preventive inspection and maintenance

Where necessary, the manual identifies additional sources of relevant information and/or technical assistance.

Intended Audience

This manual is intended for the person who uses, maintains, or troubleshoots this equipment.

000065

Conventions

Symbols

Indicates additional user information.

Indicates a reference to information elsewhere in the manual.

Styles

These are the conventions used in this manual.

Table 1-2. Styles

Style	Definition
Black text	Indicates keys on the keyboard, text to be entered, or hardware items such as buttons or switches on the equipment.
Italicized text	Indicates software terms that identify menu items, buttons or options in various windows.
Ctrl+Esc	Indicates a keyboard operation. A (+) sign between the names of two keys indicates, you press and hold the first key while pressing the second key once. For example, "Press **Ctrl+Esc**" means to press and hold down the **Ctrl** key while pressing the **Esc** key.
<**Space**>	Indicates that you must press the spacebar. When instructions are given for typing a precise text string with one or more spaces, the point where the spacebar must be pressed is indicated as: <**Space**>. The purpose of the < > brackets is to ensure you press the spacebar when required.
Enter	Indicates that you must press the "**Enter**" or "**Return**" key on the keyboard. Do not type "enter".

000066

Safety Information

Definitions

⚠ DANGER — Indicates an imminently hazardous situation which, if not avoided, WILL result in death or serious injury.

⚠ WARNING — Indicates a potentially hazardous situation which, if not avoided, COULD result in death or serious injury.

⚠ CAUTION — Indicates a potentially hazardous situation which, if not avoided may result in minor or moderate injury.

Messages

Additional safety messages may be found throughout this manual that provide appropriate safe operation information.

⚠ DANGER

Do NOT use in the presence of flammable anesthetics.

M15287-1B

⚠ WARNING

This is Class I equipment. The mains plug must be connected to an appropriate power supply.

M15287-5C

⚠ CAUTION

To reduce the risk of electric shock, do NOT remove cover (or back). Refer servicing to qualified personnel.

M15287-16A

⚠ CAUTION

Federal law restricts this device to sale by or on the order of a physician.

M15287-17A

000067

Responsibility of the Manufacturer

GE Marquette Medical Systems, Inc. is responsible for the effects of safety, reliability, and performance only if:

- Assembly operations, extensions, readjustments, modifications, or repairs are carried out by persons authorized by GE Marquette.
- The electrical installation of the relevant room complies with the requirements of the appropriate regulations.
- The equipment is used in accordance with the instructions for use.

General

This device is intended for use under the direct supervision of a licensed health care practitioner.

To ensure patient safety, use only parts and accessories manufactured or recommended by GE Marquette Medical Systems.

Contact GE Marquette Medical Systems for information before connecting any devices to this equipment that are not recommended in this manual.

If this equipment is installed in the USA using 240 V rather than 120 V, the source must be a center-tapped, 240 V, single-phase circuit.

Parts and accessories used must meet the requirements of the applicable IEC 601 series safety standards, and/or the system configuration must meet the requirements of the IEC 601-1-1 medical electrical systems standard.

The use of ACCESSORY equipment not complying with the equivalent safety requirements of this equipment may lead to a reduced level of safety of the resulting system. Consideration relating to the choice shall include:

- use of the accessory in the PATIENT VICINITY; and
- evidence that the safety certification of the ACCESSORY has been performed in accordance with the appropriate IEC 601-1 and/or IEC 601-1-1 harmonized national standard.

000068

Information Technology Equipment

The hardware components that make up the MARS unity workstation are considered to be Information Technology Equipment (ITE). These individual components have been found to comply with the standard for Safety of Information Technology Equipment, including Electrical Business Equipment EN60950 (UL 1950).

The software used in the MARS unity workstation is considered as medical software. The software has been designed and manufactured to the appropriate medical regulations and controls.

The MARS unity workstation, which consists of the hardware and software components together, is considered a medical device. However, the appropriateness of applying the ITE requirements to evaluate the hardware portions of the workstation can be justified by the fact that the MARS unity workstation does not have any applied parts nor is the MARS unity workstation intended for use in the "patient environment".

As an alternative for those requiring the MARS unity workstation to comply with medical equipment standard leakage current requirements (UL 544, UL 2601-1, CSA 22.2 No. 601, IEC 601-1), a medical grade uninterruptible power supply (UPS) can be used.

Equipment Symbols

The following symbols appear on the equipment.

Attention. Consult accompanying documents.

Ethernet.

SCSI device.

Mains power switch. "**1**" is on and "**0**" is off.

Power switch.

MD1144-005A, -006A, -008A, -279A

000069

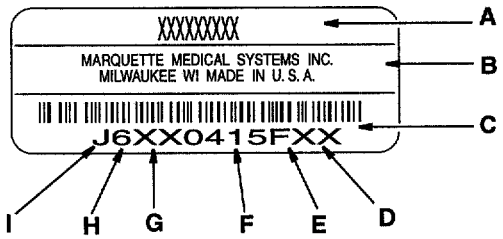
Service Information

Requirements

Refer equipment servicing to GE Marquette Medical Systems' authorized service personnel only. Any unauthorized attempt to repair equipment under warranty voids that warranty.

It is the user's responsibility to report the need for service to GE Marquette Medical Systems or to one of their authorized agents.

Every GE Marquette Medical Systems device has a unique serial number for identification. The serial number appears on the device label.



MD1113-022B

Table 1-3. Equipment Identification

Item	Description
A	name of device
B	manufacturer
C	serial number
D	device characteristics
E	division
F	product sequence number
G	product code
H	year manufactured
I	month manufactured

000070

The product codes for the MARS unity workstation include:

- RU = MARS 8000 unity workstation (Ultra 60 Creator 3D workstation)
- RT = MARS 5000 unity workstation (Ultra 10 Creator workstation)
- RS = MARS 3000 unity workstation (Ultra 5 Creator workstation)
- HK = MARS 8000 unity workstation (Ultra 1 Creator system)
- HG = MARS 8000 unity workstation (SPARCstation 20 system)
- HT = MARS 5000 unity workstation (SPARCstation 5 system)
- HV = MARS XLT network computer
- HR = tape acquisition unit
- HS = SEER acquisition unit
- HH = SPARCprinter E or Lexmark Optra Rn+ network printer

000071

124

2 Equipment Overview

000073

126

Equipment Description

Overview

The Multi-Parameter Analysis and Review System (MARS) unity workstation provides a hardware platform to support a number of software applications, including:

- MARS clinical review station (CRS) software
- MARS Holter analysis and editing system software

Hardware

The MARS unity workstations use a number of Sun Microsystem's platforms, including:

Table 2-1. Hardware Types and Product Codes

Product Name	Sun Platform Name	Product Code
MARS 8000 unity workstation (RU)	Sun Ultra 60 Creator 3D Desktop Workstation	RU
MARS 8000 unity workstation (HK)	Sun Ultra 1 Creator Workstation	HK
MARS 8000 unity workstation (HG)	Sun SPARCstation 20 System	HG
MARS 5000 unity workstation (RT)	Sun Ultra 10 Minitower Workstation	RT
MARS 5000 unity workstation (HT)	Sun SPARCstation 5 System	HT
MARS 3000 unity workstation (RS)	Sun Ultra 5 Desktop Workstation	RS

The Sun Microsystem's platforms provide many technological advances, including a multi-tasking environment.

Multi-tasking provides the ability to acquire, analyze, edit and print simultaneously.

Peripherals from Sun include the monitor, keyboard, and mouse. Either Lexmark or Hewlett-Packard provides network printer. The system includes an unattended uninterruptible power supply (UPS) and an access unit for remote system support (RSS).

Optional equipment includes a DAT drive also from Sun, a tape acquisition unit and a SEER acquisition unit manufactured by GE Marquette Medical Systems, and a network computer manufactured by NCD.

Software

MARS Clinical Review Station

The MARS clinical review station software makes the workstation a full disclosure system that connects to a GE Marquette unity monitoring network. It receives patient data from user selected hardwired and telemetry beds. Hardwired beds and telemetry beds may store up to eight channels of user selectable data.

000075

The user may configure the workstation to display 10-second strip data, 1-hour page data and/or individual event data, and print full disclosure reports in a manner most useful for an individual user.

MARS Holter analysis and editing system

The MARS Holter analysis and editing system software acquires ECG data from solid-state electronic ECG recorders (SEER), tape recorders, and the monitoring real-time network. The software provides:

- multiple techniques of scanning for complex editing
- algorithm enhancement for more precise beat and noise detection
- up to 12 high-resolution trends simultaneously on one screen
- customized final reports
- dual channel superimposition displayed at up to 240 times realtime
- programmable event definition for detailed analysis

With either software application, different users may configure their own setups, adapting the workstation to the way they work.

Software Activators

The various software applications and features all reside in a single software application. Depending on when software applications or features were purchased, you may need to use a workstation-specific software activator to begin or to continue to use that application or feature.

000076

MARS 8000 unity workstation (RU)

See the field service manual for information about connecting and setting up your MARS unity workstation.

This section only describes the MARS 8000 unity workstation (RU). For more information about the other workstations, see the appropriate field service manual:

- MARS unity workstation field service manual (R Series), PN 408287-068
- MARS unity workstation field service manual (H Series), PN 408287-050

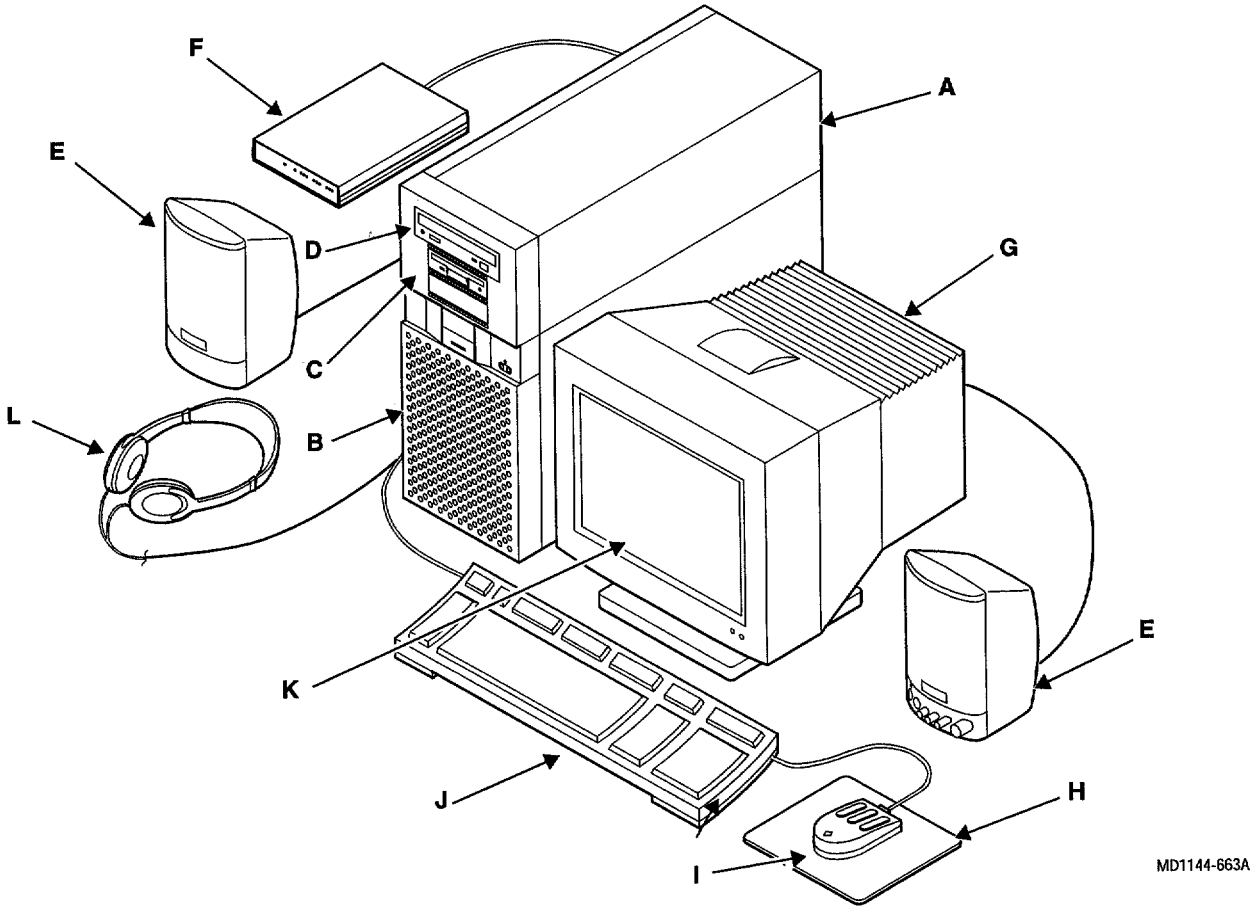


Table 2-2. MARS 8000 unity workstation (RU) System Description

Item	Name	Description
A	system box	Contains the power supply, hard disk drive(s), RAM, central processing unit(s), internal speaker, floppy diskette drive, a CD-ROM drive, and two separate network interfaces.
B	internal speaker	Used as backup to the external speakers.

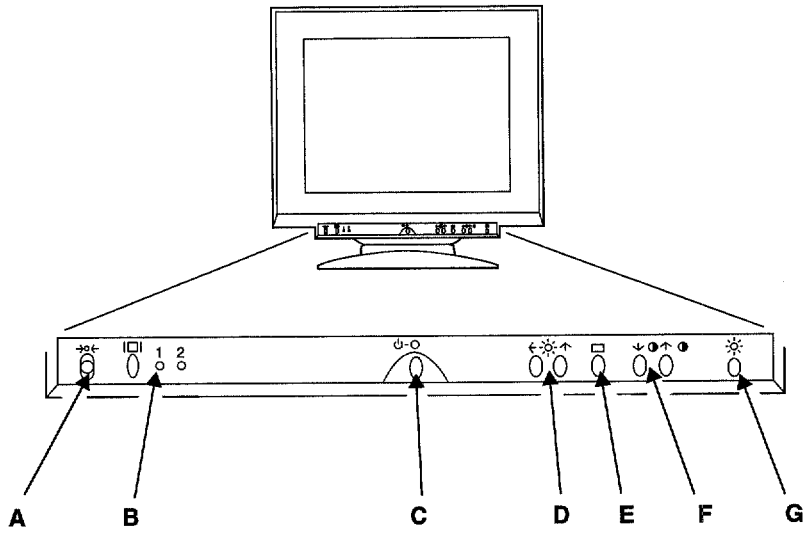
000077

Table 2-2. MARS 8000 unity workstation (RU) System Description (Continued)

Item	Name	Description
C	diskette drive slot	Insert a floppy diskette to perform software updates.
D	CD-ROM drive	Reads a Compact Disk (CD). Used to perform software updates for the MARS unity workstation, to operate the online tutorial and online service manual, or to play music CDs.
E	external speakers	Used for listening to computer-based training and Holter superimposition.
F	access unit	Used for remote system support (RSS). For locations where ISDN or switched-56 service is not available use: ■ a non-networked analog modem or ■ an analog modem (not shown) may be used in addition to the networked RSS access unit
G	monitor	Displays information and messages.
H	mouse pad	Helps the mouse move with more control.
I	mouse	Moves the mouse cursor and selects items on the screen.
J	keyboard	Use the keyboard to type information when required by the MARS unity workstation software.
K	screen	Displays the MARS unity workstation software.
L	headphones	Used to hear the computer-based training tutorial, Holter superimposition, or music CDs.
Not shown	uninterruptible power supply (UPS)	The UPS automatically provides temporary power to the MARS unity workstation in the event of a power interruption. This ensures that data acquisition and storage continues until AC power is restored to the station. If an extended power interruption occurs, the UPS performs an orderly system shutdown.
Not shown	printer	Prints selected data or reports. For more information about printers, see chapter 5, "Printing Patient Data".

000078

Workstation 21 Inch Monitor



MD1144-548A

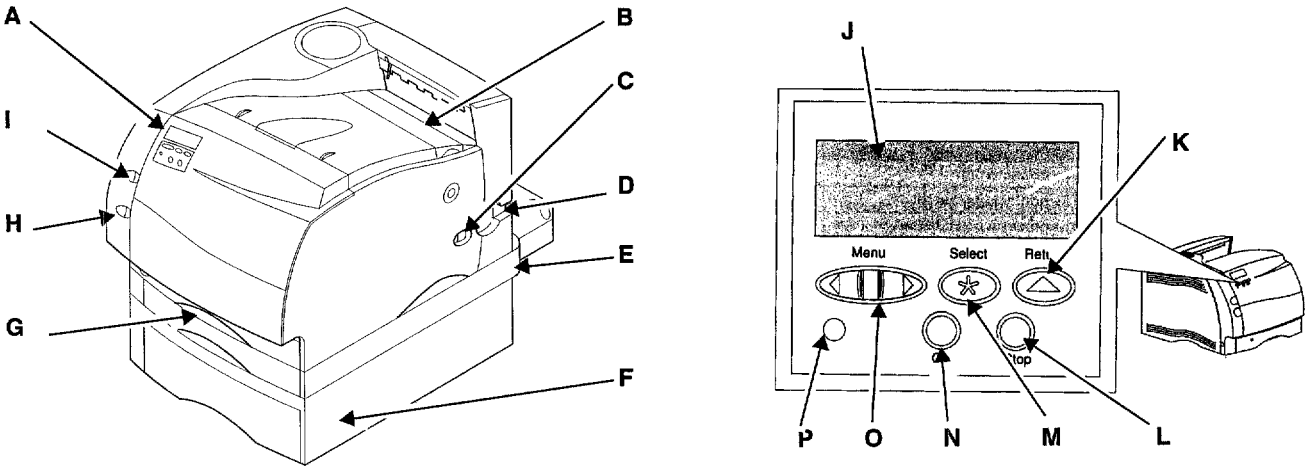
Table 2-3. Workstation Monitor (21 in) (Front View)

Item	Name	Description
A	reset button	Press to reset the adjustment data to the factory preset levels.
B	input selector button and indicator	Selects the type of video input signal (13W3 or HD15). The indicator for the current setting is lit, and you can change the setting by pressing the button.
C	power switch and indicator	Turns the monitor on or off. The indicator lights up in green when the monitor is turned on, and lights up in orange when the monitor is in power saving mode.
D	brightness buttons	Adjusts the picture brightness.
E	menu button	Displays the menu for the On-screen Display (OSD) system.
F	contrast buttons	Adjusts the contrast.
G	auto sizing and centering button	Automatically adjusts the size and centering of the images.

000079

Printers

Lexmark Optra S 1625 or 1650 Network Printer



MD1144-510A, - 492A

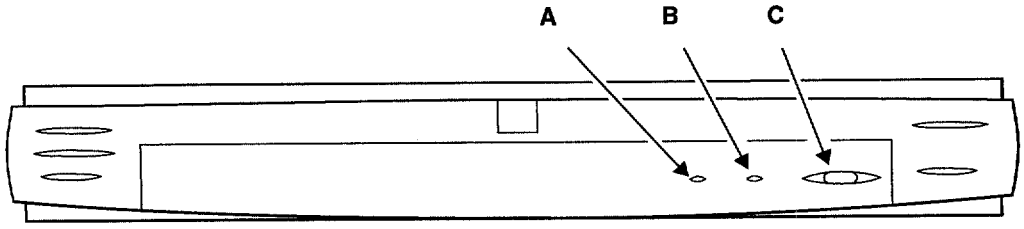
Table 2-4. Lexmark Optra S 1625 or 1650 Network Printer

Item	Name	Description
A	display panel	Displays printer status and controls operations.
B	fuser wiper cover	Provides access to the fuser wiper for replacement or maintenance.
C	mains AC power switch	Press to turn printer on and off.
D	mains AC power port	Connects mains AC power cord to the printer.
E	duplexer (optional)	Allows paper to be printed on the front and back.
F	500-sheet feeder (optional)	Contains a large supply of paper to be printed.
G	250-sheet paper tray	Contains a supply of paper to be printed.
H	lower release latch	Provides access to the front output tray.
I	upper release latch	Provides access to the toner cartridge.
J	LCD	Displays printer operation status, error messages, or menus and menu items.
K	**RETURN** button	Press to return to the previous menu level.
L	**STOP** button	Press to temporarily stop all printer activity.
M	**SELECT** button	Press to select the menu item shown on the second line of the LCD.
N	**GO** button	Press to return to printer to *Ready*, exits the displayed printer menu or clears the displayed message.
O	power indicator light	Indicates the status of the printer: ■ ON = the printer is On, but idle ■ OFF = the printer is Off ■ Blinking = the printer is On and busy
P	**MENU** button	Press to scroll through the various menu items.

000080

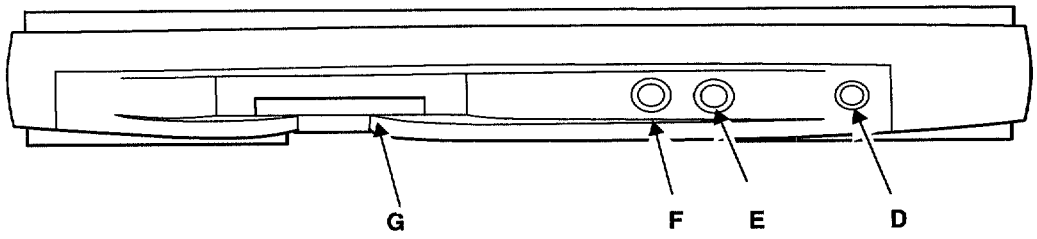
XLT Network Computer Base

Front View



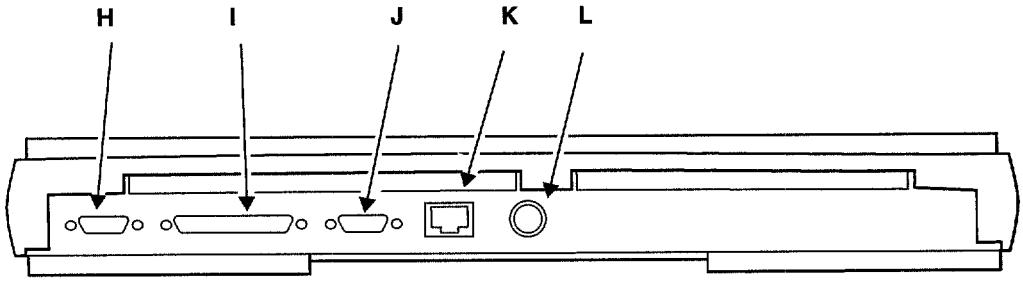
MD1144-537A

Right Side View



MD1144-538A

Back View



MD1144-536A

Table 2-5. XLT Network Computer Base

Item	Name	Description
A	network activity LED	Blinks to indicate network activity.
B	power indicator LED	Glows to indicate AC power applied.
C	power (On/Off) switch	Controls the power to the XLT.
D	power port	Connects the XLT base to an external AC power source.
E	keyboard port	Connects the keyboard to the network computer.
F	mouse port	Connects the mouse to the network computer.
G	PCMCIA card port	Used to insert optional audio adapter. Not used.
H	monitor port	Connects the monitor to the base.
I	parallel port	Connects parallel devices to the network computer. Not used.
J	serial port	Connects serial devices to the network computer. Not used.
K	twisted pair ethernet port	Connects twisted pair ethernet (10/100BaseT - autosensed) to the network computer.
L	thin ethernet port	Connects thin ethernet to the network computer.

000081

XLT Network Computer Monitors

21 -Inch

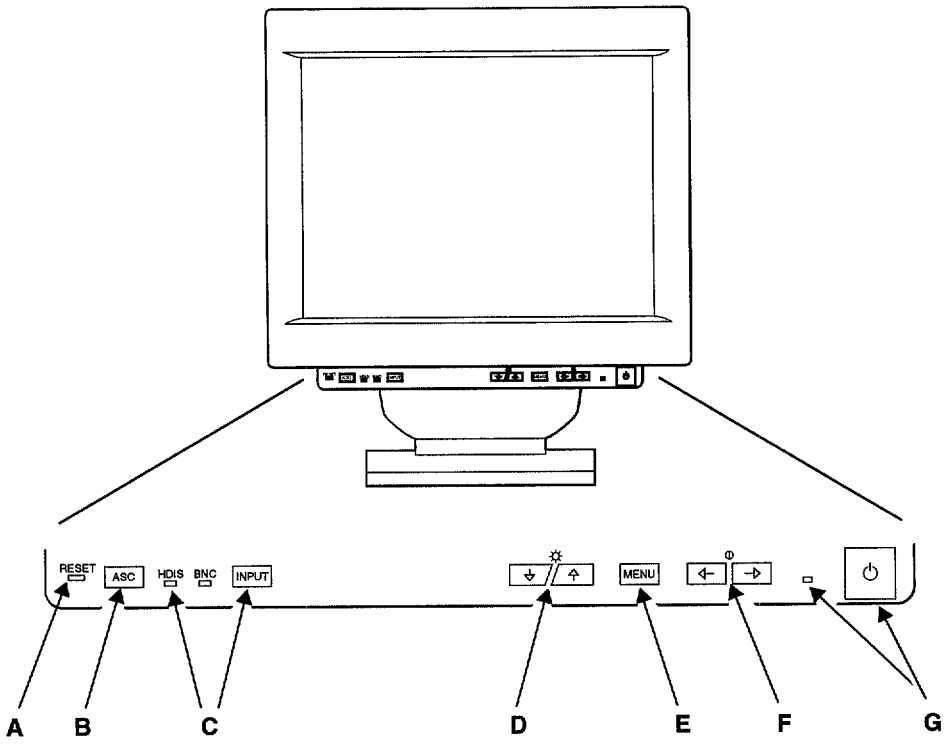
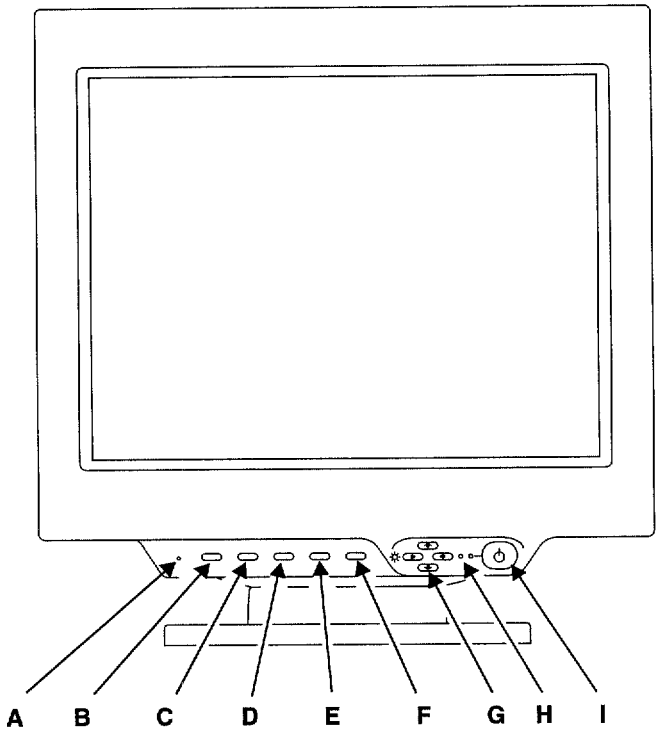


Table 2-6. XLT Network Computer Monitor (21 in) (Front View)		
Item	**Name**	**Description**
A	reset button	Press to reset the adjustment data to the factory preset levels.
B	active signal correction button	Press this button to automatically size and center the screen image
C	input button and LEDs	Press this button to select the input connector (located on the back of the unit) that the monitor should use. The currently selected connector is indicated by the LEDs.
D	brightness buttons	Press up/down arrow buttons to adjust the brightness.
E	menu button	Press this button to bring up the On Screen Display (OSD)
F	contrast buttons	Press left/right arrows to adjust contrast.
G	power switch and LED	Press to turn the monitor on or off. Indicator glows when monitor is turned on.

000082

20-Inch



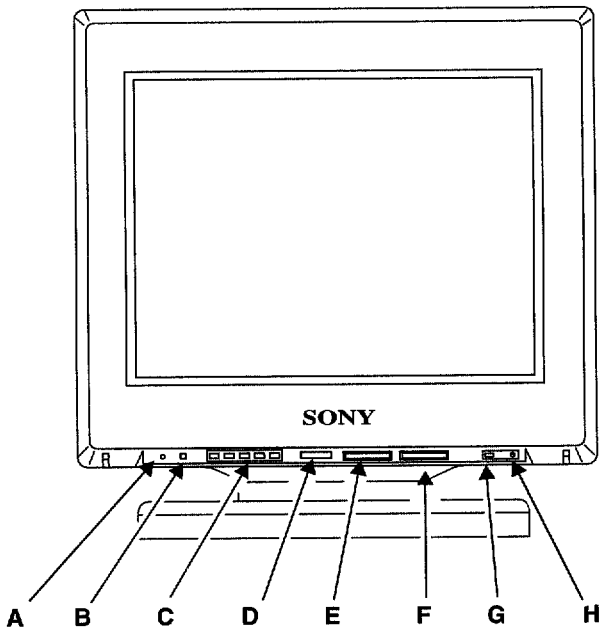
MD1144-479A

Table 2-7. XLT Network Computer Monitor (20 in) (Front View)

Item	Name	Description
A	reset button	Press to reset the adjustment data to the factory preset levels.
B	color button	Press to adjust color temperature.
C	convergence button	Press to adjust the vertical and horizontal convergence.
D	geometry button	Press to adjust the rotation and pincushion.
E	size button	Press to adjust the vertical and horizontal picture size.
F	center button	Press to adjust the vertical and horizontal position.
G	contrast/brightness buttons	Press up/down arrow buttons to adjust the brightness. Press left/right arrows to adjust brightness.
H	power saving LED	Glows when the monitor is in the Power Saving Modes.
I	power switch and LED	Press to turn the monitor on or off. Indicator glows when monitor is turned on.

000083

17-Inch



MD1144-181A

Table 2-8. XLT Network Computer Monitor (17 in) (Front View)		
Item	**Name**	**Description**
A	**RESET** switch	Recalls certain factory settings.
B	**CTRL** (control) switch	Extends the RESET and SELECT adjustments.
C	LED indicators	Control appearance of the monitor screen. ■ CENT: Centering ■ SIZE: Picture size ■ GEOM: Raster rotation and horizontal pincushion ■ CONV: Convergence ■ C TEMP: Color temperature and hue saturation
D	**SELECT** switch	Selects an item to adjust.
E	brightness +/- adjustment switch	Adjusts the picture brightness in normal operation. Acts as +/- controls in adjustment mode.
F	contrast +/- adjustment switch	Adjusts the picture contrast in normal operation. Acts as +/- controls in adjustment mode.
G	power saving LED	Indicates when the monitor is in power saving mode.
H	power switch and indicator	Turns the monitor on and off.

000084

Getting Results with Your Workstation

Powering On and Off the Workstation

Powering On the Workstation

> During normal operation, the workstation should not be powered off. It should be powered off only for service following the proper procedures.

1. Turn on the uninterruptible power supply (UPS) power switch.
2. Turn on any peripheral SCSI device power switches, including:
   - SEER acquisition unit
   - tape acquisition unit
   - DAT drive

> Connect and properly terminate all SCSI devices before powering on the workstation.
>
> Failure to properly connect and terminate SCSI cables may cause corruption of the disk drives or system failure.

3. Turn on the workstation.

If turning on a...	Then press the...
MARS 8000 unity workstation (RU)	power switch located on the front of the workstation.
MARS 5000 unity workstation (RT) or MARS 3000 unity workstation (RS)	power switch located on the back of the workstation.
MARS 8000 unity workstation (HK), MARS 8000 unity workstation (HG), or MARS 5000 unity workstation (HT)	Power On/Standby switch on the back right-hand side of the workstation.

4. Turn on the monitor power switch.
   Several screens appear momentarily.

> Watch for error messages on the screen.

5. If using a local parallel printer, turn on the local parallel printer.
   The login window appears when the workstation completes the start-up.

000085

6. In the *Please enter your user name* text entry box, type **mei** and click *OK*.
   The password window appears.
7. In the *Please enter your password* text entry box, type **mei** and click *OK*.
   Several screens appear momentarily.
   The *cmdtool* icon appears momentarily in the lower left corner of the monitor.
   The application software starts and the system screen appears.

Powering Off the Workstation

Power off the workstation properly. Failure to do so may result in the loss of data or a system failure.

During normal operation, the workstation should not be powered off. It should be powered off only for service.

1. Click *System* on the menu bar.
2. Click *System Shutdown* on the pulldown menu.

If using MARS to MUSE communication and the workstation will be powered down for an extended time, notify the MUSE system owner.

The *Shutdown MARS System? This will take about 20 seconds* window appears.

3. Click *Yes*.
   After about 20 seconds, the *ok* prompt appears.
4. Turn off the monitor.
5. Turn off any peripheral SCSI device power switches, including:
   - SEER acquisition unit
   - tape acquisition unit
   - DAT drive
6. If using a local parallel printer, turn off the local parallel printer.

000086

7. Turn off the workstation.

If turning on a...	Then press the...
MARS 8000 unity workstation (RU)	power switch located on the front of the workstation.
MARS 5000 unity workstation (RT) or MARS 3000 unity workstation (RS)	power switch located on the back of the workstation.
MARS 8000 unity workstation (HK), MARS 8000 unity workstation (HG), or MARS 5000 unity workstation (HT)	Power On/Standby switch on the back right-hand side of the workstation. It returns to its original position.

000087

Logging In and Out of the Workstation

To use the MARS unity workstation or the XLT network computer, you must log in.

Log In

The login screen appears after you power on the workstation or network computer.

For more detailed steps to power on the workstation, see "Power On Workstation" in chapter 2.

1. Type your user name in the user name text box.
2. Press the return key or click the *OK* box on the screen.
3. Type your password in the password text box.
4. Press the return key or click the *OK* box on the screen.

If you do not have a user name or password, type **mei** for both. .

For the detailed steps on how to set up a user, see "Setting Up the Users" in chapter 8, "Setting Up the Workstation".

The same user may be logged in to only one workstation or network computer at a time.

Log Out

Do not shut down the workstation. Contact authorized service personnel to perform this process.

Failure to follow the recommended method to shut down the workstation may result in the loss of data and damage to the workstation.

If the MARS workstation will be shut down for an extended period of time, notify the MUSE CV System owner.

Log out if a different user wants to log in.
When you click *Log Out*, the workstation applications restart. You must then type your user name and password to use the workstation.

Leave the workstation running because it performs scheduled file management procedures and may interfere with MUSE CV operation.

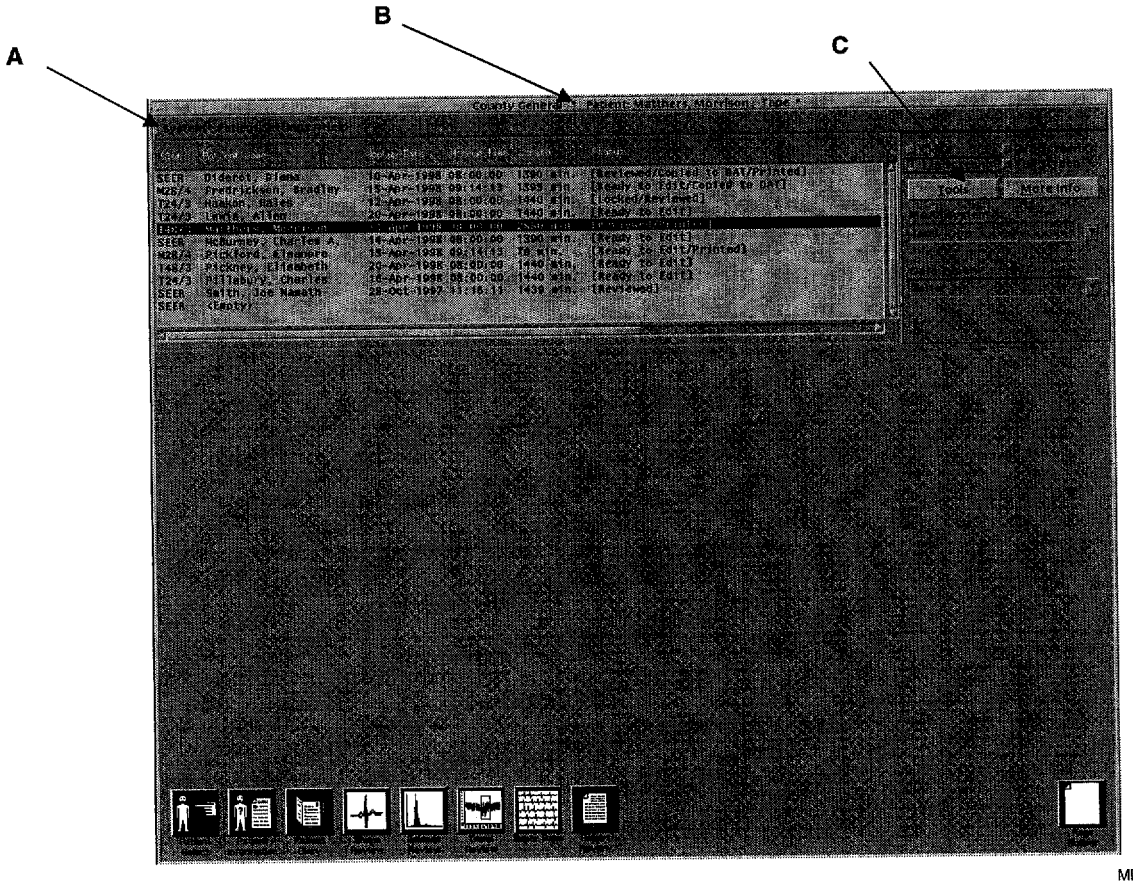
You may turn off ONLY the monitor without losing data.

000083

Screen Components

The MARS workstation's monitor screen provides you with the information needed to perform a great many tasks. Understanding the components will help you use the workstation's capabilities to make your jobs easier.

> Use the LEFT mouse button unless instructed otherwise.



MD1144-623A

000089

Table 2-9. Screen Component Example

Item	Name	Description
A	menu bar	The menu bar contains three selections: *System* ■ *Menus* = Use to select the menu that will appear at the bottom of the screen. ■ *System Setup* = Use to configure various workstation hardware and software options and user options. ■ *Research Utilities* = Usually used by researchers conducting formal studies. Data is processed by the MARS unity workstation so it can be transferred to another computer for further analysis. Users are responsible for file system maintenance and data transfers to other computers. ■ *Software Updates* = Use to update the workstation software version. Only available for the admin user. ■ *Log Out* = Ends the current user's session and allows another user to log in. ■ *System Shutdown* = Shuts down the workstation. *Patient Settings* ■ *Event Definition* = Opens the *Patient: Event Definitions Settings and Analysis Results* window for the currently selected patient. ■ *Heart Rate* = Opens the *Patient: Heart Rate Settings* window for the selected patient. *Help* ■ *Getting Started* = Starts a CD ROM-based interactive tutorial which teaches you how to use the mouse and the 3-part screen and to move through data. ■ *Service Manuals* = Starts a CD-ROM based version of the MARS unity workstation field service manual and the service manuals for the various Sun MicroSystems' workstations. ■ *CD Player* = Click this option when you want to listen to a CD while you are operating the workstation. ■ *About* = Click this option to get information about the workstation's hardware and software.
B	title bar	The title bar displays the following information: ■ site name ■ currently selected patient's unit name and bed number (for CRS) ■ currently selected patient's name ■ patient type (Tape, SEER, Acquired Bed, Monitoring or Stored Report) ■ MARS System (blank for the local workstation)
C	*Tools* button	Located in the control window. Many tools have a *Tools* button which opens a secondary window with options for changing the appearance of the data, for measurements, etc. The individual tools with a *Tool* button include: ■ *Patient Select* tool ■ *Strip Review* tool ■ *Page Review* tool ■ *Event Review* tool ■ *Trend Review* tool ■ *Episode Review* tool ■ *Shape Review* tool ■ *Waveform Measurements* tool

000090

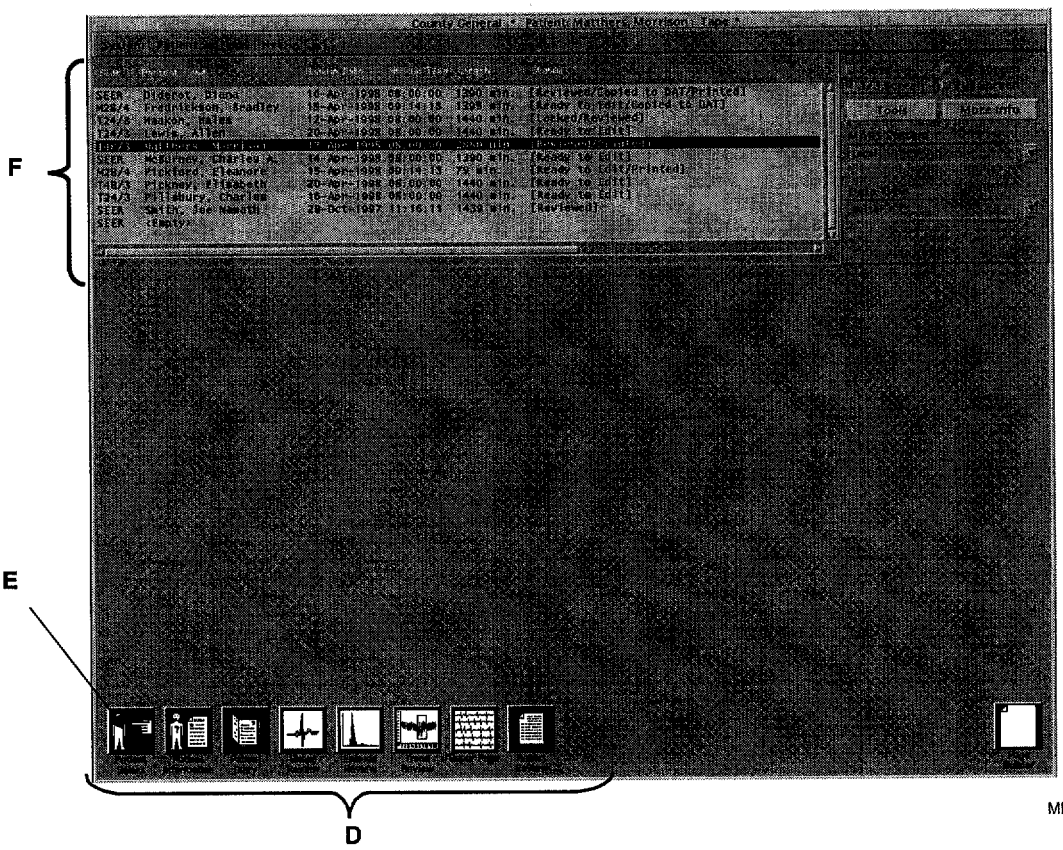


Table 2-10. Screen Component Example		
Item	**Name**	**Description**
D	*Tools* menu	The *Tools* menu, one of the default menus, contains 13 menu icons which are the building blocks for the other default menus' menu icons. The menu icons in the *Tools* menu open their associated tool in the top 1/3 of the screen. Avoid using the *Tools* menu for scanning or reviewing data. Using a default menu or creating a custom menu permits more efficient workflow by automatically closing previously opened windows.
E	*Patient Select* menu icon	An example of an individual menu icon.
F	*Patient Select* tool	An example of a tool.

000091

Scanning with the Workstation

After recording the patient's ECG data, a trained technician transfers the data to the MARS unity workstation software, scans and edits the data to correctly identify significant events, and then prints a report.

Recording the ECG Data

ECG data may be recorded from a patient in one of three ways:

- The patient wears an ambulatory tape cassette recorder that records two or three channels of ECG data for up to 48 hours.
- The patient wears a SEER ambulatory digital analysis recorder that acquires and analyzes 24 or 48 hours of 2 or 3 channels of ECG data.
- The patient is attached to a bedside monitor that acquires ECG data and transmits it to a Clinical Review Station.

See the operator's manual for the particular recording device for information on recording ECG data.

Downloading the ECG Data

To analyze patient data on the MARS unity workstation, you must first transfer or "download" it from one of the following sources:

- Holter 8500 recorder (and many other Holter tape records)
- SEER/SEER XT recorder
- SEER MC recorder
- bedside monitor
- another MARS workstation
- DAT tape

See chapter 3, "Downloading Patient Data" for more information about downloading data.

Scanning the ECG Data

Scanning the ECG data allows you to:

- select the desired patient
- enter demographic and clinical data about the patient
- review and enter information about the patient's symptoms and activities
- review and edit individual beats and/or groups of beats
- file information about events so you can document any changes in the patient's rhythms

Filed strips should "tell a story" of the entire recording period. If you are unsure of the importance of an event (strip), file it. Your primary goal is to document any changes.

000092

Printing the Reports

The final report prints filed strips, along with other components you selected. The physician reviews the final report.

See chapter 5, "Printing Patient Data" for more information about printing data.

Storing the Report

Electronic versions of the final report may be stored on the local hard disk drive, a DAT tape or a MUSE CV information system .

The MUSE CV information system does not store Full Disclosure data.

See chapter 6, "Storing Patient Data" for more information about storing data.

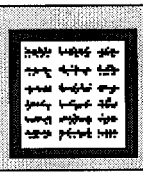
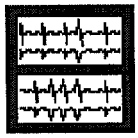
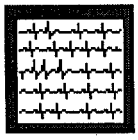
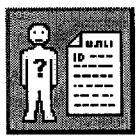
000093

Menu Icon Quick Reference

This table shows the menu icons associated to various tools. Some of these menu icons appear in the *Tools* menu. Others appear in GE Marquette default menus.

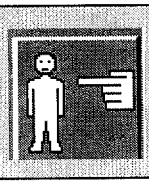
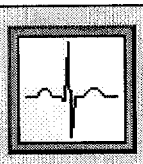
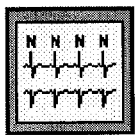
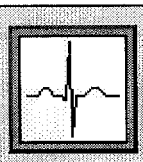
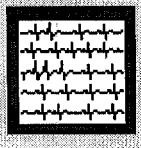
Not every user will have access to each of these menu icons.

Table 2-11. Menu Icon Quick Reference

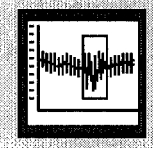
Tool Name and Menu Icon	Functions
Episode Review  MD1144-104A	■ In the *Tools* menu. ■ Displays episodes (as histograms) laid out in frequency of occurrence based on measurement value. Example: an R-R interval of 1.200 sec. versus an R-R interval of 750 sec. ■ Files episodes for the final report. ■ Use in conjunction with *Strip Review.*
Event Diary  MD1144-468	■ In the *Tools* menu. ■ Displays user-defined clinical events and the date and time they occurred. ■ Use in conjunction with *Strip Review.*
Event Review  MD1261-15A	■ In the *Tools* menu. ■ Displays user-defined clinical events in a miniaturized format. ■ Displays events by severity or chronological order. ■ Files a page of events for final report. Example: VE runs, SVT, multiformed PVCs.
Heart Rate Variability  MD1144-108	■ In the *Tools* menu. ■ Measures heart rate variability (HRV). ■ Displays HRV as histograms. ■ Prints HRV histograms. ■ Files histograms for final report. ■ User adjusts calipers for measuring.
Page Review  MD1261-14A	■ Displays waveform in a selectable page format. ■ Locates and creates regions. ■ Files a page of data to the final report. ■ Prints a page of data. ■ Starts or stops auto page. (Can review all or portions of a study). ■ Locates events or episodes. ■ Use in conjunction with *Strip Review.*
Patient Diary  MD1261-16A	■ In the *Tools* menu. ■ User enters information regarding patient activities or symptoms. ■ Use in conjunction with *Strip Review* and *Page Review* to confirm entries for the final report.
Patient Info  MD1144-065B	■ In the *Tools* menu. ■ User enters information about the patient to be included in the final report.

000094

Table 2-11. Menu Icon Quick Reference (Continued)

Tool Name and Menu Icon	Functions
Patient Select  MD1274-4A	■ In the *Tools* menu. ■ Displays a list of patient slots and their status. Example: *Ready to Edit, % Acquiring, Copied to DAT, Printed.* ■ Allows selecting of target workstations and different data types.
Report Review  MD1261-20A	■ In the *Tools* menu. ■ User deletes unwanted filed strips or information. ■ User reviews/modifies the final report BEFORE printing. ■ Prints full disclosure. ■ Contains the summary of the quantified analysis.
Shape Review  MD1144-105A	■ In the *Tools* menu. ■ Quantifies system-created labels. ■ Reviews individual beats from within templates. ■ Relabels single or multiple templates to new groups. ■ Determines the dominant shape or rhythm. ■ Use in conjunction with *Strip Review.*
Strip Review  MD1261-9A	■ In the *Tools* menu. ■ Displays waveform in a measurable 10-second strip. ■ Files an event or episode. ■ Performs superimposition. ■ Displays R-R intervals. ■ Measures waveforms with on-screen calipers. ■ Relabels a beat(s). ■ Creates a region(s). ■ Displays heart rate. ■ Displays events or episodes (example: VE couplet, ST depression, bradycardia, etc.).
ST Analysis  MD1144-105A	■ Combination of *Trend Review, Waveform Measurements* and *Strip Review.* ■ Allows user to set isoelectric and fiducial points for analysis.
Superimposition  MD1261-16A	■ Use with *Strip Review, Page Review* and *Trend Review* ■ All features of these tools are available.
Super Page  MD1261-14A	■ Combination of *Strip Review* and *Page Review.* ■ All features of both tools are available.

000095

Table 2-11. Menu Icon Quick Reference (Continued)	
Tool Name and Menu Icon	**Functions**
SVE Editor  MD1144-468	■ Opens *Event Diary* and *Strip Review.* ■ User adjusts prematurity percentage to relabel beats. ■ *Page Review* hidden behind *Event Diary.* User accesses *Page Review* by decreasing size of *Event Diary.*
Trend Review  MD1144-239A	■ In the *Tools* menu. ■ Displays episodes (as histograms) in relation to time. ■ Locates minimum and maximum episodes. Example: heart rates, R-R intervals, VE ectopy, SVE ectopy, etc. ■ Files episodes for the final report. ■ Use in conjunction with *Strip Review.*
Waveform Measurements  MD1144-466	■ In the *Tools* menu. ■ Creates ST Deviation Trends. ■ Prints ST Deviation Trends. ■ Files trends for the final report. ■ User adjusts feudalize and isoelectric points.

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3 Downloading ECG Data

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Downloading from Holter Tape Recorders

Holter tape recorders, like GE Marquette Medical System's Holter 8500 ambulatory recorder, record ECG data on cassette tapes. The cassette tapes may contain 24 to 48 hours of two or three channels of ECG data. After downloading the ECG data from the tape cassette, the workstation analyzes the data.

Verify the Slots

1. Open the *Patient Select* tool.
2. Verify that a slot exists in which to download the tape.
   - *T24/2* = 24 hour/2 channel
   - *T24/3* = 24 hour/3 channel
   - *T48/2* = 48 hour/2 channel
   - *T48/3* = 48 hour/3 channel

> The workstation will either:
> - place the tape in the next available slot for the type tape selected, or
> - place the tape in the next larger slot, or
> - if no available slots exist, prompt you to delete patient data in suitable slots and then download the tape again.
>
> The workstation considers either empty slots or "Reviewed" slots to be "available" for downloading data into that slot.

3. Click the right scroll bar arrow at the bottom of the *Patient Select* tool until the */slots* appear.
4. Verify that an appropriate slot for the data appears.
   - *h24c2.nat* = 24 hour/2 channel
   - *h24c3.nat* = 24 hour/3 channel
   - *h248c2.nat* = 48 hour/2 channel
   - *h48c3.nat* = 48 hour/3 channel

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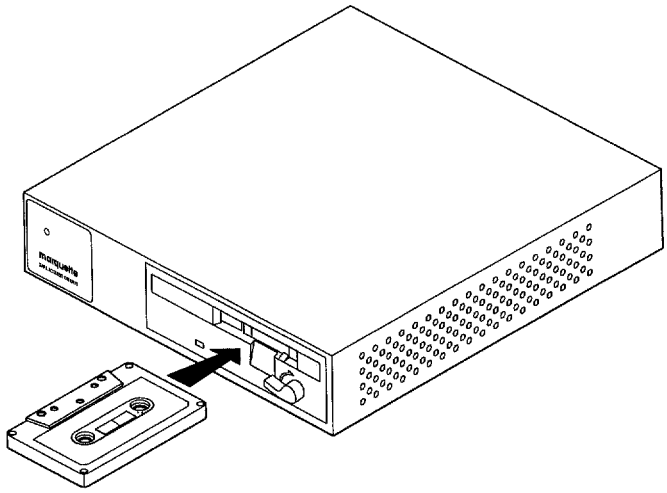
Insert the Tape

1. Insert the cassette tape, with the exposed tape to the left and the label facing up, into the tape acquisition unit until the tape "clicks" into place.



MD1144-514

2. Close the tape release lever by rotating the tape release lever clockwise to the up position.
   - The tape fast-forwards to its end.
   - The green tape motion LED light glows as the tape moves.
   - The *Tape Download/Analysis Options* window appears.

Set the Download and Analysis Options

1. Type the patient's last name in the *Last Name* text entry box.
2. Type the patient's first name in the *First Name* text entry box.
3. Set the hookup date and hookup time.
4. Select the desired *Download Options.*
   - Select 2 or 3 channels.
   - Select 24 or 48 hours of data.
   - Select the acquisition speed.
     Use *Fast Acquisition* for Holter only workstations; use *Slow Acquisition* for Combo (Holter and CRS) workstations while acquiring realtime data.
   - Select the track speed.
5. If desired, select the *Analyze From* and *Analyze To* times.

> **i** Based on the length of time selected in *Download Options*, the workstation will, by default, analyze either 24 or 48 hours of data.

6. If desired, select the recorder type.
7. If desired, select the *Pacemaker Options.*

000100

153

8. If desired, select the *Channels to be analyzed.*
9. If desired, select *2X Gain on Channels.*
10. Click *Start* to begin downloading data.

View the Downloading

> You can scan an existing study while downloading data. You do not need to view the downloading progress.

1. Watch the progress of the data download in the *Patient Select* tool.
2. Locate the data for the patient being downloaded.
   The number of minutes of data for the patient's study appears under *Length.*
   The patient's *Status* changes from *% Acquired* to *Ready to Edit.*

> A 24-hour study is 1440 minutes in length.
> A 48 hour study is 2880 minutes in length.

> Wait until the *Status* changes from *[% Acquiring]* to *[Queued for Analysis]* or *[% Analyzing]* before ejecting the tape from the tape acquisition unit.

3. When the status changes to *% Analyzing*, move the tape release lever to the down position to eject the tape and insert another tape into the tape acquisition unit.

000101

Downloading from SEER Recorders

SEER recorders analyze the ECG data as it is being acquired. The MARS unity workstation downloads the data and formats it for viewing.

SEER XT Digital Analysis Recorder

The SEER XT recorder acquires and analyzes 24 hours of 2 channel ECG data. Data is stored in the RAM of the recorder's computer and downloaded to the workstation through a SEER cable.

Verify the Slots

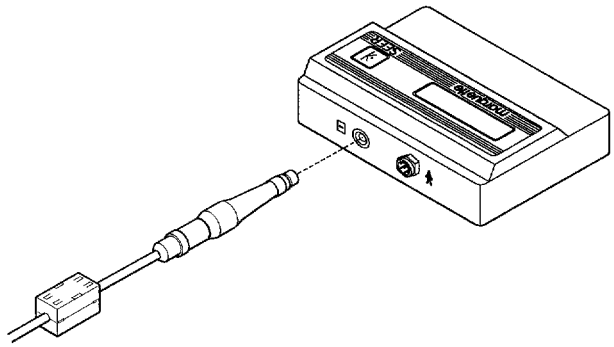
1. Open the *Patient Select* tool.
2. Verify that a slot exists in which to download the data.
   - SEER = SEER, SEER XT and SEER MC

> Click the *More Info* button to see which type of SEER a patient was downloaded from.

3. Click the right scroll bar arrow at the bottom of the *Patient Select* tool until the */slots* appear.
4. Verify that an appropriate slot for the data appears.
   - *s4.nat* = SEER or SEER XT

Connect the SEER

Connect a SEER XT recorder to the SEER cable. The recorder buzzes.



MD1144-515

The *SEER Download Options* window appears.

Set the Download Options

1. Type the patient's last name in the *Last Name* text entry box.
2. Type the patient's first name in the *First Name* text entry box.
3. Set the hookup date and hookup time.
4. Set the *Download From* and *To* times.
5. Click *Start* to begin downloading data.

000102

View the Downloading

> You can scan an existing study while downloading data. You do not need to view the downloading progress.

The patient name, the hookup date and hookup time, the length of the data in minutes, and status appear in the *Patient Select* tool.

1. Locate the data for the patient being downloaded.
   The number of minutes of data for the patient's study appears under *Length*.
   The patient's *Status* changes from *% Acquired* to *Ready to Edit*.

> A 24-hour study is 1440 minutes in length.
> A 48 hour study is 2880 minutes in length.

> Wait until the status changes from *[% Acquiring]* to *[Ready to Edit]* to remove the SEER recorder from the SEER acquisition unit.

2. When the *Patient Select* window indicates the current patient's data is *Ready to Edit*, you may remove the recorder and connect another recorder to the SEER download cable.

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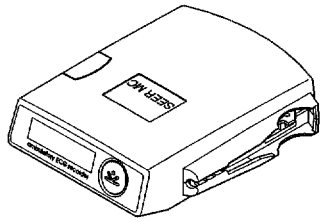
SEER MC Digital Analysis Recorder

The SEER MC recorder acquires and analyzes up to 48 hours of 2- or 3-channel ECG data. Data is downloaded to the workstation from a data card.



SEER MC recorder

MD1144-516A

Verify the Slots

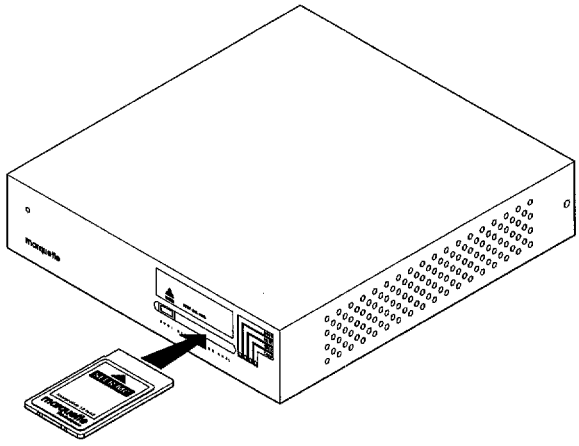
1. Open the *Patient Select* tool.
2. Verify that a slot exists in which to download the data.
   - *SEER* = SEER, SEER XT and SEER MC

> Click the *More Info* button to see which type of SEER a patient was downloaded from.

3. Click the right scroll bar arrow at the bottom of the *Patient Select* tool until the */slots* appear.
4. Verify that an appropriate slot for the data appears.
   - *s20.nat* = 20 MB card slot
   - *s8.nat* = 8 MB card slot

Insert the SEER MC Card

Insert the SEER MC data card into the SEER acquisition unit.
The SEER acquisition unit CARD light glows.
The *Data Card Download Options* window appears.



MD1144-517A

000104

Set the Download Options

1. Type the patient's last name in the *Last Name* text entry box.
2. Type the patient's first name in the *First Name* text entry box.
3. If desired, set the hookup date and hookup time.
4. If desired, set the *Download From* and *To* times or choose *Select Review first 24 hours only*
5. If desired, select *Erase card after download.*

> If you do not select the *Erase card after download* option, the card must be erased at the SEER MC recorder at the start of the next patient hookup.
>
> Erasing the card at the recorder creates a 2 - 4 minute delay and slightly depletes the recorder batteries.

6. Review the card information, including:
   - *Number of Holter ECG channels*
   - *Pacemaker mode*
   - *Hook up quality score*

> The SEER MC rates the hookup quality of each lead on a scale of 1 to 10, with 10 being the highest quality. The lowest hookup quality score of any of the leads appears in the *Data Card Download Options* window.
>
> Hookup quality scores below 6 may represent poor quality ECG data.

   - *Recorder tag number*
   - *Seer MC program version*
7. Click *Start* to begin downloading data.

View the Downloading

> You can scan an existing study while downloading data. You do not need to view the downloading progress.

The patient name, the hookup date and hookup time, the length of the data in minutes, and status appear in the *Patient Select* tool.

1. Locate the data for the patient being downloaded.
   The number of minutes of data for the patient's study appears under *Length.*
   The patient's *Status* changes from *% Acquired* to *Ready to Edit.*

> A 24-hour study is 1440 minutes in length.
> A 48 hour study is 2880 minutes in length.

000105

> Wait until the BUSY light on the SEER acquisition unit stops blinking before removing the SEER MC data card.
>
> This may take up to four minutes after the patient's status changes to *Ready to Edit.*

2. When:

   - the BUSY light on the SEER acquisition unit stops blinking, and
   - the *Patient Select* window shows the current patient's data as *Ready to Edit,*

   you may remove the MC card and insert another card into the SEER acquisition card slot.

000106

Downloading from a Bedside Monitor

Waveform data from a monitored patient is used for:

- immediate review by physicians and nurses
- acquiring data for Holter analysis

You can analyze acquired data from either admitted monitoring beds or discharged monitoring beds.

Verify the Slots

1. Open the *Patient Select* tool.
2. Select *Holter* in the *Data Type* list box.

> If using MARS to MARS communication, verify that you have available slots on the local workstation. The monitoring data will be copied from the target workstation and analyzed on the local workstation's hard drive.

3. Verify that an acquired bed slot exists in which to download the data.
   - *M28/x* = 28 hour/x number of channels
   - *M52/x* = 52 hour/x number of channels
4. Click the right scroll bar arrow at the bottom of the *Patient Select* tool until the */slots* appear.
5. Verify that an appropriate slot for the data appears.
   - *h28x.nat* = 28 hour/x number of channels
   - *h52x.nat* = 52 hour/x number of channels

Analyze the Patient Data

1. Select *Monitoring* from the *Data Type* list box.
2. Click the name of the patient whose file you want to analyze.
3. Click *Tools*.
4. Click *Analyze*.
5. Select the appropriate options on the *Download Options* screen, including:
   - *Analyze From* and *To* times
   - *Pacemaker Options*
   - *Channels to be analyzed*
   - *2X Gain on Channels*
6. Click *Start*.

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View the Downloading

You can scan an existing study while downloading data. You do not need to view the downloading progress.

1. If using MARS to MARS communication, select *Local* from the *MARS System* list box.
2. Select *Holter* in the *Data Type* list box.
   The patient data is analyzed according to the Holter algorithm.
3. Locate the data for the patient being downloaded.
   The number of minutes of data for the patient's study appears under *Length*.
   The patient's *Status* changes from *% Acquired* to *Ready to Edit*.

A 24-hour study is 1440 minutes in length.
A 48 hour study is 2880 minutes in length.

000103

Downloading from Another MARS Workstation

> MARS to MARS communication is a purchasable option that must be activated.

MARS to MARS communication uses the MARS non-realtime network or the Enterprise network to allow you to analyze and edit patient data residing on another (target) workstation basically as if it resided on your local workstation.

The local workstation is the workstation you will be using to edit the information. The target workstation is the workstation that contains the information you will be editing. Basically, the local MARS workstation "pulls" or "requests" data from the target workstation and places copies of it on the local workstation.

> The local workstation does not need to have the CRS option activated in order to view or analyze monitoring data on the target workstation.

The MARS to MARS communication option allows you to do different things based on the type of patient selected.

Table 3-1. Operations by Patient Type

Function	Holter	CRS Admitted	CRS Discharged
View patients on the target workstation or the local workstation.	X	X	X
Analyze patients on the target workstation or the local workstation.	X	X	X
Copy patients to the local workstation or to the local DAT drive.	X		X
Print reports to the printer selected on the local workstation.	X	X	X
Store the patient data to the MUSE, if you have the MARS to MUSE option.	X	X	X

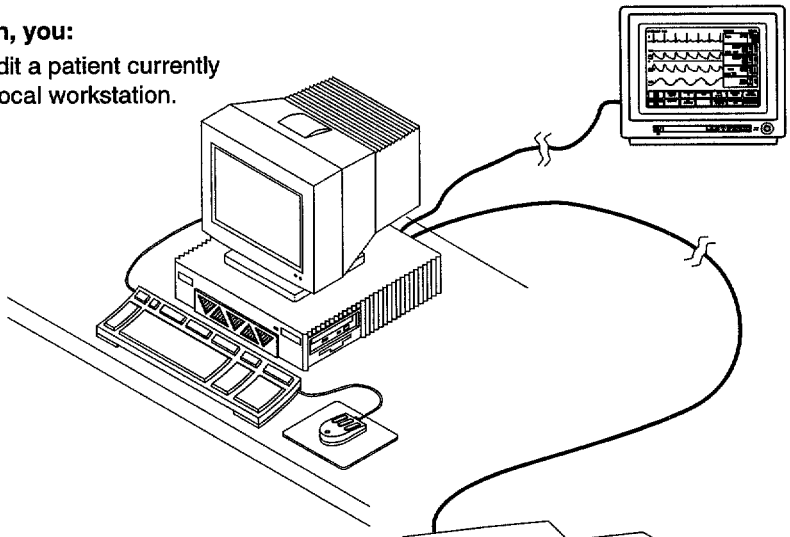
> The number of *Total Channels* and *Total Hours* set up for *Monitoring Beds* on the target workstation must be the same as those selected on the local workstation's *Acquired Beds*.

000109

Example of MARS to MARS Communication

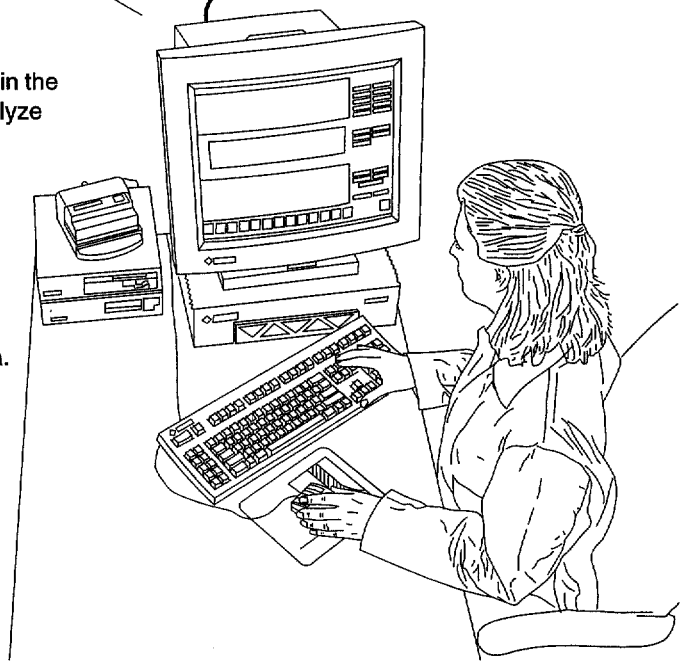
At the Target workstation, you:

- Cannot view or edit a patient currently selected by the Local workstation.



At the Local workstation, you:

- Can view or analyze any patient listed in the *Patient Select* list, but you cannot analyze target data.
- Can copy discharged monitoring patient data to the local workstation.
- Can copy target workstation's patient to the local workstation, to be edited, printed, and stored normally.
- Can reanalyze monitoring patient data.
- Cannot view the target workstation's DAT drive.
- Cannot reanalyze, delete or lock Holter patient data on the target workstation.
- Cannot delete or lock monitoring patient data on the target workstation.
- Cannot print to the target workstation's printer unless a network printer also defined on the local workstation.



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000110

Select the Data

1. Open the *Patient Select* tool.
2. Select the desired workstation from the *MARS System* list box.
3. From the *Data Type* list box, select the desired data type, including:
   - *Holter*
   - *Monitoring*
   - *Stored Reports*
4. Click the desired patient.
5. View, copy, analyze, print or store the data as desired.

Copy the Data to the Local Workstation

1. Click the name of the patient whose file you want to copy.
2. Click *Tools*.
3. Click *Copy to MARS*.
   A confirmation message appears listing the patient to be copied.
4. Click *Yes*.
   The *MARS -To-MARS Copy* progress bar appears and the patient status becomes *% Transferring*.
5. When complete, the following message appears:

   The file copy operation was successful.
6. Click *OK*.
   A copy of the patient's data now appears in the local workstation's appropriate selection.

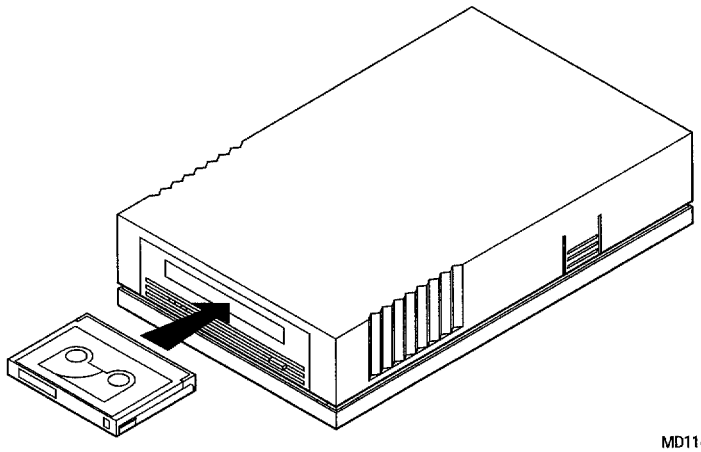
000111

Downloading from DAT Tapes

DAT tapes contain Holter ECG reports and patient files which were transferred from the workstation. Data can be analyzed or retrieved after it has been downloaded from the DAT tapes to the workstation.

Insert the DAT cartridge

Insert the DAT tape in the DAT tape drive.
Push the tape into the drive until it is drawn in and down by the DAT drive.



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When ready, the DAT drive Activity light glows green continually.

Select the Data

1. Click the *Patient Select* menu icon.
2. Click DAT in the *Data Type* list box.
3. Select the patient or patients you want to restore from DAT.

Restore the Data

1. Click *Tools*.
2. Click *Restore from DAT*. The following message appears:

   You have selected X file(s) for DAT restore.
   Are you sure you want to restore the selected file(s)?
3. Click *Yes* to restore a single patient or click *Yes to All* to restore more than one patient.
4. The DAT Activity light blinks for a few seconds and the following message appears:

   X file(s) queued for DAT restore.
5. Click *OK*.
   The workstation restores files to the following *Data Types*:
   - Tape, SEER or Monitoring Holter = *Holter*
   - Discharged Monitoring patient files = *Monitoring*
   - Report = *Stored Reports*

000112

The status of the selected file(s) changes from *Queued for Acq* to *% Acquired* and finally to *Ready to Edit.*

Eject the DAT Tape

1. Check that the Activity light is not glowing.

> Pressing the eject button while the Activity light is blinking may interrupt a tape access command.

2. Press the eject button.
   The Activity light flashes for about 30 seconds.
   The tape cartridge ejects.
3. Remove the tape cartridge.

000113

4 Scanning ECG Data

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168

000116

Before You Begin

This example uses the *MARS 8000-2* default menu.

Select a Patient

1. Click the *Patient Select* menu icon.
2. Click the arrow to the right of the *Data Type* list box in the control window to select the patient's data source.
   Each data source provides a list of patient names.

A *MARS System* list box and a *Data Type* list box are present if your workstation has MARS to MARS communication and if this feature was activated by the system administrator.

3. Click the patient name you want to review.
4. Verify that the desired patient's name appears in the title bar.

Enter Patient Information

1. Click the *Patient Information* menu icon.
2. Click the text box in which you want to enter information.
3. Type the information.
4. Use the up and down arrows to select date of birth and age.
5. Select the gender, race, and patient type from the list boxes.
6. Click the up and down arrows to set the hookup date and hookup time.
7. Click *Save.*
   A message appears confirming that your edits have been saved.
8. Click *OK.*
9. Click *Close.*

Enter the Patient's Symptoms and Activities

1. Click the *Patient Diary* menu icon.
2. Click the *Notes* button in the *Patient Diary* control window.

If entering symptoms or activities, do not use quotation marks.

3. Click the appropriate symptom or activity in the list which appears or type the symptom or activity in the text box.

000117

4. Use the up and down arrows to set the time and date the symptoms or activity occur.
5. Click *Save.*
   The *Strip Review* and *Page Review* tools update to the set date and time.

> A magenta exclamation point appears in the *Strip Review* tool:
>
> - whenever the patient pressed the patient event record button on the recorder, or
> - when a diary entry was entered by the user.

6. Repeat steps 3 through 5 for any additional symptoms or activities.
7. Click *Close.*

000118

Scanning ECG Data

This examples uses the *MARS 8000-2* menu.

For help in using the 3-part screen or moving through data, use the online tutorial.

Review the Shapes

Use the *Shape Review* menu icon to:

- review beats within templates
- relabel beats or templates

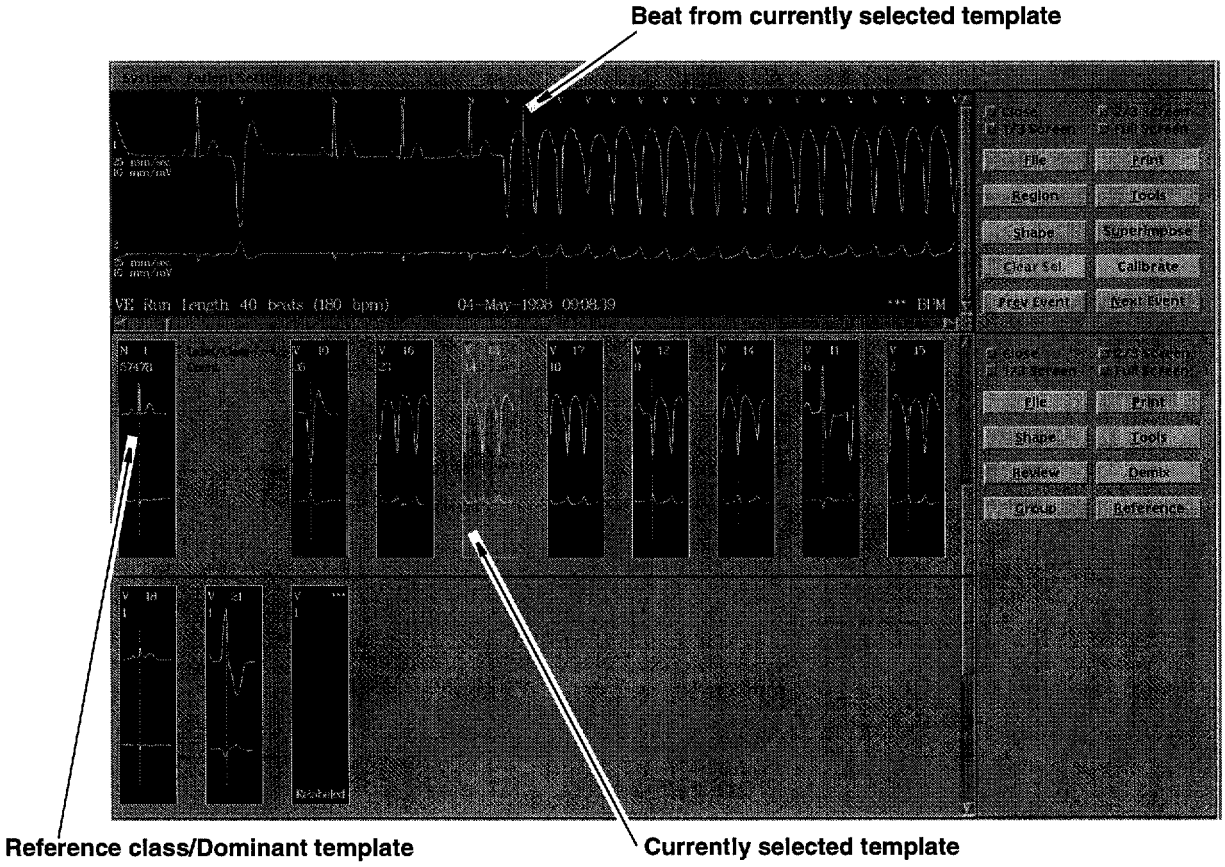
For each shape, review at least 1 to 10 beats.

000119

Open *Shape Review*

Click the *Shape Review* menu icon.

- the *Strip Review* tools opens at top 1/3 of the screen
- the *Shape Review* tool opens at bottom 2/3 of the screen



> Create regions to eliminate segments of noise, atrial fibrillation, or atrial flutter from the data analysis.
>
> See "Create Regions" for the steps to create regions.

Review the Shapes

> Click the *Group* button to review a list of all the template groups and how many templates were created for each group.

1. Click the template you want to review. The template turns gray.
2. Click *Review*.
3. Click *Next Beat* or *Previous Beat* to view beats within the template. The cursor in *Strip Review* updates to the next (or previous) beat
4. If necessary, relabel the beat or all the beats in the template.

000120

Relabel the Beats or Templates

Turn **Caps Lock** off (no green light glowing on the key) when relabeling with the keyboard.

Relabeling Beats

1. Select the beat or the beats you want to relabel.

If relabeling...	Then click...
a single beat	the **LEFT** mouse button. A green box outlines the selected beat.
multiple beats	the **MIDDLE** mouse button. Magenta boxes outline the selected beat(s).

2. Relabel the beat or the beats.

If using...	Then...
the mouse	1. Click the *Shape* button. 2. Click the button for desired beat label. 3. Click *Close*.
the keyboard	Press the key corresponding to the desired label. ■ Normal = **N** ■ Supraventricular = **S** ■ Ventricular = **V** ■ Artifact = **X** ■ Aberrant = **A** ■ Bundle Branch = **B** ■ Ventricular Escape = **E** ■ Ventricular Fusion = **F** ■ Idioventricular = **I** ■ Junctional = **J** ■ Dual Paced = **D** ■ Ventricular Paced = **P** ■ Atrial Paced = **@**

3. The outlined beat or beats changes to the new label.

The workstation underlines the relabeled beat labels.

000121

Relabeling Templates

1. Select the template or the templates you want to relabel.

If relabeling...	Then click...
a single template	the **LEFT** mouse button. The template's background turns light gray.
multiple templates	the **MIDDLE** mouse button. The selected templates': ■ background turns medium gray, and ■ becomes outlined with a green box

2. Relabel the template or the templates.

If using...	Then...
the mouse	1. Click the *Shape* button. 2. Click the button for desired template label. 3. Click *Close*.
the keyboard	Press the key corresponding to the desired label. ■ Normal = **N** ■ Supraventricular = **S** ■ Ventricular = **V** ■ Artifact = **X** ■ Aberrant = **A** ■ Bundle Branch = **B** ■ Ventricular Escape = **E** ■ Ventricular Fusion = **F** ■ Idioventricular = **I** ■ Junctional = **J** ■ Dual Paced = **D** ■ Ventricular Paced = **P** ■ Atrial Paced = **@**

File the Shapes

If uncertain about the label assigned to the beats in a template, file the shape. The number of beats in that template will be filed to the final report.

See "Filing Information" in this chapter for more information about filing.

Print the Shapes

See chapter 5, "Printing Patient Data" for more information about printing.

000122

Create Regions

In viewing the data, you may decide that an entire segment of data should be labeled as:

- noise that you want to eliminate from the data analysis, or
- atrial fibrillation or atrial flutter, or
- some other beat type.

> At least three beats must be included in the region for the system to calculate a heart rate.
> When a heart rate was not calculated for the strip displayed in the data area, ****BPM* appears in the lower right corner of the strip.

To create a region, you need to:

1. Select the *Show Regions* option.
2. Set the beginning and end of the region.
3. Label the region.

Select the *Show Regions* Option

1. In the *Strip Review* tool, click *Region* in the control window using the LEFT mouse button.
2. Select *Show Regions* to allow regions to be seen.

Set the Beginning and End of the Region

1. Using the RIGHT mouse button, click the beat that begins the region.
2. Using the LEFT mouse button, click *Start*.
   The start time appears in the box.
3. Click the horizontal scroll bar to move the strip forward in time to find the end of the region.
4. Click the beat that ends the region using the RIGHT mouse button.
5. Click *End* using the LEFT mouse button.
   The end time appears in the box and the region turns magenta.

Label the Region

If you want to relabel a region as...	Then go to...
Atrial fibrillation, Atrial flutter or Noise	"Relabeling Atrial Fib, Atrial Flutter and Noise"
any other beat type	"Relabeling Other Beats"

000123

Relabeling Atrial Fib, Atrial Flutter and Noise

Regions labeled as *Noise* are:

- eliminated from the analysis, and
- reported in the patient's final report as percent of total data.

Regions labeled as *Atrial Fibrillation* or *Atrial Flutter* are, reported in the patient's final report as percent of total data.

1. Click the label you want to apply.
   The region turns white.
2. Click *Close.*

Relabeling Other Beats

Use *Beat Relabel* if you want to relabel all the beats in a region as any of the following:

- Unknown
- Artifact
- Fusion
- Idioventricular
- Ventricular Escape
- Ventricular
- Questionable
- Bundle Branch Block
- Junctional
- Aberrant
- Supraventricular
- Paced Fusion
- Dual Paced
- Atrial Paced
- Ventricular Paced
- Normal

1. Click *Beat Relabel.*
   The *Select beat types to relabel* window appears.
2. Click the beat type of the beat that needs to be changed from the *From* list.

Selecting *All* from the *From* list will change all of the beats included in the region.

3. Click the desired beat type from the *To* list.

000124

4. Click *Ok*.
   The beats in the region change to the selected beat type.
   The *Select beat types to relabel* window closes.
5. Click *Close*.

Delete Regions

> Deleting regions does not delete actual data. It returns the regioned area to its original status.

1. Click on the desired white region.
2. Click the *Region* button.
   The selected region becomes magenta.
3. Click the *Delete Region* button.
   The selected region disappears.

000125

Review the Episodes

> This example uses the *MARS 8000-2* menu.

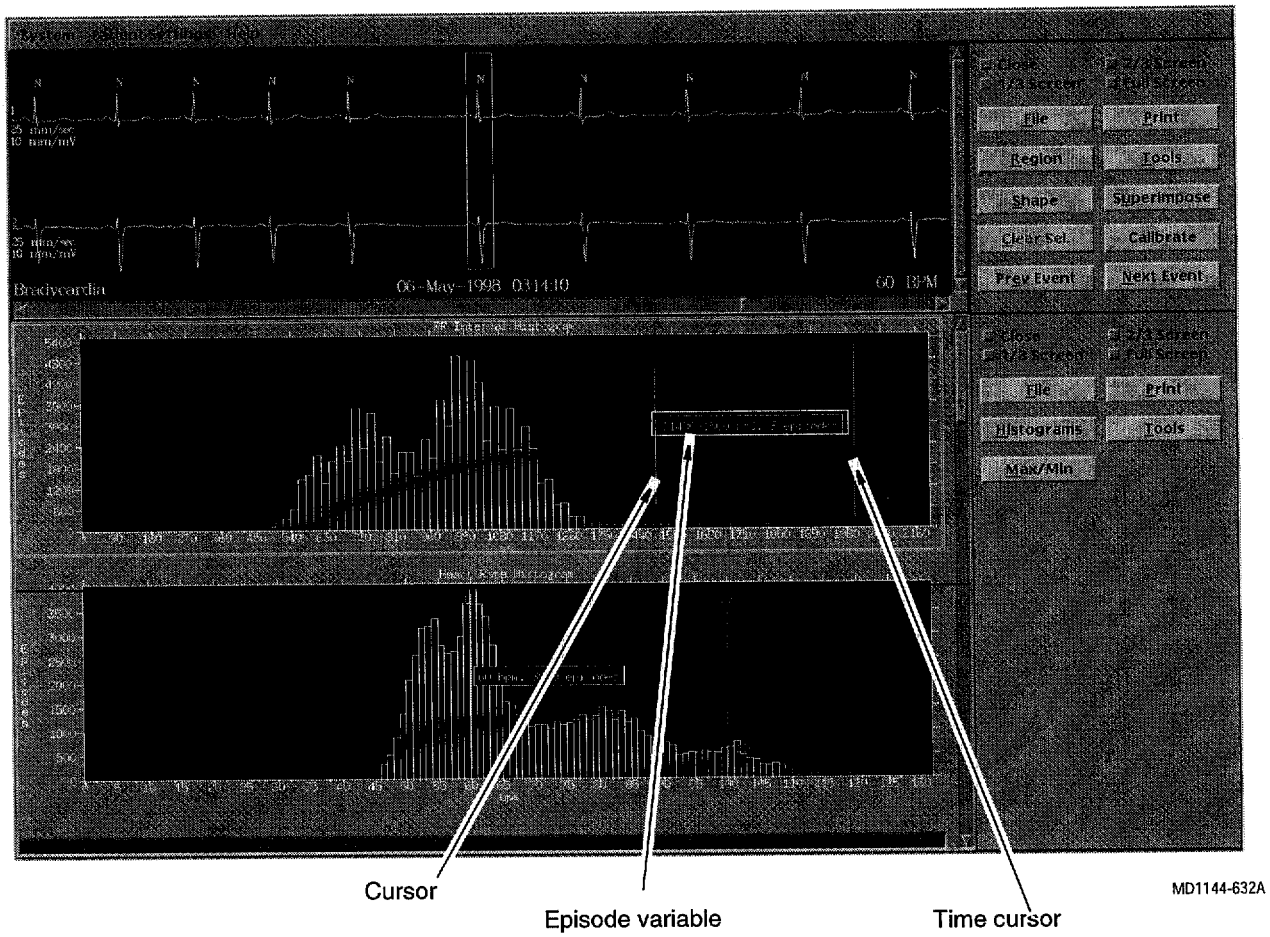
Use the *Episode Review* menu icon to review occurrences of specific cardiac events, including:

- *Heart rate*
- *SVE run length*
- *SVE run rate*
- *SVE bigeminy*
- *SVE trigeminy*
- *VE run length*
- *VE run rate*
- *VE bigeminy*
- *VE trigeminy*
- *VE quadrigeminy*
- *R-R interval*
- *N-N interval*
- *N-V interval*
- *R-R ratio*
- *N-N ratio*
- *N-V ratio*
- *Spike - QRS -Spike*

Open *Episode Review*

Click the *Episode Review* menu icon.

- the *Strip Review* tools opens at the top 1/3 of the screen
- the *Episode Review* tool opens at the bottom 2/3of the screen



000126

Review the Histograms

Review as many histograms or histogram groups as needed.
For example: Heart rate, R-R interval, VE runs.

Select the Histograms

Table 4-1. Methods of Selecting Histograms	
To...	**Then...**
View a specific histogram	1. Click *Histograms.* A list of histogram groups appears. 2. Click the histogram group you want to view. 3. Click *Select Histogram.* A list of histograms appears. 4. Click the histogram you want to view.
Scroll through the histograms using the mouse	Click above or below the slide bar in the scroll bar. or Click the up or down arrows in the scroll bar.

Edit the Histogram Limits

Setting the maximum and minimum values removes false episodes from data calculations. For example, invalid or false long R-R intervals are not included in heart rate calculations.

Use *Max/Min* to view and/or edit the current maximum and minimum limits of the histogram. The following options appear when you click *Max/Min:*

- *Maximum*
- *Minimum*
- *Lower*
- *Higher*
- *Set Min*
- *Set Max*
- *Unset Min*
- *Unset Max*

Setting Max/Min applies to the selected histogram.

For example: Setting maximum with the *Heart Rate Histogram* selected will update the maximum heart rate.

Changes to histograms may not appear updated on the screen, even though the data has been updated.

000127

180

Setting New Histogram Limit

1. Click the *Max/Min* button.

Table 4-2. Methods of Selecting Histograms	
To set a new...	**Then...**
maximum limit	1. Click *Maximum.* The histogram and strip display the waveforms for the maximum. 2. Click *Set Max* if correct *or* click *Lower* if the waveforms indicate that this is not the true maximum. The cursor in the *Episode Review* window moves to the left. 3. Repeat step 2 until the waveforms indicate a true maximum value. 4. Click *Set Max.*
minimum limit	1. Click *Minimum.* The histogram and strip display the waveforms for the minimum. 2. Click *Set Min* if correct or click *Higher* if the waveforms indicate that this is not the true minimum. The cursor in the *Episode Review* window moves to the right. 3. Repeat step 2 until the waveforms indicate a true minimum value. 4. Click *Set Min.*

2. Click *Close.*

Click *Unset Max* or *Unset Min* to undo an incorrectly set maximum or minimum value.

File the Histograms

File the new histogram and the associated strip showing the new setting.

See "Filing Information" for more information about filing.

Print the Histograms

See chapter 5, "Printing Patient Data" for more information about printing.

000128

Filing Information

Filing information adds the strip, page, histogram, shape, etc. to the final report. When you store the final report, the workstation stores the filed information.

If filing...	Then click the *File* button in...	Then...
strips	*Strip Review* tool	a 7-second strip is filed.
pages	*Page Review* tool	the page is filed.
shapes	*Shape Review* tool	the shapes displayed on the screen are filed.
histograms	*Episode Review* tool	the selected episode is filed. Also file the corresponding strip showing the setting.

- Type a comment in the *Enter Comment* text entry box.

Do not use quotation marks when typing comments.

- Click *File* button.

For filed information to appear in the final reports, include the *Filed information* report component in the report.

000129

Setting SVE Prematurity Criteria

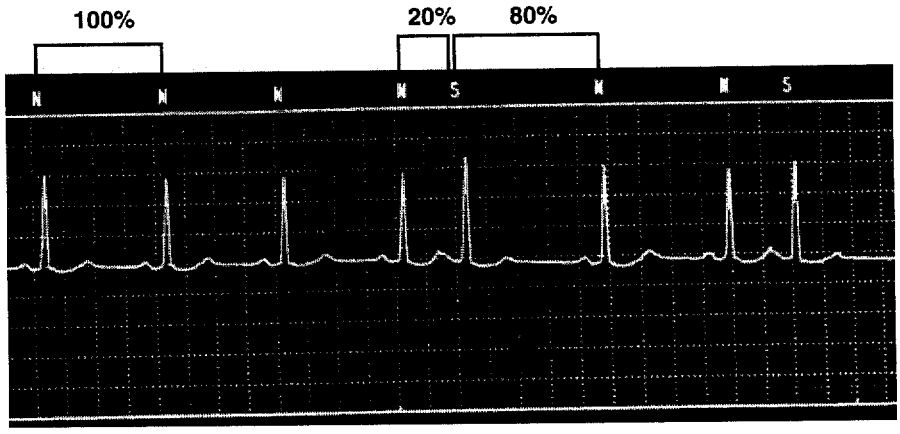
Understanding SVE Criteria

Basic Calculations

The MARS workstation's basic SVE prematurity calculation uses the previous four N-N intervals, based on the location of the cursor. It compares the average of these four N-N intervals to the current interval. If that interval exceeds the user defined SVE prematurity criteria, the workstation labels the beat supraventricular. Otherwise, the workstation labels the beat Normal.

Criteria Percentages

Additionally, the workstation labels a beat as supraventricular when the beat occurs within the first 80% of the average R-R interval. If the beat occurs within the last 20% of the average R-R interval, the workstation calls the beat normal. This is referred to as meeting a 20% default prematurity criterion. The following graphic illustrates beats labeled according to this criterion.



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For the majority of the population, 20% prematurity criterion works well to identify supraventricular ectopy. However, there may be some patients for whom the criteria does not work well. When this occurs, follow the steps below for changing incorrectly called SVEs.

Exclusions

The workstation excludes a N-N interval from the calculation of SVEs if any of the following apply:

- either beat is in an user-specified region of atrial fibrillation, atrial flutter, or noise
- a region of noise occurs between the two beats
- the N-N interval is longer than the user defined maximum
- the N-N interval is shorter than the user defined minimum
- the N-N interval is 1.5 times longer than the four beat average
- the N-N interval is longer than the user defined pause criteria

000130

The workstation treats excluded intervals as if they did not exist.

The workstation restarts the four beat average anytime it encounters atrial fibrillation or atrial flutter. The workstation ignores ventricular beats, noise regions, etc. for SVE criteria purposes. These do not affect the four beat average. Thus, the four beat N-N intervals can span several interruptions.

Additionally, waveforms with voltages lower than the mean voltage may cause some beats to not be counted.

User Edits

The workstation does not override user edited beats. A beat you label as N will not be changed by the workstation. Likewise, a beat you label as S will remain an S until you change it.

Possible Suspect Rhythms

Some examples of rhythms that may require SVE adjustment include:

- sinus arrhythmia
- marked sinus arrhythmia
- brady-tachy syndrome
- 2nd and 3rd degree heart blocks

Correcting False SVEs

If areas of ECG data contain beats that are falsely labeled SVE, use the following five steps to correct the false SVEs.

> You may not relabel *Normal* templates *Supraventricular* or *Supraventricular* templates *Normal*.
>
> Only individual beats can be relabeled.

Table 4-1. Steps to Correct False SVEs

Step	For more information, go to...
1. Edit the study, including: ■ Region areas of noise ■ Review shapes ■ Label unlabeled beats	■ "Create Regions" ■ "Review the Shapes"
2. Set the maximum R-R interval	"Review the Episodes"
3. Set the Minimum R-R interval	"Review the Episodes"
4. Review the runs of SVE using: ■ Histograms, ■ Trends or ■ SVE Editor	■ "Review the Histograms" ■ "Relabeling SVEs Using SVE Editor"
5. Set the SVE prematurity criteria.	"Relabeling SVEs Using SVE Editor" or "Changing Patient Event Definitions"

000131

184

Relabeling SVEs Using SVE Editor

You will find the *SVE Editor* menu icon in *MARS 8000-2* and *MARS 8000 ST2* default menus.

1. Click *SVE Editor.*
   The tool opens displaying 1/3 *Strip Review* and 2/3 *Event Diary.*
2. Click *Events* in the *Event Diary* control window.
3. Click *Clear All.*
   All the events listed in the *Event Review* window disappear.
4. Click *Supraventricular (S,J,A).*
   The *Event Definitions* control window appears.
5. Click *Set All.*
   Only SVE episodes appear in the *Event Review* window.
6. Click the *SVE Prem* text box.
7. Delete the current percentage.
8. Type a different percentage prematurity in the text box.

If you have...	Then...
overcalled SVEs	Increase the *SVE Prem* value by 5% at a time.
undercalled SVEs	Decrease the *SVE Prem* value by 5% at a time.

9. Click *Set All* or press the **Tab** key.
   The workstation recalculates and relabels beats based on the new prematurity criteria.
10. If necessary, repeat steps 6 through 9 until the patient's study reaches the appropriate level of SVE activity.
11. Click *Close.*
12. Click *Close.*

Relabeling SVEs by Changing Beat Labels

You can correct individual runs or episodes of incorrectly called SVE by correctly labeling the first three or four beats.

See "Relabel the Beats or Templates" for more information about relabeling shapes.

Changing SVEs by Changing Event Definitions

You can correct incorrectly called SVE by changing the SVE criteria on the *Patient: Event Definition Settings and Analysis Results* window.

See "Changing Event and Analysis Options" for more information about changing Event Definitions.

000132

Changing Patient Settings

Changing Patient Event Definitions

The *Patient: Event Definitions Settings and Analysis Results* window allows you to change event and analysis options for the current patient.

Changing Event and Analysis Options

To change the *Event Definitions* for the current patient only:

1. Click *Patient Settings* in the menu bar.
2. Click *Event Definitions* in the dropdown menu.
   The *Patient: Event Definitions Settings and Analysis Results* window appears.
3. Set the appropriate event definitions and analysis results parameters for the current patient. .

> Press the **Del** key to delete the current criteria.

If you want to...	Then...
Decrease SVE calls	Increase the *SVE Prem* value by 5% at a time.
Increase SVE calls	Decrease the *SVE Prem* value by 5% at a time.

4. If desired, click *File* to save the *Event Definitions* to the current patient's final report.
5. When finished making adjustments, click *Close*.

Changing Event Severity

To change the severity of the patient's events:

1. On the *Patient: Event Definitions Settings and Analysis Results* window, click *Event Severity*.
   The *Patient: Event Severity Settings* window appears with the current events listed with the most severe at the top.
2. Select the events from the list.
3. Set the severity by using the Up or Down buttons to adjust the event in the list.
4. When finished adjusting the severities, click *Close*.

000133

Changing the Patient's Heart Rate Setup

The *Patient Setting Heart Rate* option allows you to select which type of beats you want to include, or ignore, in the heart rate calculation.

For example, if you do not want the longest SVE run to appear as the maximum heart rate, ignore supraventricular beats so that only the normal beats within a sinus rhythm are included in the maximum heart rate calculation.

When the *Heart Rate* setup for the system does not apply to the current patient, change the setup as follows:

1. Click *Patient Settings* in the menu bar.
2. Click *Heart Rate.*
   The *Patient: Heart Rate Settings* window appears.
3. Click the desired morphology from the either the *Beats Included* or the *Beats Ignored* lists.
4. Click the arrows to move beats between the *Beats Included* and the *Beats Ignored* lists until the beats you want included for the current patient's heart rate calculations appear in the *Beats Included* list.
5. Click *Close.*

000134

Demixing Morphologies

Understanding Demixing

The MARS workstation's *Demix* feature provides a graphic method of discerning mixed morphologies within shapes and then correcting the mixed morphologies. After the workstation demixes morphologies, it creates new shapes that can be relabeled if necessary.

How Demixing Works

During the processing and analysis of Holter data, the workstation performs millions of mathematical calculations to measure, compare and classify the QRS complexes found in the study. The workstation reviews all waveforms (P waves, QRS complexes, T waves and noise) in its attempt to find and differentiate the various QRS shapes present.

For a 24 hour study, the workstation may need to review approximately 100,000 QRS complexes.

On occasion, severe baseline wander, abnormally tall T waves or extreme variations in the morphology of QRS complexes, the workstation may experience "mixing".

Proper patient preparation and hookup reduces the likelihood of mixing.

Recognizing Mixing of Morphologies

Evidence of mixing may be seen in an abnormally high heart rate caused by T waves or artifact being used in the calculations. Also, reviewing shapes, trends or histograms allows you to see evidence of potential mixing by displaying beats with clearly incorrect labels.

Occasionally, episodes of ventricular or supraventricular rhythms seen in trend or episode review are caused by artifact, normal beats or T waves being mixed into the ventricular shape classes.

000135

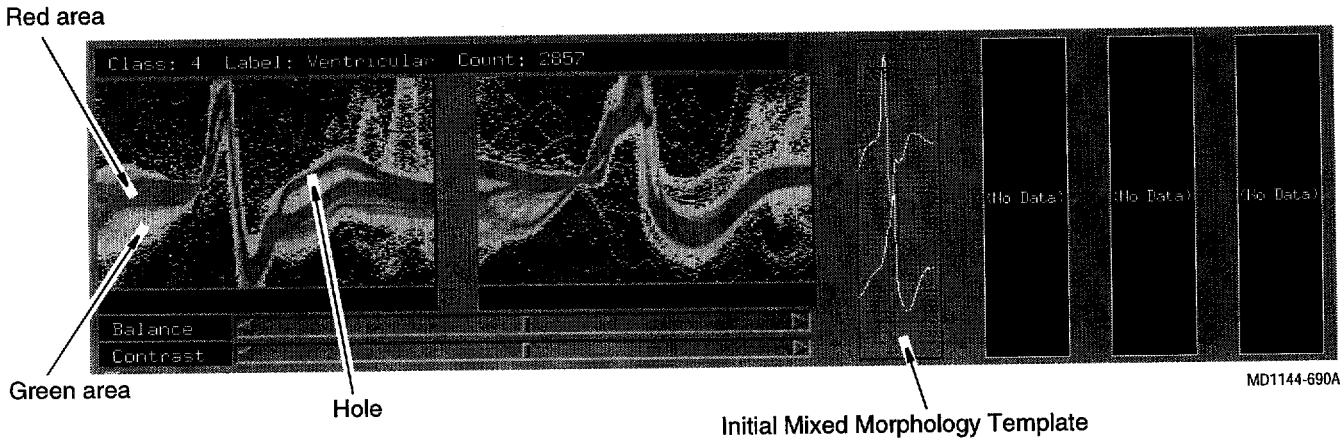
168

Understanding Mixed Shapes

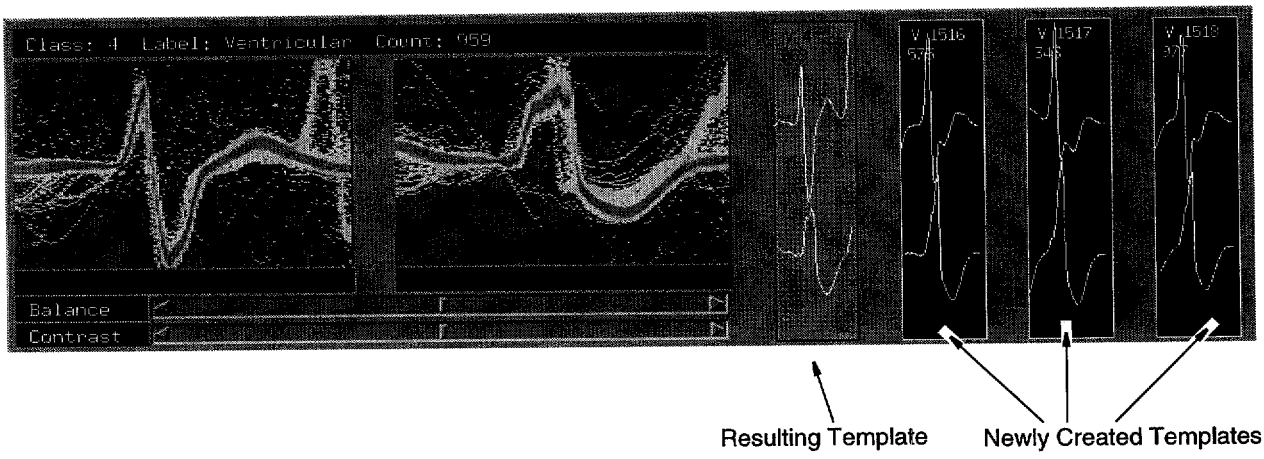
The *Demix* feature overlays the individual members of a shape class one on top of the other. Red elements (as they appear on the screen) signify areas of the various waveforms that match perfectly. Green elements and green dots represent variations of the shapes.

Often, the area of greatest difference in the QRS or T wave appears as a "hole" where the green variations or blue background shows through.

Example of a Mixed Class



Example of a Demixed Class



000136

Using Demix

This example uses the *MARS 8000-2* default menu.

1. Click the *Shape Review* menu icon.
   The Strip Review tool window appears at the top of the screen as 1/3.
   Two *Shape Review* tool windows open. One appears as 1/3 at the bottom of the screen. A second *Shape Review* window opens on top of the first at 2/3.
2. On the 2/3 sized *Shape Review* tool window, click 1/3.
   The two *Shape Review* tool windows appear as 1/3.
3. On the bottom *Shape Review* tool window, click on the suspect shape class.
4. On the middle *Shape Review* tool window, click the *Demix* button.
   The workstation runs a comparison of all members of the shapes in the selected class.
   When comparing, two colored composite waveforms appear representing the members of the class in both channels.
5. Click on the area of greatest difference in the QRS or T wave.
   Often, the area of greatest difference appears as a "hole" where the blue background shows through.
6. Click the *Manual Demix* button.
   The workstation reanalyzes the shapes and creates a separate template for the new shape class.
7. Check the demixed shape and the newly created shape to verify that no more mixing appears.
8. Repeat steps 5 through 7 until satisfied all the morphologies have been displayed.
9. Relabel the resulting shapes.

See "Relabel the Beats or Templates" for more information about relabeling shapes.

000137

5 Printing Patient Data

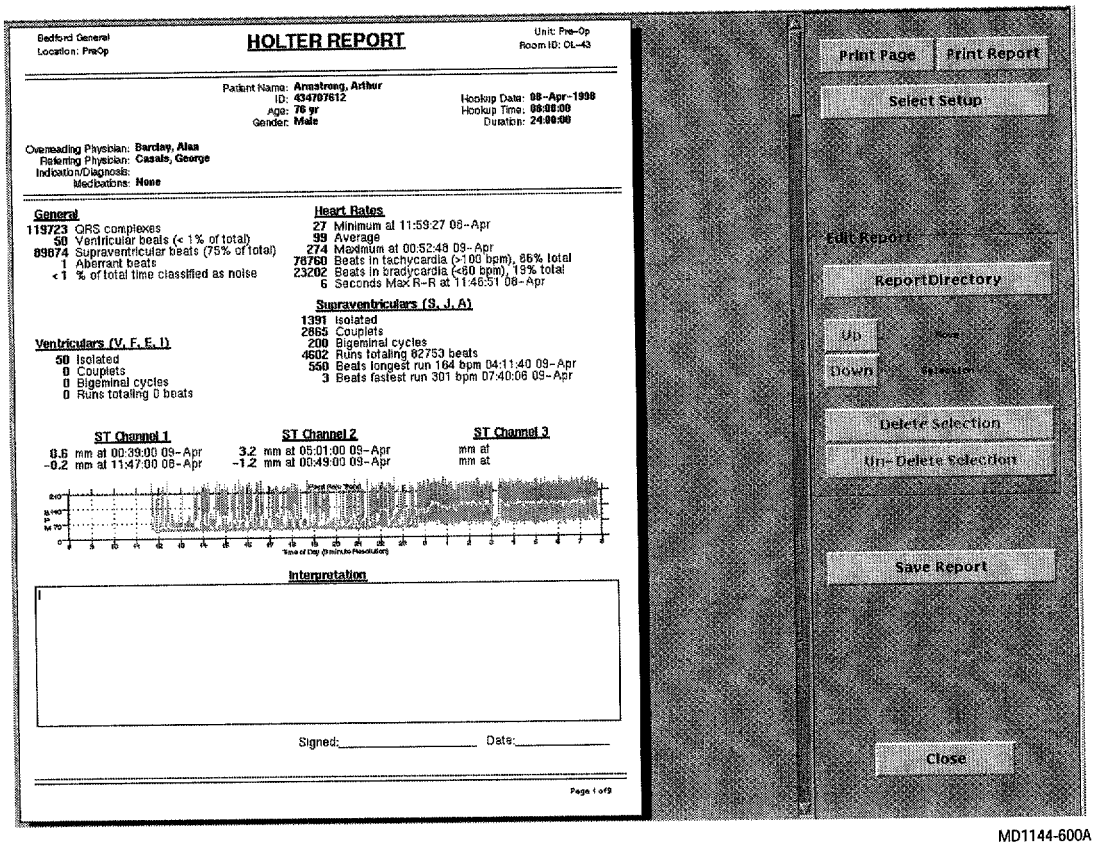
000139

Printing Final Reports

In addition to printing only the data in a data window, you can print formatted reports. *Report Review* allows you to edit the report, print the entire report or print just one page

Open the *Report Review* Tool

1. Click the *Report Review* menu icon to open the tool.
   A screen similar to the following appears.



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Select a Report Setup

If desired, select a different report setup.

1. Click *Select Setup* to select a report format.
   A list appears with the final report formats as set up in *System Setup* by the system administrator.
2. Click the desired report setup.
   An asterisk (*) appears at the end of the selected report setup.
3. Click *Close*.

000141

Print the Report

Printing All of the Report

1. Click *Print Report.*
   The following message appears:

   Background printing selected. To print this report click continue. The current patient's data cannot be edited while the report is printing.

   > To print the report immediately and prevent the above message from always appearing, select *Don't tell me about this again.*

2. Click *Continue.*

Printing a Single Page

1. Scroll to display the page you want to print.
2. Click *Print Page.*

Magnify Portions of the Screen

1. Click in the area you want to magnify using the RIGHT mouse button.
2. Click in the same area with the RIGHT mouse button to return the area to its original size.

Edit the Strip

You may edit the appearance and composition of filed and report component strips.

1. Click anywhere on the strip.
   A secondary window opens.
2. Modify any of the following components:
   - *Channel Settings*
   - *Waveform setup*
   - *Strips Per Page*
3. Click *Update.*
4. Click *Exit* when finished editing all the desired strips or components.

000142

195

Edit the Full Disclosure Data

- Click anywhere in the full disclosure waveform data of the report.
  The setup options appear.

Table 5-1. Options for Editing Full Disclosure Data

To...	Procedure
Set the Duration	Click the up and down arrows to set the time you want the report to begin and to end: ■ Right arrows control minutes. ■ Left arrows control hours.
Select the Channels	Click appropriate check boxes to select the channels you want to view. The channel choices displayed depend on the slot setup for the number of channels selected and the order of the leads.
Select the Format	■ Click the up or down arrow to set the minutes you want displayed on each page. ■ Click the up or down arrow to set the seconds you want displayed on each row.
Save the Changes	Click *Update* to update the screen. The screen refreshes momentarily. A revised page appears on the screen. The *Update* button becomes inactive until you make further changes. As soon as you change any option, the button becomes active.

Save the Report

1. Click *Save Report* to save the final report on the hard drive.
   A confirmation window appears showing the location and name of the stored report file.
2. Click *OK* to close the confirmation window.
3. Click *Close* to close *Report Review.*

See chapter 6, "Storing Patient Data" for the steps to store reports to the MUSE CV information system or to DAT.

000143

Printing from Tools

Using the *Print* Button

Click *Print* in the tool's control window.
The following print options appear:

- *Print Now*
- *Page Builder*

Using *Print Now*

Click *Print Now.*
The data window prints immediately.

> The printout of data from an active tool contains only the data displayed in the data window.
>
> For a complete report of the data, you must print a report.

> See "Printing Final Reports" for more information about printing reports.

Using *Page Builder*

1. Click *Page Builder* in the tool's control window.
   - The workstation sends the data from the chosen tool to the *Page Builder* icon.
   - If no data is recorded in a tool, the icon remains blank.

No Data Waiting to Print

Data Waiting to Print

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2. Click the *Page Builder* icon.
   - The icon turns black for a brief moment; then it turns white.
   - The printout displays data from the chosen tool, lists the name of the patient, the room number, and the unit the patient is assigned to.
3. When you select a different patient, all print requests for the previously selected patient are automatically printed.

> *Clicking the Page Builder* adds strips or pages to *Page Builder* and can hold up to three strips before printing. Adding a fourth strip causes *Page Builder* to print.
>
> Click the *Page Builder* icon to print immediately.

000144

Using the *Print Report* Button

The *Patient Select* tool *Tools* provides a *Print Report* button. For Holter or monitoring patient data, *Print Report* will print the report using:

- the user's currently selected report setup, or
- any modified setting (i.e., deleted or rearranged components)

For stored reports, *Print Report* will print the report like it with whatever settings and information that was stored.

1. Open the *Patient Select* tool.
2. Click the *Tools* button. The *Strip Tools* appear.
3. Select patient or patients to be printed.

To select more than one patient at a time:

- Click and drag the mouse pointer over the desired patients, or
- Hold down the **Shift** key as you click with the LEFT mouse button on the first and then last patient you want to select. The first patient, the last patient and all patients in between will be selected. or
- Hold down the **Control** key as you click with the LEFT mouse button to select individual patients.

Up to 25 patients may be selected at a time.

4. Click *Print Report.*
   The following message appears.

   You have selected <selected number of files> file(s) for printing? Are you sure you want to print these files?

5. Click *Yes* if printing a single report or *Yes to All* to print all the selected reports.
   The following message appears.

   <selected number of files> reports queued for printing.

6. Click *OK.*
7. Click *Close.*
   The status in *Patient Select* changes to *Queued for Print.* As the files print, the statuses change to *Printing* and then to *Printed.*

000145

000146

6 Storing Patient Data

000147

000148

Storing Data to DAT

Copy Data to a DAT Tape

If your workstation is equipped with a DAT drive, you can copy data to a digital audio tape (DAT) for long term storage. .

> If using DAT for long term storage, make multiple copies of the patient data you want to store.

> Do NOT exceed more than 100 patient records per DAT tape.

1. Insert the DAT tape in the DAT tape drive.
   Push the tape into the drive until it is drawn in and down by the DAT drive.
2. Click the *Patient Select* menu icon.
3. Click the arrow next to the *Data Type* list box. A list of data sources appears.
4. Click the data source you want to copy to a DAT tape:
   - *Holter* = Holter data
   - *Monitoring* = realtime CRS data
   - *Stored Reports* = final reports
5. Select the patient or patients you want to copy to DAT.

> To select more than one patient at a time:
> - Click and drag the mouse pointer over the desired patients, or
> - Hold down the **Shift** key as you click with the LEFT mouse button on the first and then last patient you want to select. The first patient, the last patient and all patients in between will be selected. Or
> - Hold down the **Control** key as you click with the LEFT mouse button to select individual patients.

6. Click the *Tools* button.
7. Click *Copy to DAT*. The following message appears:

   You have selected X files to copy to DAT.
   Are you sure you want to copy these files.
8. Click *Yes* to copy a single patient or click *Yes to All* to copy all selected patients.
9. The DAT Activity light blinks for a few seconds and the following message appears:

   X file(s) queued for DAT storage.

000149

10. Click *OK*.
    The status of the selected patient(s) changes to *Queued for DAT*, then *% Copied to DAT*, and finally to *Copied to DAT*.

000150

Storing Data to MUSE CV

MARS to MUSE CV communication requires the site and location information on the MARS corresponds to the information set up on the MARS workstation.

See "Setting Up the Sites and Locations" in chapter 8, "Setting Up the Workstation".

MARS unity workstation to MUSE CV information system communication allows you to transfer MARS stored reports from the MARS workstation to the MUSE CV for viewing, editing and storage at the MUSE. All transfers are done over the network.

Save the Report

The MUSE stores MARS stored reports only. Stored reports do not contain full disclosure or template data.

See "Saving the Report" in chapter 5, "Printing Patient Data" for the steps to save a report.

Store the Report to MUSE

1. Click the *Patient Select* menu icon.
2. Click the arrow next to the *Data Type* list box. A list of data sources appears.
3. Click *Stored Reports.*
4. Select the patient or patients you want to store to the MUSE.

To select more than one patient at a time:

- Click and drag the mouse pointer over the desired patients, or
- Hold down the **Shift** key as you click with the LEFT mouse button on the first and then last patient you want to select. The first patient, the last patient and all patients in between will be selected. Or,
- Hold down the **Control** key as you click with the LEFT mouse button to select individual patients.

5. Click *Tools.*
6. Click *Store to MUSE.* The following message appears:

000151

You have selected X file(s) to for MUSE storage.
Are you sure you want to store the selected file(s) to MUSE.

If storing...	Then click...
one patient	*Yes*
more than one patient	*Yes to All*

7. The following message appears:

   X reports(s) queued for storage to MUSE.

8. Click *OK*.
   The status of the selected patient(s) changes to *Queued for MUSE*, then *Storing to MUSE*, and finally to *Stored to MUSE*.

View and Save the Stored Reports on the MUSE

The MARS stored reports appear as Holter reports on the MUSE Edit List. They may be printed or stored at the MUSE CV system.

000152

7 Using the Clinical Review Station

000153

Managing Patient Data

Introduction

Depending on your hardware, you can view data from up to 64 beds. This includes both monitored and discharged beds. Patient data from discharged beds remains available for viewing for a period of time. The length of time data remains available depends on your unit's patient admission and discharge rates.

Because the MARS CRS has a limited amount of storage space, "old" discharged patient data must be removed from the workstation to allow for the storage of "new" patient data.

Select the Beds to View

Use *Select Bed* to choose the beds the CRS workstation will view.

For more information about *Select Bed*, see chapter 8, "Setting Up the Workstation."

Select a Patient

1. Click the *Patient Select* menu icon.
   The *Patient Select* tool opens.
2. Click *Monitoring* in the *Data Type* list box.

A *MARS System* list box and a *Data Type* list box are present if your workstation has MARS to MARS communication and if this feature was activated by the system administrator.

3. Click the patient name you want to review.

Bed numbers with an asterisk at the end of their name have data coming from a telemetry source, rather than from a hard-wired bedside monitor.

Sorting Patient Data

1. Click the *Tools* button.
2. Click *Sort.*
   The *Select sort method* window appears.
3. Select the desired sort method, including:
   - *Patient name*
   - *Time*
   - *Status*
   - *Unit*
4. Click *Close.*

000155

Admit a Patient

Admit patients at the bedside monitor or a telemetry unit.

When admitted to the bedside monitor and/or a telemetry unit, the patient automatically appears *Admitted* at the CRS workstation. The workstation monitors and stores up to 52 hours of ECGs and multiparameter waveforms for that patient.

Discharge a Patient

Discharge patients at the bedside monitor or a telemetry unit.

When discharged from the bedside monitor and/or a telemetry unit, CRS workstation places a discharged file for the patient on the CRS workstation. Data from discharged beds remains available for a limited period of time. How long that data remains available depends on your unit's admission and discharge rates. Data from discharged beds can be reviewed by the CRS workstation or analyzed as Holter data on a MARS unity workstation.

Transfer the Patient's Data to Another Bed

When a patient is transferred to a different bed in the same unit or to a bed in another unit on the CRS system, you can transfer the patient's data to the new bed. Transfer the stored data to the new bed and begin appending newly acquired data to the transferred data.

At the Bedside/Telemetry Unit

At the bedside monitor and/or a telemetry unit, discharge and readmit the patient.

At the CRS

1. Select the patient from the *Patient Select* tool.
2. Click the *Tools* button.
3. Click *Transfer*.
   A message appears in the control window.

If transferring data from...	Then this message appears...
an admitted bed	*Transfer patient information from* _____ *to* unit/bed/name
a discharged bed	*Transfer patient information from* unit/bed/name to _____

4. Click the bed number to which you want to transfer the patient's data.
   The bed name replaces the dashed line.
5. Click *OK*.
   The following message appears in the control window

000156

"THIS OPERATION IS NOT REVERSABLE. PLEASE CONFIRM AGAIN"

6. Click *OK.*
   It may take up to 30 seconds or more to perform the transfer.
   The data area reverts to the previous screen.

Delete the Patient's Data

You may want to delete patient data when:

- You know you will no longer collect data from that patient.
- The *Patient Select* list is crowded with names of discharged patients.

> The CRS workstation automatically deletes the data representing the oldest discharged bed when it needs a slot for a new admitted patient.

> Only discharged patient's may be deleted.

1. Select the desired patient from the *Patient Select* tool.
2. Click the *Tools* button.
3. Click *Delete.*
   The following message appears:

   "THIS OPERATION CANNOT BE REVERSED. PLEASE CONFIRM AGAIN."
4. Click *Delete.*

000157

Enter Patient Information

1. Click the *Patient Information* menu icon.
2. Click the text box in which you want to enter information.

> Admitted or discharged monitoring patient names may not be edited using *Patient Information*. Change the name at the bedside monitor.
>
> Analyzed the data as a Holter. The patient name may be edited then.

3. Type the information.
4. Click the up and down arrows to select date of birth, age, gender, race, and patient type.
5. Click the up and down arrows to set the hookup date and hookup time.
6. Click *Save*.
   A message appears confirming that your edits have been saved.
7. Click *OK*.
8. Click *Close*.

000158

Reviewing Patient Data

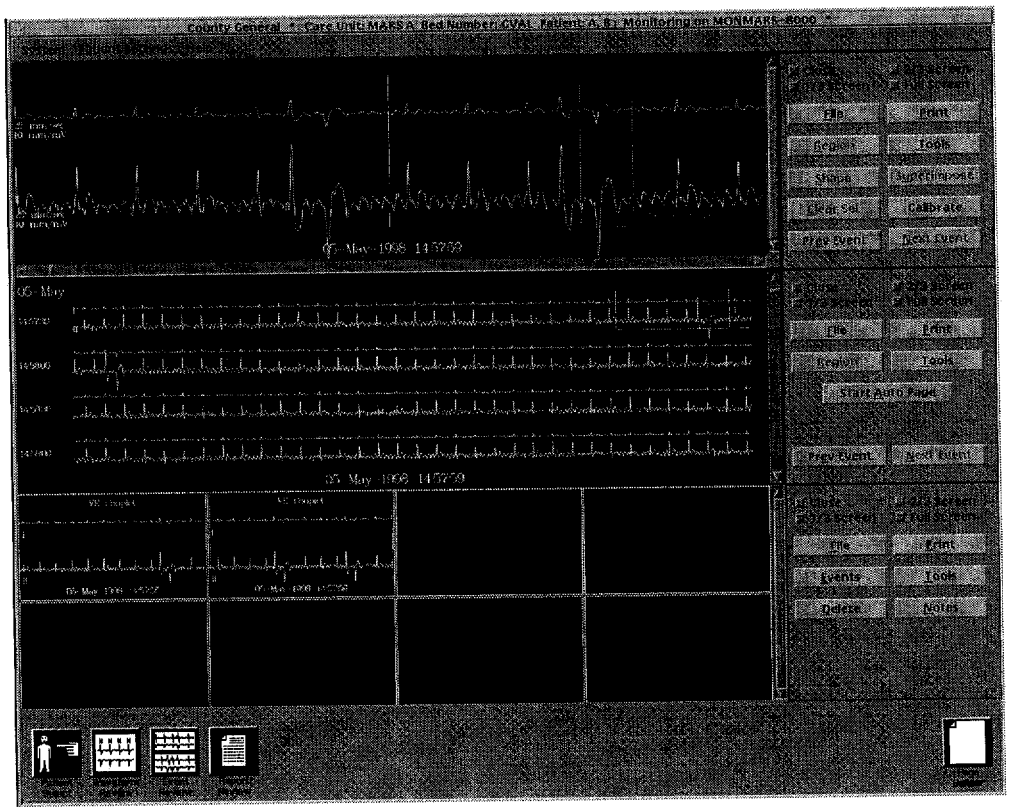
> This example uses the default *CRS* menu and its *Waveform Review* menu icon.

Waveform Review provides a quick method of reviewing events and the data surrounding those events.

Open *Waveform Review*

Click the *Waveform Review* menu icon.
The following tools open:

- *Strip Review* tool at 1/3 (top)
- *Page Review* tool at 1/3 (middle)
- *Event Review* tool at 1/3 (bottom)



MD1144-630A

000159

Viewing Waveform Data

Click an event in the *Event Review* tool. A green box outlines the selected event, and the:

- *Strip Review* tool shows a 10 second strip with the event in the center of the data window.
- *Page Review* tool shows a time cursor with the same 10 seconds in relation to the surrounding data.

Change the Appearance of Data

Strip Review tool, *Page Review* tool and *Event Review* tool allow the waveform data to be displayed in a number of different ways. The waveform data in each tool may be displayed differently.

1. Click the *Tools* button in the desired tool.

Table 7-1. Adjusting Waveform Displays with the *Tools* button

To change the...	Then...
Waveforms to view	The number of channels or waveforms available for display depends upon the initial setup. If the system is set up for the maximum number of beds, waveforms will be limited to two. 1. Click the desired channel. 2. Click the arrows to move between *Display* and *Don't Display* columns. 3. Click the *Up* and *Down* buttons to set the order in which you want the channels to appear.
Number of waveforms to view in a single strip window	Depending on the number of channels displayed, *Strip Review* tool can display the selected number of waveforms in a single window. ■ Click the arrows to set the number of *Chans/Screen*.
Gain and Offset	1. Click the arrow to the right of the gain text box to display the options. 2. Click the desired gain. 3. Click the up and down arrows to select the offset.
Time scale	Using the *Strip Review* and *Page Review*: 1. Click the arrow to the right of the *Time Scale* list box to display the options. 2. Click the desired time scale.
Grid	Using the *Strip Review*: 1. Click the arrow to the right of the *Grid* list box. 2. Click the desired grid format.
Cursor types	Using the *Strip Review*: Click the box next to the desired cursor type. ■ Cursor: Provides a green line where you click the left mouse button. The date and time of that point appears at the bottom of the window. ■ Calipers: The calipers can be moved by clicking and dragging the small boxes at the bottom of the calipers. ■ Tic Marks: Marks the width of the calipers.
Time Focus	1. Click the up and down arrows to select the date and time to which you specifically want to view. 2. Click *Set*.

2. Click *Close*.

000160

Move Through Data

Click in the tool you want to move through.

Table 7-2. Methods of Moving Through Data

To...	Then...
Automatically page through the study	Using the *Page Review* tool: ■ Click the *Start Auto Page* button in the control window of *Page Review*. The *Start Auto Page* button changes to the *Stop Auto Page* button. The page continuously advances in time, allowing you to scan the data. ■ Click the *Stop Auto Page* button when you want to stop scanning the page.
Move one line at a time	Using the *Strip Review* tool and *Page Review* tool: ■ Press the up arrow or down arrow key to move one line at a time.Or, ■ Click the up and down arrows in the scroll bar.
Move one page at a time	Using the *Page Review* tool: Press **page up** or **page down** on the keyboard to move one page at a time.
Scroll through the data using the mouse	■ Click above or below the slide bar in the scroll bar. Or, ■ Click the up and down arrows in the scroll bar.
Move backward and forward in time	■ Click to the left or to the right of the slide bar in the scroll bar.Or, ■ Click the left and right arrows in the scroll bar.
View more rows of events	For *Event Review* tool. Press **page up** or **page down** on the keyboard to more rows of events.

Manage Events

Table 7-3. Managing Events

To...	Then...
Select the events to display	1. Click the *Events* button. 2. Click the desired type of event to appear, including: ■ *Crisis* ■ *Warning* ■ *Advisory* 3. Define the types of events included in each class of event at the bedside monitor and/or telemetry unit.
Select the number of events to display	1. Click the *Events* button. 2. Click the *Max per event* arrows to set the number of each class of events that will appear.
Delete events	1. Using the MIDDLE mouse button, click the desired event or events. 2. Click the *Delete* button. A confirmation message appears. 3. Click *Yes*. The selected event or events are deleted.

000161

File the Data

Filing data adds the strip, page, event, etc. to the final report. When you store the final report, the workstation stores the filed information.

> For filed information to appear in the final reports, include the *Filed Information* report component in the report.

If filing...	Then click the *File* button in the...	Then...
strips	*Strip Review* tool	a 7 second strip is filed.
pages	*Page Review* tool	the page is filed.
event	*Event Review* tool	all the miniature event strips visible in the i data window are filed.
shapes	*Shape Review* tool	the shapes displayed on the screen are filed.
histograms	*Episode Review* tool	the selected episode is filed. Also file the corresponding strip showing the setting.

- Type a comment in the *Enter Comment* text entry box.
- Click *File* button.

Print the Data

> See chapter 5, "Printing Patient Data" for more information about printing.

000162

8 Setting Up the Workstation

000163

General Setups

Introduction

All MARS workstations require setup. This section describes setups that Holter, CRS and combo (Holter and CRS) workstations use.

Back Up the Settings

After making any changes to the system settings, you should back up your system settings.

See "Back Up Your Settings" in this chapter for the steps to back up your settings.

Setting Up the Slots

The workstation places acquired (Holter and monitoring) data into files called "slots". In order to have the proper combination of slots for the types of files you will be using, you must create them.

Slot Setup must be done BEFORE the system acquires data.

When creating slots, any existing data will be erased. If desired, copy the data to DAT tape.

You must have system administrator privileges to set up slots.

After setting up slots, CRS workstations must select the beds to be monitored using *Select Beds*.

Determine the Slot Parameters

If using MARS to MARS communication to acquire beds from Monitoring, the local workstation must have the same number of channels and Total Hours selected as the target workstation has selected for *Monitoring Beds*.

If using CRS or combo and changing the number of channels (Total Channels) or the channels monitored or not monitored, manually record the channel information before creating slots.

000165

Before setting up slots, determine what you need for each of the following parameters and record that information in the spaces provided below:

> For version 4.1, you will need to set the minimum number of discharged beds.
>
> For version 4.0a, four slots have been reserved for discharged beds.

_____ Maximum Number of Admitted† or Monitored Beds

_____ Total number of hours (28, 52, 76†, or 100†)

_____ Number of channels (1 – 8)

_____ Minimum Number of Discharged Beds†

_____ Maximum Number of Analyzed† or Acquired Beds

List of Monitored Channels in order of priority:

_____, _____, _____, _____, _____,

_____, _____, _____, _____, _____

_____ Number of 24-hour tapes

_____ Number of channels (1 – 3)

_____ Number of 48-hour tapes

_____ Number of channels (1 – 3)

_____ Number of SEERs or SEER XTs

_____ Number of SEER MC 8Meg cards

_____ Number of SEER MC 20 Meg cards

_____ Number of SEER MC 40 Meg cards†

† = Available on version 4.1 only

Open the *Slot Creation Setup*

1. Log in as the admin user.
2. Click *System* on the menu bar.
3. Click *System Setup.*
4. Click *Slots.*
   The *System: Slot Creation Setup* window appears.

000166

Set Up the Admitted or Monitoring Bed Slots

In order to see patient data from the bedside monitors, set the maximum number of beds to be see on the network.

- Version 4.0a calls these *Monitored* beds.
- Version 4.1 calls these *Admitted* beds.

1. Click the arrows to set the maximum number of desired slots.
2. Click the arrows to set the number of *Total Channels* to be monitored.
3. Click the arrow by the *Total Hours* list box to set the number of total hours monitored
4. Select the desired monitored parameters.
   - Click the left or right arrow to add or remove the parameter from the desired list box.

Based on the number of *Total Channels* selected for *Monitoring Beds*, if a lead fails for more than 10 seconds, the next available parameter in the *Monitored Channels* is displayed.

5. Set the priority of the selected monitored parameters.
   - Click the desired parameter.
   - Click *Up* or *Down* to move the parameter up or down in priority.

Set Up the Discharged Beds

A certain number of beds will be reserved for holding discharged patient's data:

- Version 4.0a reserves 4 beds.
- Version 4.1 allows you to set a minimum number of discharged beds.

Click the arrows to set the minimum number of desired discharged slots.
The values for *Total Channels* and *Total Hours* appear for *Discharged Beds*.

000167

Set Up the Acquired or Analyzed Beds

> In order to perform Holter analysis on monitoring patient data, set the maximum number of beds to use for Holter data acquisition/analysis.
>
> - Version 4.0a calls these *Acquired* beds.
> - Version 4.1 calls these *Analyzed* Beds.

Click the arrows to set the number of desired slots.
The *Total Channels* and *Total Hours* values appear for *Acquired Beds* or *Analyzed Beds.*

Set Up the Tape, SEER, and SEER MC Slots

1. Select the quantities and types of slots desired. For each type of slot, click the arrows to set the number of desired slots.
2. For 24-hour tapes and 48-hour tapes slots, click the *Total Channels* arrow to set the total number of channels acquired.

> Do not create more than 100 Holter (24-hour tape, 48-hour tape, SEER and SEER MC) slots.

Create the Slots

1. Click *Apply.*
   The following message appears:

   About to REPLACE the current patient slot files. WARNING! - ALL current patient data will be REMOVED, Continue?
2. Click *Continue.*
   The following message appears:

   About to REPLACE the current patient slot files. WARNING! - ALL current patient data will be REMOVED, Continue?
3. Click *Continue.*
   The following message appears:

   Slot creation about to begin
4. Click *OK.*
   The percentage of progress appears in the *Slot Creation Progress* indicator.

   When the *Slot Creation Progress* indicator reaches 100%, the following message appears:

   Slot creation and channel selection completed successfully. Rebooting the workstation.
5. Click *OK.*
   The workstation boots.
6. Login at the password text entry box.

000168

Selecting the Units and Beds to Acquire Data

When selecting beds to acquire data, be aware that the CRS stores data from both hard-wired bedside monitors and telemetry units. You should include every available hard-wired monitor and every telemetry device in your unit when you set up the system.

1. Click *System* on the menu bar.
2. Click *System Setup.*
3. Click *Select Bed.*
   The *System: Select Beds Setup* window appears.
4. Click the name of a care unit to select it.
5. Select a bed.

> Bed names with an asterisk (*) are telemetry beds.

Selecting Beds Using the Mouse

1. Click the bed name in the *Don't Monitor* list to select it.
2. Click the left arrow to move the name from the *Don't Monitor* list to the *Monitor* list.
3. Click *OK* when finished choosing beds to be monitored.

Selecting Beds Manually

1. Click in the *2. Type in bed name* text box located under *Manual Entry Procedure.*
2. Type the name of the bed in the text box.
3. Click *Add Bed.*
4. Click *OK* when finished entering beds to be monitored.

000169

Setting Up the Sites and Locations

Site setup is necessary if you are planning to transfer Holter data to a MUSE cardiovascular information system.

> Ensure that the locations and site numbers correlate with the sites and locations used on the MUSE CV information system.
>
> Contact the MUSE system owner to verify the information.

Site information appears in:

- the application title bar next to the currently selected patient name
- *Patient Information* Tool window
- Patient Demographics report component in *Report Review*

> You must have system administrator privileges to set up sites.

Open the *Site Setup*

1. Log in as the admin user.
2. Click *System* on the menu bar.
3. Click *System Setup.*
4. Click *Site.*
   The *System: Site and Locations Setup* window appears.

Set Up the Sites and Locations

1. Click in the *Site #* text box.
2. Type number of the site where the Holter data from this system will be stored on the MUSE system.
3. Click in the *Site Name* text box.
4. Type the name of your facility or hospital.
5. Click the arrow by the *Location #* text box.
6. Click the appropriate number on the pulldown list.
7. Click in the *Location Name* text box.
8. Type your location name.
9. Click *OK.*
   A *Confirmation* window appears.
10. Click *Continue.*
11. Click *OK* when the message appears that confirms successful completion of the site setup changes.

000170

Setting Up the Users

Use the *System: User Setup* window to create new users and to enter the names, passwords, and preferences for all workstation users.

> You must have system administrator privileges to set up and view information for all users.
>
> All other users can set up and view only their individual user information.

> The default user name and password of all other users is:
>
> - *User Name*: mei
> - *Password*: mei
>
> DO NOT change this default user information! All system users can log into the system with this name and password.

Create a New User

1. Login as the admin user.
2. Click *Users* on the *System Setup* menu.
   The *System: User Setup* window for the system administrator appears.
3. Click *New User.*
   A new window appears with *newuser* in the *User Name* text entry box.
4. Click the *First Name* text entry box.
5. Type the user's first name.
6. Click the *Last Name* text entry box.
7. Type the user's last name.
8. Type the new user's name in the *User Name* text entry box. This is the name the user must type when logging into the system.
9. Type the new user's password in the first *Password* field.

> Do NOT leave the *Password* field blank. Type a password in the *Password* field.

10. Type the same password in the second *Password* field.

000171

Select the User's Menus

The user's menus appear in a list box labeled *User Menu List.*

Adding Any Additional Menus

Double click on the desired menu on the *Master Menu List.* The selected menu appears in the user's *User Menu List.*

Removing Any Undesired Menu

1. Click on the undesired menu.
2. Click the *Remove Menu From User Menu List* button.

Select the User's Language

1. Click the language you want in the *Language* list box.
2. Only one language may be assigned to a particular user. However, users may change their language whenever they desire by using the *User* window.

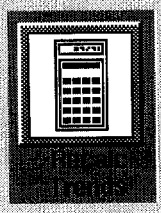
> Software activators need to be set up in the language used. If using a language other than English, set the software activators after selecting the language.

Select the *Auto Recalc* Preferences

Click *On* or *Off* for *Auto Recalc.*

For optimum system performance:

- *Auto Recalc* is *On* [the default for MARS 8000 (RU), MARS 8000 (HK), MARS 5000 (RT) and MARS 3000 (RS)]. The system automatically recalculates *Trends* and *Histograms* to reflect the changes.
- *Auto Recalc* is *Off* [the default for MARS 8000 (HG) and MARS 5000 (HT)]. The system DOES NOT recalculate *Trends* and *Histograms* as beats are relabeled. Instead, a *Recalc Trends* icon appears at the bottom of the display.



MD1144-633A

To recalculate all *Trends* and *Histograms*, click this icon one time when you want to see the updates.

000172

Save the User's Information

1. Click *Save Changes.*

If you are...	Then go to...
adding more users	"Create a New User".
NOT adding more users	step 2.

2. Click *Close.*

000173

Selecting a Printer

> Only the admin user, can change printer options (such as duplex, tray 2, or A4 paper settings). These options only apply to network printers.

1. Click *System* on the workstation menu bar.
   The *System* pulldown menu appears.
2. Click *System Setup* on the pulldown menu.
   The *System Setup* pulldown menu appears.
3. Click *Printer Manager* on the pulldown menu.
   The *User: Printer Settings* window appears.
4. Click the desired printer from the *User: Printer Settings* list box.
5. Click *Close.*
   The *User: Printer Settings* window closes.

000174

Backing Up and Restoring Settings

Back Up Your Settings

Back up your settings regularly.

This backups all of the workstation's system and user settings.

Store the backup in a safe place for emergency use.

1. Login as admin.
2. Click *System.*
3. Click *System Setup.*
4. Click *Backup and Restore.*
   The *System Setup Backup/Restore Tool* window opens.
5. Click *Backup System Setups.*
6. Click *Apply.*
   After a few seconds, a message appears.
   Follow the steps on the message to label your backup diskette.
7. Click *Continue.*
   Another confirmation message appears.
8. Click *Continue.*
   The status of the backup appears in the window.

   After a few minutes, the floppy diskette ejects and the following message appears:

   The backup was successful.
   Store the diskette in a safe place.
   Ensure you perform a backup of the system setups whenever you change the workstation setups.
9. Click *OK.*
   The *System Setup Backup/Restore Tool* window closes.

000175

Restore Your Settings

> **i** You will typically only need to restore your setting after a drive rebuild or an exchange.

1. Login as admin.
2. Click *System.*
3. Click *System Setup.*
4. Click *Backup and Restore.*
   The *System Setup Backup/Restore Tool* window opens.
5. Click *Restore System Setups.*
6. Click *Apply.*
   The following message appears:

   Place backup diskette you wish to restore from into the diskette drive and select Continue.
7. Insert the desired backup diskette into the floppy diskette drive.
8. Click *Continue.*
   A message appears listing the workstation and date and time of the backup on the floppy diskette you inserted.

If the backup is...	Then...
correct	1. click *Continue.* 2. Go to step 8.
incorrect	1. click *Exit.* The floppy diskette ejects. 2. Go to step 2.

   The following message appears:

   Are you sure you want to apply this backup?
9. Click *Continue.*
   After about 15 minutes, the following message appears:

   The restore completed successfully. Rebooting the workstation.

If the above message...	Then...
appears	click *OK.*
does not appear	the restore failed. Contact the MARS unity workstation Technical Support line at: ■ 1-800-558-7044 (for calls from within the United States), or ■ 1-561-575-5000, ext. 4243 (for international calls).

10. Click *OK.*
    The workstation reboots.
11. Login as usual.

000176

Appendix A: Using HRV

000177

Introduction

Overview

The *Heart Rate Variability* option is not for sale in the United States.

Before using the HRV tool, you should accurately edit the entire 24-hour Holter recording because mislabeled beats can cause inaccurate measurements of HRV.

Heart rate variability is the recurrent changes in R-R intervals characteristic of a balanced cardiac control mechanism.

Intended Use

For help in using the 3-part screen or moving through data, use the online tutorial.

Use the *Heart Rate Variability* tool to:

- analyze heart rate variability and display the results as a spectral analysis and time domain
- measure and report heart rate variability (HRV)
- review HRV measurements interactively
- adjust the parameters used to compute HRV measurements

Use the *Heart Rate Variability* tool:

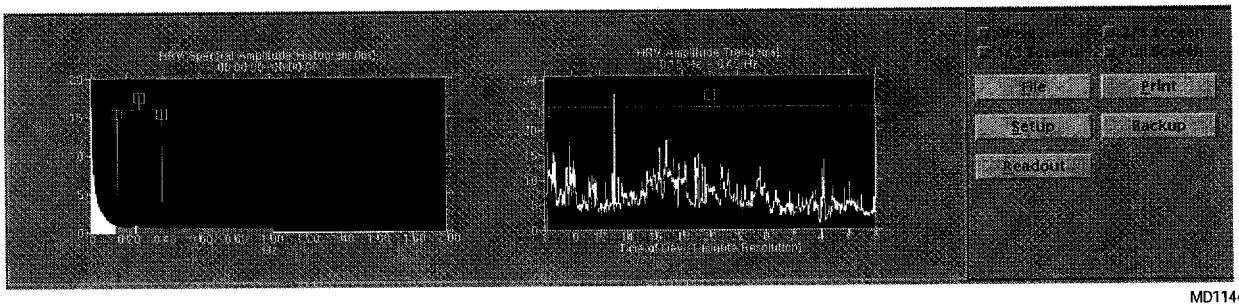
With...	To...
Strip Review tool	review HRV spectra and file strips
Report Review tool	display HRV spectra and trends and to print time domain measurements
Episode Review tool	investigate interval lengths and ratios

000179

Opening HRV

Open *Heart Rate Variability*

Click the *Heart Rate Variability* menu icon. A screen similar to the following appears.



MD1144-615A

000180

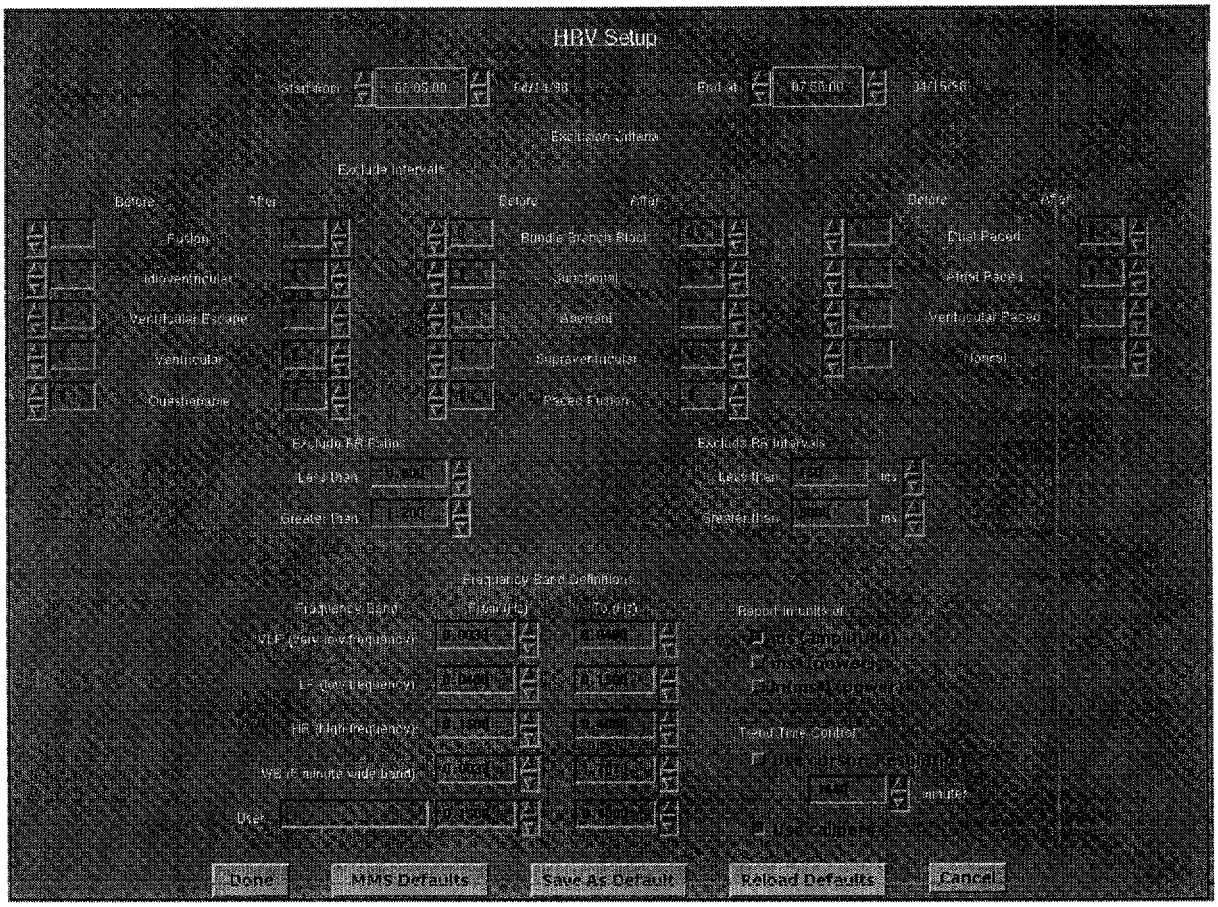
Setting Up HRV

Set Up the Data Parameters

The *Heart Rate Variability* tool lets you choose what data will be displayed. You can change the:

- period of time analyzed
- exclusion of R-R intervals based on:
  - beat type
  - R-R interval length
  - R-R interval ratios
- units for reporting the data
- user interface for the time trends control
- frequency band definitions

Click *Setup.*
A screen similar to the following appears.



MD1144-617A

000181

Set the Analysis Time

You can limit the time range for spectral analysis time domain measurements.

To set the...	Then click the...
start time (first minute of the spectrum)	*Start from* arrows
end time (last minute of the spectrum)	*End at* arrows

> Because of the way the workstation processes data, the first minute a spectrum can be computed is five minutes after the hookup time and the last is five minutes before the end of the tape.
>
> For example:
> If the patient is hooked up at 8:00 and 1440 minutes of data are recorded, the HRV analysis program sets the *Start from* time to *8:05* and the *End at* time to *7:55*.

Set the Exclusion Intervals for Beat Types

As a default, the only beats used in the calculations are beats labeled normal and bundle branch block.

Click the up and down arrows to set the *Before* and *After* interval for each of the following beat types.

Fusion	Bundle Branch Block	Dual Paced
Idioventricular	Junctional	Atrial Paced
Ventricular Escape	Aberrant	Ventricular Paced
Ventricular	Supraventricular	Normal
Questionable	Paced Fusion	

For example:

If intervals are...	And exclusion intervals are set to...	Then the excluded intervals are...
N N N N V N N N N	Before After 1 Ventricular 1	 N N N N V N N N N
N N N N V N N N N	Before After 2 Ventricular 2	 N N N N V N N N N

000182

Set the Exclusion Range for R-R Ratios

Click the up and down arrows of *Less than* and *Greater than* text boxes to set the range for the R-R ratios.

The R-R ratio is the ratio between two consecutive intervals that have not already been excluded.

Use the *Episode Review* tool to determine the appropriate values. The R-R ratio should be set so that sinus beats are included but premature ectopics and escape ectopics are excluded.

Set the Exclusion Range for R-R Intervals

Click the up and down arrows of *Less than* and *Greater than* text boxes to set the maximum and minimum range for the R-R intervals.

> Only intervals not excluded because of beat type are used in the calculations.
>
> When beats are excluded, a cubic spline process interpolates the R-R intervals using the surrounding R-R intervals.

Set the Time Intervals for Analysis

You can adjust the time interval for the data in the HRV Power Trend by using either the cursor or the calipers.

To view a...	Then...
fixed spectra time quantity	1. Click the check box next to *Use cursor.* 2. Click the up and down arrows by the minutes box to set a time interval.
flexible spectra time quantity	Click *Use calipers*

Set the Units for Reporting the Data

Click the check box next to the unit you want to use for reporting, including:

- power (ms^2)
- natural log of power (ln (ms^2))
- amplitude (ms)

> GE Marquette Medical Systems uses the five-minute 1024 point Fast Fourier Transform calculations with detrending to compute spectral density. Computations are done using floating point arithmetic.

Set the Frequency Band Definitions

Modify the frequency band definitions by clicking the up and down arrows to the right of each text box.

000183

The following table lists the GE Marquette Medical Systems default ranges.

Frequency Band	Range (in Hz)
Very low frequency	0.0033 to 0.0400
Low frequency	0.0400 to 0.1500
High frequency	0.1500 to 0.4000
5-minute wide band	0.0033 to 1.7070
User	0.1500 to 0.4000

Do not select a frequency of 0.0000-0.0033 Hz (ULF). Incorrect results occur if you use this frequency.

Save the Settings

To...	Then click...
Save the currents as the default settings	*Save As Default*
Use the MMS default settings	*MMS Defaults*
Return to the workstation defaults after making changes	*Reload Defaults*

Exit the *HRV Setup* Screen

To...	Then click...
view the results of the Fast Fourier Transform calculations	*Done*
exit without saving your changes	*Cancel*

The first time you calculate HRV using either *Report Review* or *HRV*, those changes remain as long as the patient file is open. Additional calculations do not appear.

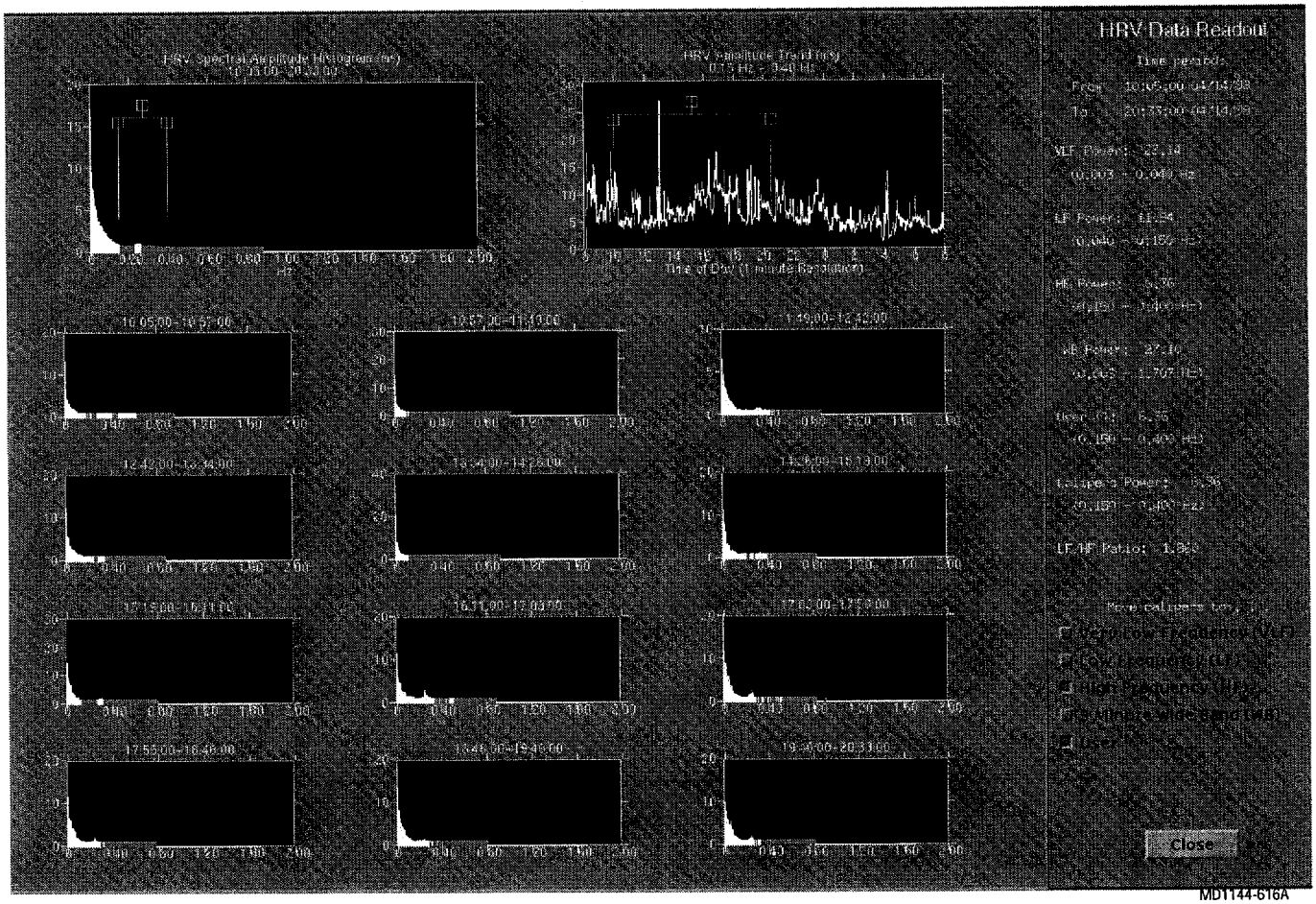
To work around this feature, change to another patient, then go back to the desired patient.

000184

Reviewing the Analysis

Review the Spectral Analysis

1. Click *Full Page* in the control window.
2. Click *Readout.*
   A screen similar to the following appears.



MD1144-616A

File the Data

Do NOT use the *File* button.

Add the HRV report component of *Report Review* to get the desired information.

Print the Data

You cannot print the data in the *HRV Data Readout* window.

You must write down the information so you can refer to it.

For more information about printing, see chapter 6, "Printing Patient Data".

000185

238

View Time Domain Measurements

Click the *Report Review* menu icon.
The calculations for the time domains appear on the first page of the report when the HRV report is selected.

See chapter 5, "Printing Patient Data" for more information about reports.

The time domain measurement computes various indices not directly related to specific cycle lengths. Calculations of the mean R-R interval and standard deviation of the mean offer a set of simple numbers to differentiate patients with diminished variability.

The following time domain measurements are available:

Time Domain	Description
Mean NN	Average of all intervals between normal beats EXCLUDING: ■ ectopy or noise intervals ■ intervals exceeding a user-specified longest and shortest NN interval
SSNN	Standard deviation of intervals of all normal beats. Reflects variability within 5-minute periods above 0.0033 Hz.
SDANN	Standard deviation of 5-minute mean R-R intervals. Sensitive to the lowest frequencies of heart rate variability.
ASDNN	Mean of 5-minute standard deviations of intervals.
rMSSD	Root mean square of the difference of successive R-Rs. Sensitive to the highest frequency components of heart rate variability.
pNN50	Percentage of intervals more than 50 ms different from the previous interval. Sensitive to the highest frequency components of heart rate variability.
pNN50a	Percentage of intervals more than 50 ms longer than the previous interval.
pNN50b	Percentage of intervals more than 50 ms shorter than the previous interval.
BB50	Count of intervals more than 50 ms different from the previous interval.
BB50a	Count of intervals more than 50 ms longer than the previous interval.
BB50b	Count of intervals more than 50 ms shorter than the previous interval.

000186

Modify the Frequency Bands

1. Click *Readout.*
   The *HRV Data Readout* window appears.
2. Click the appropriate check boxes to adjust the calipers.
   The calipers in the *HRV Amplitude Trend* graph move.
   Data is recalculated and the *HRV Data Readout* changes.
3. Click *Close.*

Restore the Heart Rate Parameters

Click *Backup.*
The system returns either to the previous settings or to the previous caliper adjustments.

000187

Appendix B: Maintenance

000189

Introduction

Recommended Maintenance

For detailed information about maintenance, see the appropriate filed service manual:

- "MARS unity workstation field service manual (R Series)," PN 408287-068.
- "MARS unity workstation field service manual (H Series)," PN 408287-050.

Maintenance/Repair Log

A "Maintenance/Repair Log" is included in this appendix to aid in keeping a record of the work done on the unit.

Unless you have an Equipment Maintenance Contract, GE Marquette Medical Systems does not in any manner assume responsibility for performing the recommended maintenance procedures. The sole responsibility rests with the individual or institution using the equipment. GE Marquette Medical Systems service personnel may, at their discretion, follow the procedures provided in this manual as a guide during visits to the equipment site.

000191

Workstation - Inspecting and Cleaning

Inspecting the Workstation

Perform a visual inspection daily. Turn off the unit and disconnect from power before making an inspection or cleaning the unit. If you notice any items that need repair, contact an authorized service person to make the repairs.

- Check the case and display screen for cracks or other damage.
- Inspect all cords and cables for fraying or other damage.
- Inspect all plugs, cables, and connectors for bent prongs or pins.
- Verify that all cords and connectors are securely seated.
- Inspect keys and controls for proper operation.
  - Toggle keys should not stick in one position.
  - Knobs should rotate fully in both directions.

> Properly shutdown, turn off the unit and disconnect from all power before inspecting or cleaning.
> Do not immerse any part of the equipment in water.
> Do not use organic solvents, ammonia-based solutions, or abrasive cleaning agents which may damage equipment surfaces.

Cleaning the Workstation

Clean the workstation as described below.

Exterior Surfaces

Clean the exterior surfaces once per month, and more frequently if needed, with a clean, soft cloth and a mild dishwashing detergent diluted in water.

- Wring excess water from the cloth. Do not drip water or any liquid on the writer assembly, and avoid contact with open vents, plugs, or connectors.
- Dry the surfaces with a clean cloth or paper towel.

000192

Monitor Screen

Wipe the screen with a soft, dry, clean cloth to remove dust.

> Never use abrasive materials to clean the screen. They can damage the antireflective coating.

To remove fingerprints and other soil:

1. Wipe the screen with a soft cloth moistened with a solution of isopropyl alcohol, water, and mild detergent. You can also use an ammonia-based window cleaner.
2. Wipe the screen immediately with a cloth dampened with clean water.
3. Dry the screen with a soft, clean cloth.

000193

Tape Acquisition Unit

Demagnetize the tape acquisition unit, clean the tape drive, and checkout the tape acquisition unit on a weekly basis.

See Storage Device Cleaning Instructions, PN 409623-001 for the steps to clean and demagnetize the tape acquisition unit.

Checking the Tape Acquisition Unit

The checkout procedure verifies that the tape acquisition unit can accurately read a Holter tape, transfer data into the workstation, and display the data in the software.

Follow these steps to verify the operation of the tape acquisition unit.

Prepare the Workstation

1. Power on the workstation.

See "Powering On the Workstation" in chapter 2, "Equipment Overview" for the required steps.

2. Login to the workstation.
3. Click *System* on the menu bar.
4. Click *Menus*.
5. Click *Tools*.
   The *Tools* menu icons appear at the bottom of the screen.
6. Click the *Patient Select* menu icon.
   The *Patient Select* window opens.

Load the Tape

1. Insert the Holter installation tape (PN 3613-602), label-side up, and turn the tape release lever clockwise to the up position.
   The tape fast forwards to its end.
   The green tape motion LED glows as the tape moves.
   The *Tape Download/Analysis Options* window appears.
2. Click in the *Last Name* text entry box.
3. Type **Test** in the *Last Name* text entry box.

000194

Acquire the Data

1. Click *Start*.
   The workstation begins to acquire the ECG data.
   Test appears under *Patient name* in the *Patient Select* window.
   The workstation acquires and analyzes the ECG data.
   When analysis completes, the *Status* changes to *Ready to Edit*.
2. Verify the length of tape in minute under *Length*:

If length under *Length* is...	Then...
≥1420 minutes	go to "Verifying the Heart Rates".
< 1420 minutes	contact the MARS unity workstation Technical Support Line at 1-800-558-7044 or 1-561-575-5000 ext. 4243.

Verify the Heart Rates

1. Click *Test* under *Patient name* in the *Patient Select* window.
   Test appears as the *Patient* in the title bar.
2. Click the *Report Review* menu icon.
   A final report appears in *Report Review* window.
3. Under the *General* section of the Summary, add up the number of beats listed for *Ventricular beats* and *Supraventricular beats*.

If the total number of Ventricular beats and Supraventricular beats is...	Then go to...
≤ 300 beats	"Verify the Average Heart Rate"
> 300 beats	"Change the Shapes to Normal".

Change the Shapes to Normal

The following procedures allow abnormal beats to be relabeled as normal to force a consistent heart rate calculation. For this, consider the following types of beats as abnormal:

- Ventricular
- Supraventricular.

If changing...	Then go to...
Ventricular beats	"Changing Ventricular beats to Normal beats"
Supraventricular beats	"Changing Supraventricular beats to Normal beats"

Changing Ventricular beats to Normal beats

1. Click *Close* to close the *Report Review* window.
2. Click the *Shape Review* menu icon.
3. Click the *Group* button.
4. Click *Ventricular*.

000195

5. Click *OK*.
   The *Go to New Group* list box closes.
   The Ventricular shapes appear with a reference template on the left hand side of the window and the Ventricular templates on the right hand side.
   The first Ventricular template appears light grey.
6. Click on the first Ventricular template.
7. Click the *Shape* button.
   The Shape option buttons appear.
8. Click the *Normal* button.
   The Shape option buttons disappear and the workstation relabels the shapes in the Ventricular template as Normal.
9. Repeat steps 6 through 8 for each Ventricular template.
10. Close the *Shape Review* menu icon.

Changing Supraventricular beats to Normal beats

1. Click *Close* to close the *Report Review* window.
2. Click and drag the *Shape Review* menu icon to the top of the screen.
   The *Shape Review* tool opens.
3. Click and drag the *Strip Review* tool icon to the middle of the screen.
   The *Strip Review* tool opens.
4. In the *Shape Review* window, click the *Group* button.
5. Click *Supraventricular*.
6. Click *OK*.
   The *Go to New Group* list box closes.
   The Supraventricular shapes appear with a reference template on the left hand side of the window and the Supraventricular templates on the right hand side.
   The first Supraventricular template appears light grey.
7. Click on the first Supraventricular template.
   The *Strip Review* tool window shows the first supraventricular beat in the selected template.

> For long runs of Supraventriculars, click on the first three of four Supraventriculars in the run.

8. Using the MIDDLE mouse button, click the first beat in the run of Supraventriculars.
   Magenta boxes outline the selected beats.
9. Press the S key.
   The beats changes to the new label.

> The workstation underlines the relabeled beat labels.

000196

10. Repeat steps 7 through 10 until the number of Supraventricular beats equals or is less than 300 Supraventriculars.
11. Close all the open tools.

Verify the Average Heart Rate

1. Click the *Report Review* menu icon.
   The final report appears in *Report Review* window.
2. Verify the *Average* heart rate from the Heart Rate section.

If the Average heart rate...	Then...
= 93, 94, or 95	go to "Verifying the Events".
≠ 93, 94, or 95	contact the MARS unity workstation Technical Support Line at 1-800-558-7044 or 1-561-575-5000 ext. 4243.

3. Click *Close*.

Verify the Events

1. Click the *Patient Diary* tool icon.
   The *Patient Diary* tool opens.
2. The *Patient Diary* tool displays a minimum of four events.
   The four events occur at approximately 09:00, 10:00, 11:00 and 12:00

> Multiple events may occur within several seconds of each other.

If time events occur...	Then...
1 hour ± 30 seconds apart	go to step 3.
> 1 hour ± 30 seconds apart	contact the MARS unity workstation Technical Support Line at 1-800-558-7044 or 1-561-575-5000 ext. 4243.

3. Close the *Patient Diary* tool.

Configure the Tools for Measuring

Arrange the Tool Icon Windows

1. Click and drag the *Event Review* tool icon to the top of the screen.
   The *Event Review* tool opens.
2. Click and drag the *Strip Review* tool icon to the middle of the screen.
   The *Strip Review* tool opens.
3. Click and drag the *Page Review* tool icon to the bottom of the screen.
   The *Page Review* tool opens.

000197

Configure *Strip Review* tool

1. In the *Strip Review* tool, click the *Tools* button.
   The *Strip Tools* window opens.
2. Click the *Tools* button.
   The *Strip Tools* window opens.

> All three channels must be displayed.

3. Under *Channel Settings*, click on any channel listed in the *Don't Display* list box.
4. Click the left arrow to move the channel to the *Display* list box.
5. Set the *Gain* to *x1*.
6. Under *Data Window Settings*, set the *Time Scale* to *25 mm/sec*.
7. Set the *Grid* to *Full*.
8. Set the *Chans/Screen* to *3*.
9. Click *Close*.

Measure the Cal Pulses

Locate the Cal Pulses to Measure

1. In the *Page Review* tool, click and drag the vertical scroll bar's slide bar to the place where the calibration pulses end and the ECG data starts.

> The calibration pulses start at approximately *08:00*.
>
> The ECG data starts at approximately *08:07*.

2. Click the mouse at the point where the calibration pulses change to ECG data.
   All three screens update with that data.

Print the Reference Page

1. Click *Print* in the *Event Review* tool.
   The *Print* control window appears.
2. Click *Page Builder*.
   The *Event Review* control window appears.
3. Click *Print* in the *Strip Review* tool.
   The *Print* control window appears.
4. Click *Page Builder*.
   The *Strip Review* control window appears.
5. Click *Print* in the *Page Review* tool.
   The *Print* control window appears.
6. Click *Page Builder*.
   The *Page Review* control window appears.

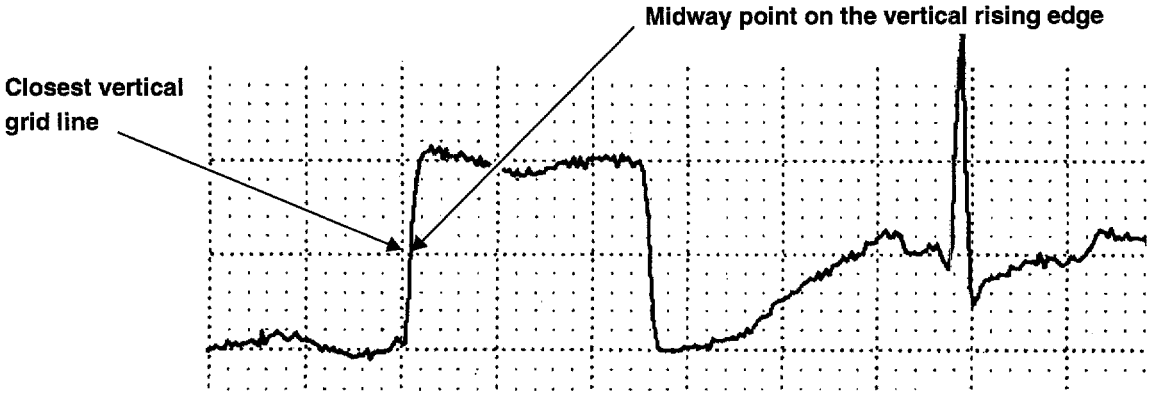
000198

7. Click the *Page Builder* tool in the lower right hand corner. The current *Event Review, Strip Review,* and *Page Review* data windows print.

Measure the Skew

> If using only two channels, measure the calibration pulse skew between the two channles available.

1. From the *Event Review, Strip Review,* and *Page Review* data printed page, measure the amount of calibration pulse skew between channel 1 and channel 3.
2. Find the midway point on the vertical rising edge of a calibration pulse for channel 1.
3. Measure the distance from that midway point to the closest vertical grid line. .



MD1144-717A

4. Find the corresponding calibration pulse in channel 3.
5. Find the midway point on the vertical rising edge of the calibration pulse for channel 3.
6. Measure the distance from that midway point to the same vertical grid line
7. Compare the measurements for channel 1 and channel 3.

If the difference between measurements are...	Then...
≤ 0.5 mm	go to "Measure the Duration and Amplitude".
> 0.5 mm	contact the MARS unity workstation Technical Support Line at 1-800-558-7044 or 1-561-575-5000 ext. 4243.

000199

Measure the Duration and Amplitude

Measure the calibration pulse widths and amplitudes on all three channels using the data printed on the reference page.

Table B-1. Duration and Amplitude Measurements		
Measurement Type	**Measurement**	**Position**
Duration	25 mm	rising edge to rising edge
Amplitude	10 mm	vertical rising edge height

If the duration and amplitude measure...	Then...
correctly	go to "Print the Report".
incorrectly	contact the MARS unity workstation Technical Support Line at 1-800-558-7044 or 1-561-575-5000 ext. 4243.

Print the Report

1. Click the *Report Review* menu icon.
2. Click *Select Setup.*
3. Click *holterfd.*
   The report formats to use the Holter report with full disclosure format.
   An asterisk (*) appears after holterfd.
4. Click *Close.*
5. Click *Print Report.*
   The Holter report with full disclosure report containing approximately 27 pages prints.
   The *Report Review* window closes.
6. Review the full disclosure data and ensure the data consistency.
7. Eject the Holter installation tape.

000200

DAT Drive

> The user has the responsibility to make multiple copies of the data and to catalog the data for long term storage.

> Do NOT exceed more than 100 patient records per DAT tape.

Care and Maintenance of Tape Cartridge

Write Protect

- To prevent writing to the data cassette, slide the write-protect tab open.
- To allow writing to the data cassette, slide the write-protect tab closed.

Recommended Operating Conditions

> Avoid extreme changes in temperature and humidity whenever possible.

Operate cartridges used for data interchange under the following conditions:

- Temperature: 41 F to 113 F (5 C to 45 C)
- Relative Humidity: 20% to 80% (non-condensing)
- Maximum Wet Bulb Temperature: 78.8 F (26 C)
- Before use, condition the cartridge by exposing to the operating environment for a time at least equal to the period which it has been out of the operating environment (up to a maximum of 24 hours).

000201

Cleaning

Frequency

Clean the tape drive after the first four hours of operation.

After the initial cleaning, clean the tape drive after every 25 hours of use and during each preventative maintenance inspection.

> Do not use any methods other than a DDS approved cleaning tape cartridge to clean the tape drive.

Cleaning Kit

To clean the DAT drive, you will need:

- DAT drive cleaning kit, PN 409669-001

Cleaning the DAT drive

1. Power on the workstation.

> See "Powering On the Workstation" in chapter 2, "Equipment Overview" for the required steps.

2. Insert the DAT cleaning cassette into the DAT drive.
   The cassette loads and runs for about 10 seconds.
   The cleaning cassette ejects.

000202

Maintenance/Repair Log

Unit Serial Number:

Institution Name:

Date	Maintenance/Repair	Technician

000203

Unit Serial Number:

Institution Name:

Date	Maintenance/Repair	Technician

000204

Appendix C: Glossary

000205 218

Terms

algorithm A set of ordered steps for solving a specific problem determining specific information.

ambulatory electrocardiography Monitoring a patient's ECG for an extended period of time for the purpose of clinically evaluating their cardiac activity.

amplitude The strength or volume of the signal. The deflection above or below the ECG baseline.

analog A representation of an object that resembles the original. Analog implies continuous operation in contrast with digital, which is broken up into numbers.

annotations One-letter labels (indicators) placed above a waveform (e.g., N = normal).

artifact The sporadic noise that interferes with or deforms the ECG signal. It is usually caused by poor patient prep, patient movement, or cable or lead wire fractures.

calipers Adjustable indicators that can be displayed on the screen for measuring the waveform (e.g., PR intervals, QT intervals).

class A group of beats with the same morphology.

computer A device that controls the system's operating programs and components. Also called CPU.

CRS Clinical Review Station. Allows data from monitoring beds to be viewed on the MARS workstation.

cursor A visual position indicator that appears on the screen displays. The cursor may be a small illuminated square, a solid line, or a dotted line.

delete Remove an item of data from the system.

demagnetizing Removing a residual magnetic field from a metallic surface.

digital A method of coding data for computer analysis. Information converted into numbers.

download To transfer data from the recorder to the Holter system.

edit To make changes, additions or deletions.

event definitions Parameters that can be system- or user-defined for patient events.

fiducial points Points that the system uses for reference or measurement.

000207

file Inserts the appropriate item in the final report. The *Filed information* report component must be selected in *Report Review* tool for the filed information to appear in the report. Tools that allow filing, include: *Strip Review, Page Review, Patient Diary, Event Review, Event Diary, Trend Review, Shape Review,* and *Waveform Measurements.* Also, the *Patient: Event Definitions Settings and Analysis Results* may be filed.

To file information, click the *File* button.

full disclosure The hard copy printout of the waveforms from the entire monitoring period.

gain Amplitude setting. Can be user-defined (e.g., x2).

hardware The physical equipment and components of the computer system.

high resolution display An electronically clarified display that shows graphics with great detail and higher quality.

histogram A graphic display of occurrences (cardiac events) plotted against another value or time scale by intervals (msec) or ratios (percentage).

icon A pictorial representation of a menu function.

mains Voltage of a supply mains between 2 line conductors of a polyphase system or voltage between the line conductor and the neutral of a single-phase system.

menu A list of available options and commands for the operator's selection.

menu icon Menu icons, the individual pictures at the bottom of screen, represent 1 to 3 tools. The number of tools opened varies based on the desired use. To "use" or open a particular tool, click the associated menu icon.

noise Any electrical signal foreign to the electrocardiogram or anything that distorts the waveform.

***Page Builder* icon** Click to print any data queued using the *Page Builder* button. Located in the lower righthand corner.

***Page Builder* button** A print option that allows for multiple strips to be printed on a single page. Clicking the *Page Builder* button queues the selected pages until either the *Page Builder* tool fills or until the user clicks the *Page Builder* icon.

program A collection of instructions that tell the computer what to do. It carries out the tasks of the computer system without operator intervention. A program is called software.

prospective data Patient data viewed in real time.

region A user-defined region area (e.g., atrial fibrillation, artifact, junctional rhythm).

RSS Remote System Support. An access unit (digital or analog) provides a connection to MMS to help troubleshoot and repair the workstation.

retrospective data Patient data viewed then grouped by occurrence by the system.

R-R values Measurements displayed on the screen between one R-R interval.

000208

software Instructions for the computer. The programs and information that control the operation of the computer.

storage disk A device where data can be placed for a long period of time and retrieved when needed.

strip display A display of real time, actual size waveforms.

superimposition A method of rapidly analyzing ECG data by overlaying each new heartbeat over the previous one in an "animated" pattern on the display screen. This can be done at rates up to 240 times real time.

supply mains A permanently installed power source.

template An example of the average QRS complex in a class.

time scale Millimeters per second. Can be user defined (e.g., 25 mm/sec.)

tool An application that allows the user to perform a function to assist them in the scanning process. Tools allow you to perform such functions as entering patient data, viewing waveforms or printing data. Tools may occupy the full screen or only part of the screen.

***Tools* button** Many tools have a *Tools* button which opens a secondary window with options for changing the appearance of the data, for measurements, etc. The tools with a *Tool* button include:

- *Patient Select* tool
- *Strip Review* tool
- *Page Review* tool
- *Event Review* tool
- *Trend Review* tool
- *Episode Review* tool
- *Shape Review* tool
- *Waveform Measurements* tool

***Tools* menu** One of the default menus, the *Tools* menu contains 13 menu icons which are the building blocks for the other default menus' menu icons. The menu icons in the *Tools* menu open their associated tool in the top 1/3 of the screen.

trend graph A graphic display that shows the maximum, minimum, and average values of a 5-minute period.

trends A graphic display of patient events in real time (e.g., heart rate displays in 5-minute increments over the 24-hour study.

000209

Appendix D: Technical Description

000211

Technical Specifications

Table B-1. MARS 8000 unity workstation (RU)	
Item	**Description**
Type	Sun Microsystems Ultra 60
Nominal Voltage Range	100-120 VAC or 200-240 VAC (auto sensing)
Nominal Frequencies	50 Hz or 60 Hz (auto sensing)
Maximum Power Consumption	350 Watts
Thermal Dissipation	360 BTU/hour
Processors	One 300 MHz UltraSPARC processor
Processor Clock Speed	360 MHz
Internal Memory	1286 MB or 196 MB
Storage	
Hard drive	One 4.2 GByte SCSI hard drive and one 9.1 GByte SCSI hard drive
Diskette	1.44 Mbyte, 3.5 inch
External DAT (optional)	4 Gbyte DAT, 4mm DDS2
CD-ROM drive	Internal 32x speed
Interface Ports	Two serial (DB-25); one parallel, one ethernet/fast ethernet (twisted pair, 10BaseT/ 100BaseT, self-sensing); or one Multiple Interchange Interface (MII) for external transceiver; two UPA graphics slots; 40 MB/sec Ultra SCSI I/O; and audio I/O (line-in, line-out, microphone in, headphone/speaker out).
Expansion Slots	Four full-size 32- or 64-bit PCI slots (three 33 MHz 5-volt; one 33 MHz or 66 MHz 3.3-volt)
Keyboard	Sun Microsystems Type 5c
Mouse	Optomechanical, 3 button
Physical	
Height	45.00 cm (17.70 in)
Width	19.00 cm (7.50 in)
Depth	49.80 cm (19.60 in)
Weight	17.60 kg (38.80 lbs)
Communication Requirements	
ISDN	Cisco 760 series access unit.
Switched-56	Combinet CB-600 access unit
Analog modem	Multitech

000213

Table D-2. MARS 5000 unity workstation (RT)	
Item	**Description**
Type	Sun Microsystems Ultra 10
Nominal Voltage Range	100-120 VAC or 200-240 VAC (auto sensing)
Nominal Frequencies	50 Hz or 60 Hz (auto sensing)
Maximum Power Consumption	250 Watts
Processors	One 300 MHz UltraSPARC processor
Processor Clock Speed	300 MHz
Internal Memory	128 MB
Storage	
Hard drive	One 4.3 Gbyte hard drive
Diskette	1.44 Mbyte, 3.5 inch
External DAT (optional)	4 Gbyte DAT, 4mm DDS2
CD-ROM drive	Internal 24x speed
Interface Ports	Two serial (one DB-25, one DB-9); one parallel; one ethernet/fast ethernet (twisted pair, 10BaseT/100BaseT, self-sensing with Ultra SCSI); one UPA graphics slot; and audio I/O (line-in, line-out, microphone in, headphone/speaker out).
Expansion Slots	Four 32-bit PCI slots (full-size, 33 MHz, 5-volt)
Keyboard	Sun Microsystems Type 5c
Mouse	Optomechanical, 3 button
Physical	
Height	40.00 cm (15.75 in)
Width	17.60 cm (6.93 in)
Depth	43.50 cm (17.10 in)
Weight	20.00 kg (44.00 lbs)
Communication Requirements	
ISDN	Cisco 760 series access unit.
Switched-56	Combinet CB-600 access unit
Analog modem	Multitech

000214

Table D-3. MARS 3000 unity workstation (RS)	
Item	**Description**
Type	Sun Microsystems Ultra 5
Nominal Voltage Range	100-120 VAC or 200-240 VAC (auto sensing)
Nominal Frequencies	50 Hz or 60 Hz (auto sensing)
Maximum Power Consumption	200 Watts
Processors	One 270 MHz UltraSPARC processor with built-in graphics
Processor Clock Speed	270 MHz
Internal Memory	128 MB
Storage	
Hard drive	One 4.3 Gbyte hard drive
Diskette	1.44 Mbyte, 3.5 inch
External DAT (optional)	4 Gbyte DAT, 4mm DDS2
CD-ROM drive	Internal 32x speed
Interface Ports	Two serial (one DB-25, one DB-9); one parallel; one ethernet/fast ethernet (twisted pair, 10BaseT/100BaseT, self-sensing with Ultra SCSI); and audio I/O (line-in, line-out, microphone in, headphone/speaker out).
Expansion Slots	Three 32-bit PCI slots (33 MHz, 5-volt, two full-size, one short)
Keyboard	Sun Microsystems Type 5c
Mouse	Optomechanical, 3 button
Physical	
Height	11.20 cm (4.40 in)
Width	43.60 cm (17.10 in)
Depth	43.00 cm (16.90 in)
Weight	18.00 kg (39.70 lbs)
Communication Requirements	
ISDN	Cisco 760 series access unit.
Switched-56	Combinet CB-600 access unit
Analog modem	Multitech

000215

Table D-4. MARS 8000 unity workstation (HK)	
Item	**Description**
Type	Sun Microsystems Ultra 1 Creator Model 170E
Nominal Voltage Range	100-120 VAC or 200-240 VAC (auto sensing)
Nominal Frequencies	50 Hz or 60 Hz (auto sensing)
Maximum Power Consumption	250 Watts
Thermal Dissipation	488 BTU/hour
Processors	One 167 MHz UltraSPARC processor with built-in graphics
Processor Clock Speed	167 MHz
Internal Memory	64, 128 or 196 Mbyte
Storage	
Hard drive	Dual 2.1 Gbyte hard drive
Diskette	1.44 Mbyte, 3.5 inch
DAT (optional)	4 Gbyte DAT, 4mm DDS2
CD-ROM drive	Internal 644 Mbyte 12x speed, Photo CD compatible
Interface Ports	Two serial, one parallel, one ethernet/fast ethernet twisted pair (10BaseT/100BaseT) one Multiple Interchange Interface (MII) for external transceiver, one fast/wide SCSI-2 (68 pin)
Expansion Slots	Two SBus slots
Keyboard	Sun Microsystems Type 5c
Mouse	Mechanical, Compact, 3 button
Height	10.25 cm (4.03 in)
Width	41.7 cm (16.4 in)
Depth	44.3 cm (17.44 in)
Weight	12.5 kg (27.5 lbs)
Communication Requirements	
ISDN	Cisco 760 series access unit.
Switched-56	Combinet CB-600 access unit
Analog modem	Multitech

000216

Table D-5. MARS 8000 unity workstation (HG)	
Item	**Description**
Type	Sun Microsystems SPARCstation 20
Nominal Voltage Range	100-120 VAC or 200-240 VAC (auto sensing)
Nominal Frequencies	50 Hz or 60 Hz (auto sensing)
Thermal Dissipation	683 BTU/hour
Maximum Power Consumption	350 Watts
Processors	Two 50.00 MHz SuperSPARC processors
Processor Clock Speed	50.00 MHz
Internal Memory	64 Mbyte
Storage	
Hard drive	One 2.1 and one 1.05 Gbyte hard drive
Diskette	1.44 Mbyte, 3.5 inch
DAT (optional)	5 Gbyte DAT, 4mm DDS2
CD-ROM drive	Internal 644 Mbyte double speed
Interface Ports	Two serial, one parallel, two network, one SCSI
Keyboard	Sun Microsystems Type 5c
Mouse	Mechanical, Compact, 3 button
Physical - System box	
Height	7.8 cm (3.07 in)
Width	41.7 cm (16.4 in)
Depth	40.9 cm (16.1 in)
Weight	12.7 kg (27 lbs)
Communication Requirements	
ISDN	Cisco 760 series access unit.
Switched-56	Combinet CB-600 access unit
Analog modem	Multitech

000217

Table D-6. MARS 5000 unity workstation	
Item	**Description**
Type	Sun Microsystems SPARCstation 5
Nominal Voltage Range	100-120 VAC or 200-240 VAC (auto sensing)
Nominal Frequencies	50 Hz or 60 Hz (auto sensing)
Maximum Power Consumption	230 Watts
Maximum Heat Output	785 BTU/hr
Processors	Either One 110 MHz or 170 MHz SuperSPARC processor
Processor Clock Speed	110 MHz or 170 MHz
Internal Memory	32 or 64 Mbyte
Storage	
Hard drive	One 2.1Gbyte hard drive
Diskette	1.44 Mbyte, 3.5 inch
DAT (optional)	5 Gbyte DAT
CD-ROM drive	Internal 644Mbyte, 12x speed
Interface Ports	Two serial, one parallel, two network, one SCSI
Keyboard	Sun Microsystems Type 5c
Mouse	Opto-mechanical, Compact, 3 button
Physical – System box	
Height	7.8 cm (3.07 in)
Width	41.7 cm (16.4 in)
Depth	40.9 cm (16.1 in)
Weight	12.7 kg (27 lbs)
Communication Requirements	
ISDN	Cisco 760 series access unit.
Switched-56	Combinet CB-600 access unit
Analog modem	Multitech

Table D-7. 21 inch Monitor	
Item	**Description**
Type	Sun Microsystems
Size	21 inch

000218

Table D-7. 21 inch Monitor (Continued)	
Item	**Description**
Picture Tube	0.25 – 0.27 mm aperture grille pitch 21 inches measured diagonally 90–degree deflection
Viewable Image Size	Approximately 403.8 x 302.2 mm (w/h) (16x12 inches) 19.8" viewing image measured diagonally
Resolution	Horizontal: Max. 1600 dots Vertical: Max. 1200 lines
Standard Image Area	Approximately 388 x 291 mm (w/h) (15 3/8 x 11 1/2 inches) or Approximately 364 x 291 mm (w/h) (14 3/8 x 11 1/2 inches)
Deflection Frequency	Horizontal: 30 to 96 kHz Vertical: 48 to 160 Hz
AC Input Voltage/Current	100 to 240 V, 50 – 60 Hz., 2.0 – 1.0 A
Power Consumption	Max. 160 W
Dimensions	500.3 x 502.5 x 476.5 mm (w / h / d) (19 3/4 x 19 7/8 x 18 7/8 inches)
Weight	31 kg (68 lb 5 oz)

Table D-8. 19 inch Monitor	
Item	**Description**
Type	Sun Microsystems
Size	19 inch
CRT	19 inch picture tube, 0.26 mm dot pitch, Invar shadow mask, Black matrix, Medium Short persistence phosphors, Dark Tint Anti–Reflection coat
Input Signal	Video: 0.70 Vp-p, Analog Sync: Separate H, V or Composite H/V TTL level or Sync. on Green at 0.30 Vp-p
Synchronization	Horizontal: 31 – 96 kHz Vertical: 50 – 160 Hz
Resolution	Horizontal: Up to 1600 dots Vertical: Up to 1280 dots
Video Clock Frequency	200 MHz (typical)
Viewable Image Size	18.0 inches (458 mm), diagonal (typical)
Viewable Image Area	Horizontal: 367 mm (typical) Vertical: 276 mm (typical)
Power Supply	AC 100 – 120 / 200 – 240 V, Automatically select. Provided with Power Save Circuit. Power Consumption: 130 W (typical)

000219

Table D-8. 19 inch Monitor (Continued)	
Item	**Description**
Dimensions	448 x 454 x 460 mm (w / h / d) including Tilt & Swivel base
Weight	25 kg

Table D-9. Uninterruptible Power Supply (UPS) (Oneac 600)	
Item	**Description**
Type	ONEAC Model ON 600 for 120 V ONEAC Model ON 600I for 230 V
Input Connector	NEMA 5-15 P for 120 V IEC320 for 230 V
Output Sockets	6 for 120 V 4 for 230 V
Maximum Capacity	600 Volt-amps, 400 Watts
Thermal dissipation	193 BTU/hr
Height	31 cm (12 in)
Width	21 cm (8.3 in)
Depth	39 cm (15.3 in)
Weight	22 kg (47 lbs)

Table D-10. Uninterruptible Power Supply (UPS) (Oneac 900)	
Item	**Description**
Type	ONEAC Model ON 900 for 120 V ONEAC Model ON 900 for 230 V
Input Connector	NEMA 5-15 P for 120 V IEC320 for 230 V
Output Sockets	6 for 120 V 4 for 230 V
Maximum Capacity	900 Volt-amps, 600 Watts
Thermal dissipation	193 BTU/hr
Height	31 cm (12 in)
Width	21 cm (8.3 in)
Depth	39 cm (15.3 in)
Weight	31 kg (65 lbs)

Table D-11. Tape Acquisition Unit	
Item	**Description**
Type	GE Marquette Medical Systems, Inc. Tape Acquisition Unit
Nominal Voltage Range	100-120 VAC or 200-240 VAC (auto sensing)
Nominal Frequencies	50 Hz or 60 Hz (auto sensing)
Maximum Power Consumption	55 Watts
Processor	DSP56002 microprocessor
Processor Clock Speed	66 MHz
Tape Drive	Braemer CD350 Holter playpack tape drive
Media	
Cassette Tape	C-60 or C-120 cassette tapes
Interface Ports	One SCSI
Channels	1 or 2 (user selectable) and clock track
Resolution	12 bits
Sampling Frequency	128 samples/sec (real time)
Playback Speed	
Cassette	1000 times real time
Frequency Response	0.66 to 50 Hz overall (recorder to system)
Phase Response	Linear, less than 6 degrees phase shift at 0.5 Hz
Tape Playback Options	The tape is played back at approximately 1000 times real time. Analog amplifiers with gain and phase equalization optimized for Holter tape processing are provided for all channels. Tape speed variations are compensated by a time warp filter circuit synchronized to the clock track on the tape.
Effective Sampling Rates	
Marquette 8500	Cassette, 1 mm/sec; phase-locked, 128 samples/sec
Height	7.11 cm (2.8 in)
Width	24.38 cm (9.6 in)
Depth	26.42 cm (10.4 in)
Weight	2.3 kg (5.1 lb)

000221

Table D-12. SEER Acquisition Unit	
Item	**Description**
Type	GE Marquette Medical Systems, Inc. SEER Acquisition Unit
Nominal Voltage Range	100-120 VAC or 200-240 VAC (auto sensing)
Nominal Frequencies	50 Hz or 60 Hz (auto sensing)
Maximum Power Consumption	30 Watts
Processor	MC68331 microprocessor
Processor Clock Speed	15.2 MHz
Media	
SEER recorder	SEER or SEER XT recorder
PC Card	Standard 68 pin PC Card memory card (formerly PCMCIA) for SEER MC
Interface Ports	One SEER port, one RS-232 serial, one SCSI
Height	7.11 cm (2.8 in)
Width	24.38 cm (9.6 in)
Depth	26.42 cm (10.4 in)
Weight	2.3 kg (5.1 lb)

Table D-13. DAT Drive	
Item	**Description**
Type	Sun Microsystems
Nominal Voltage Range	100-120 VAC or 200-240 VAC (auto sensing)
Nominal Frequencies	50 Hz or 60 Hz (auto sensing)
Tape Drive	DDS-2 tape drive
Tape Speed	0.64 inches/ second
Media	DAT, Computer grade, 4 mm DDS-2 data storage cartridge devices
Formatted Capacity	
Uncompressed	2 Gbytes
Compressed	5 Gbytes @ 2.5:1 compression
Transfer Rate	550 Kbytes/second
Interface Ports	Two 68-pin SCSI
SCSI Termination	Auto SCSI termination
Buffer	1 Mbyte

000222

Table D-13. DAT Drive (Continued)	
Item	**Description**
Height	7.0 cm (2.76 in)
Width	19.0 cm (7.48 in)
Depth	31.0 cm (12.2 in)
Weight	3.38 kg (7.45 lbs)

Table D-14. XLT network computer	
Item	**Description**
Type	NCD Explora 450 Display Station
Nominal Voltage Range and Frequency	North America: 90-132 VAC, 60 Hz (+/- 3 Hz) European/Australian: 180-265 VAC, 50 Hz (+/- 3 Hz) Japanese: 85-110 VAC, 47 - 63 Hz
Maximum Power Consumption	19 Watts
Microprocessors	PowerPC 403GCX@66MHz
Coprocecesor	S3 Trio64V2/DX
Communications	
Thin Ethernet	Built in 10Base2 thin ethernet transceiver with BNC connector
Twisted pair	Built in 10/100BaseT twisted pair ethernet transceiver (auto-sensing)
Serial port	RS-232 C up to 115.2K baud
Parallel port	25 pin connector; PC compatible
PC-Card	Type I/II PCMCIA slot with standard PC card, 68 pin connector
Display Memory	2 MB
Keyboard	101 key PS/2 style keyboard 123 key Sun Type 5 keyboard 97 key Kana keyboard
Mouse	Mechanical, Three button, PS/2
Height	5.3 cm (2.1 in)
Width	32.5 cm (12.8 in)
Depth	33.5 cm (13.8 in)
Weight	2.49 kg (5.5 lbs)

000223

Table D-15. XLT 21 inch Monitor	
Item	**Description**
Type	Sony Trinitron Multiscan GDM-500PS
Size	21 inch
Resolution	1600 x 1200 maximum at 85Hz
Horizontal Frequency	30 - 107 kHz
Vertical Frequency	46 - 160 Hz
Viewable Image Size	19.8 in measured diagonally
Aperture Grille Pitch	0.26-0.27 mm (variable)
Height	505.5 mm (19.9 in)
Width	497.8 mm (19.6 in.)
Depth	474.0 mm (18.7 in.)
Weight	30.0 kg (68.3 lbs)
AC Power Requirements	100 – 240V AC; 50 – 60 Hz International Energy Star, NUTEK, and VESA DPMS compliant
Power Consumption	Operation: 160 watts (maximum) Suspend: 15 watts (maximum) Active off: 5 watts (maximum) Power off: 0 watts (maximum)

Table D-16. XLT 17 inch Monitor	
Item	**Description**
Type	Sony Trinitron Multiscan 17 se
Size	17 inch
Resolution	1152 x 900
Horizontal Frequency	68.7 kHz
Vertical Frequency	75 Hz
Active Display Area	328 mm x 242 mm (13.8 in x 10.6 in)
Input Voltage	100-120 V 2.7A, or 200-240 V 1.5A (auto sensing)
Dot Pitch	0.25 mm
Weight	22.5 kg (49.5 lbs)

000224

Table D-16. XLT 17 inch Monitor (Continued)	
Item	**Description**
AC Power	100-120V 3A, or 200-240V 1.6A auto-sensing (The 17" monitor meets the United States Environmental Protection Agency (EPA) Energy Star™ guidelines for increased energy efficiency. In particular, the 17" monitor is capable of entering a low-power state when it is inactive and used with an Energy Star capable frame buffer and appropriate Sun system software.)
Active Display Area - Underscan	300 mm x 225 mm (11.8 in x 8.8in)
Video	RGB noncomposite, 700 mV peak, 75 Ohms
Sync	Combined sync, 2.5 - 5 V, 75 Ohms
Color Temperature	x = 0.283, y = 0.298 (9300 °K +8 mpcd)
Antiglare Treatment	Thin film treatment
Electrostatic Potential	Within ± 500V

Table D-17. Safety	
Item	**Description**
Certification	UL listed CSA certified TUV certified EN 60950 (UL 1950) CE marking for Council Directive 93/42/EEC
Type of Protection Against Electrical Shock	Class 1
Degree of Protection Against Ingress of Liquids	Ordinary
Handling of Disposable Supplies and Other Consumables	■ Use only parts and accessories manufactured or recommended by GE Marquette. ■ Follow manufacturer's instructions for use for disposable/consumable product. ■ Follow local environmental guidelines concerning the disposal of hazardous materials (e.g. lead acid batteries).
Patient Mode of Operation	Continuous
Patient Leakage Current	Not applicable
Degree of Protection Against Electrical Shock	Not applicable
Maintenance Frequency	■ Recommended user daily visual inspection and cleaning. ■ Recommended six-month routine maintenance checks and test procedures performed by qualified technical personnel.
Repair Guidelines	Calibration instructions, equipment descriptions, and all other service information to repair those parts of the equipment designated as field repairable by qualified technical personnel is available in the service manual. Upon request, GE Marquette will provide circuit diagrams and component parts lists for printed circuit boards deemed repairable by qualified technical personnel.

000225

Table D-18. Environmental-System-wide	
Item	**Description**
Power	20 amps
Operating Conditions	
Temperature	10 to 35 degrees C (50 to 90 degrees F)
Relative Humidity	20% to 80%
Maximum Altitude	2,500 meters (8,200 feet)
Storage/Transport Conditions	
Temperature	-20 to 43 degrees C (-40 to 110 degrees F)
Relative Humidity	8% to 80%
Maximum Altitude	10,350 meters (34,000 feet)

000226

Index

000229

000230

U

V

W

000231

Appendix B
Heart Rate Variability Physician's Guide

MARS® unity workstation Heart Rate Variability

physician's guide

Software Version 4

PN 405024-105 Revision A

marquette

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000234

287

NOTE

This manual reflects software version 4.

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000235

Contents

000236

Revision History

Each page of the document has the document part number and revision letter at the bottom of the page. The revision letter identifies the document's update level.

The revision history of this document is summarized in the table below.

Revision History PN 405024-105		
Revision	**Date**	**Comment**
A	10 December 1998	Initial Release.

000237

1 — Autonomic Nervous System

Introduction

Heart rate variability is the recurrent changes in R-R intervals characteristic of a balanced cardiac control mechanism. Research suggests that decreased variability in normal-to-normal beat intervals can be a prognostic indicator for certain disease states. The influence of the autonomic nervous system has considerable effect on the integrity of cardiovascular homeostasis.[1] It is the antagonistic components of the autonomic system that comprise the core of study in heart rate variability.

Related Manuals

For additional information on heart rate variability, please refer to the MARS unity workstation User's Guide.

000238

1. Fox, S.I., Human Physiology, LA City College, William C. Brown Publishers.

Heart Rate Variability Definition

GE Marquette Medical Systems, Inc. offers a software program for the measurement of heart rate variability. In conjunction with GE Marquette's 24-hour MARS ambulatory ECG analysis and editing system, a non-invasive clinical method for assessing the integrity of autonomic input to the cardiovascular system is provided. There have been numerous research studies analyzing sequential R-R intervals in stunningly diverse clinical populations including sudden cardiac death associated with myocardial infarction, diabetes, congestive heart failure, sleep apnea, hypertension, alcohol abuse, and syncope. As a measure of the body's autonomic response, heart rate variability is a versatile test, providing a window to a previously difficult to obtain measurement.

000239

Influence of the Autonomic Nervous System

The autonomic nervous system controls the visceral functions of the body including arterial pressure, gastrointestinal motility, secretion, urinary output, body temperature, and cardiac muscle. The autonomic nervous system is activated primarily by centers located in the spinal cord, brain stem, and hypothalamus. The autonomic signals in turn are transmitted to the body through two major subdivisions: sympathetic or thoracolumbar division and parasympathetic or craniosacral division.

Mass activation of the sympathetic system prepares the body for intense physical activity in emergencies: the heart rate increases, blood glucose rises, and blood is diverted to the skeletal muscles — away from the visceral organs and skin. The "theme" of the sympathetic system has aptly been summarized in the phrase *fight or flight*.

The effects of parasympathetic nerve stimulation are in many ways opposite to the effects of sympathetic response. The parasympathetic system, however, is not normally activated as a whole. Stimulation of separate parasympathetic nerves can result in slowing of the heart, dilation of visceral blood vessels, and increased activity of the digestive tract.

000240

Table 1: Effects of Autonomic Nerve Stimulation on Various Visceral Effector Organs [1]

Effector organ	Sympathetic effect	Parasympathetic effect
Eye		
Iris (readial muscle)	Dilates pupil	—
Iris (sphincter muscle)	—	Constricts pupil
Ciliary muscle	Relaxes (for far vision)	Contracts (for near vision)
Glands		
Lacrimal (tear)	—	Stimulates secretion
Sweat	Stimulates secretion	—
Salivary	Decreases secretion; saliva becomes thick	Increases secretion; saliva becomes thin
Stomach	—	Stimulates secretion
Intestine	—	Stimulates secretion
Adrenal medulla	Stimulates secretion of hormones	—
Heart		
Rate	Increases	Decreases
Conduction	Increases rate	Decreases rate
Strength	Increases	—
Blood vessels	Mostly constricts; affects all organs	Dilates in a few organs (eg. penis)
Lungs		
Bronchioles (tubes)	Dilates	Constricts
Mucous glands	Inhibits secretion	Stimulates secretion
Gastrointestinal tract		
Motility	Inhibits movement	Stimulates movement
Sphincters	Stimulates closing	Inhibits closing
Liver	Stimulates hydrolysis of glycogen	—
Adipose (fat cells)	Stimulates hydrolysis of fat	—
Pancreas	Inhibits exocrine secretions	Stimulates exocrine secretions
Spleen	Stimulates contraction	—
Urinary bladder	Helps set muscle tone	Stimulates contraction
Pilorector	Stimulates erection of hair and "goosebumps"	—
Uterus	If pregnant, contraction If not pregnant, relaxation	—
Penis	Erection; ejaculation	Erection (due to vasodilation)

Table 2: Effects of Autonomic Nerve Activity on the Heart [1]

Region affected	Sympathetic nerve effects	Parasympathetic nerve effects
S-A node	Increased rate of diastolic depolarization; increased cardiac rate	Decreased rate of diastolic depolarization; decreased rate
A-V node	Increased conduction rate	Decreased conduction rate
Atrial muscle	Increased strength of contraction	Decreased strength of contraction
Ventricular muscle	Increased strength of contraction	No significant effect

000241

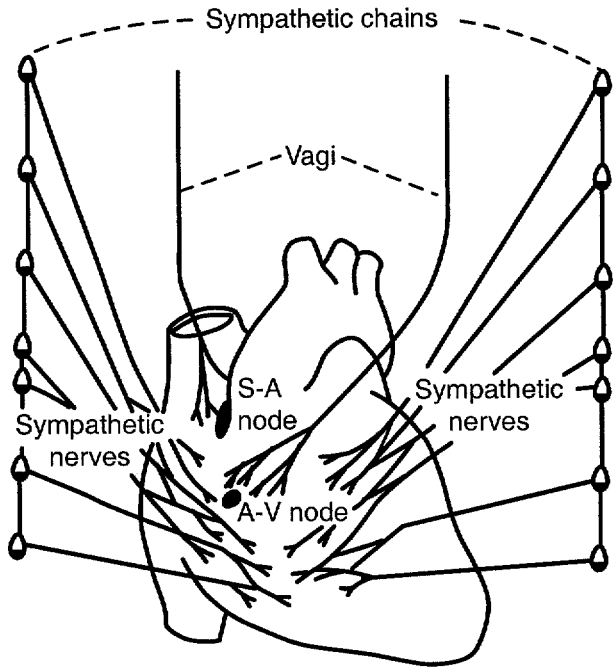


Figure 1: The cardiac nerves.[2]

The heart is well-supplied with both sympathetic and parasympathetic (vagal) nerves. These nerves affect cardiac pumping in two ways: by changing the heart rate and by changing the strength of the heart's contractions.

The different responses of visceral organs to sympathetic and parasympathetic nerve activity are due to the fact that the postganglionic fibers of these two divisions release different neurotransmitters.

Acetylcholine is the neurotransmitter of all preganglionic fibers (both sympathetic and parasympathetic). Acetylcholine is also the transmitter released by all parasympathetic postganglionic fibers at their synapses with effector cells. Transmission at the autonomic ganglia, and at the synapses of the postganglionic parasympathetic nerve fibers, is said to be *cholinergic*.

The neurotransmitter released by most postganglionic sympathetic nerve fibers is norepinephrine (noradrenalin). Transmission at these synapses is *adrenergic*.

000242

2. Guyton, Normal Functions and Mechanism of Disease, Basic Human Physiology, W.B. Saunders & Company.

The effects of sympathetic and parasympathetic stimulation on the S-A node illustrates the antagonism of these two systems. Sympathetic and vagus (parasympathetic) nerve fibers to the heart are continually active. Norepinephrine released from sympathetic nerve endings, as well as other catecholamines (such as epinephrine secreted by the adrenal medulla), stimulates an increase in the spontaneous rate of firing of the S-A node.

Acetylcholine released from the parasympathetic endings hyperpolarizes the S-A node and thus decreases the rate of the spontaneous firing. The actual pace set by the S-A node at any one time depends on the net effect of these antagonistic influences.

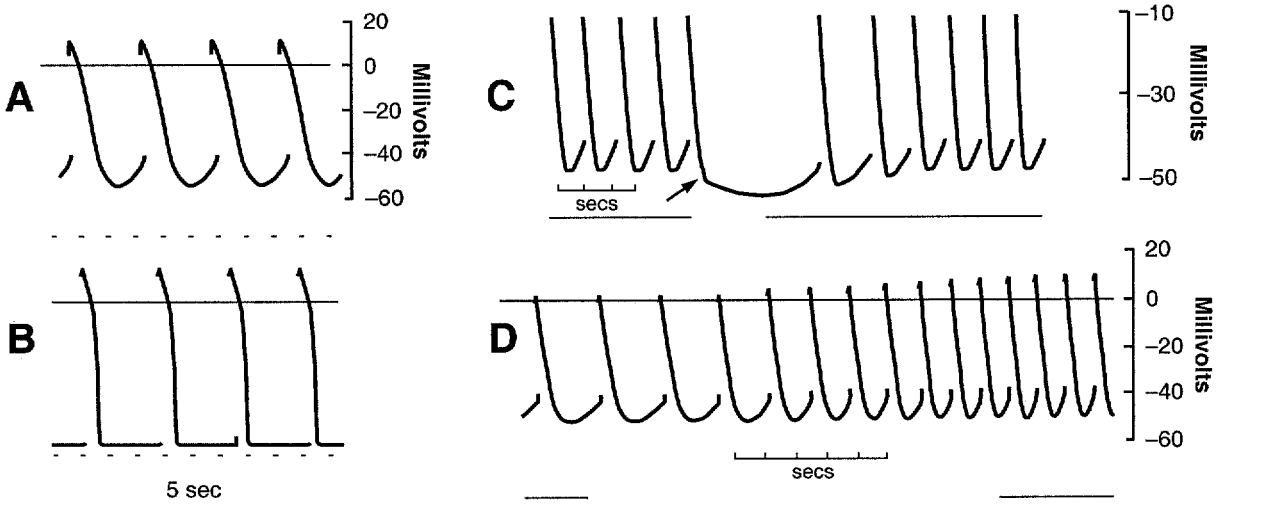


Figure 2: The transmembrane potentials from the cells of the frog's atrium. In panel A the transmembrane potential from a pacemaker cell (a cell that depolarizes in the absence of an extrinsic stimulus) is shown. In panel B is the transmembrane potential of the follower cell. Note its stable (horizontal) potential until stimulated. In panel C the response (hyperpolarization) of the pacemaker cell to vagal stimulation (break in line) is shown. In panel D its response (more rapid depolarization) to sympathetic stimulation (break in line) is shown.[1]

000243

Baroreceptors

The business of circulation is the production of blood flow. Yet, the most important controlled variable to which the sensors are attuned is blood pressure, a product of flow and resistance. "Nature like the human engineer, finds it easier to measure pressure than flow." [2]

When a person moves from a lying to a standing position, there is a shift of 500 - 700 ml of blood from the veins of the thoracic cavity to veins in the lower extremities, which expand to contain the extra volume of blood. This "pooling" of blood reduces the effective blood volume by decreasing the venous return and cardiac output. The resulting fall in blood pressure is almost immediately compensated by the baroreceptor reflex. Baroreceptors are spray type nerve endings abundant in the walls of the major arteries (especially the internal carotids). Baroreceptor information to the medulla oblongata stimulates sympathetic and inhibits parasympathetic nerve activity, resulting in increased cardiac rate and vaso-constriction.

The baroreceptor reflex can also mediate the opposite response. When blood pressure rises above an individual's normal range, the baroreceptor reflex causes a slowing of the cardiac rate and vasodilation due to decreased sympathetic and increased parasympathetic nerve activity. In addition, the renin-angiotensin system senses blood pressure fluctuation and, through the elaboration of angiotensin II, plays the role of the guardian of the overall peripheral vascular resistance. Researchers have found that a blockade of the renin-angiotensin system leads to a drop in peripheral resistance.

000244

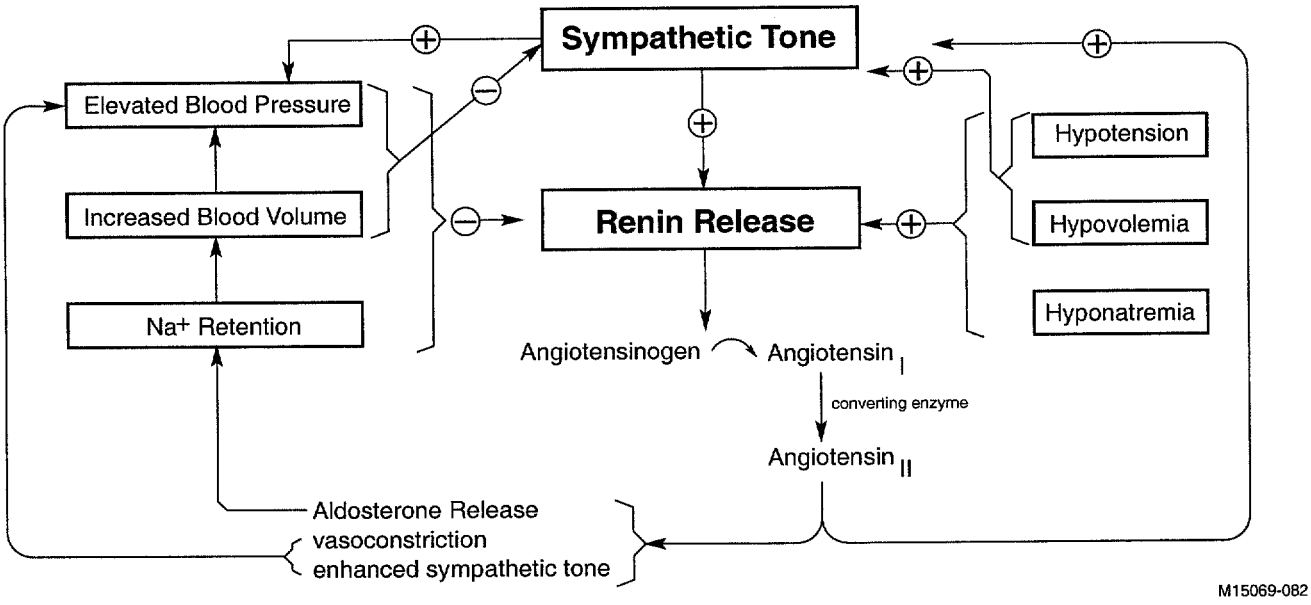


Figure 3: The interactions of the renin-angiotensin and sympathetic nervous systems in regulating homeostasis are shown schematically along with the physiologic variables that modulate their function. Arrows with a [+] represent stimulation, and those with a [-] represent inhibition.[2]

It has been shown recently that analysis of the baroreflex sensitivity can identify subgroups at both lower and higher risk for sudden death. [3] "Specifically, it has been found that depressed baroreflex sensitivity is associated with a higher risk of developing ventricular fibrillation during transient acute myocardial ischemia." [3]

000245

3. Kleiger, R.E., Miller, J.P., Bigger, J.T., et al: Decreased Heart Rate Variability and It's Association with Increased Mortality After Acute Myocardial Infarction, The American Journal of Cardiology, Volume 59, February 1987.

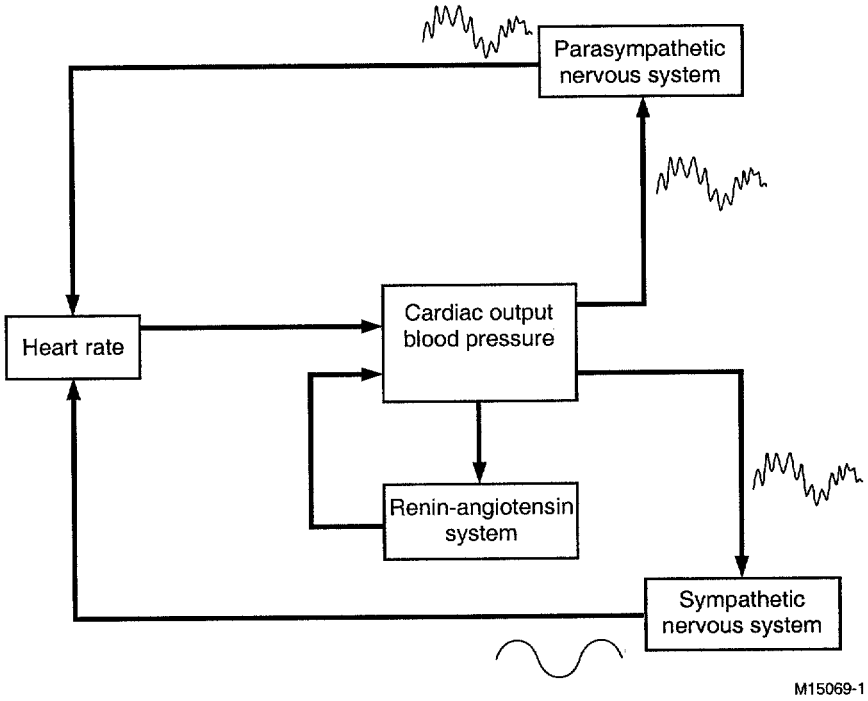


Figure 4: Simplified model of cardiovascular control showing modulation of heart rate by parasympathetic and sympathetic feedback loops, where sympathetic control acts as a low-pass filter, allowing only slow fluctuations to feed back onto the sinoatrial node.[4]

000246

4. Akselrod, S., Gordon, D., Madwed, J.B., et al: Hemodynamic Regulation: Investigation by Spectra Analysis, American Journal of Physiology, 1985.

Autonomic Balance and Heart Rate Variability

The highly sophisticated mechanism for autonomic transmissions is complex and interactive. Measurement of its index can provide valuable insight in the determination of health versus disease.

"Cardiac electrical instability has been identified as one of the primary factors responsible for sudden cardiac death. Electrical stability of the heart has been found to be *reduced* by an elevation of sympathetic efferent activity and to be *increased* by a major increase in vagal efferent activity. Measurements of respiratory sinus arrhythmia and heart rate variability have been reported to provide indirect, non-invasive estimates of the level of vagal cardiac efferent activity." [5, 6]

"Present study suggests that patients with decreased heart rate variability have decreased vagal tone or increased sympathetic tone and may have higher risk for ventricular fibrillation." [3] In conjunction with this, "diminished heart rate variability has been reported in patients to be at risk of sudden death when compared with those not at increased risk." [7]

The study of heart rate variability based on the physiology method of autonomic balance offers the clinician intriguing possibilities.

5. Billman, G.E., Schwartz, P.J., Stone, H.L., The Effects of Daily Exercise on Susceptibility to Sudden Cardiac Death, Circulation, Volume 69, Number 6, June 1984.
6. Kent, K.M., Smith, E.R., Redwood, D.R., et al: Electrical Stability of Acutely Ischemic Myocardium. Influence of Heart Rate and Vagal Stimulation, Circulation, 47:291, 1973.
7. Martin, G.J., Magid, N.M., Meyers, G., et al: Heart Rate Variability and Sudden Death Secondary to Coronary Artery Disease During Ambulatory Electrocardiographic Monitoring, American Journal of Cardiology, Volume 60, July 1987.

000247

2 — Frequently Asked Questions

Following are a number of frequently asked MARS unity workstation heart rate variability (HRV) questions and their respective answers.

1. What is the formula for the DES (discrete event series) interpolation?

Each QRS occurs at some instant in time. These times are not equally spaced. A cubic spline interpolation is used to produce a function defined continuously in time which can be resampled at equal spacings.

Resampling is done to produce 1024 samples of the RR interval function for every 300 seconds (5 minutes).

Four QRS times are required to allow the cubic spline to define the continuous function between the middle two QRS beats. The window of four beats is then shifted by one QRS to allow interpolation of the next interval.

2. Which sequences of artifacts/ectopic beats are interpolated? Which are excluded?

It is better to think in terms of intervals being excluded rather than beats. Each interval connects two heart beats. The HRV setup screen allows specification of a count of intervals (0-99) to be excluded before each particular beat type. A count (0-99) of intervals following each beat type can also be excluded. For example, two intervals before each PVC and five intervals after each PVC can be excluded if desired.

A maximum and a minimum acceptable RR interval length can be set. Intervals exceeding these limits are excluded.

A maximum percent deviation of one interval to the previous interval can be set. Intervals exceeding the allowance are excluded. This rule requires that the previous interval was accepted.

After intervals are excluded, the remaining intervals are used to supply the data points through which the cubic spline is formed.

3. What is the frequency of sampling of ECG waveforms?

ECG data can be sampled at various rates resulting in QRS timing information at different resolutions. Seer-XT solid state Holter recorders supply data at 120 samples/second. Analog tapes are digitized at 128 samples/second.

000248

4. What does FFT stand for?

The Fast Fourier Transform (FFT) has been known and used since 1942. It is a non-parametric technique for spectral estimation. That means a model for the signal is not assumed apriori.

5. What is the frequency of sampling for the FFT of the periodogram?

The cubic spline interpolated RR interval function is sampled at 1024 samples / 300 seconds or 3.413 samples/second. This means the highest observable frequency (Nyquist rate) of HRV is 1.707 Hz.

6. Which spectral window is employed?

A Hanning window is used. This window is also called a raised cosine window. The spectral coefficients are scaled to properly account for the attenuation of signal energy due to the window.

7. What detrending algorithm is used?

The lowest observable frequency of HRV by this program is one cycle in 300 seconds or 0.00333 Hz. To avoid distortion at the lowest observable frequency the trend is determined from a larger window, in such a way that it does not respond to 0.00333 Hz or in fact any of the frequencies measured by the 1024 point FFT.

A linear trend is fit to the FFT input samples of a 600 second (10 minute) window. The middle 5 minutes are detrended, windowed and processed by FFT.

8. Why do I need ten minutes of data to get spectra for only one minute?

The algorithm requires ten minutes of data to estimate any trend that lasts longer than the 5 minute window for spectral analysis. The ten minute window is shifted by one minute for each additional spectrum computed. So 11 minutes of data is enough to compute two spectra. The number of spectra computed is always 9 less than the number of minutes of QRS timing information available.

9. What does the time of a spectrum mean?

If the QRS timing information begins at 8:00 am, it is likely that the first spectrum computed is identified as being at 8:05 A.M. Although each spectrum characterizes a 5 minute region of time, the spectrum is assigned to the instant in time at the center of the 5 minutes. The five minutes is also in the middle of the 10 minute detrending window. So the "name" of the first spectrum is 5 minutes into it's ten minute detrending window.

10. What happens if I have a region of noise in the spectrum window?

If there are periods of unreadable signal that are marked as noise regions within the spectrum window, the gaps in the RR interval series are handled in the same way as gaps from excluded beats. The cubic spline will interpolate through the gaps based on data that is before and after the gap. If there is no data in front of the window and the first thing in the window is a noise region, then the RR interval series will be interpolated from a heart rate of 70 BPM.

11. Why are there different units for report?

The option of being able to display spectral measurements in different units was done because there are different ways to look at the spectral information. There is no right or wrong units, and researchers have chosen different units to do their work. We have chosen to allow users to also choose the units in which the spectral measurements are made. The three units we have chosen are: 1) milliseconds (ms) which is an easy unit to use to visualize the amplitude of variation at a particular frequency value, but has little meaning when measured over an interval; 2) milliseconds squared (ms**2) which is a standard unit for expressing power and is useful for expressing the total power (or variance in a statistical model) at a particular frequency or over a particular frequency range; 3) natural log of milliseconds squared (ln(ms**2)) which is another common unit for expressing power. Taking the natural log of the millisecond squared value changes the scale to a logarithmic one which may be useful for decreasing the dynamic range of the data or for bringing out relationships that become linear in a logarithmic scale. The natural log of milliseconds squared is useful to express measurements at a particular frequency or over a frequency range.

Frequently Asked Questions:

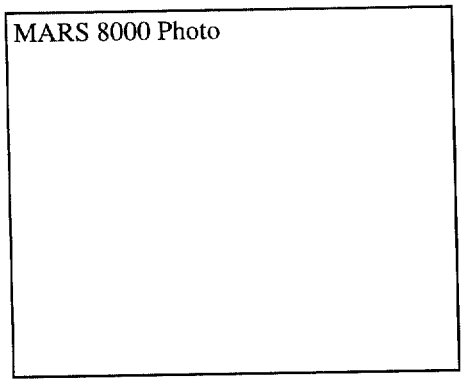
Appendix C
Part 1
Proposed Promotional Material

Fade from old 8000 through the laser series and ending with the MARS platforms

MARS Holter Systems

- Our commitment to Ambulatory Monitoring is clearly demonstrated in the continuous evolution of Holter systems taking advantage of the latest technology. From the first 8000 system, delivered in 1982 to today's MARS Unity workstation MMS has provided upgrades of hardware and software. This allows customers to more easily make purchasing decisions with confidence
- Innovation and optimal use of technology have allowed MMS to continuously break new ground in the use of Holter for clinical practice and leading edge research.
- The MARS is not limited to the traditional sources of Holter data. Mars is able to analyze data from most tape based recorders. The SEERMC and SEER XT digital recorders are also compatible with MARS. Using The MMS Unity Network MARS is able to analyze patient monitoring and telemetry data from a variety of MMS patient monitors. This unique capability provides for better patient care and offers a cost savings by using existing electrodes, eliminating hookup time and detailed quantitative analysis to assist in treatment and discharge decisions.
- As a key Component of MMS suite of arrhythmia management tools MARS Holter systems can provide important answers about the effectiveness of medical therapy and Pacemaker performance. and helps physicians make discharge decisions for patients undergoing monitoring or telemetry observation.
- A variety of review and editing tools offers complete control of the analysis process.
- The User definable menu system, based on these editing tools, allows the analyst to operate more effectively with a high degree of confidence. These menus can be designed based on user preference, clinical protocol or patient type.
- The high resolution color graphics and data presentation present subtle details with diagnostic quality.
- The analysis of Heart rate variability is done instantaneously, offering time domain and spectral analysis. A number of tools are available to analyze discreet frequency bands and time resolutions.

SEER MC
8500 recorder
Patient monitor



- The MARS Unity Workstation family of products offers a wide range of solutions for the review analysis and management of arrhythmias in a variety of areas throughout the Hospital. From The CCU to the Holter lab or the Telemetry Unity to a physicians office MARS provides access to vital ECG and hemodynamic data or complete quantitative Holter analysis.

- Based on powerful workstation technology, MARS offers technology, speed ease of use and networkability. The end result clear, readable and accurate information to allow complete detection analysis and reporting of arrhythmia. The Hardware is highly upgradable, providing assurance that MARS will have a long product life.

- The unique MARS user interface allows operation of the system based operator preference, clinical protocol or the needs of the care unit. These custom menu's provide faster more accurate results.

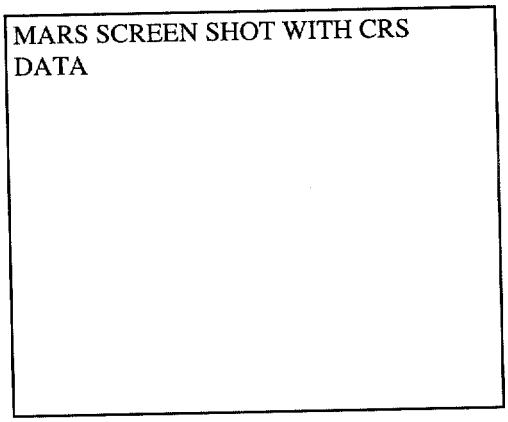
- Overall, MARS offers greater economy and a wide range of options to accommodate the clinical, operational and budgetary needs of virtually any patient monitoring or Holter

MARS CRS Full disclosure System

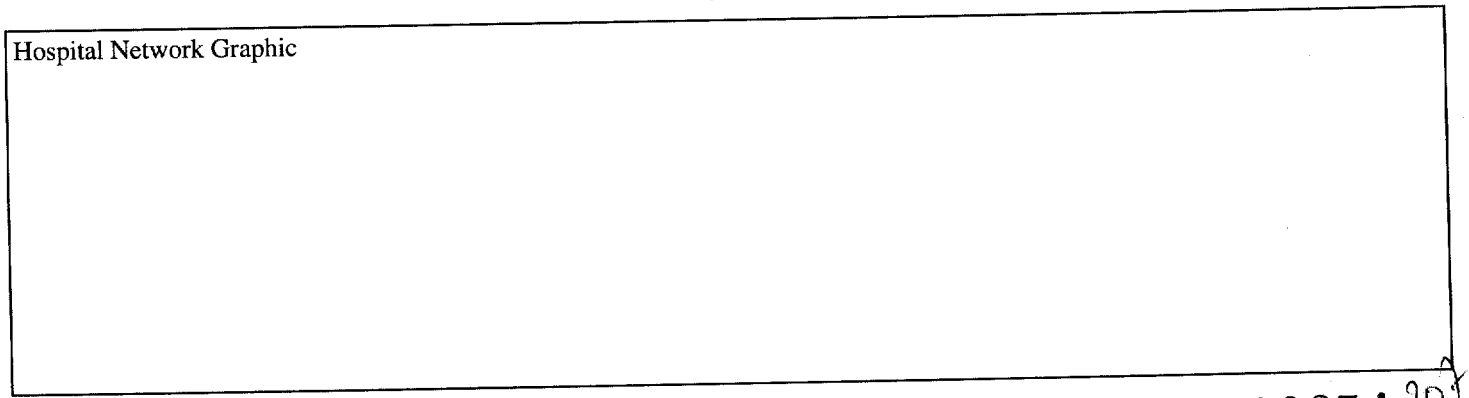
- The MARS CRS collects real-time full disclosure data in the critical care or telemetry environment Using Marquette's Unity Network.

- The MARS 8000 CRS is capable of acquiring 128 channels of data providing correlation of Hemodynamic wave-forms as well as ECG. This leads to faster answers and greater confidence.

- The MARS 5000 CRS is able to acquire up to 48 beds and is an economical solution for smaller CCU's and Telemetry units.



- Customizable Menus allow different units to have there own unique review protocols allowing fast answers when seconds count.
- Patient data can be reviewed in strip, page and Alarm event formats, all at the same time or in any combination.
- MARS-MARS offers sharing data between systems with the click of a mouse.
- MARS XLT allows two units to view their patients who are stored on the same MARS
- Full Disclosure can affords greater confidence when making transfer and discharge decisions and can help avoid unnecessary additional patient days.



PERSPECTIVE

Heart Rate Variability—Exploring the Potential

Research in heart rate variability seems to demonstrate the great potential and flexibility of this new test. Studies of heart rate variability, the "sinus arrhythmia" associated with healthy autonomic nervous system modulation of the heart, cover a spectrum of disciplines from cardiology to neurology.

We see more and more studies lately that correlate low heart rate variability with patients at risk for sudden cardiac death. Research now underway may ultimately demonstrate that low heart rate variability is a reliable predictor of sudden cardiac death for certain groups of patients, therefore providing the opportunity to modify treatment for these patients.

In the cardiac transplant patient, low heart rate variability is, of course, a normal condition due to denervation of the transplanted organ. But studies now underway indicate that increased heart rate variability occurs prior to allograft rejection and therefore may provide an early warning signal of a failed transplant. This may be the first simple, non-invasive method for monitoring the health of a cardiac transplant patient throughout their lifetime.

Heart rate variability is also being used in neurologic studies because it provides an easily accessible 'window' to the autonomic nervous system. These studies range from evaluating the progression of diabetic neuropathy, predicting sudden infant death syndrome, diagnosing sleep apnea and Lyme's disease, to monitoring patients under general anesthesia and evaluating the severity of head trauma.

"... heart rate variability provides an easily accessible 'window' to the autonomic nervous system ..."

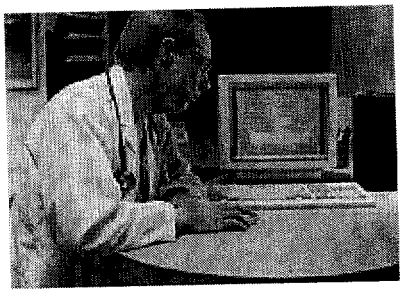
Marquette Electronics has formed partnerships with researchers at the forefront of the work in heart rate variability. The research tools provided by our Laser Holter system, including a new Heart Rate Variability Spectral Analysis Research Program, have given us the opportunity to support and participate in this exciting area of study. From our perspective, the great potential of heart rate variability to help in so many areas of medicine ensures that the exploration will continue.

For more information about Heart Rate Variability, please call Marquette Electronics at (800) 558-5120, or (414) 355-5000, ext. 2683.

marquette electronics

U.S.A.: 8200 W. Tower Ave. • Milwaukee, Wisconsin 53223 • (414) 355-5000 • TLX 297991 MEI MIL • FAX (414) 357-3456
Europe: 15, rue Rougemont • 75009 Paris, France • Tel. (33) (1) 42.46.00.19 • FAX (33) (1) 48.01.04.41
Asia/Pacific: 181 Johnston Rd. • Suite 1010 • Wanchai, Hong Kong • Tel. (852) 8381398 • FAX (852) 8381507

Appendix C
Part 2
Predicate Promotional Material



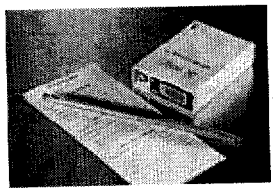
Today's healthcare environment places an ever-increasing importance on quickly and accurately identifying patient problems before they become critical and require hospitalization. In the physician's office, Spacelabs Medical is known as a world leader in Ambulatory Blood Pressure (ABP) and Holter monitoring for the early diagnosis of hypertension and cardiac conditions.

Our ABP monitors are among the smallest and lightest on the market today, with advanced reporting software that allows rapid analysis of patient information. Extensive testing by independent clinicians has validated their accuracy time and time again, making them widely recognized as the "gold standard" for ABP.

Our Holter systems come in a variety of configurations to meet multiple needs, with exclusive features like Heart Rate Variability and Lorenz Scatter Plot display capability.

Our advanced technology and history of product innovation makes Spacelabs Medical your source for diagnostic ambulatory monitoring.

Ambulatory Blood Pressure Monitors

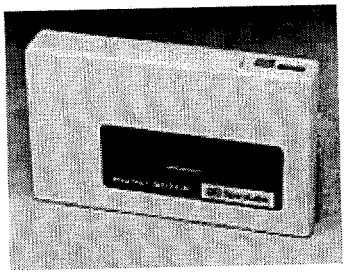


Spacelabs Medical is the world leader in ambulatory blood pressure (ABP) monitoring. The use of ABP is a routine procedure in many European countries and is increasing in the U.S. Many physicians are using ABP to detect "white coat" hypertension and to adjust drug therapy for their hypertensive patients.

Both the 90217 Ultralite and 90207 ABP monitors feature a compact, lightweight design that optimizes patient comfort -- a key factor in successful ABP monitoring. Comfort helps ensure patient compliance and, consequently, may decrease the number of artifactual readings.

Order ABP Brochure

Holter Recorders

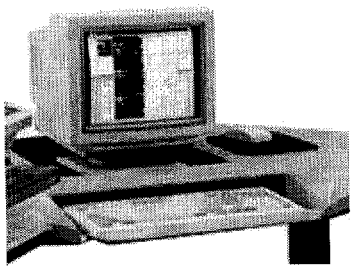


The Model 90205 Holter recorder weighs just 8 ounces and provides up to 48 hours of continuous ECG recording on two channels, plus a third discrete timing track. Automatic calibration ensures accurate, reliable ST measurements, while a patient event marker allows easy correlation between ECG waveforms and the patient's diary entries.

The Model 90208 pacemaker recorder can be used for ECG recording and pacemaker analysis. As an ECG recorder, it records three channels of continuous ECG over a 24-hour period. As a pacemaker analyzer, it records two channels of continuous ECG and one channel of pacer detection that records pacer flags to facilitate pacer analysis, over a 24-hour period.

000257

310



FT1000A and FT3000 Medical Workstations
The FT1000A is designed to meet the specific workstation needs for physicians' offices, while the FT3000 adds more capacity and options for busy hospital applications.

The FT3000 offers Heart Rate Variability (HRV) analysis and the Lorenz Scatter Plots as options. The Optical option allows storage of 60 to 80 24-hour full-disclosure scans.

Spacelabs medical | Patient Monitoring | Intesys CIS | Vita-Stat | Spacelabs Medical Data

What's New | About Spacelabs Medical | Patient Monitoring Products | Burdick, Inc.
Intesys Clinical Information Systems | Vita-Stat Health Screening Products | Spacelabs Medical Data
Supplies Products | Investor Information | Job Opportunities | How to Reach Us Worldwide
Service and Support | Search | Suggestions

000258

311

Appendix D
Sample Reports

Patient Name: **Test #2,**
ID:
Age: **0 yr**
Gender: **Unknown**

Hookup Date: **31-Jan-1999**
Hookup Time: **18:04:19**
Duration: **24:00:00**

Overreading Physician: ,
Referring Physician: ,
Indication/Diagnosis:
Medications:

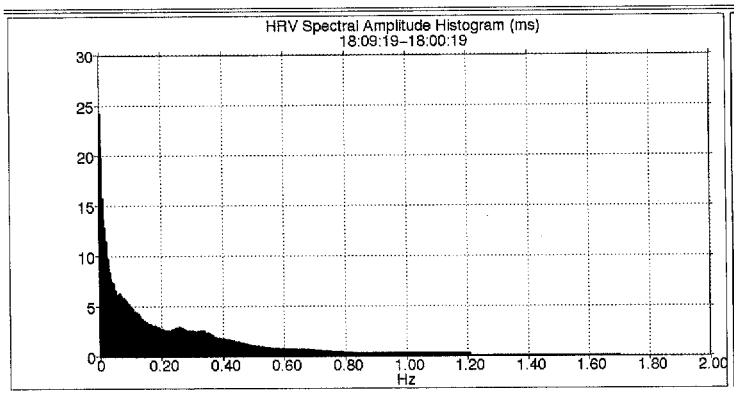
Interpretation

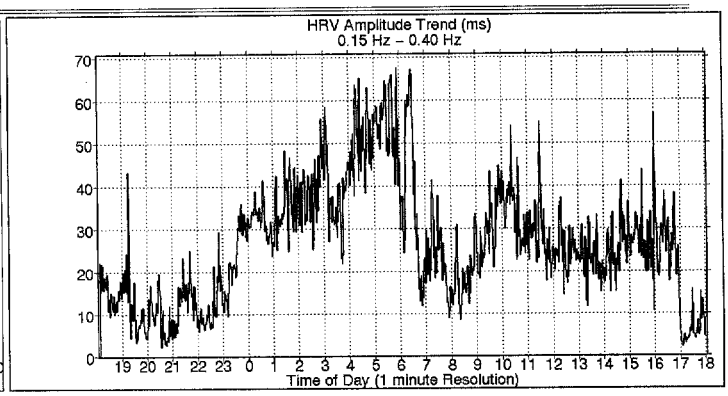
Signed:_____ Date:_____

000260

Patient: Test #2,
ID:

Site: UltrA 60 CARDIOLOGY VALIDATION
Location: Unknown
Hookup: 31-Jan-1999





Spectral Power

40.11 ms	Very Low Frequency:	(0.0033 – 0.0400 Hz)
30.03 ms	Low Frequency:	(0.0400 – 0.1500 Hz)
21.90 ms	High Frequency:	(0.1500 – 0.4000 Hz)
55.54 ms	Wideband Frequency:	(0.0033 – 1.7070 Hz)
21.90 ms	User Frequency	(0.1500 – 0.4000 Hz)
	Low/High Ratio: 1.37	

Exclusions

Time analyzed: 86400 sec. (24:00:00)
from 18:04:19 01/31/99 to 18:04:19 02/01/99
Time excluded: 4% (01:07:11)
Exclude RR interval ratios: < 0.80 > 1.20
Exclude RR intervals: < 150 ms > 5000 ms

Time Domain

682 ms	Mean NN	average of all intervals
200 ms	SDNN	standard deviation of all intervals
187 ms	SDANN	standard deviation of 5 min. means of intervals
77 ms	ASDNN	mean of 5 min. standard deviations of intervals
48 ms	rMSSD	root-mean-square of successive differences
21.2%	pNN50	percentage of intervals more than 50 ms different than previous interval
10.1%	pNN50a	percentage of intervals more than 50 ms longer than previous interval
11.1%	pNN50b	percentage of intervals more than 50 ms shorter than previous interval
25283 beats	BB50	count of intervals more than 50 ms different than previous interval
12020 beats	BB50a	count of intervals more than 50 ms longer than previous interval
13263 beats	BB50b	count of intervals more than 50 ms shorter than previous interval

before	Intervals Excluded	after
1	Fusion	1
1	Idioventricular	1
1	Ventricular Escape	1
1	Ventricular	1
1	Questionable	1
1	Junctional	1
1	Aberrant	1
1	Supraventricular	1
1	Paced Fusion	1
1	Dual Paced	1
1	Atrial Paced	1
1	Ventricular Paced	1

000261

314

Report Directory

000262

BNS

Patient Name: **Test #2,**
ID:
Age: **0 yr**
Gender: **Unknown**

Hookup Date: **31-Jan-1999**
Hookup Time: **18:04:19**
Duration: **24:00:00**

Overreading Physician: ,
Referring Physician: ,
Indication/Diagnosis:
Medications:

General

125101 QRS complexes
0 Paced beats (< 1%)
4 Ventricular beats (< 1%)
600 Supraventricular beats (< 1%)
0 BB beats (< 1%)
0 Junctional beats (< 1%)
0 Aberrant beats
0 % of total time in AF/AFL
< 1 % of total time classified as noise

Ventriculars (V, F, E, I)

4 Isolated
0 Couplets
0 Bigeminal cycles
0 Runs totaling 0 beats

Heart Rates

44 Minimum at 04:34:33 01-Feb
87 Average
201 Maximum at 19:31:56 31-Jan
43221 Beats in tachycardia (>100 bpm), 35% total
13135 Beats in bradycardia (<60 bpm), 10% total
1.6 Seconds Max R-R at 04:52:36 01-Feb

Supraventriculars (S, J, A)

113 Isolated
78 Couplets
3 Bigeminal cycles
42 Runs totaling 331 beats
76 Beats longest run 95 bpm 04:39:54 01-Feb
4 Beats fastest run 180 bpm 03:45:04 01-Feb

ST Channel 1

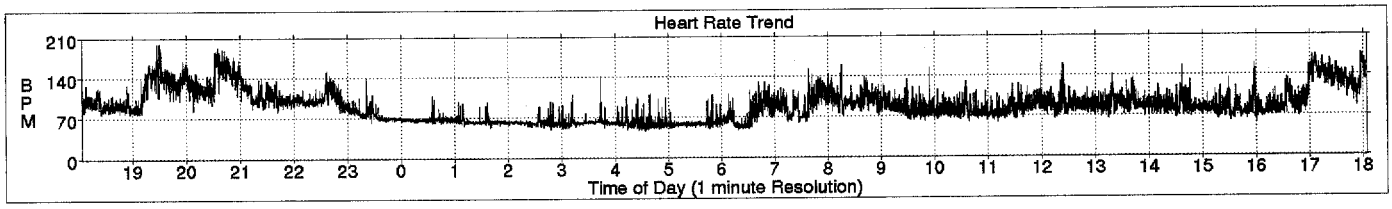
1.4 mm at 15:14:19 01-Feb
-2.1 mm at 20:35:19 31-Jan

ST Channel 2

1 mm at 01:08:19 01-Feb
-1.5 mm at 20:55:19 31-Jan

ST Channel 3

0.9 mm at 17:08:19 01-Feb
-1.2 mm at 19:33:19 31-Jan

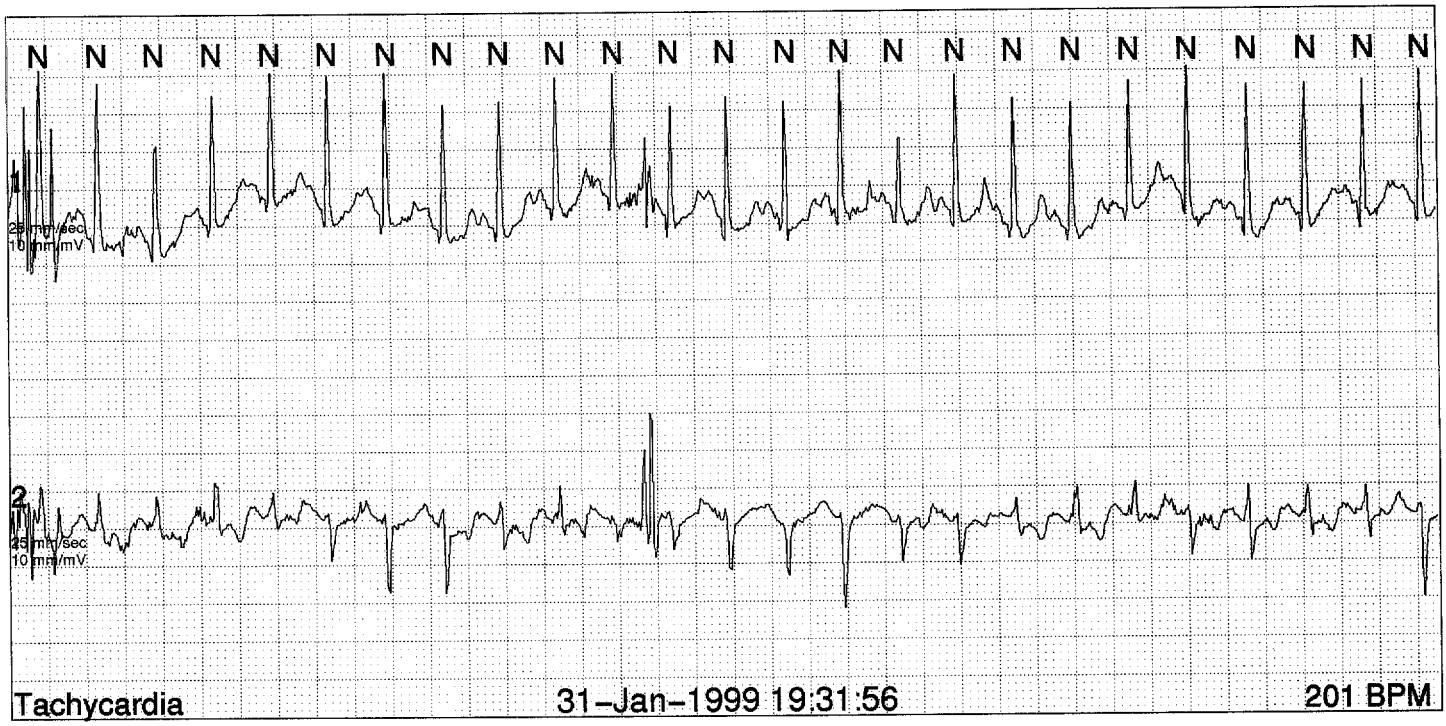


Interpretation

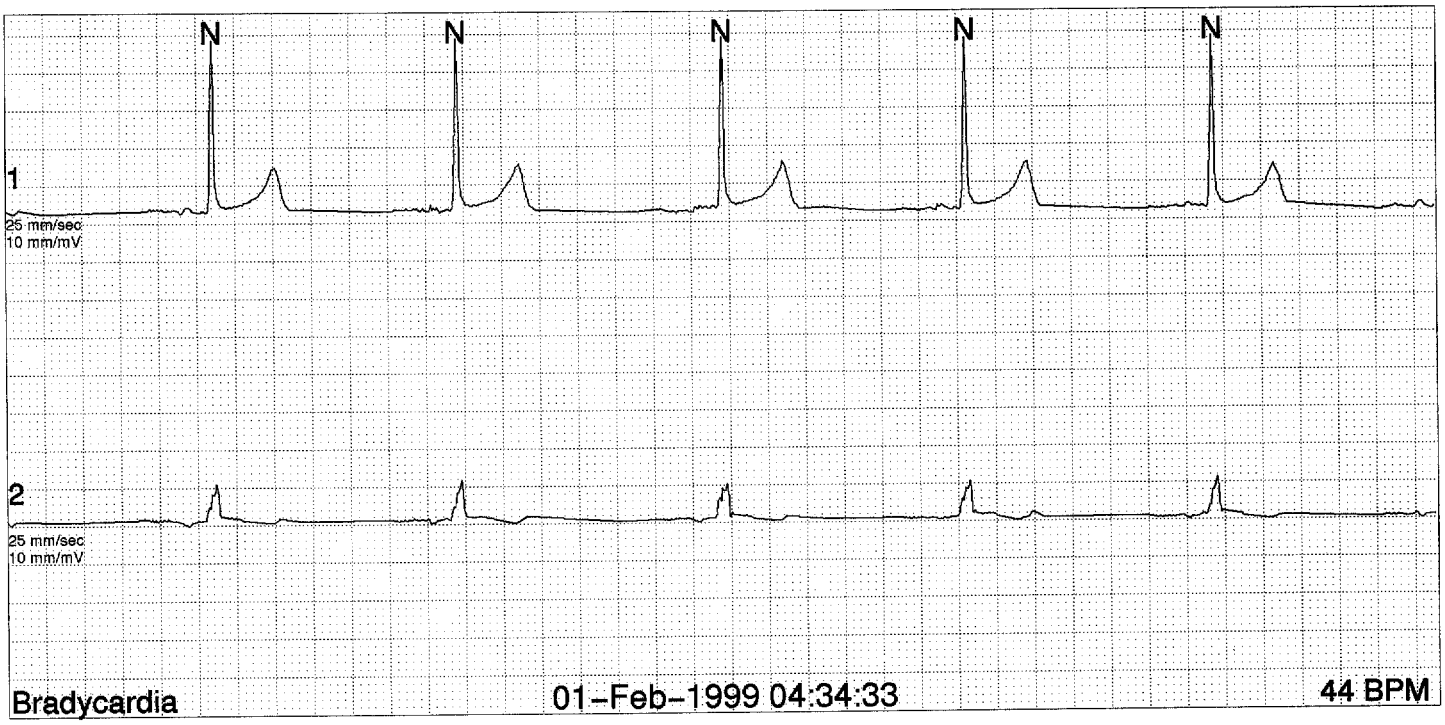
Signed:_____ Date:_____

000263

Max Heart Rate

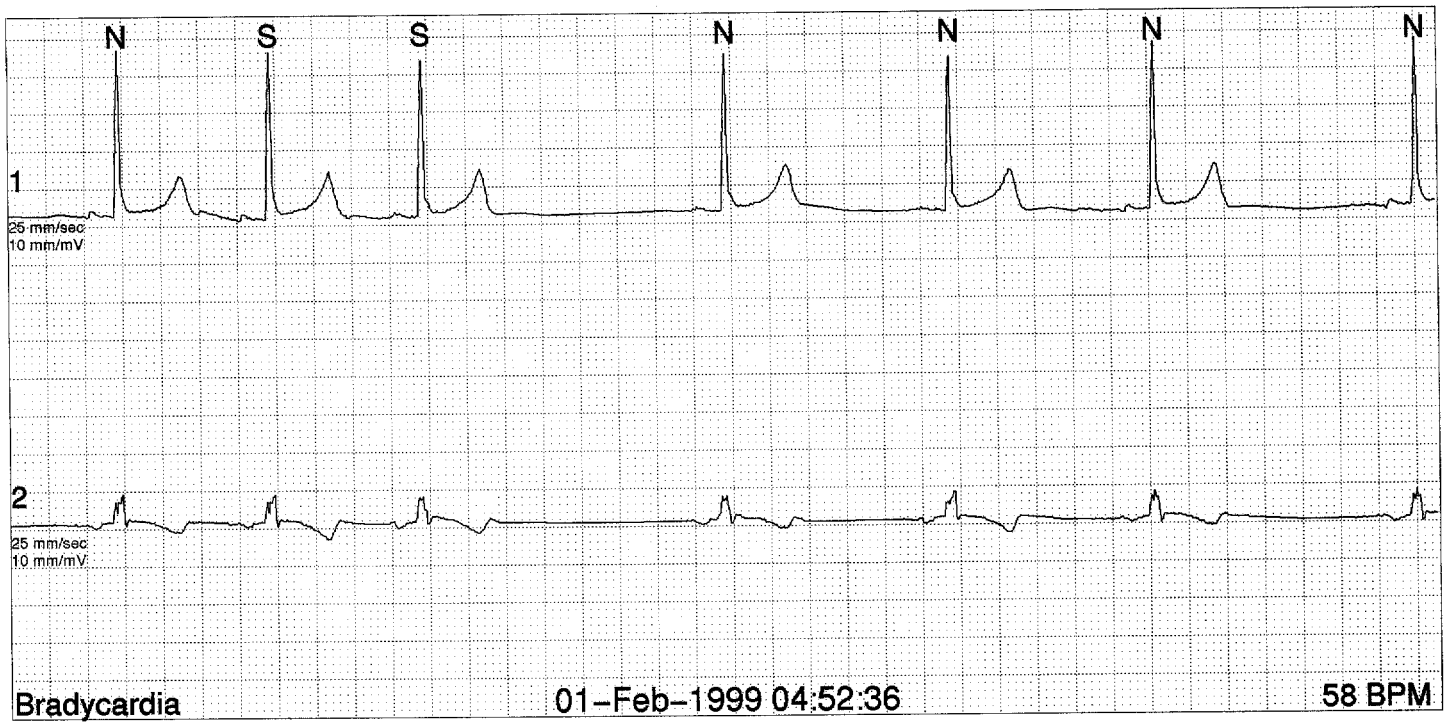


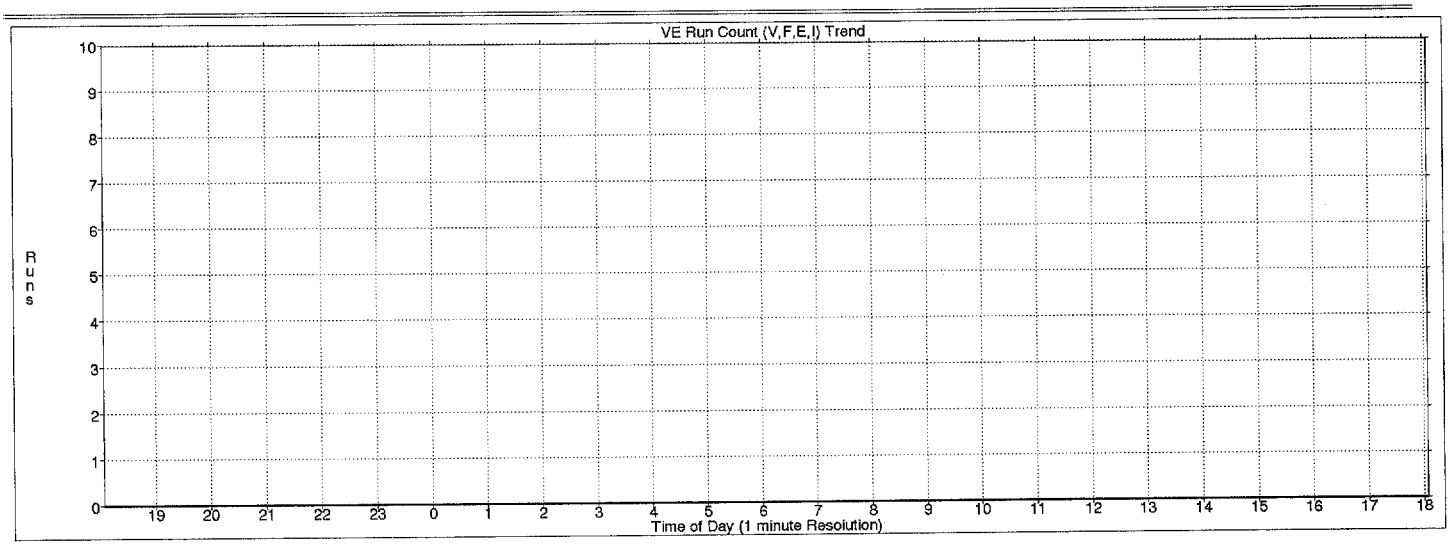
Min Heart Rate



000264

Max R-R





000265

Patient Name: **Test #2,**
ID:
Age: **0 yr**
Gender: **Unknown**

Hookup Date: **31-Jan-1999**
Hookup Time: **18:04:19**
Duration: **24:00:00**

Overreading Physician: ,
Referring Physician: ,
Indication/Diagnosis:
Medications:

General

125101 QRS complexes
0 Paced beats (< 1%)
4 Ventricular beats (< 1%)
600 Supraventricular beats (< 1%)
0 BB beats (< 1%)
0 Junctional beats (< 1%)
0 Aberrant beats
0 % of total time in AF/AFL
< 1 % of total time classified as noise

Ventriculars (V, F, E, I)

4 Isolated
0 Couplets
0 Bigeminal cycles
0 Runs totaling 0 beats

Heart Rates

44 Minimum at 04:34:33 01-Feb
87 Average
201 Maximum at 19:31:56 31-Jan
43221 Beats in tachycardia (>100 bpm), 35% total
13135 Beats in bradycardia (<60 bpm), 10% total
1.6 Seconds Max R-R at 04:52:36 01-Feb

Supraventriculars (S, J, A)

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78 Couplets
3 Bigeminal cycles
42 Runs totaling 331 beats
76 Beats longest run 95 bpm 04:39:54 01-Feb
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ST Channel 1

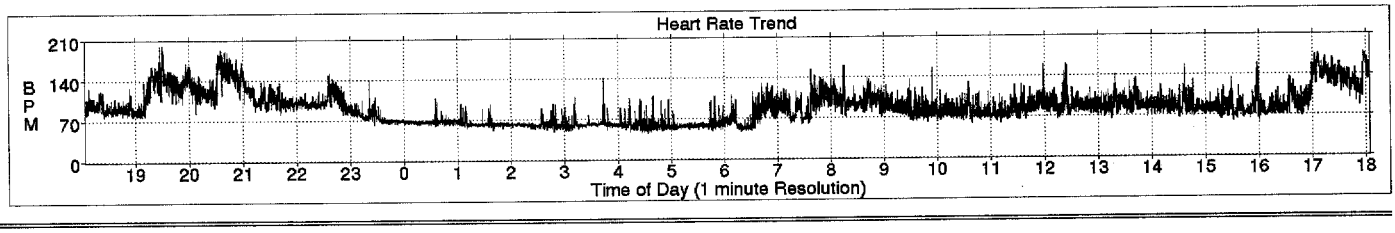
1.4 mm at 15:14:19 01-Feb
-2.1 mm at 20:35:19 31-Jan

ST Channel 2

1 mm at 01:08:19 01-Feb
-1.5 mm at 20:55:19 31-Jan

ST Channel 3

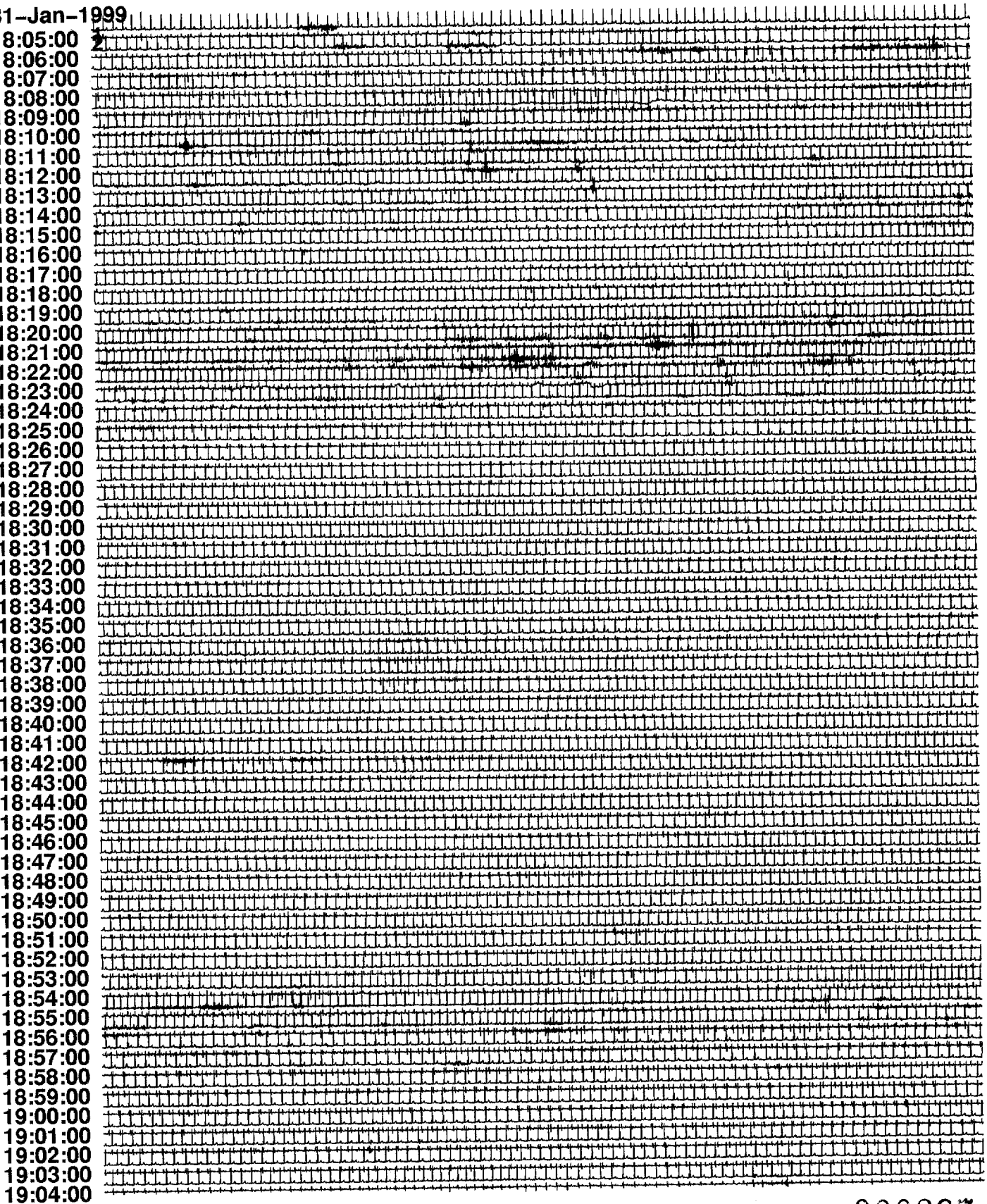
0.9 mm at 17:08:19 01-Feb
-1.2 mm at 19:33:19 31-Jan



Interpretation

Signed:_____ Date:_____

000266


31-Jan-1999
18:05:00
18:06:00
18:07:00
18:08:00
18:09:00
18:10:00
18:11:00
18:12:00
18:13:00
18:14:00
18:15:00
18:16:00
18:17:00
18:18:00
18:19:00
18:20:00
18:21:00
18:22:00
18:23:00
18:24:00
18:25:00
18:26:00
18:27:00
18:28:00
18:29:00
18:30:00
18:31:00
18:32:00
18:33:00
18:34:00
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18:42:00
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18:47:00
18:48:00
18:49:00
18:50:00
18:51:00
18:52:00
18:53:00
18:54:00
18:55:00
18:56:00
18:57:00
18:58:00
18:59:00
19:00:00
19:01:00
19:02:00
19:03:00
19:04:00

000267

Patient Name: **Test #2,**
ID:
Age: **0 yr**
Gender: **Unknown**

Hookup Date: **31-Jan-1999**
Hookup Time: **18:04:19**
Duration: **24:00:00**

Overreading Physician: ,
Referring Physician: ,
Indication/Diagnosis:
Medications:

General

125101 QRS complexes
0 Paced beats (< 1%)
4 Ventricular beats (< 1%)
600 Supraventricular beats (< 1%)
0 BB beats (< 1%)
0 Junctional beats (< 1%)
0 Aberrant beats
0 % of total time in AF/AFL
< 1 % of total time classified as noise

Ventriculars (V, F, E, I)

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0 Couplets
0 Bigeminal cycles
0 Runs totaling 0 beats

Heart Rates

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87 Average
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Supraventriculars (S, J, A)

113 Isolated
78 Couplets
3 Bigeminal cycles
42 Runs totaling 331 beats
76 Beats longest run 95 bpm 04:39:54 01-Feb
4 Beats fastest run 180 bpm 03:45:04 01-Feb

ST Channel 1	ST Channel 2	ST Channel 3
1.4 mm at 15:14:19 01-Feb	**1** mm at 01:08:19 01-Feb	**0.9** mm at 17:08:19 01-Feb
-2.1 mm at 20:35:19 31-Jan	**-1.5** mm at 20:55:19 31-Jan	**-1.2** mm at 19:33:19 31-Jan

Interpretation

Signed:_____ Date:_____

000268

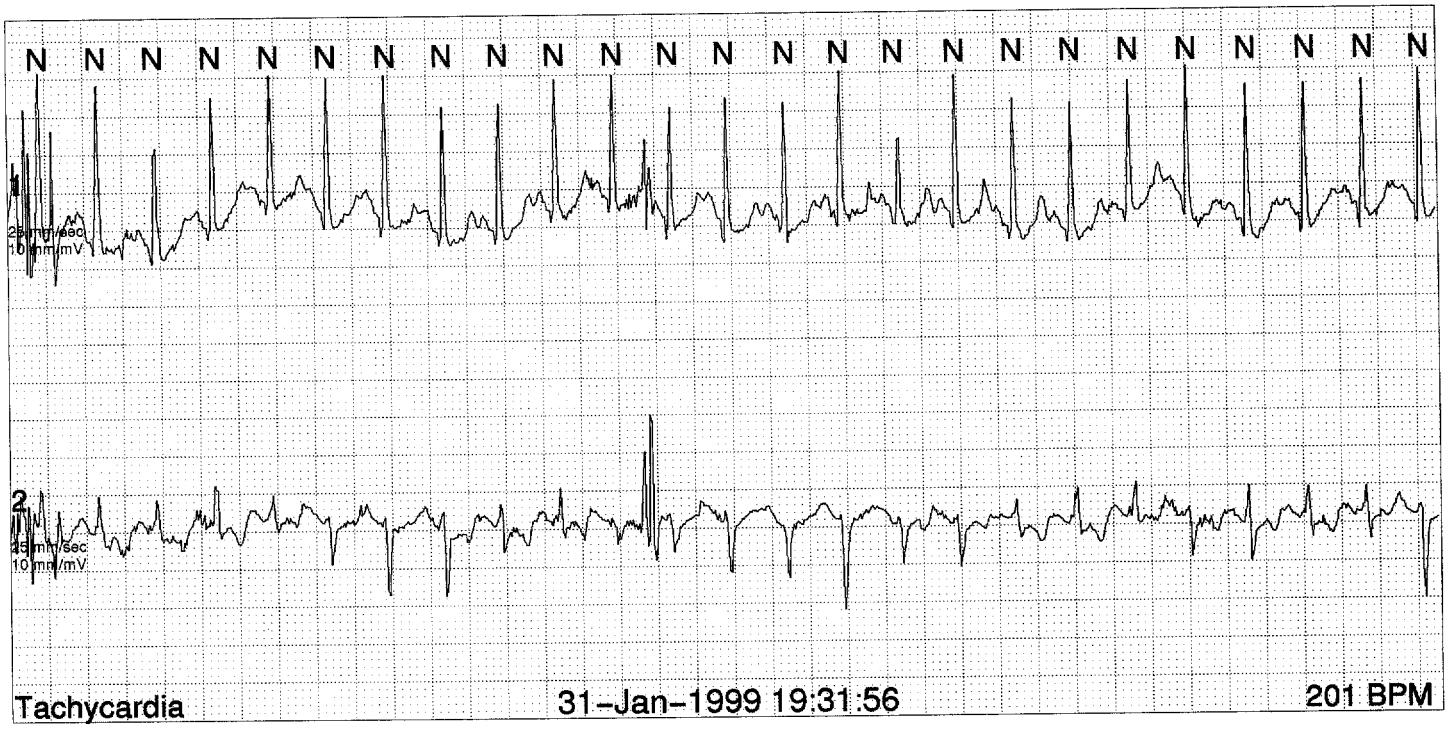
Hourly Summary

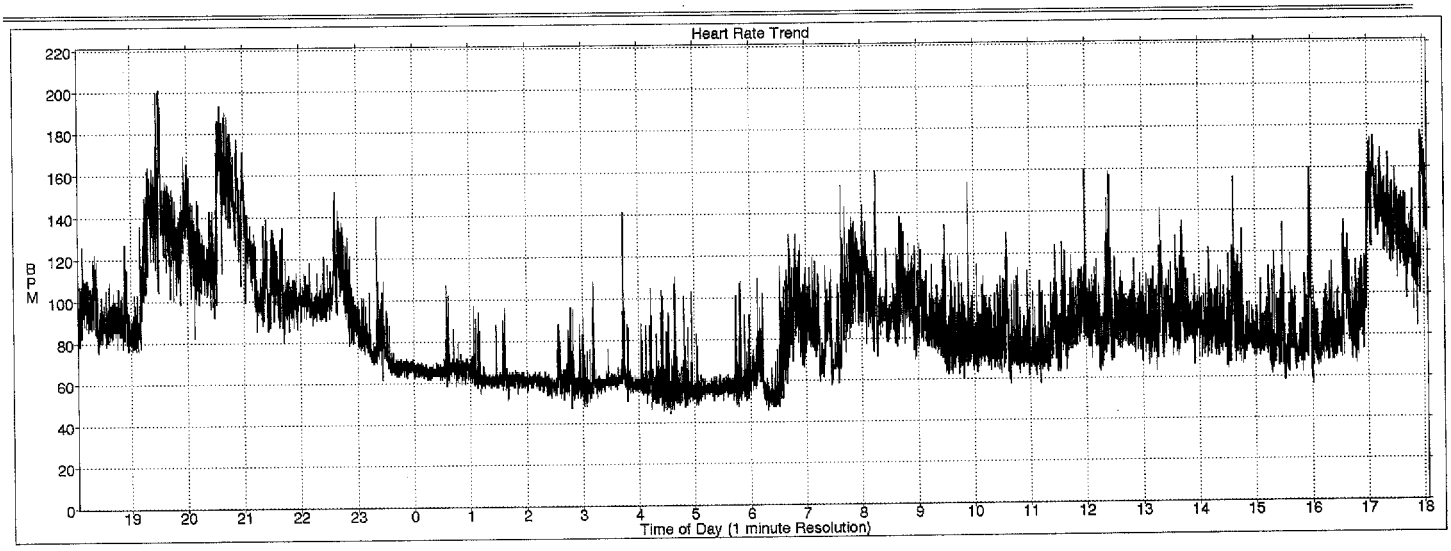
*RR_Pause_Criteria: 2000

		Heart Rate					Ventricular					Supraventricular				
Hour	Min.s Used	#QRS's	Min.	Ave.	Max.	Pauses	Iso	Cplt	Runs	Max Run	Max Rate	Iso	Cplt	Runs	Max Run	Max Rate
18	56	5161	75	93	127	0	0	0	0	0	0	0	0	0	0	0
19	58	7520	76	129	201	0	0	0	0	0	0	2	0	2	6	157
20	56	7906	82	139	193	0	0	0	0	0	0	3	0	1	8	166
21	60	6562	80	109	159	0	0	0	0	0	0	0	1	0	0	0
22	60	6218	78	104	152	0	0	0	0	0	0	1	0	0	0	0
23	60	4518	61	75	140	0	0	0	0	0	0	0	1	0	0	0
00	60	4018	58	67	107	0	0	0	0	0	0	0	0	0	0	0
01	60	3787	51	63	97	0	0	0	0	0	0	0	0	0	0	0
02	60	3653	47	61	96	0	0	0	0	0	0	4	7	1	3	78
03	60	3644	48	61	141	0	0	0	0	0	0	1	1	3	4	180
04	60	3531	44	59	110	0	0	0	0	0	0	40	24	21	76	95
05	60	3474	47	58	108	0	0	0	0	0	0	2	0	0	0	0
06	60	4370	45	73	130	0	1	0	0	0	0	5	5	4	5	89
07	60	5469	57	91	153	0	0	0	0	0	0	4	1	1	3	87
08	60	5925	69	99	160	0	0	0	0	0	0	3	0	0	0	0
09	60	5031	60	84	154	0	0	0	0	0	0	6	11	1	4	177
10	60	4698	57	78	130	0	1	0	0	0	0	7	8	0	0	0
11	60	4955	57	83	160	0	0	0	0	0	0	5	5	2	8	113
12	60	5317	63	89	159	0	0	0	0	0	0	6	0	1	6	106
13	60	5394	63	90	141	0	0	0	0	0	0	2	1	1	5	103
14	60	5081	64	85	156	0	0	0	0	0	0	0	5	1	6	150
15	60	4874	58	81	160	0	1	0	0	0	0	8	5	1	3	100
16	59	5138	56	86	157	0	1	0	0	0	0	13	3	1	3	91
17	60	8243	84	138	177	0	0	0	0	0	0	1	0	1	6	114
18	4	614	129	154	168	0	0	0	0	0	0	0	0	0	0	0
	1432	125101	44	87	201	0	4	0	0	0	0	113	78	42	76	180

000269

Max Heart Rate





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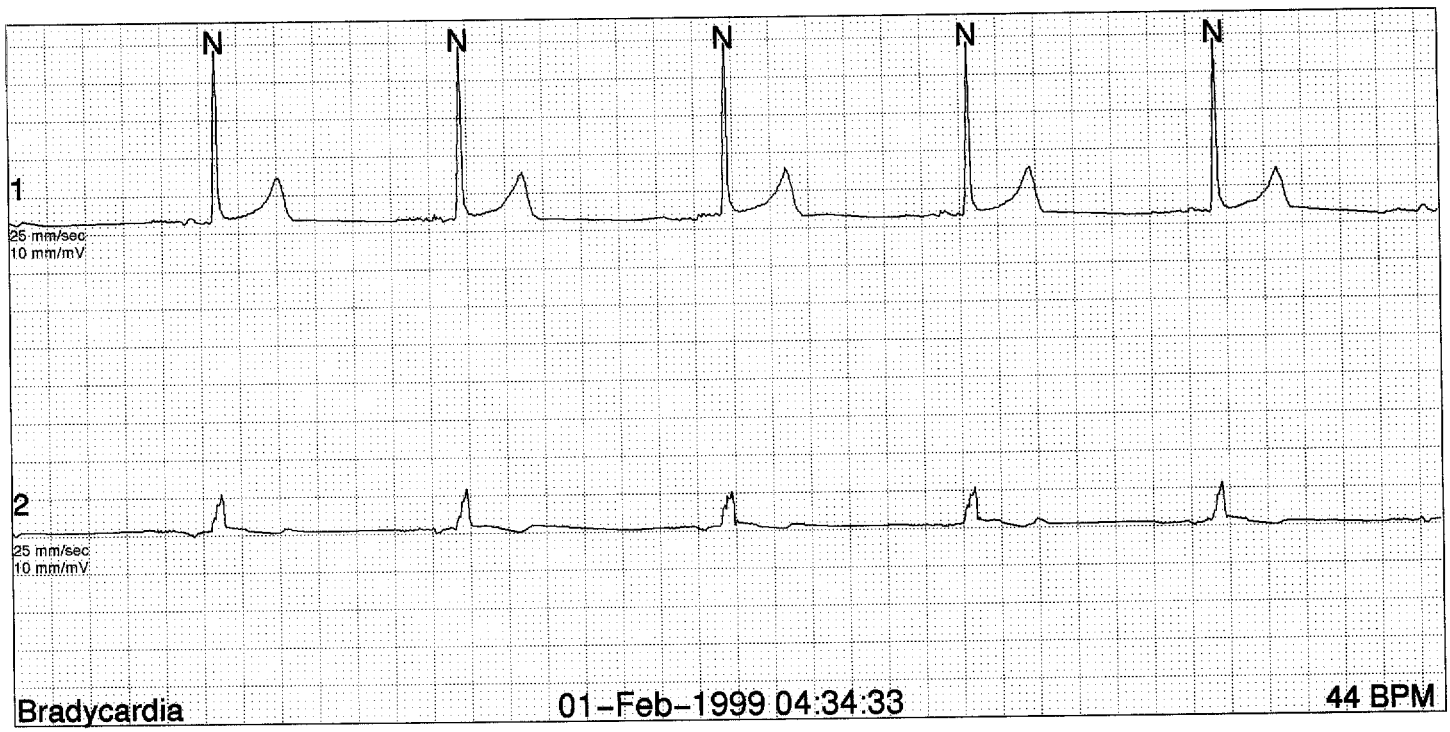
323

Min Heart Rate



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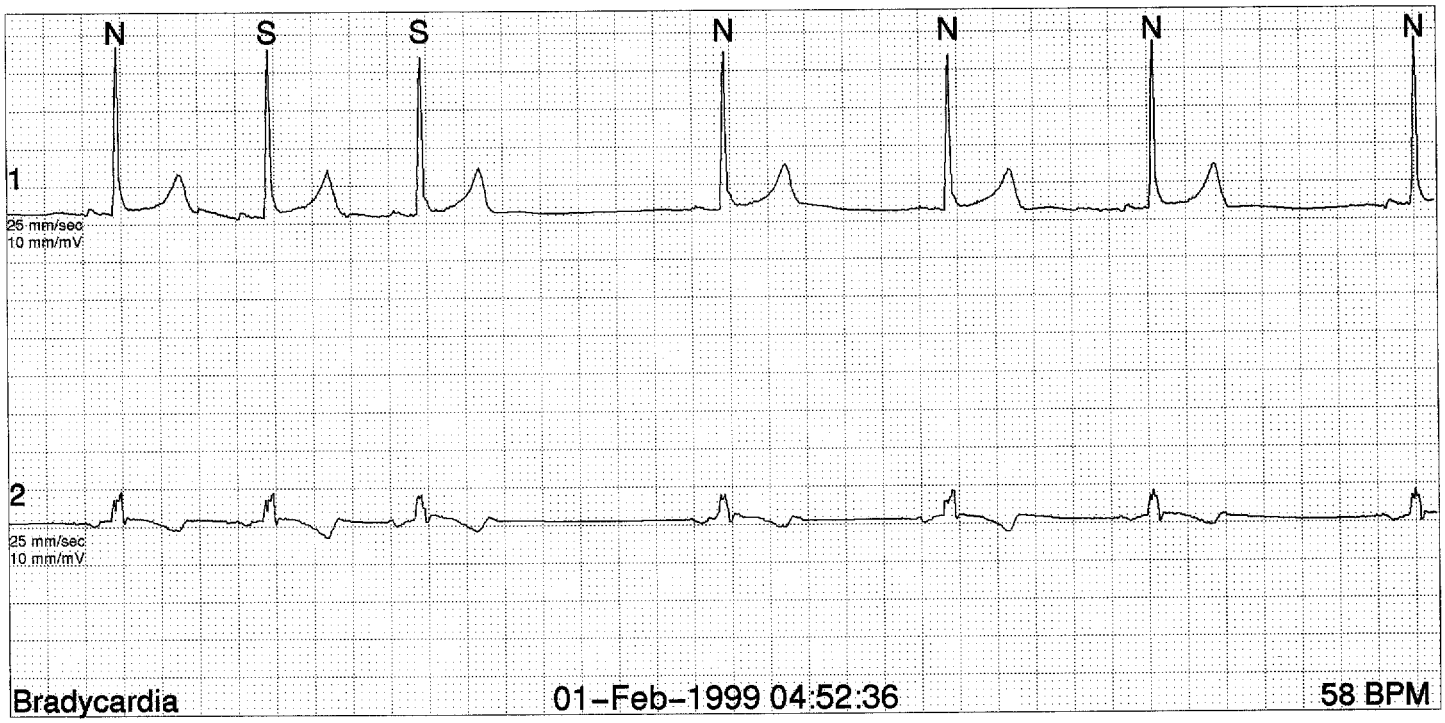
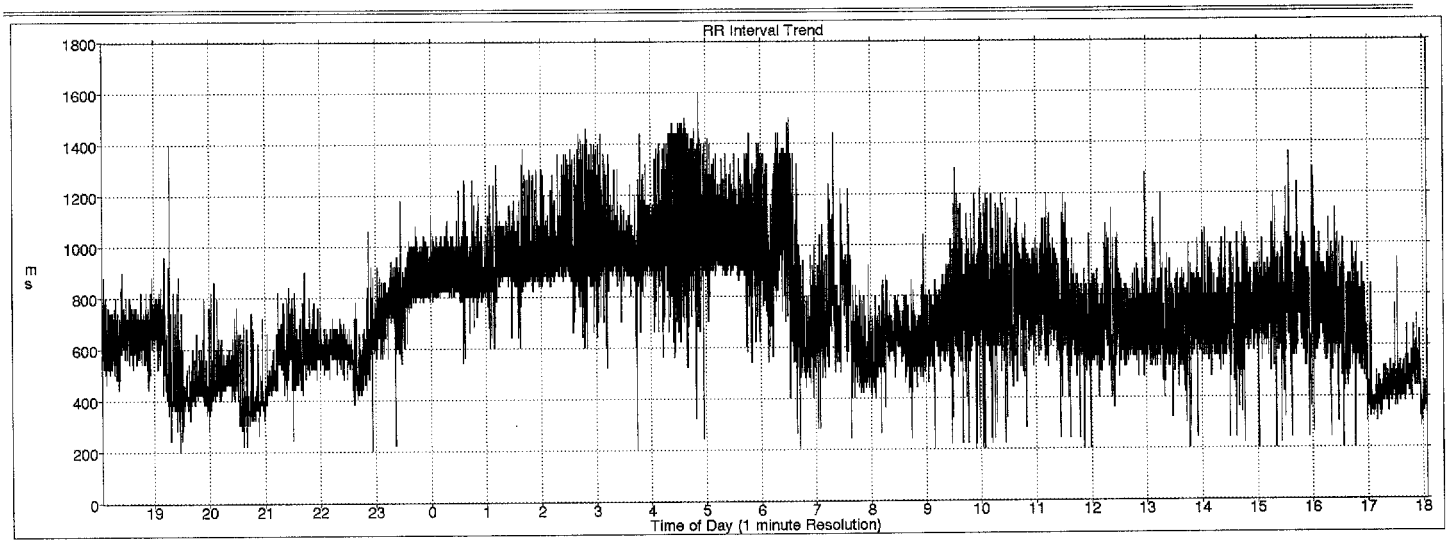
Max R-R





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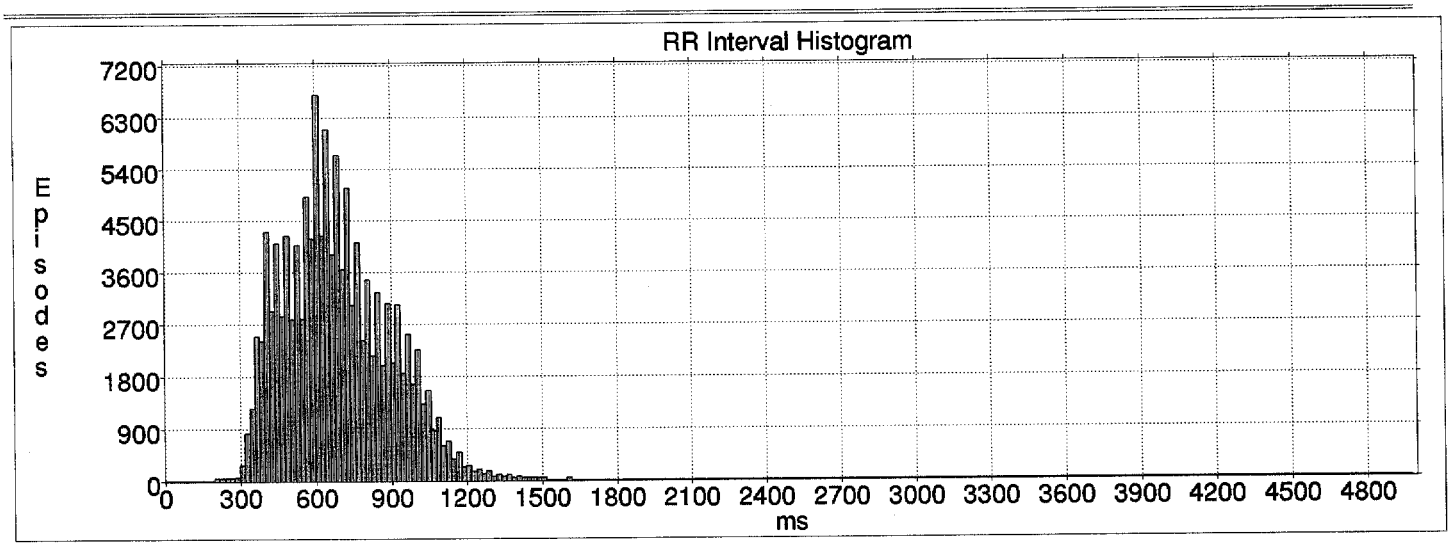
RR Interval Histogram
Episodes
7200
6300
5400
4500
3600
2700
1800
900
0
0 300 600 900 1200 1500 1800 2100 2400 2700 3000 3300 3600 3900 4200 4500 4800
ms

000273

326

UltrA 60 CARDIOLOGY VALIDATION
Location: Unknown

FULL DISCLOSURE REPORT

Patient Name: **Test #2,**
ID:
Age: **0 yr**
Gender: **Unknown**

Hookup Date: **31-Jan-1999**
Hookup Time: **18:04:19**
Duration: **24:00:00**

Overreading Physician: ,
Referring Physician: ,
Indication/Diagnosis:
Medications:

Interpretation

Signed:_____ Date:_____

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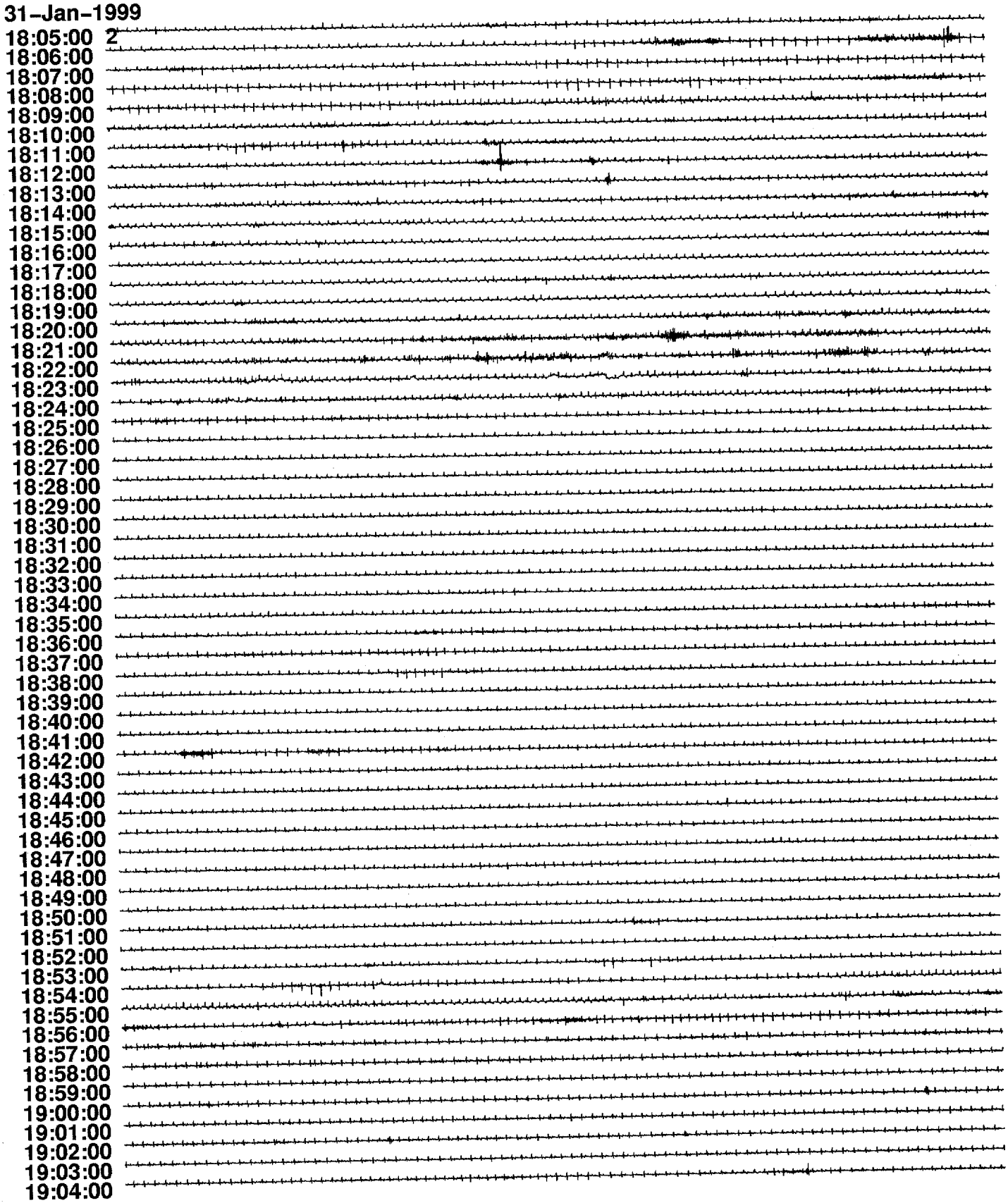
Report Directory

31-Jan-1999



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Version: 4.1

(bpos)

329

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DUPLICATE

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PREMARKET NOTIFICATION 510(K)

MARS Unity Workstation w/HRV Option

Volume II of III

Submitted: May 24, 1999

GE Marquette Medical Systems, Inc.
8200 West Tower Avenue
Milwaukee, Wisconsin 53223 USA
(414) 355-5000

APPENDICES

Appendix E
Part 1
System Requirements Specification (SRS)

Appendix E
Part 2
Software Detailed Requirements (SDR)

Appendix E
Part 3
GE Marquette HRV Software Detailed Requirements (SDR)

Appendix E
Part 4
MARS Electrical Detailed Requirements (EDR)

Appendix F
Part 1
MARS Unity Workstation Hazard Analysis

Appendix F
Part 2
HRV Hazard Analysis

Appendix G
ISO9001, EN46001 Certificates

(b)(4)Proprietary Information

(b)(4)Proprietary Information

(b)(4)Proprietary Information

Appendix H
Part 1
Product Development Process DDM0100

Appendix I
Risk Analysis During New Product Design and Review

Appendix J
Part 1
Validation Test Plan

Appendix J
Part 2
Validation Test Results and Summary

Appendix J
Part 3a
MARS System Integration Test Plan-Overview

[] Verify the *Tools* window opens.

12.5.2 Autoscale

[] Verify the *Autoscale* button opens as enabled (indented).

12.5.2.1 Click to disable (unindented) the *Autoscale* button.

[] Verify the scale for the displayed trend changes.

12.5.2.2 Click to enable (indented) the *Autoscale* button.

[] Verify the scale for the displayed trend returns to the previous values.

12.5.3 Cursor Labels

[] Verify the *Cursor Labels* button opens as enabled (indented).

12.5.3.1 Click to disable (unindented) the *Cursor Labels* button.

[] Verify the numeric window associated with the vertical cursor disappears.

12.5.3.2 Click to enable (indented) the *Cursor Labels* button.

[] Verify the numeric window reappears.

12.5.4 Set the **Go To Time.**

12.5.4.1 Click the up and down arrows next to the date and time boxes to change the *Go To Time*.

[] Verify the *Go To Time* button is grayed out until time is scrolled.

12.5.4.2 Click the *Go To Time* button.

[] Verify the cursor in the display window goes to the correct time.

12.5.4.3 Using the left mouse button, place the cursor in a displayed trend.

[] Verify the *Go To Time* updates to that time.

12.5.5 **Screen Size**

12.5.5.1 Click on the *Screen Size* list box.

12.5.5.2 Select *12 hours.*

[] Verify the displayed trend changes to 12 hours of data.

12.5.6 **Plot Size**

12.5.6.1 Click the *Plot Size* list box.

Appendix K
Part 1
HRV Software Test Plan

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PREMARKET NOTIFICATION 510(K)

MARS Unity Workstation w/HRV Option

Volume III of III

Submitted: May 24, 1999

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APPENDICES

Appendix L
Published Scientific Literature on HRV Techniques/Methods

Appendix M
MARS Unity Workstation Specification Sheets

MARS® 3000
ARRHYTHMIA REVIEW STATION.

The MARS 3000 is perfect for hospitals, clinics and office practices. Designed for lower volume users requiring high-level clinical performance, it incorporates many advanced review features and analysis programs found in all of the MARS Series systems.

Flexible, User-Friendly Operation

Beat classifications can be reviewed through template groups and where necessary entire template groups can be re-labeled with one keystroke for highly efficient editing. Users can custom-tailor operation menus to their data review requirements and clinical data types. On-screen classification annotations displayed above each heartbeat on full size ECG strips and abnormal beats in full disclosure display can be custom colored to highlight them in context. And report pages can be previewed on-screen as they will actually appear on the printed page, prior to printing.

Preliminary Test Results in Seconds

The MARS 3000 accepts data cards from the SEER® MC solid-state, digital recorder. The SEER MC analyzes each heartbeat as it occurs. This built-in analysis capability, and rapid transfer to the MARS 3000 hard disk drive via digital data card download, means preliminary test results and ECG data can be viewed by clinicians within seconds. In many cases, clinicians can quickly review data associated with significant symptoms before patients leave the office.

Feature Highlights

- The MARS-to-MARS interface option enables you to link to other MARS systems in local and wide area networks through enterprise-wide networking, enhancing arrhythmia management efforts or allowing easy expansion of data-handling capacity.

- Optional Waveforms Measurement software provides high-resolution ST-segment measurements to as fine as 15 second resolution, with user adjustable measurement points.
- MARS-to-MUSE CV® Information System interface allows convenient, centralized archival and retrieval, as well as comprehensive cardiovascular data sharing.
- True system multi-tasking provides the answer for productive arrhythmia services – offering the capability to review a recording while a report for a second patient is being printed and a tape is being analyzed for a third patient.
- The MARS 3000 acquires data from the SEER® MC and SEER® XT, as well as most conventional Holter tape recorders.

The MARS 3000 – a high-performance arrhythmia management system with advanced features and analysis programs designed to meet hospital, clinic and office requirements.

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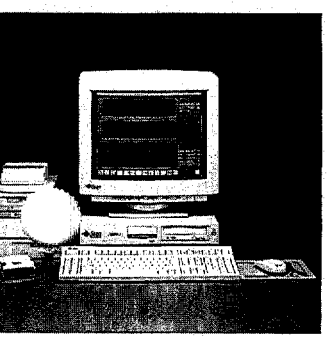
87

Specifications

MARS® 3000
ARRHYTHMIA REVIEW STATION.



Performance Specifications – Hardware Description

Sun Microsystems Ultra 5 workstation with UltraSparc IIi processor and 256 KB external cache

Memory: 128 Mb DIMM (upgradeable to 1 Gb)

Monitor: 17″ color (1152 x 900 resolution, 76 Hz refresh rate)

Creator graphics processor: 24-bit

Disk drives: Sun CD internal 32X CD-ROM drive
4.3 Gb enhanced IDE hard disk drive
1.44 Mb internal floppy disk drive

Keyboard: Sun Country includes mouse kit

Power supply: Oneac un-interruptible power supply

STANDARD INTERFACES

Expansion bus: Three 32-bit PCI slots 33 MHz

Network: Ethernet/Fast Ethernet, twisted pair standard (10-baseT and 100-baseT)

Serial connector: Sub-D 25 pin

Parallel connector: Sub-D 25 pin

ENVIRONMENT

AC power: 110-120:220-240 VAC 47-63 Hz

Operating: 10 to 35°C (50 to 95°F)

Non-operating: -20 to 60°C (-4 to 140°F)

Operating acoustic noise: 5.2 bels ISO 9296

Idling acoustic noise: 5.1 bels ISO 9226

SUN ULTRA 5 CHASSIS DIMENSIONS AND WEIGHTS

Height: 11.2 cm (4.40 in)

Width: 43.6 cm (17.10 in)

Depth: 43.0 cm (16.90 in)

Weight: 18 kg (39.70 lbs)

REGULATIONS (meets/exceeds these requirements)

Safety: UL 1950, CSA C22.2 No. 950. TUV EN 60950, CB Scheme with Nordic deviations, EMKO-TSE (74-SEC) 203, ZH1/618

RFI/EMI: FCC Class B, DOC Class B, VCCI Class 2, EN 55022 Class B, EN 61000-3-2

Immunity: EN 50082-1

X-ray: DHHS 21 Subchapter J; PTB German X-ray Decree

Power management: Energy Star compliant

HARDWARE OPTIONS

SEER acquisition unit: Access to data and analysis results in less than 1 minute

Tape acquisition unit: 1000x real-time downloads

Storage unit: 5 Gb DAT (Digital Audio Tape)

Printers: HP 6M Laser (6 pages/min), Ethernet Network, Ethernet Network with Duplexer, Token Ring Network, Token Ring Network with Duplexer

Network integration: Includes necessary hardware and site assessment

Remote Access Unit for system support

Software Description

Operating System: Sun Solaris 2.6

HOLTER ANALYSIS/EDITING SOFTWARE User-defined menus can be created using the following tools:

*Patient settings: Provide user-defined event settings to help identify all significant patient rhythm disturbances and ST abnormalities (similar to alarm settings in patient monitoring). Also allows user definition of heart rate calculations.

*Patient select: Access and manage patient files

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*Patient ID: Patient demographic, physician, diagnosis and medication entries

*Patient diary: Correlation of patient symptoms and activities with rhythm data

Shape review: Review and edit results of initial patient data analysis

Episode review (histograms): Severity-based review and documentation of significant events

Trend review: Time-based review and documentation of significant events, heart rates

*Page review: Allows complete data review using manual or automatic paging as well as quick access to any time during the study. Offers Region tool, channel selection, gain, resolution and beat color selection

*Strip review: Allows complete data review using superimposition (up to 240 x real-time). Offers Region tool, channel selection, gain adjustment, selectable resolution, template editing and on-screen calipers.

*Event review: Allows review, documentation and editing of all events which exceed user-defined patient settings (strip view)

*Event diary: Allows review, documentation and editing of all events which exceed user-defined patient settings (text list review)

**Waveform measurement: 3 channel high-resolution ST segment analysis with selectable measurement points, analysis speed and channel selection

*Report review: On-screen review and confirmation of all final report text, strip and page data

User-definable trend groups, histogram groups, final report setup and menu design

*CD ROM-based tutorials

*CD ROM-based service manuals

*Remote system support with either analog or ISDN access

*High level pacemaker detection and review from MMS recorders

*Data acquisition from: SEER® XT, SEER® MC, 8500 2-3 channel, DelMar Avionics 453, ICR 7200, Nihon Khoden 3253 and 4502, Spacelabs 90205, Rozinn 151, Reynolds Tracker. Please call for additional information regarding other supported recorder types.

SOFTWARE OPTIONS

MARS to MARS connectivity: Allows access to data on MARS systems on a network

MARS to MUSE®: Store, retrieve and print Holter reports on the MUSE CVIS, via local or enterprise network

Note: MARS 3000 does not support CRS software or the MARS XLT network computer. These capabilities are provided by the MARS 5000 and MARS 8000 Arrhythmia Review Stations

*MARS 3000 Outreach Standard Software Features

**Optional for MARS 3000

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MARS® 5000
ARRHYTHMIA REVIEW STATION.

This affordable, high-performance solution is ideally suited to facilities with moderate-volume arrhythmia management demands.

Convenient Software Simplifies Use

Readily identifiable toolbar icons facilitate efficient navigation. Powerful applications put the operator firmly in command.

User-configurable menus allow the operator to conveniently meet clinical protocols and care unit needs, as well as individual access, review and printing preferences.

Network Connection Offers Quick, Easy Access to Information

Acquire data from multiple sources for more comprehensive, and timely, assessment.

Use the optional MARS-to-MARS interface to link various hospital departments through an enterprise-wide network, enhancing arrhythmia management capabilities or allowing easy expansion of data-handling capacity.

The MARS 5000 Productivity-Enhancing Power

Exceptional processing power enables the MARS 5000 to provide the high-resolution color graphics and data needed to present subtle ECG details with diagnostic quality.

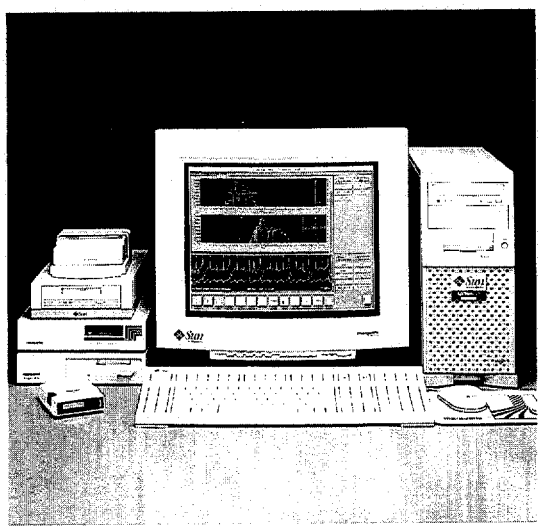
The MARS 5000 power also supports multitasking efficiency, enabling the operator to download, process, review and print simultaneously.

Customized Holter Analysis Enhances Accuracy and Ease of Use

Advanced capabilities make the MARS 5000 an extremely practical tool for Holter monitoring at hospitals, clinics and physician offices.

Event definitions enable the operator to easily tailor analysis to individual patient abnormalities, helping enhance clinical decision making.

Powerful editing tools give users the flexibility to dynamically update up to 100,000 beats of information with a single keystroke. Report design tools make it easy to produce highly accurate final reports precisely the way the individual physicians prefer to review them.



Plus, an optional interface provides seamless connectivity with the MUSE CV℠ Information System for convenient, centralized archival and retrieval, as well as comprehensive cardiovascular data sharing.

Full Disclosure for Confident Decision Making

The MARS 5000 in the CRS application, accommodates 192 channels of waveform data with up to 28 hours of data per channel. This capability makes the MARS 5000 an ideal solution for a wide variety of patient monitoring environments.

Acquire data from virtually any monitor on the GE Marquette's non-proprietary Unity Network, including GE Marquette Eagle℠ and Solar℠ Monitors. Then, review the data in strip, page or alarm event formats... individually or in combination on the same screen. This versatility allows you to review data precisely how you want to see it, for efficient, confident decision making.

The MARS 5000 – helping you get to the heart of arrhythmia management... quickly, easily and cost-effectively.

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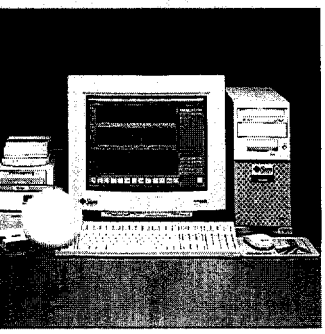
91

Specifications

MARS® 5000
ARRHYTHMIA REVIEW STATION.



Performance Specifications – Hardware Description

Sun Microsystems Ultra 10 workstation with UltraSparc IIi processor and 512 KB external cache

Memory: 128 Mb DIMM (upgradeable to 1 Gb)

Monitor: 19″ or 21″ color (up to 1280 x 900 resolution, 76 Hz refresh rate)

Creator graphics processor: 24-bit

Disk drives: Sun CD internal 24X CD-ROM drive
4.3 Gb enhanced IDE hard disk drive
1.44 Mb internal floppy disk drive

Keyboard: Sun Country includes mouse kit

Power supply: Oneac un-interruptible power supply

STANDARD INTERFACES

Expansion bus: Four 32-bit PCI slots 33 MHz

Graphics slot: One UPA graphics slot

Network: Ethernet/Fast Ethernet, twisted pair standard (10-baseT and 100-baseT)

Serial connector: Sub-D 25 pin

Parallel connector: Sub-D 25 pin

Audio I/O: One line in/line out-speaker out

ENVIRONMENT

AC power: 110-120:220-240 VAC 47-63 Hz

Operating: 10 to 35°C (50 to 95°F)

Non-operating: -20 to 60°C (14 to 140°F)

Operating acoustic noise: 5.2 bels ISO 9296

Idling acoustic noise: 5.2 bels ISO 9226

SUN ULTRA 10 CHASSIS DIMENSIONS AND WEIGHTS

Height: 40.2 cm (15.7 in)

Width: 17.6 cm (6.9 in)

Depth: 43.5 cm (17 in)

Weight: 10 kg (22 lb)

REGULATIONS (meets/exceeds these requirements)

Safety: UL 1950, CSA C22.2 No. 950. TUV EN 60950, CB Scheme with Nordic deviations, EMKO-TSE (74-SEC) 203, ZH1/618

RFI/EMI: FCC Class B, DOC Class B, VCCI Class 2, EN 55022 Class B, EN 61000-3-2

Immunity: EN 50082-1

X-ray: DHHS 21 Subchapter J; PTB German X-ray Decree

Power management: Energy Star compliant

HARDWARE OPTIONS

SEER acquisition unit: Access to data and analysis results in less than 1 minute

Tape acquisition unit: 1000x real-time downloads

Storage unit: 5 Gb DAT (Digital Audio Tape)

Furniture

Printers: HP 6M Laser (6 pages/min), Ethernet Network, Ethernet Network with Duplexer, Token Ring Network, Token Ring Network with Duplexer

Network integration: Includes necessary hardware and site assessment

Remote Access Unit for system support

Software Description

Operating System: Sun Solaris 2.6

HOLTER ANALYSIS/EDITING SOFTWARE User-defined menus can be created using the following tools:

Patient settings: Provide user-defined event settings to help identify all significant patient rhythm disturbances and ST abnormalities (similar to alarm settings in patient monitoring). Also allows user definition of heart rate calculations.

Patient select: Access and manage patient files

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Patient ID: Patient demographic, physician, diagnosis and medication entries

*Patient diary: Correlation of patient symptoms and activities with rhythm data

*Shape review: Review and edit results of initial patient data analysis

*Episode review (histograms): Severity-based review and documentation of significant events

*Trend review: Time-based review and documentation of significant events, heart rates

Page review: Allows complete data review using manual or automatic paging as well as quick access to any time during the study. Offers Region tool, channel selection, gain, resolution and beat color selection

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Event diary: Allows review, documentation and editing of all events which exceed user-defined patient settings (text list review)

*Waveform measurement: 3 channel high-resolution ST segment analysis with selectable measurement points, analysis speed and channel selection

Report review: On-screen review and confirmation of all final report text, strip and page data

*User-definable trend groups, histogram groups, final report setup and menu design

CD ROM-based tutorials

CD ROM-based service manuals

Remote system support with either analog or ISDN access

*High level pacemaker detection and review from MMS recorders

*Data acquisition from: SEER® XT, SEER® MC, 8500 2-3 channel, DelMar Avionics 453, ICR 7200, Nihon Khoden 3253 and 4502, Spacelabs 90205, Rozinn 151, Reynolds Tracker. Please call for additional information regarding other supported recorder types.

SOFTWARE OPTIONS

MARS to MARS connectivity: Allows access to data on MARS systems on a network

*MARS to MUSE®: Store, retrieve and print Holter reports on the MUSE CVIS, via local or enterprise network

Note: MARS 5000 does not support Combo software (operating both CRS and Holter software) or the MARS XLT network computer. These capabilities are provided by the Mars 8000 Arrhythmia Review Station.

*Holter only

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MARS® 8000
ARRHYTHMIA REVIEW STATION.

This advanced system delivers the high-speed, high-capacity performance that busy hospitals, clinics and research institutions demand. For maximum accuracy and efficiency, optional combination software allows the MARS 8000 to perform Holter and full-disclosure functions simultaneously.

A Unique Approach to Productivity

The MARS 8000 is all about power. Specifically developed with high-resolution graphics in mind, it presents subtle ECG details with diagnostic quality. High processing power also speeds reporting.

Networking capabilities assure quick, easy access to the information you need.

Powerful software applications provide operators with convenient tools for meeting clinical protocols, care unit needs and individual clinician preferences.

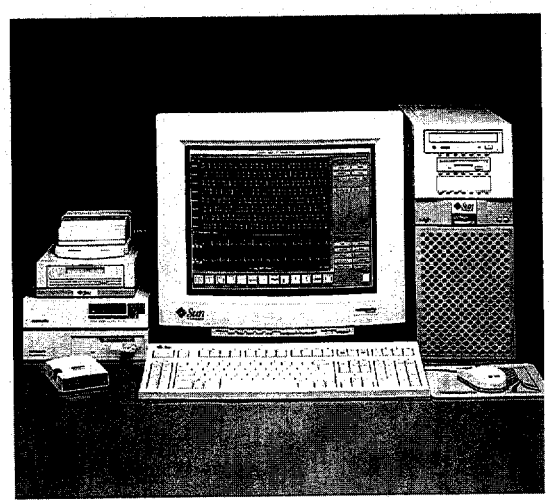
And multitasking efficiency enables operators to download, process, review and print simultaneously.

Holter: Flexible Acquisition... Quick Turnaround... Tailored Reporting

The extensive acquisition capabilities of the combination Holter/Full-Disclosure option enable this MARS 8000 to aquire Holter data from any monitoring sources on the GE Marquette's non-proprietary Unity Network. Monitoring data acquisition means there's no need to "schedule" a Holter procedure, so clinicians can have accurate reports in their hands, presented precisely how they want to see them, in minutes rather than hours.

Full-Disclosure: High-Efficiency Reporting... Enhanced Clinical Decision Making

The MARS 8000 CRS acquires up to 512 channels of data, complete with ECG data from the GE Marquette's non-proprietary Unity Network and hemodynamic waveform correlation for more confident decision making. Because reports can readily be



created to accommodate individual preferences, clinicians can view results in the format that is most meaningful and efficient for them.

Feature Highlights

- The MARS-to-MARS interface option enables you to link various hospital departments as well as outreach facilities through an enterprise-wide network, enhancing arrhythmia management efforts or allowing easy expansion of data-handling capacity.
- The MARS-to-MUSE CV® Information System interface option allows convenient, centralized archival and retrieval, as well as comprehensive cardiovascular data sharing.
- The MARS XLT workstation allows you to add a second seat to the MARS 8000, cost-effectively doubling production capacity.
- Acquires Holter data from most tape-based recorders, SEER® MC and SEER® XT digital recorders, most GE Marquette monitors and telemetry systems.

The MARS 8000 – a fast, easy way to get to the heart of arrhythmia management.

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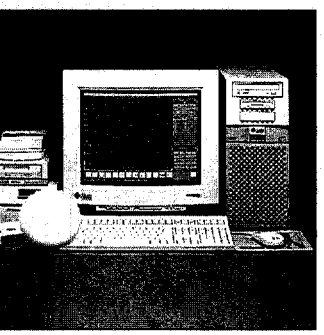
Specifications

MARS® 8000
ARRHYTHMIA REVIEW STATION.



Performance Specifications

HARDWARE DESCRIPTION

Sun Microsystems Ultra 60 with a 360 MHz superscalar:
SPARC Version 9, UltraSparc II:
MMU Memory Management,
16 Kb data and 16 Kb instruction Cache on chip

Drive: One 9 Gb internal hard disk

RAM: 128 Mb, upgradable to 2 Gb with 128 Mb SIMMS in pairs

Monitor: 21″ color (1280 x 1024, 76 Hz/ 67 Hz refresh rate)

CD-ROM drive: Sun CD 32X CD ROM

Internal floppy disk drive: 1.44 Mb

Keyboard: Sun Country includes mouse kit

Power supply: Oneac un-interruptible

STANDARD INTERFACES

Network: Ethernet/Fast Ethernet, twisted pair standard (10-baseT and 100-baseT) or MII for external transceiver

I/O: 40 Mb/sec Ultra SCSI (SCSI-3) (synchronous)

Serial: Two RS-232C/RS-423 serial ports (DB25)

Parallel: Centronics-compatible parallel port (DB25) (ECP mode capable)

Audio: 16-bit audio, 8 kHz to 48 kHz; internal speaker and external microphone; line in, line out, headphone output

Expansion bus: Four full-size PCI slots compliant with PCI specification version 2.1; three slots operating at 33 MHz, 32- or 64-bit data bus width, 5 volt; one slot operating at 33 or 66 MHz, 32- or 64-bit data bus width, 3.3 volt

UPA graphics slot: Two UPA graphics slot supporting up to two Creator, Creator 3D, or Elite 3D m3, or one Elite 3D m6 graphics options

ENVIRONMENT

AC power: 100-240 VAC, 47-63 Hz, 0.4 K VA

Operating: 5 to 40°C (41 to 104°F) 20% to 80% relative humidity, noncondensing

Non-operating: −40 to 60°C (−6 to 140°F) 5% to 95% relative humidity, noncondensing

Operating acoustic noise: 6.1 bels

Idling acoustic noise: 5.9 bels

Declared noise emissions in accordance with ISO 9296, measured at 23°

Dimensions

Sun Ultra 60 chassis	21″ color monitor
Height: 45.0 cm (17.7 in)	50.2 cm (19.9 in)
Width: 19.0 cm (7.5 in)	50.0 cm (19.4 in)
Depth: 49.8 cm (19.6 in)	47.6 cm (18.9 in)
Weight: 22.65 kg (50 lb)	31.0 kg (68.3 lb)

REGULATIONS: (meets/exceeds these requirements)

Safety: UL 1950, CSA C22.2 No. 950. TUV EN 60950, CB Scheme with Nordic deviations, EMKO-TSE (74-SEC) 203, ZH1/618

RFI/EMI: FCC Class B, DOC Class B, VCCI Class 2, EN 55022 Class B, EN 61000-3-2

Immunity: EN 50082-1

X-ray: DHHS 21 Subchapter J; PTB German X-ray Decree

Power management: Energy Star compliant

HARDWARE OPTIONS

SEER acquisition unit: Access to data and analysis results in less than 1 minute

Tape acquisition unit: 1000x real-time downloads

Storage unit: 5 Gb DAT (Digital Audio Tape)

RAM: 128 Mb modules (required for XLT Network Computer support)

Furniture

Printers: Ethernet Network, Ethernet Network with duplexer, Token Ring Network, Token Ring Network with Duplexer, Parallel Cable for interface to CIC printer in the CCU environment

Network integration: Includes necessary hardware and site assessment

Remote Access Unit for system support

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96

SOFTWARE DESCRIPTION

Operating System: Sun Solaris 2.6

HOLTER ANALYSIS/EDITING SOFTWARE

User-defined menus can be created using the following tools:

Patient settings: Provide user-defined event settings to help identify all significant patient rhythm disturbances and ST abnormalities (similar to alarm settings in patient monitoring). Also allows user definition of heart rate calculations.

Patient select: Access and manage patient files

Patient ID: Patient demographic, physician, diagnosis and medication entries

*Patient diary: Correlation of patient symptoms and activities with rhythm data

*Shape review: Review and edit results of initial patient data analysis

*Episode review (histograms): Severity-based review and documentation of significant events

*Trend review: Time-based review and documentation of significant events, heart rates

Page review: Allows complete data review using manual or automatic paging as well as quick access to any time during the study. Offers Region tool, channel selection, gain, resolution and beat color selection

Strip review: Allows complete data review using superimposition (up to 240 x real-time). Offers Region tool, channel selection, gain adjustment, selectable resolution, template editing and on-screen calipers.

Event review: Allows review, documentation and editing of all events which exceed user-defined patient settings (strip view)

Event diary: Allows review, documentation and editing of all events which exceed user-defined patient settings (text list review)

*Waveform measurement: 3 channel high-resolution ST segment analysis with selectable measurement points, analysis speed and channel selection

*Report review: On-screen review and confirmation of all final report text, strip and page data

*User-definable trend groups, histogram groups, final report setup and menu design

CD ROM-based tutorials

CD ROM-based service manuals

Remote system support with either analog or ISDN access

*High level pacemaker detection and review from MMS recorders

*Data acquisition from: SEER® XT, SEER MC, 8500 2-3 channel, DelMar Avionics 453, ICR 7200, Nihon Khoden 3253 and 4502, Spacelabs 90205, Rozinn 151, Reynolds Tracker. Please call for additional information regarding other supported recorder types.

SOFTWARE OPTIONS

MARS to MARS connectivity: Allows access to data on MARS systems on a network

*MARS to MUSE®: Store, retrieve and print Holter reports on the MUSE CVIS, via local or enterprise network

Note: MARS 8000 Holter analysis system supports the MARS XLT network computer

Heart rate variability: Not available for use in the USA

MARS CRS software (Combo): Allows the system to function as a CRS and Holter system. The MARS is able to perform Holter analysis on CRS data.

*Holter only

97

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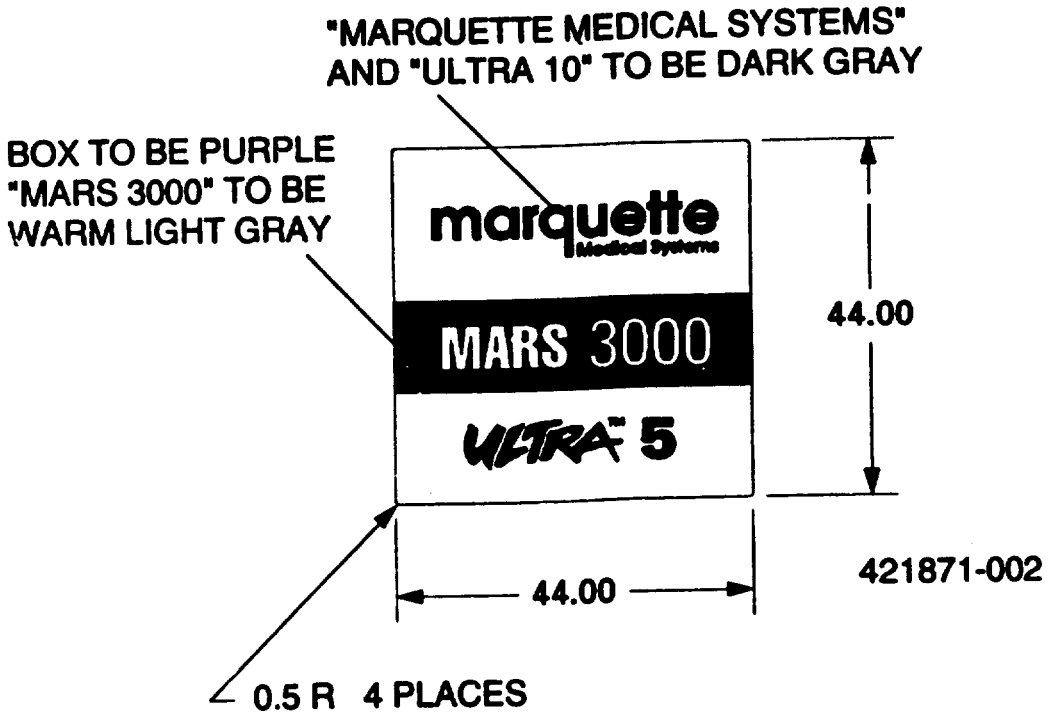
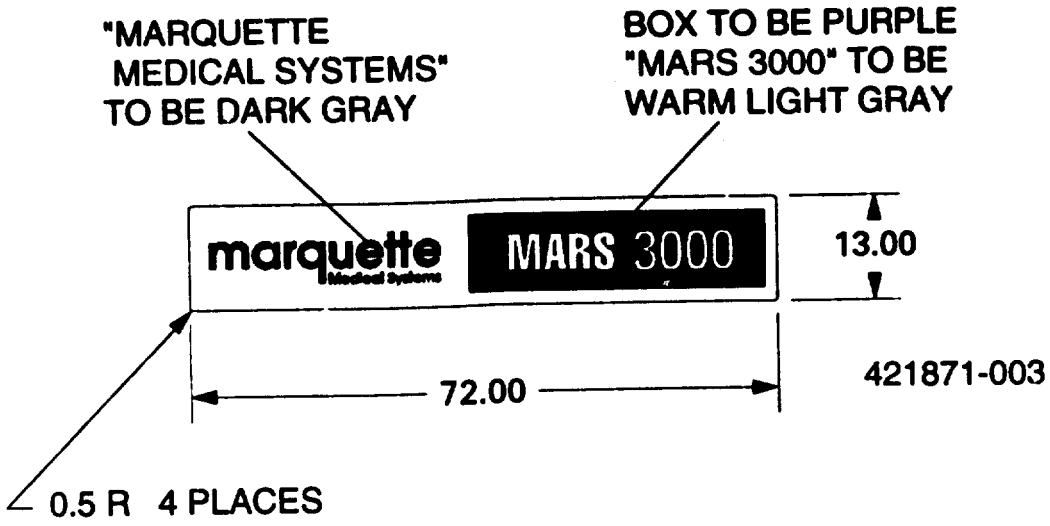
MO5198DEO 1/99 Printed in USA

Appendix N
MARS Unity Work Assembly Drawings

Appendix O
MARS Unity Workstation Device Label Drawings





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NOTES:

1. MATERIAL: SUBSURFACE PRINTED .010" THICK VELVET TEXTURE MATTE BACK POLYCARBONATE.

2. ADHESIVE: B-196, 3M#467, 3M#9471, OR 3M#Y9761 .002" THICK ACRYLIC PRESSURE SENSITIVE ADHESIVE.

3. FINISH: BACKGROUND TO BE OPAQUE. (UNLESS OTHERWISE SPECIFIED)
BACKGROUND TO BE WARM LIGHT GRAY - MATCH TO MUNSELL 5Y8/1.
WHERE SPECIFIED TEXT AND GRAPHICS ARE TO BE DARK GRAY - MATCH TO MUNSELL N4.5.
WHERE SPECIFIED TEXT AND GRAPHICS ARE TO BE PURPLE- MATCH TO MUNSELL 7.5PB3/4.

4. ARTWORK 421871-001 ISSUE 1 PROVIDED BY MARQUETTE MEDICAL SYSTEMS.

5. THIS SET OF LABELS TO BE SUPPLIED ON A COMPOSITE SHEET. THIS COMPOSITE SHEET TO HAVE INDIVIDUAL LABEL NEXT TO EACH LABEL, WITH SET PART NUMBER, REVISION LEVEL, ISSUE NUMBER, AND VENDOR IDENTIFICATION ON THE SHEET. LABELS TO BE DIE-CUT TO LINER. WEB BETWEEN LABELS NOT TO BE REMOVED.

6. LABELS MUST BE UL RECOGNIZED AND EACH PACKAGE MUST BE MARKED AS SPECIFIED IN THE CURRENT UL RECOGNIZED COMPONENT DIRECTORY.

7. PACKAGE PER MS-2008.

8. PLACEMENT OF TEXT AND GRAPHICS IS FOR REFERENCE ONLY. PLEASE REFER TO ARTWORK.

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DO NOT SCALE DRAWING UNLESS OTHERWISE SPECIFIED: DIMENSIONS ARE IN MILLIMETERS AND TOLERANCES ARE: 2 PLACE DECIMALS: +/- .50 3 PLACE DECIMALS: +/- .250 ANGLES: +/- .12.7° SUPPLIER PACKAGE PER MS-2008 REMOVE ALL BURRS AND SHARP EDGES	DRAWN BY T. HUNTER ENG. APPROVED Chepolaro TYPE CODE: 2901	DATE 10-21-98 10-26-98	marquette Medical Systems cardiology division TITLE LABEL SET MARS ULTRA 5
MATERIAL SEE NOTE 1	FINISH SEE NOTE 3		PART NUMBER 421871-001 REV A DIST D SCALE none SHEET 1 OF 1

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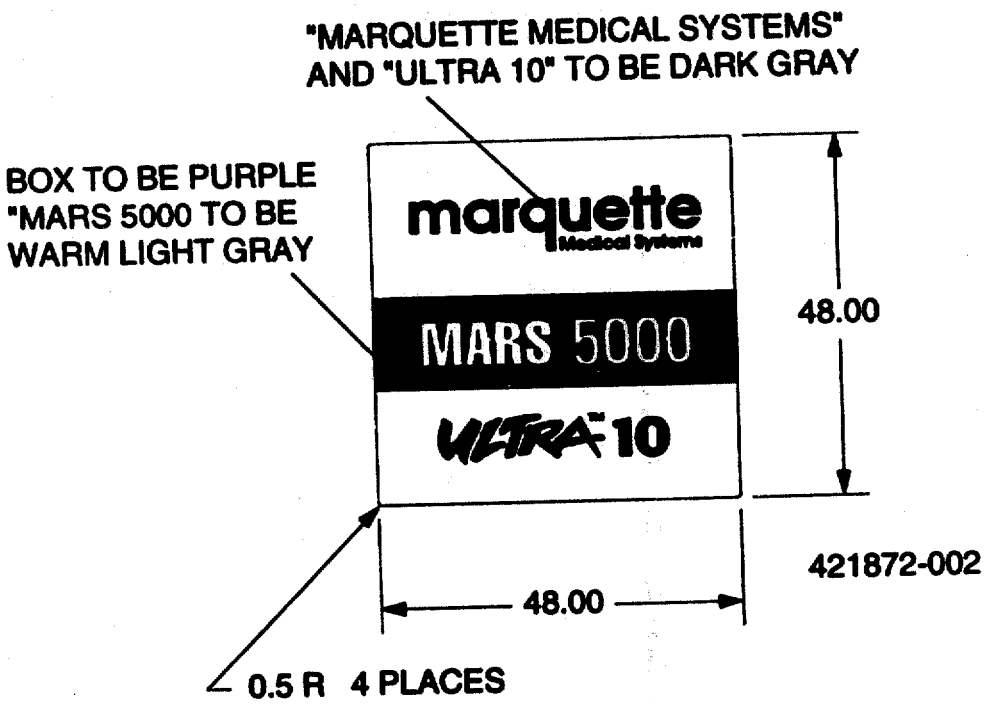

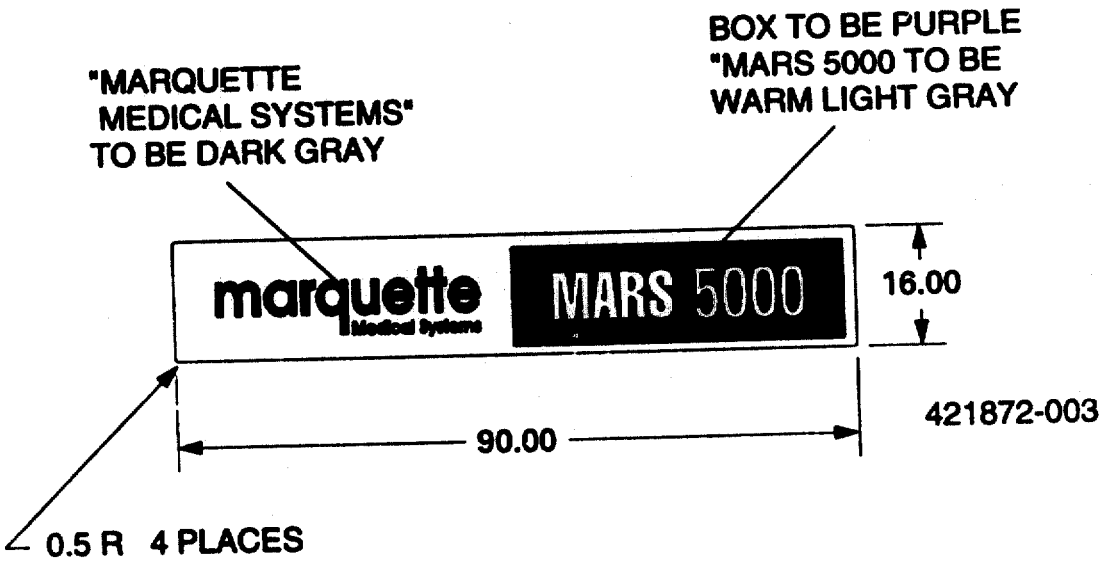

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421782-001

NOTES:

1. MATERIAL: SUBSURFACE PRINTED .010" THICK VELVET TEXTURE MATTE BACK POLYCARBONATE.

2. ADHESIVE: B-196, 3M#467, 3M#9471, OR 3M#Y9761 .002" THICK ACRYLIC PRESSURE SENSITIVE ADHESIVE.

3. FINISH: BACKGROUND TO BE OPAQUE. (UNLESS OTHERWISE SPECIFIED)
BACKGROUND TO BE WARM LIGHT GRAY - MATCH TO MUNSELL 5Y8/1.
WHERE SPECIFIED TEXT AND GRAPHICS ARE TO BE DARK GRAY - MATCH TO MUNSELL N4.5.
WHERE SPECIFIED TEXT AND GRAPHICS ARE TO BE PURPLE- MATCH TO MUNSELL 7.5PB3/4.

4. ARTWORK 421872-001 ISSUE 1 PROVIDED BY MARQUETTE MEDICAL SYSTEMS.

5. THIS SET OF LABELS TO BE SUPPLIED ON A COMPOSITE SHEET. THIS COMPOSITE SHEET TO HAVE INDIVIDUAL LABEL NEXT TO EACH LABEL, WITH SET PART NUMBER, REVISION LEVEL, ISSUE NUMBER, AND VENDOR IDENTIFICATION ON THE SHEET. LABELS TO BE DIE-CUT TO LINER. WEB BETWEEN LABELS NOT TO BE REMOVED.

6. LABELS MUST BE UL RECOGNIZED AND EACH PACKAGE MUST BE MARKED AS SPECIFIED IN THE CURRENT UL RECOGNIZED COMPONENT DIRECTORY.

7. PACKAGE PER MS-2008.

8. PLACEMENT OF TEXT AND GRAPHICS IS FOR REFERENCE ONLY. PLEASE REFER TO ARTWORK.

DO NOT SCALE DRAWING UNLESS OTHERWISE SPECIFIED: DIMENSIONS ARE IN MILLIMETERS AND TOLERANCES ARE: 2 PLACE DECIMALS: +/- .50 3 PLACE DECIMALS: +/- .250 ANGLES: +/- .12.7° SUPPLIER PACKAGE PER MS-2008 REMOVE ALL BURRS AND SHARP EDGES	DRAWN BY T. HUNTER	DATE 10-21-98	marquette Medical Systems cardiology division
	ENG. APPROVED [signature]	10-28-98	TITLE LABEL SET MARS ULTRA 10
	TYPE CODE: 2901		
MATERIAL SEE NOTE 1	FINISH SEE NOTE 3	PART NUMBER 421872-001	REV A
		DIST D SCALE none	SHEET 1 OF 1

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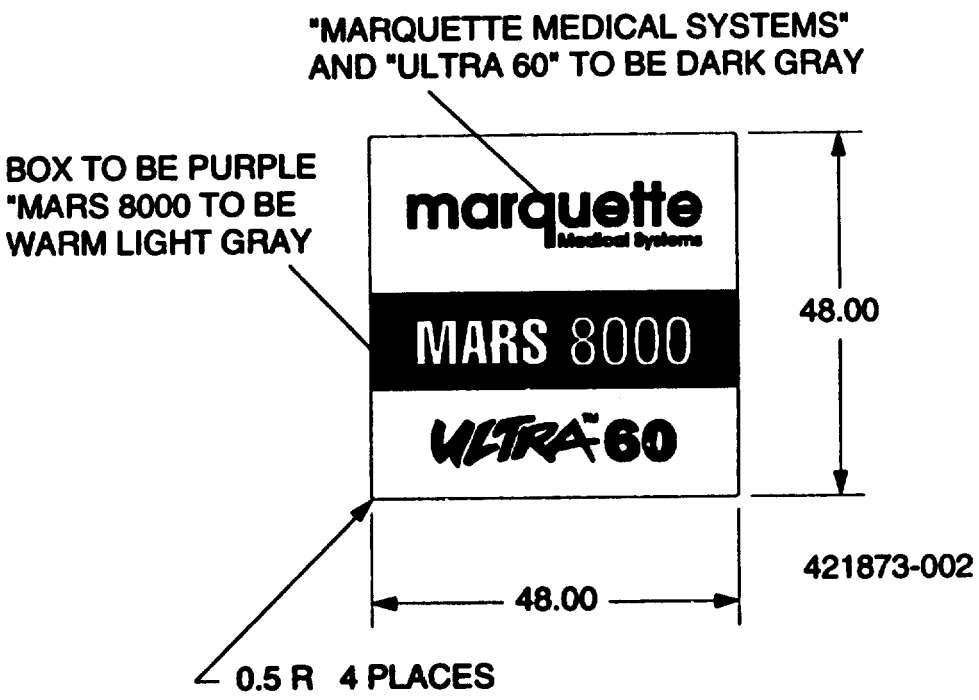

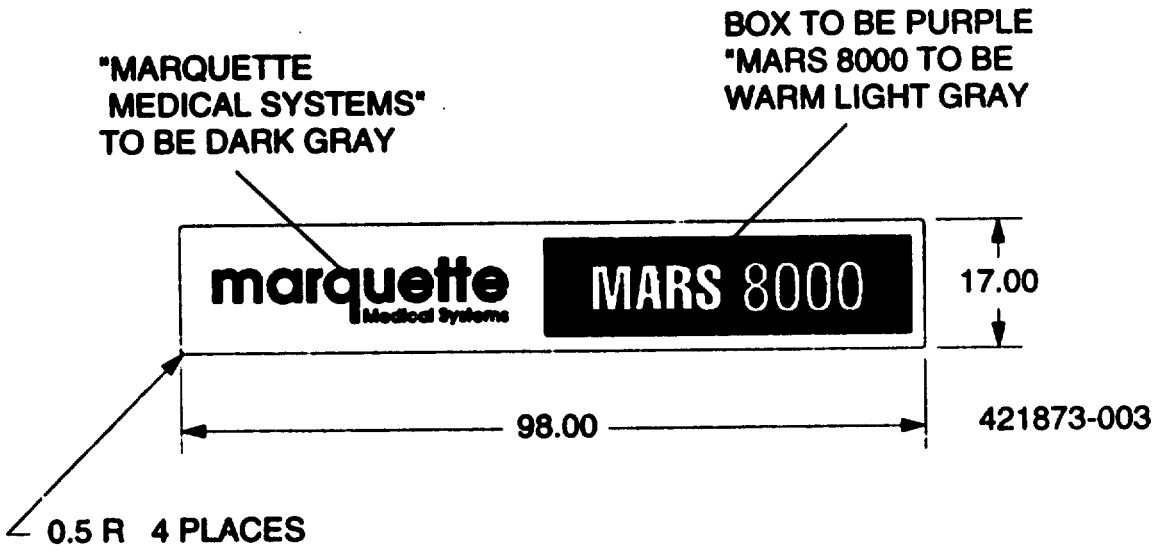

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RIAL: SUBSURFACE PRINTED .010" THICK VELVET
JRE MATTE BACK POLYCARBONATE.

SIVE: B-196, 3M#467, 3M#9471, OR 3M#Y9761 .002" THICK
LIC PRESSURE SENSITIVE ADHESIVE.

SH: BACKGROUND TO BE OPAQUE. (UNLESS OTHERWISE SPECIFIED)
KGROUND TO BE WARM LIGHT GRAY - MATCH TO MUNSELL 5Y8/1.
RE SPECIFIED TEXT AND GRAPHICS ARE TO BE DARK GRAY - MATCH TO MUNSELL N4.5.
RE SPECIFIED TEXT AND GRAPHICS ARE TO BE PURPLE- MATCH TO MUNSELL 7.5PB3/4.

ORK 421873-001 ISSUE 1 PROVIDED BY MARQUETTE MEDICAL SYSTEMS.

ET OF LABELS TO BE SUPPLIED ON A COMPOSITE SHEET. THIS COMPOSITE
TO HAVE INDIVIDUAL LABEL NEXT TO EACH LABEL, WITH SET PART NUMBER,
ION LEVEL, ISSUE NUMBER, AND VENDOR IDENTIFICATION ON THE SHEET.
S TO BE DIE-CUT TO LINER. WEB BETWEEN LABELS NOT TO BE REMOVED.

S MUST BE UL RECOGNIZED AND EACH PACKAGE MUST BE MARKED AS
FIED IN THE CURRENT UL RECOGNIZED COMPONENT DIRECTORY.

AGE PER MS-2008.

EMENT OF TEXT AND GRAPHICS IS FOR REFERENCE ONLY. PLEASE REFER
TWORK.

DO NOT SCALE DRAWING UNLESS OTHERWISE SPECIFIED: DIMENSIONS ARE IN MILLIMETERS AND TOLERANCES ARE: 2 PLACE DECIMALS: +/- .50 3 PLACE DECIMALS: +/- .250 ANGLES: +/- .12.7° SUPPLIER PACKAGE PER MS-2008 REMOVE ALL BURRS AND SHARP EDGES	DRAWN BY T. HUNTER	DATE 10-21-98	marquette Medical Systems cardiology division
	ENG. APPROVED Cheplao	10-21-98	TITLE LABEL SET MARS ULTRA 60
	TYPE CODE: 2901		
MATERIAL SEE NOTE 1	FINISH SEE NOTE 3	PART NUMBER 421873-001	REV A
		DIST D SCALE none	SHEET 1 OF 1

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Appendix P
HRV Software Detailed Design - SDD

Appendix Q
Part 1
MARS 8000 Ultra 60 Hardware Validation Test Plan

Appendix R
Part 1
MARS Product Traceability Analysis

Appendix S
MARS Hardware/Software Evolution - Summary of Changes

Appendix T
OEM Data

Appendix B: Technical Description

001151

Workstations

MARS 8000 (RU)

Item	Description
Type	Sun Microsystems Ultra 60
Nominal Voltage Range	100-120 VAC or 200-240 VAC (auto sensing)
Nominal Frequencies	47-63 Hz (auto sensing)
Maximum Power Consumption	350 Watts
Thermal Dissipation	590 BTU/hour
Processors	One 360 MHz UltraSPARC-II processor
Processor Clock Speed	360 MHz
Internal Memory	384 MB standard (expandible to 2GB)
Storage	
Hard drive	one 9.1 GByte SCSI hard drive
Diskette	1.44 Mbyte, 3.5 inch
External DAT (optional)	4 Gbyte DAT, 4mm DDS2
CD-ROM drive	Internal 32x speed
Interface Ports	serial - two RS-232C / RS-423 DB-25 parallel - one DB-25 network - one ethernet/fast ethernet twisted pair (10BaseT/100BaseT) self-sensing one MII for external transceiver audio - line-in, line-out, microphone in, speaker/headphone out graphics - two UPA graphic slots I/O - 40 MB/sec Ultra SCSI
Expansion Slots	Four full-size 32- or 64-bit PCI slots (three 33 MHz 5-volt; one 33/66 MHz 3.3-volt)
Keyboard	Sun Microsystems Type 5c
Mouse	opto-mechanical, 3 button
Communication Requirements	
ISDN	Cisco 760 series access unit.
Switched-56	Combinet CB-600 access unit
Analog modem	Multitech
Physical Specifications	
Height	45.00 cm (17.70 in)
Width	19.00 cm (7.50 in)
Depth	49.80 cm (19.60 in)
Shipping Weight	22.65 kg (50.00 lbs)

001153

367

MARS 5000 (RT)

Item	Description
Type	Sun Microsystems Ultra 10
Nominal Voltage Range	100-120 VAC or 200-240 VAC (manually selectable)
Nominal Frequencies	47-63 Hz (auto sensing)
Maximum Power Consumption	250 Watts
Thermal Dissipation	420 BTU/hour (estimated)
Processors	One 333 MHz UltraSPARC-IIi processor
Processor Clock Speed	333 MHz
Internal Memory	256 MB standard (expandable to 1 GB)
Storage	
Hard drive	One 9.1 Gbyte hard drive
Diskette	1.44 Mbyte, 3.5 inch
External DAT (optional)	4 Gbyte DAT, 4mm DDS2
CD-ROM drive	Internal 32x speed
Interface Ports	serial -one DB-25, one DB-9 parallel - one DB-25 network - one ethernet/fast ethernet twisted pair (10BaseT/100BaseT) self-sensing one MII for external transceiver audio - line-in, line-out, microphone in, speaker/headphone out graphics - one UPA graphic slot IO - SCSI controller
Expansion Slots	Four 32-bit PCI slots (full-size, 33 MHz, 5-volt)
Keyboard	Sun Microsystems Type 5c
Mouse	Opto-mechanical, 3 button
Communication Requirements	
ISDN	Cisco 760 series access unit.
Switched-56	Combinet CB-600 access unit
Analog modem	Multitech
Physical Specifications	
Height	40.00 cm (15.75 in)
Width	17.60 cm (6.93 in)
Depth	43.50 cm (17.10 in)
Shipping Weight	20.00 kg (44.00 lbs)

001154

MARS 3000 (RS)

Item	Description
Type	Sun Microsystems Ultra 5
Nominal Voltage Range	100-120 VAC or 200-240 VAC (manaually selectable)
Nominal Frequencies	47-63 Hz (auto sensing)
Maximum Power Consumption	200 Watts
Thermal Dissipation	340 BTU/hour (estimated)
Processors	One 270 MHz UltraSPARC processor with built-in graphics
Processor Clock Speed	270 MHz
Internal Memory	128 MB standard (expandable to 512 MB)
Storage	
Hard drive	One 4.3 Gbyte hard drive
Diskette	1.44 Mbyte, 3.5 inch
External DAT (optional)	4 Gbyte DAT, 4mm DDS2
CD-ROM drive	Internal 32x speed
Interface Ports	serial -one DB-25, one DB-9 parallel - one DB-25 network - one ethernet/fast ethernet twisted pair (10BaseT/100BaseT) self-sensing audio - line-in, line-out, microphone in, speaker/headphone out graphics - UPA graphics IO - SCSI controller
Expansion Slots	Three 32-bit PCI slots (33 MHz, 5-volt, two full-size, one short)
Keyboard	Sun Microsystems Type 5c
Mouse	Optomechanical, 3 button
Communication Requirements	
ISDN	Cisco 760 series access unit.
Switched-56	Combinet CB-600 access unit
Analog modem	Multitech
Physical Specifications	
Height	11.20 cm (4.40 in)
Width	43.60 cm (17.10 in)
Depth	43.00 cm (16.90 in)
Weight	18.00 kg (39.70 lbs)

001155

369

Workstation Monitors

21 inch Monitor

Standard with MARS 8000 (RU) workstation

Item	Description
Type	Sun Microsystems
Size	21 inch
Dot Pitch	0.25 – 0.27 mm
Viewable Image Size	19.8" diagonally
Resolution (maximum)	1600 x 1200 pixels
Frequency	Horizontal: 30 to 96 kHz Vertical: 48 to 160 Hz
Power Supply	100 to 240 V, 50 – 60 Hz., 2.0 – 1.0 A (auto sensing)
Power Consumption (maximum)	160 W
Dimensions	19 3/4 x 19 7/8 x 18 7/8 in (500.3 x 502.5 x 476.5 mm)
Shipping Weight	31 kg (68 lb 5 oz)

19 inch Monitor

Standard with MARS 5000 (RT) workstation

Item	Description
Type	Sun Microsystems
Size	19 inch
Dot Pitch	0.26 mm
Frequency	Horizontal: 31 to 96 kHz Vertical: 50 to 160 Hz
Resolution (maximum)	1280 x 1600 pixel
Viewable Image Size	18.0 inches (458 mm), diagonal (typical)
Power Supply	AC 100 – 120 / 200 – 240 V (auto sensing)
Power Consumption	130 W (typical)
Dimensions (w x h x d)	17.63 x 17.87 x 18.11in. (448 x 454 x 460 mm)
Weight	55 lbs. (25 kg)

001156

17 inch Monitor

Standard with MARS 3000 (RU) workstation

Item	Description
Type	Sun Microsystems
Diagonal Size	17 inch
Resolution (maximum)	1152 x 9 00
Line Frequency	31 - 72 kHz
Refresh Frequency	50-120 Hz
Resolution (maximum)	1152 x 900 pixels
Line Voltage	90-264 V / 50/60 Hz (auto sensing)
Power Consumption Normal operation Stand-by Suspend Auto power off	 < 100 W ~ 70 W < 30 W < 5 W
Dot Pitch	0.27 mm
Weight	18kg (40 lbs)
Dimensions (w x h x d)	16.6 x 16.25 x 17 in. (422 mm x 413 mm x 433 mm)

001157

371

Printers

Lexmark Optra S 1625 Network Printer

Item	Description
Type	Lexmark Optra S 1625 network printer
Speed	16 ppm (at 300 dpi)
Resolution	300, 600 or 1200 dpi
Paper	8 1/2 x 11 inches or A4
Maximum Monthly Duty Cycle	65,000 prints
Power Consumption	
Printing	315 Watts
Idle (Power Saver On)	16 Watts
Idle (Power Saver Off)	95 Watts
Thermal Output	
Printing	1075 BTU/hour
Idle (Power Saver On)	55 BTU/hour
Idle (Power Saver Off)	324 BTU/hour
Dimensions (h x w x d)	13.2 x 15.9 x 19.5 in. (33.5 x 40.5 x 49.4 cm)
Weight	41 lbs. (18.6 kg)

MARS Laser Printer 6+ (HP 6MP)

Item	Description
Type	HP 6MP
Speed	6 ppm
Resolution	600 dpi (with resolution enhancement)
Paper	8 1/2 x 11 inches or A4
Maximum Monthly Duty Cycle	12,000 prints
Fuser Unit Life	200,000 prints
Power Consumption	
Printing	175 Watts
Idle	8 Watts
Dimensions (h x w x d)	7.87 x 15.75 x 17.52 in. (20.0 x 40.0 x 44.5 cm)
Weight	24.5 lbs. (11.1 kg)

001158

Uninterruptible Power Supply (UPS)

Oneac

Item	Description					
	ON 400I	**ON 600I**	**ON400J**	**ON 900J**	**ON 400A**	**ON 600A**
Input Connector	IEC 320	IEC 320	NEMA 5-15R	NEMA 5-15R	NEMA 5-15R	NEMA 5-15R
Output Sockets	IEC 320	IEC 320	NEMA 5-15R	NEMA 5-15R	NEMA 5-15R	NEMA 5-15R
No of outlets	4	4	4	4	4	4
Maximum Capacity	400 VA (280 W)	600 VA (400 W)	400 VA (280 W)	900 VA (600 W)	400 VA (280 W)	600 VA (400 W)
Input Voltage	230 V (50/60 Hz)		120 V (50/60 Hz)	120 V (50/60 Hz)	120 V (60 Hz)	120 V (60 Hz)
Physical Specifications						
Height	7.5 in. (19.1 cm)	7.5 in. (19.1 cm)	7.5 in. (19.1 cm)	12 in. (30.5 cm)	7.5 in. (19.1 cm)	7.5 in. (19.1 cm)
Width	8.5 in. (21.6 cm)	8.5 in. (21.6 cm)	8.5 in. (21.6 cm)	8.5 in. (21.6 cm)	8.5 in. (21.6 cm)	8.5 in. (21.6 cm)
Depth	15.5 in (39.4 cm)	18.5 in (47.0 cm)	15.5 in (39.4 cm)	18.5 in (47.0 cm)	15.5 in (39.4 cm)	18.5 in (47.0 cm)
Weight	33 lbs. (15 kg)	50 lbs (23 kg)	33 lbs. (15 kg)	64 lbs (29 kg)	30 lbs (14 kg	41 lbs (18 kg)

001159

373

Peripheral Devices

Tape Acquisition Unit

Item	Description
Type	Marquette Medical Systems, Inc. Tape Acquisition Unit
Nominal Voltage Range	100-120 VAC or 200-240 VAC (auto sensing)
Nominal Frequencies	50 Hz or 60 Hz (auto sensing)
Maximum Power Consumption	55 Watts
Processor	DSP56002 microprocessor
Processor Clock Speed	66 MHz
Tape Drive	Braemer CD350 Holter playpack tape drive
Media	
Cassette Tape	C-60 or C-120 cassette tapes
Interface Ports	One SCSI
Channels	1 or 2 (user selectable) and clock track
Resolution	12 bits
Sampling Frequency	128 samples/sec (real time)
Playback Speed	
Cassette	1000 times real time
Frequency Response	0.66 to 50 Hz overall (recorder to system)
Phase Response	Linear, less than 6 degrees phase shift at 0.5 Hz
Tape Playback Options	The tape is played back at approximately 1000 times real time. Analog amplifiers with gain and phase equalization optimized for Holter tape processing are provided for all channels. Tape speed variations are compensated by a time warp filter circuit synchronized to the clock track on the tape.
Effective Sampling Rates	
Marquette 8500	Cassette, 1 mm/sec; phase-locked, 128 samples/sec
Physical Specifications	
Height	2.8 in (7.1 cm)
Width	9.6 in (24.4 cm)
Depth	10.4 in (26.4 cm)
Weight	5.1 lb (2.3 kg)

001160

SEER Acquisition Unit

Item	Description
Type	Marquette Medical Systems, Inc. SEER Acquisition Unit
Nominal Voltage Range	100-120 VAC or 200-240 VAC (auto sensing)
Nominal Frequencies	50 Hz or 60 Hz (auto sensing)
Maximum Power Consumption	30 Watts
Processor	MC68331 microprocessor
Processor Clock Speed	15.2 MHz
PC Card Media (SEER MT)	Standard 68 pin PC Card memory card (formerly PCMCIA)
Interface Ports	One SEER port, one RS-232 serial, one SCSI
Physical Specifications	
Height	2.8 in (7.1 cm)
Width	9.6 in (24.4 cm)
Depth	10.4 in (26.4 cm)
Weight	5.1 l lbs (2.3 kg)

DAT Drive

Item	Description
Type	Sun Microsystems
Nominal Voltage Range	100-120 VAC or 200-240 VAC (auto sensing)
Nominal Frequencies	50 Hz or 60 Hz (auto sensing)
Tape Drive	DDS-2 tape drive
Tape Speed	0.64 inches/ second
DAT Media	Computer grade, 4 mm DDS-2 data storage cartridge devices
Capacity Compressed Uncompressed	 5 Gbytes @ 2.5:1 compression 2 Gbyte
Transfer Rate	550 Kbytes/second
Interface Ports	Two 68-pin SCSI
SCSI Termination	Auto SCSI termination
Buffer	1 Mbyte
Physical Specifications	
Height	2.76 in (7.0 cm)
Width	7.48 in (19.0 cm)
Depth	12.2 in (31.0 cm)
Weight	7.45 lbs (3.38 kg)

External Speakers

Item	Description
Physical Specifications (HD-100)	
Height	9.25 in (235 mm)
Width	4.75 in (120 mm)
Depth	4.75 in (120 mm)
Physical Specifications (HDM/325 3D)	
Height	10.82 in (275 mm)
Width	5.12 in (130 mm)
Depth	4.73 in (120mm)

Cisco Series 760 Access Unit (ISDN)

Item	Description
Physical Specifications	
Height	2.125 in (54 mm)
Width	9.75 in (248 mm)
Depth	8.375 in (213 mm)

MultiTech MultModem (Analog)

Item	Description
Physical Specifications	
Height	1.00 in (25.4 mm)
Width	4.25 in (108 mm)
Depth	5.625 in (143 mm)

001162 376

XLT Network Computer

XLT Base

Item	Description
Type	NCD Explora 450 Display Station
Nominal Voltage Range and Frequency	North America: 90-132 VAC, 60 Hz (+/- 3 Hz) European/Australian: 180-265 VAC, 50 Hz (+/- 3 Hz) Japanese: 85-110 VAC, 47 - 63 Hz
Maximum Power Consumption	19 Watts
Microprocessors	PowerPC 403GCX@66MHz
Coprocecesor	S3 Trio64V2/DX
Communications	
Thin Ethernet	Built in 10Base2 thin ethernet transceiver with BNC connector
Twisted pair	Built in 10/100BaseT twisted pair ethernet transceiver (auto-sensing)
Serial port	RS-232 C up to 115.2K baud
Parallel port	25 pin connector; PC compatible
PC-Card	Type I/II PCMCIA slot with standard PC card, 68 pin connector
Display Memory	2 MB
Keyboard	101 key PS/2 style keyboard 123 key Sun Type 5 keyboard 97 key Kana keyboard
Mouse Mechanical	Mechanical three button, PS/2
Physical Specifications	
Height	5.3 cm (2.1 in)
Width	32.5 cm (12.8 in)
Depth	33.5 cm (13.8 in)
Weight	2.49 kg (5.5 lbs)

001163

XLT 17" Monitor

Item	Description
Type	Sony Trinitron Multiscan 17 se
Size	17 inch
Resolution	1152 x 900
Horizontal Frequency	68.7 kHz
Vertical Frequency	75 Hz
Active Display Area	328 mm x 242 mm (13.8 in x 10.6 in)
Input Voltage	100-120 V 2.7A, or 200-240 V 1.5A (auto sensing)
Dot Pitch	0.25 mm
Weight	49.5 lbs (22.5 kg)
AC Power	100-120V 3A, or 200-240V 1.6A auto-sensing

XLT 21" Monitor

Item	Description
Type	Sony Trinitron Multiscan GDM-500PS
Size	21 inch
Resolution	1600 x 1200 maximum at 85Hz
Horizontal Frequency	30 - 107 kHz
Vertical Frequency	46 - 160 Hz
Viewable Image Size	19.8 in measured diagonally
Aperture Grille Pitch	0.26-0.27 mm (variable)
AC Power Requirements	100 – 240V AC; 50 – 60 Hz (auto sensing) International Energy Star, NUTEK, and VESA DPMS compliant
Power Consumption	Operation: 160 watts (maximum) Suspend: 15 watts (maximum) Active off: 5 watts (maximum) Power off: 0 watts (maximum)
Physical Specifications	
Height	505.5 mm (19.9 in)
Width	497.8 mm (19.6 in.)
Depth	474.0 mm (18.7 in.)
Weight	68.3 lbs (30.0 kg)

001164

Safety

Item	Description
Certification	UL listed CSA certified TUV certified EN 60950 (UL 950) CE marking for Council Directive 93/42/EEC
Type of Protection Against Electrical Shock	Class 1
Degree of Protection Against Ingress of Liquids	Ordinary
Handling of Disposable Supplies and Other Consumables	■ Use only parts and accessories manufactured or recommended by Marquette. ■ Follow manufacturer's instructions for use for disposable/consumable product. ■ Follow local environmental guidelines concerning the disposal of hazardous materials (e.g. lead acid batteries).
Patient Mode of Operation	Continuous
Patient Leakage Current	Not applicable
Degree of Protection Against Electrical Shock	Not applicable
Maintenance Frequency	■ Recommended user daily visual inspection and cleaning. ■ Recommended six-month routine maintenance checks and test procedures performed by qualified technical personnel.
Repair Guidelines	Calibration instructions, equipment descriptions, and all other service information to repair those parts of the equipment designated as field repairable by qualified technical personnel is available in the service manual. Upon request, Marquette will provide circuit diagrams and component parts lists for printed circuit boards deemed repairable by qualified technical personnel.

379

001165

Environmental - System Wide

Item	Description
Power	20 amps
Operating Conditions	
Temperature	10 to 35 degrees C (50 to 90 degrees F)
Relative Humidity	20% to 80%
Maximum Altitude	2,500 meters (8,200 feet)
Storage/Transport Conditions	
Temperature	-20 to 43 degrees C (-40 to 110 degrees F)
Relative Humidity	8% to 80%
Maximum Altitude	10,350 meters (34,000 feet)

380

001166

Appendix U
MARS Unity Workstation Supplies List

MARS Unity Workstation Accessories List

Following is a list of accessories that may be used with the MARS Unity Workstation.

Part Number	Description
413308-001	Laser Cartridge Sun SPARC II
413308-002	Laser Cartridge HP LJ5, HP LJ6
413308-003	Laser Cartridge Sun SPARC E
413308-004	Laser Cartridge Lexmark
6136-901R	Laser EP Cartridge, Side Load
6136-903R	Laser EP-S Cartridge, Top Load
9242-101	Laser Printer Paper, 20 lb. Bond, All White, 8.5"x11" (216mm x 280mm), 5000 sheets/package

Appendix V
Part 1
Recommended Course of Action

Appendix V
Part 2
Product Sales and Discontinuance