GE Healthcare

# MUSE™ v9

## Cardiology Information Systems Regulatory and Safety Guide

2059568-016 Revision B

Familiarize yourself with this information before attempting to use this system.
Keep this manual with your Operator Manual and equipment at all times, and periodically review it.

MUSE v9 Cardiology Information System
English
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**Publication Information**

The information in this manual applies only to MUSE™ v9 Cardiology Information System. It does not apply to earlier product versions. Due to continuing product innovation, specifications in this manual are subject to change without notice.

MUSE, MAC, and Marquette are trademarks owned by GE Medical Systems *Information Technologies*, Inc., a General Electric Company going to market as GE Healthcare. All other trademarks contained herein are the property of their respective owners.

This product complies with the requirements concerning medical devices from the following regulatory bodies. For more information about compliance, refer to the Regulatory and Safety Guide for this product.

CE 0459

The document part number and revision are at the bottom of each page. The revision identifies the document's update level. The revision history of this document is summarized in the following table.

| Revision | Date | Comments |
|---|---|---|
| A | 8 April 2015 | Initial Release |
| B | 28 July 2015 | Commercial release. |

To access other GE Healthcare Diagnostic Cardiology documents, go to the Common Documentation Library (CDL), located at www.gehealthcare.com/documents, and click ***Cardiology***.

To access Original Equipment Manufacturer (OEM) documents, go to the device manufacturer's website.

**NOTE:**

All illustrations in this document are provided as examples only. Depending on system configuration, screens in the document may differ from the screens on your system.

All patient names and data are fictitious. Any similarity to actual persons is coincidental.

If you require additional assistance, contact your GE Healthcare representative, or GE Healthcare support at one of the following numbers:

- North America: 1-800-558-7044
- Europe: +49 761 45 43 -0
- Asia: +86 21 3877 7888

This document is intended as a supplement to, not a substitute for, thorough product training. If you have not received training on the use of the system, you should request training assistance from GE Healthcare.

To see available training, go to the GE Healthcare training website (www.gehealthcare.com/training). Select *Education>Product Education-Technical> Diagnostic Cardiology*.

For more self-paced course offerings, tools, and reference guides you may find useful, please visit the GE Healthcare Education Store at www.gehealthcare.com/educationstore.

# Contents

# 1

# Regulatory Information

**Familiarize yourself with this information before attempting to use this system. Keep this manual with your Operator Manual and equipment at all times, and periodically review it.**

This section provides information about the regulatory compliance of this system. The system software is considered medical software. As such, it was designed and manufactured to the appropriate medical regulations and controls.

## Indications for Use

The MUSE™ Cardiology Information System is intended to store, access and manage cardiovascular information on adult and pediatric patients. The information consists of measurements, text, and digitized waveforms. The MUSE™ Cardiology Information System provides the ability to review and edit electrocardiographic procedures on screen, through the use of reviewing, measuring, and editing tools including ECG serial comparison and interpretive 12-lead analysis. The MUSE™ Cardiology Information System is intended to be used under the direct supervision of a licensed healthcare practitioner, by trained operators in a hospital or facility providing patient care.

## Contraindications

**WARNING:**
CONTRAINDICATION: The system is not intended for primary monitoring.

**CAUTION:**
CONTRAINDICATION: The system is not intended for pediatric serial comparison.

**WARNING:**
CONTRAINDICATION: The system is not intended for real-time patient monitoring.

**WARNING:**
CONTRAINDICATION: The system is not intended for the transfer of time-sensitive data.

# Prescription Device Statement

**CAUTION:**
United States federal law restricts this device to sale by or on the order of a physician.

# MUSE System Accuracy

Accuracy of the system is 100% data reproduction, dependent on zoom settings, and resolution of display and/or printer being used.

# Responsibility of the Purchaser/Customer

The customer is responsible for providing appropriate desks, chairs, electrical wall outlets, network connections, and analog phone lines, and for locating any of the system components described in this manual in compliance with all local, state, and national codes.

Lack of data security may compromise patient privacy. GE Healthcare recommends that you should take appropriate steps to secure the privacy of communication on your network when using this product.

# Modem Requirements

Modems supplied by GE Healthcare are designed to comply with applicable country requirements (such as USA FCC 47CFR68, CE EU R&TTE 1999/5/EC). Refer to the device for a registration number and ringer equivalence number (REN). The modem is designed for use on standard device telephone lines. Connection to telephone company-provided coin service (central office implemented systems) is prohibited. Connection to party lines service is subject to state tariffs.

An analog telephone line is required. A digital PBX line does not work. If you have any questions about your telephone line, such as how many pieces of equipment you can connect to it, the telephone company provides this information upon request.

The registration number and ringer equivalence number (REN) are listed on the equipment label. To assure proper service from your telephone company, connect no more than five RENs per telephone line. In some cases, you may not be able to use five RENs on a given line.

If any of your telephone equipment is not operating properly, you should immediately remove it from your telephone line, as it may cause harm to the telephone network. If the telephone company notes a problem, they may temporarily discontinue service. When practical, they notify you in advance of this disconnection. If advance notice is not feasible, you are notified as soon as possible. When you are notified, you are given the opportunity to correct the problem and you are informed of your right to file a complaint.

# 2

# Safety Information

This section provides information about the safe use of this system.

Disregarding the safety information provided in this manual is considered abnormal use of this system and could result in injury, data loss, or a voided warranty.

## Safety Conventions

A **Hazard** is a source of potential injury to a person, property, or the system.

This manual uses the terms DANGER, WARNING, CAUTION, and NOTICE to point out hazards and to designate a degree or level of seriousness. Familiarize yourself with the following definitions and their significance.

### Definitions of Safety Conventions

| Safety Convention | Definition |
|---|---|
| **DANGER** | Indicates an imminent hazard, which, if not avoided, will result in death or serious injury. |
| **WARNING** | Indicates a potential hazard or unsafe practice, which, if not avoided, could result in death or serious injury. |
| **CAUTION** | Indicates a potential hazard or unsafe practice, which, if not avoided, could result in moderate or minor injury. |
| **NOTICE** | Indicates a potential hazard or unsafe practice, which, if not avoided, could result in the loss or destruction of property or data. |

## Safety Hazards

The following safety messages alert you to potentially hazardous conditions that could arise during the normal use of this product and recommend steps that can be taken to avoid those conditions. Safety messages pertaining to hazardous conditions

that may arise during specific actions may also be provided during the discussion of those actions in this or other manuals for this product.

**WARNING:**
PATIENT SAFETY: All computer-generated tracings should be overread by a qualified physician.

**CAUTION:**
DATA CORRUPTION: Installation of software not specified by GE Healthcare may cause damage to the equipment, loss or corruption of data.

DO NOT load any software other than that specified by GE Healthcare onto the system.

**WARNING:**
INCORRECT TREATMENT: If a record containing a default PID (for example, 000000911) comes into the MUSE system with a patient name, it triggers a mismatch. When you open the name field, the system report displays Unknown Patient, and the Report Name displays the patient's name (for example, John Doe).

If the report does belong to John Doe, change the PID number to John Doe's correct PID.

**WARNING:**
INCORRECT TREATMENT: Failure to have a unique Patient ID (PID) in patient demographics may cause incorrect patient data associated with the PID.

Always assign the proper PID and name before transmission to the system. Do not confirm patient records containing default PIDs. Refer to the *MUSE Cardiology Information System Operator's Manual* for information on setting up a default PID.

**CAUTION:**
LOSS OF DATA: Database backup is the responsibility of the customer.

GE Medical Systems *Information Technologies*, Inc. is not responsible for data loss of any kind as a result of customer's failure to backup data.

# Security Updates

The GE Healthcare ***Product Security Database*** identifies which security patches from third-party vendors have been approved for use on GE Healthcare products. The database does not contain information about third-party patches that are not related to security.

**NOTE:**
In order to access this site, you need an SSO number. If you do not have one, you can obtain one during the login process.

To find security patches for your product, do the following:

1. Browse to the GE Healthcare ***Product Security Database***: http://prodsecdb.gehealthcare.com

   The GE Healthcare ***Single Sign On*** (SSO) page opens.

2. Enter your SSO user ID and password and click ***Log In***.

   The ***Home Page*** opens.

   **NOTE:**
   If you do not have an SSO account, click ***Sign Up Now!*** and follow the instructions to complete the registration for an account. After the registration is completed, the account is generated and the ***Home Page*** opens.

3. Click ***Search*** and select ***Product Patch Table***.

   The ***Product – Patch Mapping Search Result*** page opens, providing you a list of all the patches that match the search criteria and their ***Patch Assessment Status***. Patches with a ***Patch Approved*** status were verified by GE Healthcare and you may download them from the third-party vendor and install them on the identified product.

For more information about the patch, click on the link for that patch in ***Patch Assessment Details***.

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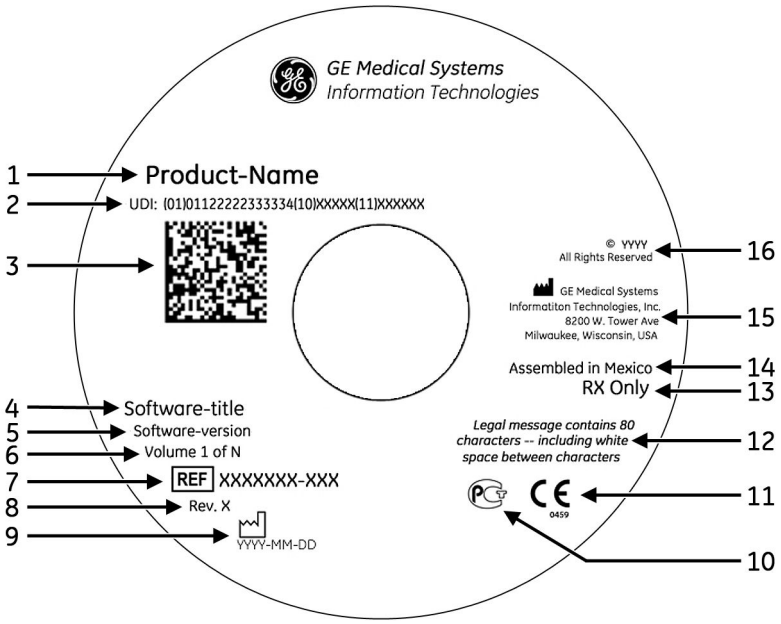
# Product and Packaging Information

This section identifies the following:

- Software labels and their locations
- Symbol Descriptions page 12

## Software Label

The following illustration and table describe the label on your CD or DVD.




### Descriptions of the CD/DVD Label

| Item | Description |
|---|---|
| 1 | **Product Name** |
| 2 | **UDI**<br>Unique Device Identification required for all medical devices. It consists of the software UDI plus the CD/DVD production date. It is required when reporting a damaged or defective disk. |

### Descriptions of the CD/DVD Label (cont'd.)

| Item | Description |
|---|---|
| 3 | 2D Barcode |
| 4 | Software Title |
| 5 | Software Version |
| 6 | Volume Number |
| 7 | Part Number |
| 8 | Revision |
| 9 | Date of Manufacture |
| 10 | GOST-R Mark |
| 11 | CE Mark |
| 12 | Legal message |
| 13 | Prescription Notice |
| 14 | Country of Origin |
| 15 | Manufacturer's Name and Address |
| 16 | Copyright Notice |

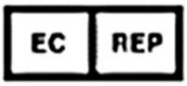
# Symbol Descriptions

The following table describes symbols or icons that are on the device or its packaging.

Any symbol on your device or packaging with markings in color indicates there may be a danger, warning, or mandatory action. Any symbol on your device or packaging that is in black and white provides additional information or may indicate a caution. Familiarity with these symbols assists in the use and disposal of the equipment.

For equipment symbols not shown, refer to the original equipment manufacturer (OEM) manuals.

| Symbol | Description |
|---|---|
|  | **Catalog or Orderable Part Number**<br>Indicates the manufacturer's catalog or part number. |
|  | **Serial Number**<br>Indicates the manufacturer's serial number. |
|  | **Batch Code or Lot Number**<br>Indicates the manufacturer's batch code or lot number. |

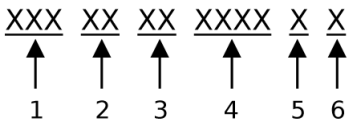
| Symbol | Description |
|---|---|
|  | **Date of Manufacture** (Year-Month)<br>Indicates the original manufacture date for this device. |
|  | **Manufacturer**<br>Indicates the name and address for the manufacturer of this device. It may also include the date it was manufactured. |
|  | **Authorized Representative in the European Community**<br>Indicates the name and address of the authorized representative in the European Community for this device. |
| Rx Only | **Rx Only**<br>US Federal law restricts this device to sale by or on the order of a physician. |
|  | **Consult Instructions for Use**<br>Consult the operating instructions. |
|  | **Follow Instructions For Use**<br>Read and understand the operator's manual before using the device or product. |
|  | **CAUTION:**<br>CONSULT ACCOMPANYING DOCUMENTS<br>There may be specific warnings or precautions associated with the device that are not otherwise found on the label.<br>Consult the accompanying documentation for more information about safely using this device. |
|  | **CE Mark**<br>Indicates the device or product conforms with applicable EU (European Union) directives. |
|  | **PCT (GOST-R) Mark**<br>Indicates the device or product conforms with applicable Russian Gosstandart technical and safety standards. |

# 4

# Equipment Identification

## Serial Number Format

Each device has a serial number that uniquely identifies it and provides important information. You need the product code and the entire serial number before servicing or requesting support for your product. The serial number format is shown in the following illustration:




### Serial Number Format

| Item | Name | Description |
|---|---|---|
| 1 | Product Code | Three-letter code that uniquely identifies the product line. |
| 2 | Year Manufactured | Two-digit code identifying the year the device was manufactured. Values range from 00 to 99<br>For example: 00 = 2000, 04 = 2004, 05 = 2005 (and so on). |
| 3 | Fiscal Week Manufactured | Two-digit code identifying the week the device was manufactured.<br>Values range from 01 to 52. GE Healthcare's fiscal weeks correspond to the calendar week. For example, 01 = first week in January. |
| 4 | Product Sequence | Four-digit number identifying the order in which this device was manufactured. Values range from 0001 to 9999. |
| 5 | Manufacturing Site | One-letter code identifying the site where the device was manufactured. For example, F = Milwaukee, N = Freiburg, P = Bangalore, W = Wuxi, H = Helsinki. |
| 6 | Miscellaneous Characteristic | One-letter code identifying manufacturing status. For example, P = device is a prototype, R = device was refurbished, U = device was upgraded to meet the specifications of another product code, A = device is in production. |

# Unique Device Identifier (UDI)

Medical devices require a unique marking for identification—the Unique Device Identifier (UDI). In the event that you need to access the UDI for this software product, on the menu bar select ***Help*** > ***About***.

If the UDI does not display, contact your GE Healthcare service representative.

GE Medical Systems
*Information Technologies*, Inc.
8200 West Tower Avenue
Milwaukee, WI 53223 USA
Tel: +1 414 355 5000
+1 800 558 7044 (US Only)
Fax: +1 414 355 3790

EC REP
GE Medical Systems
*Information Technologies* GmbH
Munzinger Straße 5
79111 Freiburg Germany
Tel: +49 761 45 43 -0
Fax: +49 761 45 43 -233

**Asia Headquarters**
GE Medical Systems
*Information Technologies*, Inc.
Asia; GE (China) Co., Ltd.
1 Huatuo Road
Zhangjiang Hi-tech Park Pudong
Shanghai, People's Republic of China 201203
Tel: +86 21 3877 7888
Fax: +86 21 3877 7451

GE Medical Systems *Information Technologies*, Inc., a General Electric Company, going to market as GE Healthcare.

**www.gehealthcare.com**

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