

HIMSS/NEMA Standard HN 1-2013

Manufacturer Disclosure Statement for Medical Device Security

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FOREWORD

This document consists of the Manufacturer Disclosure Statement for Medical Device Security (MDS²) form and related instructions how to complete the form. The intent of the MDS² form is to supply healthcare providers with important information to assist them in assessing the **vulnerability** and risks associated with protecting **private data** transmitted or maintained by **medical devices** and systems. Because security **risk assessment** spans an entire organization, this document focuses on only those elements of the security **risk assessment process** associated with **medical devices** that maintain or transmit **private data**. A standardized form 1) allows manufacturers to quickly respond to a potentially large volume of information requests from providers regarding the security-related features of the **medical devices** they manufacture; and 2) facilitates the providers' review of the large volume of security-related information supplied by the manufacturers.

The manufacturer-completed MDS² should:

- (1) Be useful to healthcare provider organizations worldwide. The information presented should be useful for any healthcare delivery organization that aspires to have an effective information security **risk management** program.
- (2) Include **device**-specific information addressing the technical security-related attributes of the individual **device** model.
- (3) Provide a simple, flexible way of collecting the technical, **device**-specific elements of the common/typical information needed by provider organizations (device **users/operators**) to begin **medical device** information security (i.e., confidentiality, integrity, availability) **risk assessments**.

HIMSS and NEMA grant permission to make copies and use this form.

PLEASE BE ADVISED—The MDS² form is not intended to nor should it be used as the sole basis for medical device procurement. Writing procurement specifications requires a deeper and more extensive knowledge of security (including the individual facility's/provider's situation) and the healthcare mission.

Using the information provided by the manufacturer in the MDS² form together with information collected about the care delivery environment (e.g., through tools such as ACCE, American College of Clinical Engineering/ECRI's *Guide for Information Security for Biomedical Technology*), the provider's multidisciplinary **risk assessment** team can review assembled information and make informed decisions on implementing a local security management plan.

This form was originally adapted from portions of the ACCE/ECRI Biomedical Equipment Survey Form, a key tool found in *Information Security for Biomedical Technology: A HIPAA* Compliance Guide* (ACCE/ECRI, 2004). This form was published originally in 2004, MDS² v. 1.0 (2004-11-01) and then as a joint HIMSS/NEMA standard in 2008, HIMSS/NEMA Standard HN 1-2008.

*Health Insurance Portability and Accountability Act.

In 2010, International Electrotechnical Commission standard IEC 80001-1, *Application of risk management for IT-networks incorporating medical devices*, was published. The standard deals with the application of **risk management** to IT-networks incorporating **medical devices** and provides the roles, responsibilities and activities necessary for **risk management**. In 2012, a Technical Report (TR) supplement to IEC 80001 was published, IEC/TR 80001-2-2, *Guidance for the communication of medical device security needs, risks and controls*. In this supplement, 19 relevant **security capabilities** of a **medical device** or IT component are defined. The 19 high-level **security capabilities** are "...intended to be the starting point for a security-centric discussion

between vendor and purchaser or among a larger group of stakeholders involved in a Medical Device IT-Network project." Since this goal closely matches the primary objective of the MDS² initiative, HIMSS and NEMA have undertaken an expansion and re-categorization of the MDS² information provided by manufacturers in order to closely align with the 19 IEC/TR 80001-2-2 security categories.

HIMSS and NEMA recommend that the information in the MDS² form be used as part of each organization's security compliance and **risk assessment** efforts. In the preparation of this standards publication, input of **users** and other interested parties has been sought and evaluated.

Inquiries, comments, and proposed or recommended revisions should be submitted to the concerned NEMA product subdivision by contacting the:

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CHANGES FROM PREVIOUS (2008) MDS² REVISION

- 1) Alignment of MDS² with International Electrotechnical Commission (IEC) standard 80001-1 supplement, IEC/TR 80001-2-2, *Guidance for the communication of medical device security needs, risks and controls*.
 - a) The order and numbering of the (2008) MDS² questions has been changed and questions are now placed in either the MANAGEMENT OF PRIVATE DATA section or under the appropriate heading in one of the 19 categories in the SECURITY CAPABILITIES section of the MDS² form.
 - b) The amount of MDS² data requested of **device** manufacturers has been increased to more adequately address the 19 **security capabilities** of IEC/TR 80001-2-2.
 - c) MDS² term definitions have been added or updated to be consistent with definitions used in IEC 80001 when applicable.

All of the MDS² security-related questions of previous MDS² revisions remain in this latest revision with no (or only minor) changes. A cross reference of the 2008 MDS² questions vs. 2013 MDS² questions is provided in the Annex.

2) De-localization

Several region-specific references and standards have been removed or replaced with more generic/less region-specific references. The term "Protected Health Information" (PHI), defined in USA HIPAA legislation has been replaced in this MDS² revision by the term "**private data**," as defined in IEC 80001.

Section 1 GENERAL

1.1 SCOPE

Information provided on the MDS² form is intended to assist professionals responsible for security **risk assessment processes** in their management of **medical device** security issues. The information on the MDS² form is not intended, and may be inappropriate, for other purposes.

1.1.1 The Role of Healthcare Providers in the Security Management Process

The provider organization has the ultimate responsibility for providing effective security management. **Device** manufacturers can assist providers in their security management programs by offering information describing:

- the type of data maintained/transmitted by the manufacturer's **device**;
- how data is maintained/transmitted by the manufacturer's **device**;
- any security-related features incorporated in the manufacturer's **device**.

In order to effectively manage medical information security and comply with relevant regulations, healthcare providers must employ **administrative, physical, and technical safeguards**—most of which are extrinsic to the actual **device**.

1.1.2 The Role of Medical Device Manufacturers in the Security Management Process

The greatest impact manufacturers can have on **medical device** security is to incorporate **technical safeguards** (i.e., security features) in their **devices** to facilitate healthcare providers' efforts in maintaining effective security programs and meeting any relevant regulatory requirements and/or standards. The **medical device** manufacturing industry is increasingly aware of the importance of having effective security functionality in their **devices**. Manufacturers are generally including such security-related requirements in the production of new **devices** based on provider needs and requirements.

1.2 REFERENCES

The following reference documents are included herein as suggested further reading, supportive material, and related publications:

Application of risk management for IT-networks incorporating medical devices -- Part 1: Roles, responsibilities and activities, IEC 80001-1:2010

Application of risk management...-- Part 2-1: Step by Step Risk Management of Medical IT-Networks; Practical Applications and Examples, IEC 80001-2-1:2012

Application of risk management...-- Part 2-2: Guidance for the communication of medical device security needs, risks and controls, IEC/TR 80001-2-2:2012

Health Insurance Portability and Accountability Act of 1996 (HIPAA), Pub. L. 104-191 (USA)

Health Insurance Reform: Security Standards; Final Rule, 45 CFR pts.160, 162, 164 (USA, 2003).

EC Data Protection Directive, 95/46/EC (EU 95/46), 1995.

Act on the Protection of Personal Information (Act No. 57 of 2003, Japan).

Personal Information Protection and Electronic Documents Act (PIPEDA), Statutes of Canada, 2000.

Guide for Information Security for Biomedical Technology: A HIPAA Compliance Guide, May 2004, American College of Clinical Engineering (ACCE)/ECRI.

1.3 DEFINITIONS

administrative safeguards: Administrative actions, policies, and procedures to manage the selection, development, implementation, and maintenance of security measures to protect **private data** and to manage the conduct of an organization's workforce in relation to the protection of that information.

anti-malware: See **anti-virus software**.

anti-virus software: A program that monitors a computer or network to identify all major types of **malware** and prevent or contain **malware** incidents. See also **virus scanner**.

audit trail: Data collected and potentially used to facilitate a security audit.

biometric data: Identifies a human via a measurement of a physical feature or repeatable action of the individual (e.g., hand geometry, retinal scan, iris scan, fingerprint patterns, facial characteristics, DNA sequence characteristics, voice prints, handwritten signature).

device: A product/system, including hardware, firmware and/or (only) software, etc. Unless otherwise clear from the context, in this MDS² document, "device" refers to the **medical device** (the manufacturer's product) which is being addressed by the manufacturer in the MDS² form. See also **medical device**.

electronic media: (1) Electronic storage media, including memory devices in computers (hard drives) and any removable/transportable digital memory media, such as magnetic tapes or disks, optical disks, or digital memory cards. (2) Transmission media used to exchange information already in electronic storage media, including, for example, the Internet (wide open), extranet (using Internet technology to link a business with information accessible only to collaborating parties), leased lines, dial-up lines, and private networks, and the physical movement of removable/transportable electronic storage media. Certain transmissions, including of paper via facsimile and of voice via telephone, are not considered to be transmissions via **electronic media** because the information being exchanged did not exist in electronic form before the transmission.

electronic protected health information (ePHI): (As defined in U.S. HIPAA legislation, 45 CFR 160.103) **individually identifiable health information (IIHI)** that is (1) transmitted by or (2) maintained in **electronic media**.

emergency access: The **process** or mechanism by which a **device user** can quickly and easily access **private data** in urgent (emergency) situations, bypassing the device's established access controls.

individually identifiable health information (IIHI): Information that is a subset of health information, including demographic information collected from an individual, and: (1) Is created or received by a health care provider, health plan, employer, or health care clearinghouse; and (2) Relates to the past, present, or future physical or mental health or condition of an individual; the provision of health care to an individual; or the past, present, or future payment for the provision of health care to an individual; and (i) That identifies the individual; or (ii) With respect to which there is a reasonable basis to believe the information can be used to identify the individual.

intended use: Use for which a product, **process** or service is intended according to the specifications, instructions and information provided by the manufacturer. (source: ISO 14971: 2007, *Application of risk management to medical devices*, definition 2.5).

malware: Malicious software. A software program that is inserted into a system, usually covertly, with the intent of compromising the confidentiality, integrity, or availability of the victim's data, applications, or operating system or of otherwise annoying or disrupting the victim. (source: NIST SP 800-83, *Guide to Malware Incident Prevention and Handling*)

medical device: Any instrument, apparatus, implement, machine, appliance, implant, in vitro reagent or calibrator, software, material or other similar or related article:

a) intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the specific purpose(s) of:

- diagnosis, prevention, monitoring, treatment or alleviation of disease,
- diagnosis, monitoring, treatment, alleviation of or compensation for an injury,
- investigation, replacement, modification, or support of the anatomy or of a physiological **process**,
- supporting or sustaining life,
- control of conception,
- disinfection of **medical devices**,
- providing information for medical or diagnostic purposes by means of in vitro examination of specimens derived from the human body;

b) which does not achieve its primary intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its intended function by such means.

operator: Person handling equipment. The person(s) using a **medical device** for its intended purpose.

personal identification number (PIN): A number or code assigned to an individual and used to provide verification of identity.

physical safeguards: The physical measures, policies, and procedures to protect an organization's electronic information systems and related buildings and equipment from natural and environmental hazards and unauthorized intrusion.

private data: Any information relating to an identified or identifiable person.

process: A set of inter-related or interacting activities which transforms inputs into outputs.

remote service: A support service (e.g., testing, diagnostics, software upgrades) while not physically or directly connected to the device (e.g., remote access via modem, network, Internet).

removable media: **Electronic media** that can be removed from a system without the use of tools.

risk assessment: Conducting an accurate and thorough analysis of the potential risks and **vulnerabilities** to the integrity, availability, and confidentiality of **private data**.

risk management: (1) The ongoing **process** of assessing risk, taking steps to reduce risk to an acceptable level, and maintaining that level of risk. (2) Security measures sufficient to reduce risks and **vulnerabilities** to a reasonable and appropriate level.

security capability: The broad category of technical, administrative or organizational controls to manage risks of confidentiality, integrity, and availability and accountability of data and systems.

technical safeguards: The technology, policies, and procedures to protect data, including **private data** and control access to it.

token: A physical authentication **device** that the **user** carries (e.g., smartcard, SecureID[™], etc.). Often combined with a **PIN** to provide a two-factor authentication method that is generally thought of as superior to simple password authentication.

user: See **operator**.


virus: See **malware**.

virus scanner: A computer program (**anti-virus software**) that detects a **virus** computer program, or other kind of **malware** (e.g., worms and Trojan horses), warns of its presence, and attempts to prevent it from affecting the protected computer. **Malware** often results in undesired side effects generally unanticipated by the **user**.

vulnerability: A flaw or weakness in **device** procedures, design, implementation, or internal controls that could be exercised (accidentally triggered or intentionally exploited) and result in a security breach or a violation of the **device's** security policy.

1.4 ACRONYMS

| | |
|------|--------------------------|
| CD | Compact Disk |
| CF | Compact Flash |
| COTS | Commercial Off-The-Shelf |
| DVD | Digital Versatile Disk |
| IP | Internet Protocol |
| LAN | Local Area Network |
| OS | Operating System |
| ROM | Read Only Memory |
| SD | Secure Digital |
| USB | Universal Serial Bus |
| VPN | Virtual Private Network |
| WAN | Wide Area Network |
| WiFi | Wireless Fidelity |



Section 2

INSTRUCTIONS FOR OBTAINING, USING, AND COMPLETING MDS² FORM

2.1 OBTAINING THE MDS² FORM (PROVIDERS)

Completed MDS² forms for many **devices** may be available directly from the **device** manufacturer (e.g., manufacturer website).

NOTE—If a manufacturer does not have a completed MDS² form for the appropriate **device**(s), enter manufacturer and model information in the appropriate boxes on the top of a blank MDS² form, and submit the form(s) and these instructions to the manufacturer's compliance office for completion.

2.2 USING THE MDS² FORM (PROVIDERS)

2.2.1 Device Description

The first two sections of the MDS² form are used to identify the **device** (DEVICE DESCRIPTION) and describe the type of data maintained/transmitted by the **device** and how the data is maintained/transmitted, etc. (MANAGEMENT OF PRIVATE DATA).

PLEASE BE ADVISED—An indication of a device's ability to perform any listed function (i.e., a "Yes" answer) is not an implicit or explicit endorsement or authorization by the manufacturer to configure the device or cause the device to perform those listed functions.

It is important to distinguish between capability and permission. Unless otherwise indicated, the questions contained on the MDS² form generally refer to device capability. Permission is typically a contractual matter separate from the MDS² form. Making changes to a medical device without explicit manufacturer authorization may have significant contractual, safety and liability issues.

2.2.2 Explanatory Notes

The MDS² form contains space for explanatory notes if the manufacturer needs to explain specific details of the manufacturer's answers to questions.

NOTE—Manufacturers may elect to attach supplementary material if additional space for recommended practices or explanatory notes is necessary.

2.2.3 Security Capabilities

The final section of the MDS² (SECURITY CAPABILITIES) contains information on the specific security-related capabilities of the **device**. The information is organized into categories aligned with IEC 80001-2-2, *Guidance for the communication of medical device security needs, risks, and controls*.

2.3 COMPLETING THE MDS² FORM (MANUFACTURERS)

2.3.1 General

The manufacturer shall provide the information requested in the MDS² form to the appropriate requesting organization, including all requested descriptive information on the type of data maintained/transmitted by the **device**, how the data is maintained/transmitted, and other security-related features incorporated in the **device**, as appropriate.

2.3.2 MDS² Form Completion Guidance

DEVICE DESCRIPTION section:

Device Category: This is a free-text field. The manufacturer should use standard terminology that customers would reasonably understand to differentiate key modalities or **device** functionality.

Device Model: This is a free-text field. The manufacturer should fill in the name of the **device** under which it is placed on the market.

Document ID: The document ID is the manufacturer's unique tag used internally to track **device** documentation.

Manufacturer Contact Information: This information identifies how the person or department accountable for the final version of the form can be contacted.

Intended use of device in network-connected environment: This allows the manufacturer to describe the intended function and use of the **device** and, if relevant, how the **device** is expected to be used if connected to a customer's network environment.

MANAGEMENT OF PRIVATE DATA section:

The manufacturer shall answer all questions either "Yes," "No," "N/A" (not applicable), or "See Note."

If additional information is needed for proper interpretation of an answer, manufacturers are encouraged to provide information in explanatory notes.

The following clarifications and suggested guidance are provided to assist the manufacturer in answering the questions:

NOTE—the numbers in this subsection, below, correlate to the question numbers in the MDS² form.

- A Can this **device** display, transmit or maintain **private data** (including **electronic Protected Health Information [ePHI]**)?
- B Types of **private data** elements that can be maintained by the **device**:
 - B.1 Demographic (e.g., name, address, location, unique identification number)?
 - B.2 Medical record (e.g., medical record #, account #, test or treatment date, **device** identification number)?
 - B.3 Diagnostic/therapeutic (e.g., photo/radiograph, test results, or physiologic data with identifying characteristics)?
 - B.4 Open, unstructured text entered by **device user/operator**?
 - B.5 **Biometric** data?
 - B.6 Personal financial information (e.g., credit card numbers, health insurance information, etc.)?
- C Maintaining **private data** - Can the **device**:
 - C.1 Maintain **private data** temporarily in volatile memory (i.e., until cleared by power-off or reset)?
 - C.2 Store **private data** persistently on local media?
 - C.3 Import/export **private data** with other systems?
 - C.4 Maintain **private data** during power service interruptions?
- D Mechanisms used for the transmitting, importing/exporting of **private data** – Can the **device**:
 - D.1 Display **private data** (e.g., video display, etc.)?

- D.2 Generate hardcopy reports or images containing **private data**?
- D.3 Retrieve **private data** from or record **private data** to **removable media** (e.g., disk, DVD, CD-ROM, tape, CF/SD card, memory stick, etc.)?
- D.4 Transmit/receive or import/export **private data** via dedicated cable connection (e.g., IEEE 1073, serial port, USB, FireWire, etc.)?
- D.5 Transmit/receive **private data** via a wired network connection (e.g., LAN, WAN, VPN, intranet, Internet, etc.)?
- D.6 Transmit/receive **private data** via an integrated wireless network connection (e.g., WiFi, Bluetooth, infrared, etc.)?
- D.7 Import **private data** via scanning?
- D.8 Other?

SECURITY CAPABILITIES Section:

The Security Capabilities section of the MDS² form contains questions regarding the specific security-related features of the **device**. The questions are organized into the **security capabilities** categories of IEC 80001-2-2, Guidance for the communication of **medical device** security needs, risks and controls.

The manufacturer shall answer all questions either “Yes,” “No,” “N/A” (not applicable), or “See Note” unless the applicable question requires otherwise.

If additional information is needed for proper interpretation of these answers, manufacturers are encouraged to provide information in explanatory notes.

The following clarifications and suggested guidance are provided to assist the manufacturer in answering the questions:

NOTE—the numbers in this subsection, below, correlate to the question numbers in the MDS² form.

1 AUTOMATIC LOGOFF (ALOF): The **device**'s ability to prevent access and misuse by unauthorized **users** if **device** is left idle for a period of time.

1-1 Can the **device** be configured to force reauthorization of logged-in **user(s)** after a predetermined length of inactivity (e.g., auto-logoff, session lock, password protected screen saver)?

GUIDANCE: Does the **device**, by default or by configuration, always:

- enforce reauthorization after a specified period of inactivity;
- activate a password-protected screen saver after a preselected period of inactivity that effectively prevents **user** access even without logging the **user** off?

The notes section may be used to indicate if/how an auto-logoff or screen lock function can be disabled (e.g., per session or globally with appropriate **user** security warnings/notification?)

1-1.1 Is the length of inactivity time before auto-logoff/screen lock **user** or administrator configurable? (Indicate time [fixed or configurable range] in notes.)

GUIDANCE: Can the **user** or administrator configure the amount of time that must lapse before auto-logoff or screen lock occurs? The notes section should be used to indicate whether a **device** with adjustable auto-logoff/screen lock can be configured:

- to a **user** determined time;
- by specific role (e.g., administrator, **user**).

1-1.2 Can auto-logoff/screen lock be manually invoked (e.g., via a shortcut key) by the **user**?

GUIDANCE: Can the **user/operator** manually invoke the auto-logout/screen lock via a shortcut key combination (e.g., CTRL-ALT-DELETE)?

2 AUDIT CONTROLS (AUDT): The ability to reliably audit activity on the **device**.

2-1 Can the **medical device** create an **audit trail**?

GUIDANCE: If the answer is no, then answers to 2.2.1 ~ 2.3.2 should be "N/A" and move to question 3-1. Indicate in the notes if the **audit trail** can differentiate between the creation/display/export etc. of **private data** vs. other data. If so, indicate in the notes if the data subject (e.g., patient) is identified for each **private data** event in the log.

2-2 Indicate which of the following events are recorded in the audit log:

2-2.1 Login/Logout?

2-2.2 Display/presentation of data?

GUIDANCE: Does the **audit trail** track the display, printing or other means of presenting data?

2-2.3 Creation/modification/deletion of data?

GUIDANCE: If yes, indicate in notes which (creation and/or modification and/or deletion) of these forms of data manipulation are tracked.

2-2.4 Import/export of data from **removable media**?

GUIDANCE: If yes, indicate in notes which of these forms of data manipulation are tracked.

2-2.5 Receipt/transmission of data from/to external (e.g., network) connection?

GUIDANCE: If yes, indicate in notes which of these forms of data manipulation are tracked.

2-2.5.1 **Remote service** activity?

2-2.6 Other events? (Describe in the notes section.)

GUIDANCE: If yes, indicate in notes which other forms of data manipulation are tracked.

2-3 Indicate what information is used to identify individual events recorded in the audit log:

2-3.1 **User ID**?

2-3.2 Date/time?

GUIDANCE: Indicate in the notes how the **device** time is set. e.g., indicate if the **device** can synchronize time to a Network Time Server (NTP, SNTP, etc.)

3 AUTHORIZATION (AUTH): The ability of the **device** to determine the authorization of **users**.

3-1 Can the **device** prevent access to unauthorized **users** through **user** login requirements or other mechanism?

GUIDANCE: If the **device** can prevent unauthorized access, indicate in the notes what physical or **technical safeguards** the **device** uses to prevent access (password, biometrics, keycard, etc.)

3-2 Can **users** be assigned different privilege levels within an application based on 'roles' (e.g., guests, regular **users**, power **users**, administrators, etc.)?

- 3-3 Can the **device** owner/**operator** obtain unrestricted administrative privileges (e.g., access operating system or application via local root or administrator account)?

GUIDANCE: Indicate in the notes if the **device** supports more than one privileged account (e.g., administrator, root).

Indicate in the notes if the manufacturer imposes any restrictions on **users** regarding the use of administrator accounts.

- 4 CONFIGURATION OF SECURITY FEATURES (CNFS): The ability to configure/re-configure **device security capabilities** to meet **users'** needs.

- 4-1 Can the **device** owner/**operator** reconfigure product **security capabilities**?

GUIDANCE: Indicate in the notes if the manufacturer imposes any restrictions on **users** regarding the reconfiguring of product **security capabilities**.

- 5 CYBER SECURITY PRODUCT UPGRADES (CSUP): The ability of on-site service staff, **remote service** staff, or authorized customer staff to install/upgrade **device's** security patches.

- 5-1 Can relevant OS and **device** security patches be applied to the **device** as they become known/available?

GUIDANCE: If the manufacturer does not authorize **users** to apply OS and **device** security patches, or has any restrictions on this activity, then the existence of these restrictions should be mentioned in a note. The manufacturer may optionally choose to describe any restrictions directly in the note or reference external documents where a description of these restrictions can be found or simply write, "Information on manufacturer restrictions/limitations can be provided upon request," for example.

- 5-1.1 Can security patches or other software be installed remotely?

GUIDANCE: If the manufacturer does not authorize **users** to install OS/**device** security patches or other software remotely, or has any restrictions on this activity, then the existence of these restrictions should be mentioned in a note.

The manufacturer may optionally choose to describe any restrictions directly in the note or reference external documents where a description of these restrictions can be found or simply write, "Information on manufacturer restrictions/limitations can be provided upon request," for example.

- 6 HEALTH DATA DE-IDENTIFICATION (DIDT): The ability of the **device** to directly remove information that allows identification of a person.

- 6-1 Does the **device** provide an integral capability to de-identify **private data**?

GUIDANCE: Mention in the notes if the de-identification **process** references/adheres to any specific de-identification standard/guideline. Also mention if the de-identification procedure is configurable.

- 7 DATA BACKUP AND DISASTER RECOVERY (DTBK): The ability to recover after damage or destruction of **device** data, hardware, or software.

- 7-1 Does the **device** have an integral data backup capability (e.g., backup to remote storage or **removable media** such as tape, disk)?

GUIDANCE: This refers to an integrated feature or option that supports information backup to remote storage or **removable media** (e.g., optical disk, magnetic disk, tape, etc.) If appropriate, mention in a note any limitations or restrictions on data backup/disaster recovery.

- 8 EMERGENCY ACCESS (EMRG): The ability of the **device user** to access **private data** in case of an emergency situation that requires immediate access to stored **private data**.

- 8-1 Does the **device** incorporate an **emergency access** (“break-glass”) feature?

GUIDANCE: See “Definitions” section for a description of the term **emergency access**. If applicable, describe in the notes for section 2 (e.g., question 2-2.6) the **device**’s ability to log instances of **emergency access**. The manufacturer may also choose to mention in the notes for question 8-1:

- If/how the **device** prompts an emergency **user** for a (temporary/“emergency”) **user** name and/or hospital/clinic ID # that is then recorded in the audit log.
- If/how the **device** identifies or “flags” data acquired during an “emergency” session (e.g., data acquired without an authorized **user** logged in).

- 9 HEALTH DATA INTEGRITY AND AUTHENTICITY (IGAU): How the **device** ensures that data processed by the **device** has not been altered or destroyed in a non-authorized manner and is from the originator.

- 9-1 Does the **device** ensure the integrity of stored data with implicit or explicit error detection/correction technology?

GUIDANCE: This question refers only to the integrity of stored data. Information regarding system controls intended to prevent unauthorized changes to the application program or system in general should be provided in the notes to the System and Application Hardening (SAHD) section.

- 10 MALWARE DETECTION/PROTECTION (MLDP): The ability of the **device** to effectively prevent, detect and remove malicious software (**malware**).

- 10-1 Does the **device** support the use of **anti-malware** software (or other **anti-malware** mechanism)?

GUIDANCE: The manufacturer may optionally choose to describe any restrictions on **malware** support (purchase/installation/configuration) directly in the note or reference external documents where a description of these restrictions can be found.

- 10-1.1 Can the **user** independently (re-)configure **anti-malware** settings?

- 10-1.2 Does notification of **malware** detection occur in the **device user** interface?

GUIDANCE: Optionally, in the notes describe how the **user** is notified when **malware** is detected.

- 10-1.3 Can only manufacturer-authorized persons repair systems when **malware** has been detected?

GUIDANCE: Optionally, in the notes describe any restrictions on who is or is not authorized by the manufacturer to repair **malware** infected systems, or reference external documents where a description of these restrictions can be found.

- 10-2 Can the **device** owner install or update **anti-virus software**?

GUIDANCE: Answer “Yes” if the **device user/owner** has the ‘technical’ ability to install or update **anti-virus software**. However, if the manufacturer does not authorize **users** to install or update **anti-virus software**, or has any restrictions on this activity, then the existence of these restrictions should be mentioned in a note.

- 10-3 Can the **device** owner/**operator** (technically/physically) update **virus** definitions on manufacturer-installed **anti-virus** software?

GUIDANCE: Answer “Yes” if the system **user/owner** has the technical ability to update **virus** definitions/**virus** signature files. However, if the manufacturer does not authorize **users** to update these **virus** signature files or has any restrictions on this activity, then the existence of these restrictions should be mentioned in a note. For whitelisting

solutions, indicate in the notes if the **device** manufacturer restricts the owner's/**user's** ability to modify the list of authorized applications (the white list).

- 11 **NODE AUTHENTICATION (NAUT):** The ability of the **device** to authenticate communication partners/nodes.
- 11-1 Does the **device** provide/support any means of node authentication that assures both the sender and the recipient of data are known to each other and are authorized to receive transferred information?
- 12 **PERSON AUTHENTICATION (PAUT):** The ability of the **device** to authenticate **users**.
- 12-1 Does the **device** support **user/operator**-specific username(s) and password(s) for at least one **user**?
- GUIDANCE: If the **device** supports identification beyond username and password, describe it briefly in the notes (e.g., "uses XYZ secure **token** mechanism").
- 12-1.1 Does the **device** support unique **user/operator**-specific IDs and passwords for multiple **users**?
- 12-2 Can the **device** be configured to authenticate **users** through an external authentication service (e.g., MS Active Directory, NDS, LDAP, etc.)?
- GUIDANCE: If yes, please specify which mechanism in the notes section.
- 12-3 Can the **device** be configured to lock out a **user** after a certain number of unsuccessful logon attempts?
- GUIDANCE: If yes, provide any detail in notes as desired.
- 12-4 Can default passwords be changed at/prior to installation?
- GUIDANCE: If the manufacturer imposes specific restrictions, please explain in the notes.
- 12-5 Are any shared user IDs used in this system?
- GUIDANCE: Answer "Yes" if, by design, the **device** is intended to be used with shared IDs. If yes, specify if the shared IDs are for service and/or **user** mode. Additionally, indicate if the IDs/passwords are common across multiple instances of the same model(s) of the **device**. (This excludes "emergency" or "break glass" accounts.)
- 12-6 Can the **device** be configured to enforce creation of **user** account passwords that meet established (organization specific) complexity rules? If there are any limitations to password constraints please list in the notes section.
- GUIDANCE: Answer "Yes" if password complexity is configurable. Answer "No" if password complexity is not configurable, regardless of complexity requirements. Indicate complexity rules and limits in the notes.
- 12-7 Can the **device** be configured so that account passwords expire periodically?
- GUIDANCE: If yes, provide in the notes the expiration frequency or administration controls available.
- 13 **PHYSICAL LOCKS (PLOK):** Physical locks can prevent unauthorized **users** with physical access to the **device** from compromising the integrity and confidentiality of **private data** stored on the **device** or on **removable media**.
- 13-1 Are all **device** components maintaining **private data** (other than **removable media**) physically secure (i.e. cannot remove without tools)?

GUIDANCE: This question refers to the typical installation and configuration of the manufacturer's **device**.

Consider internal data storage drives and any other storage media that maintain **private data**. Answer "Yes," if any such media can be physically accessed and removed without tools. In this context, a physical key required for access is considered a tool.

- 14 ROADMAP FOR THIRD PARTY COMPONENTS IN DEVICE LIFE CYCLE (RDMP): Manufacturer's plans for security support of third-party components within the **device's** life cycle.
- 14-1 In the notes section, list the provided or required (separately purchased and/or delivered) operating system(s) - including version number(s).
- 14-2 Is a list of other third party applications provided by the manufacturer available?
- GUIDANCE: In the notes section, list the other third-party applications used by the **device** and provided by the manufacturer. If components are proprietary, please specify whether this information is available upon request prior to sale.
- 15 SYSTEM AND APPLICATION HARDENING (SAHD): The **device's** inherent resistance to cyber-attacks and **malware**.
- 15-1 Does the **device** employ any hardening measures?
- 15-2 Does the **device** employ any mechanism (e.g., release-specific hash key, checksums, etc.) to ensure the installed program/update is the manufacturer-authorized program or software update?
- GUIDANCE: Optionally describe in the notes section the mechanism(s) used to protect changes to the application programs, system configuration and/or **device** data.
- 15-3 Does the **device** have external communication capability? (network, modem, etc.)
- GUIDANCE: If yes, indicate in the notes if the **device** must initiate the external connection or accepts incoming connections.
- 15-4 Does the file system allow the implementation of file-level access controls (e.g., New Technology File System (NTFS) for MS Windows platforms)?
- GUIDANCE: Provide a summary in the notes section of the file-level access controls (e.g., **user** access versus administrator access, remote versus local access, etc.)
- 15-5 Are all accounts which are not required for the intended use of the **device** disabled or deleted, for both **users** and applications?
- GUIDANCE: Indicate in the notes if any accounts are closed/disabled by the manufacturer (at or prior to the installation of the **device**) or are expected to be disabled by the end **user**.
- 15-6 Are all shared resources (e.g., file shares) which are not required for the **intended use** of the **device**, disabled?
- GUIDANCE: Indicate in the notes if any shared resources are closed/disabled by the manufacturer (at or prior to the installation of the **device**) or are expected to be disabled by the end **user**.
- 15-7 Are all communication ports which are not required for the **intended use** of the **device** closed/disabled?
- GUIDANCE: Indicate in the notes if the ports are closed/disabled by the manufacturer (at or prior to the installation of the **device**) or are expected to be disabled by the end **user**.

- 15-8 Are all services (e.g., telnet, file transfer protocol [FTP], internet information server [IIS], etc.), which are not required for the **intended use** of the **device** deleted/disabled?

GUIDANCE: Indicate in the notes if the unneeded services are deleted/disabled by the manufacturer (at or prior to the installation of the **device**) or are expected to be disabled by the end **user**.

- 15-9 Are all applications (COTS applications as well as OS-included applications, e.g., MS Internet Explorer, etc.) which are not required for the **intended use** of the **device** deleted/disabled?

GUIDANCE: Indicate in the notes if the unneeded applications are deleted/disabled by the manufacturer (at or prior to the installation of the **device**) or are expected to be disabled by the end **user**.

- 15-10 Can the **device** boot from uncontrolled or **removable media** (i.e., a source other than an internal drive or memory component)?

GUIDANCE: Describe in the notes what external media is accepted by the **device**.

- 15-11 Can software or hardware not authorized by the **device** manufacturer be installed on the **device** without the use of tools?

GUIDANCE: Answer “Yes” if the **device user/owner** has the ‘technical’ ability to install hardware or software. However, if the manufacturer does not authorize **users** to install hardware or software, or has any restrictions on this activity, then the existence of these restrictions should be mentioned in a note.

- 16 SECURITY GUIDES (SGUD): Availability of security guidance for **operator** and administrator of the **device** and manufacturer sales and service.

- 16-1 Are security-related features documented for the **device user**?

GUIDANCE: Answer “Yes” if the manufacturer provides a dedicated security document or security documentation within the **user** manual, service manual, or other documentation available to **users**.

- 16-2 Are instructions available for **device/media sanitization** (i.e., instructions for how to achieve the permanent deletion of personal or other sensitive data.)?

GUIDANCE: Answer “Yes” if the manufacturer provides such instructions within any documentation available to **users**.

- 17 HEALTH DATA STORAGE CONFIDENTIALITY (STCF): The ability of the **device** to ensure unauthorized access does not compromise the integrity and confidentiality of **private data** stored on **device** or **removable media**.

- 17-1 Can the **device** encrypt data at rest?

GUIDANCE: See also section 18 for specific questions regarding encryption of data prior to network transmission or media export.

- 18 TRANSMISSION CONFIDENTIALITY (TXCF): The ability of the **device** to ensure the confidentiality of transmitted **private data**.

- 18-1 Can **private data** be transmitted only via a point-to-point dedicated cable?

GUIDANCE: Clarification: a point-to-point dedicated cable is a cabling system that is not accessible to the general public (e.g., it is in physically controlled space such as examining rooms or communication closets or building plenum).

- 18-2 Is **private data** encrypted prior to transmission via a network or **removable media**? (If yes, indicate in the notes section to which standard the encryption mechanism adheres.)

18-3 Is **private data** transmission restricted to a fixed list of network destinations?

GUIDANCE: Clarification: a fixed list is an explicit mechanism that limits the connections and nature of connections on a per-**device** basis.

19 TRANSMISSION INTEGRITY (TXIG): The ability of the **device** to ensure the integrity of transmitted **user**.

19-1 Does the **device** support any mechanism intended to ensure data is not modified during transmission? (If yes, describe in the notes section how this is achieved.)

20 OTHER SECURITY CONSIDERATIONS (OTHR): Additional security considerations/notes regarding **medical device** security.

20-1 Can the **device** be serviced remotely?

GUIDANCE: **Remote service** refers to **device** maintenance activities performed by a service person via network or other remote connection. Describe in the notes any manufacturer restrictions on **remote service**.

20-2 Can the **device** restrict remote access to/from specified **devices** or **users** or network locations (e.g., specific IP addresses)?

20-2.1 Can the **device** be configured to require the local **user** to accept or initiate remote access?



Section 3 MDS² FORM

To access and download the current HN 1 MDS² *Worksheet*, type the following into your web browser:

<http://www.nema.org/Standards/ComplimentaryDocuments/MDS2-Worksheet.xls>

or double click on the icon below.



MDS2-Worksheet.xls





| Manufacturer Disclosure Statement for Medical Device Security – MDS ² | | | |
|---|--|----------------------------------|---------------------------|
| DEVICE DESCRIPTION | | | |
| Device Category | Manufacturer | Document ID | Document Release Date |
| Device Model | Software Revision | Software Release Date | |
| Manufacturer or Representative Contact Information | Company Name | Manufacturer Contact Information | |
| | Representative Name/Position | | |
| Intended use of device in network-connected environment: | | | |
| MANAGEMENT OF PRIVATE DATA | | | |
| Refer to Section 2.3.2 of this standard for the proper interpretation of information requested in this form . | | | Yes, No, N/A, or See Note |
| | | | Note # |
| A | Can this device display, transmit, or maintain private data (including electronic Protected Health Information [ePHI])? | | |
| B | Types of private data elements that can be maintained by the device : | | |
| | B.1 Demographic (e.g., name, address, location, unique identification number)? | | |
| | B.2 Medical record (e.g., medical record #, account#, test or treatment date, device identification number)? | | |
| | B.3 Diagnostic/therapeutic (e.g., photo/radiograph, test results, or physiologic data with identifying characteristics)? | | |
| | B.4 Open, unstructured text entered by device user/operator ? | | |
| | B.5 Biometric data ? | | |
| | B.6 Personal financial information? | | |
| C | Maintaining private data - Can the device : | | |
| | C.1 Maintain private data temporarily in volatile memory (i.e., until cleared by power-off or reset)? | | |
| | C.2 Store private data persistently on local media? | | |
| | C.3 Import/export private data with other systems? | | |
| | C.4 Maintain private data during power service interruptions? | | |
| D | Mechanisms used for the transmitting, importing/exporting of private data – Can the device : | | |
| | D.1 Display private data (e.g., video display, etc.)? | | |
| | D.2 Generate hardcopy reports or images containing private data? | | |
| | D.3 Retrieve private data from or record private data to removable media (e.g., disk, DVD, CD-ROM, tape, CF/SD card, memory stick, etc.)? | | |
| | D.4 Transmit/receive or import/export private data via dedicated cable connection (e.g., IEEE 1073, serial port, USB, FireWire, etc.)? | | |
| | D.5 Transmit/receive private data via a wired network connection (e.g., LAN, WAN, VPN, intranet, Internet, etc.)? | | |
| | D.6 Transmit/receive private data via an integrated wireless network connection (e.g., WiFi, Bluetooth, infrared, etc.)? | | |
| | D.7 Import private data via scanning? | | |
| | D.8 Other? | | |
| Management of private data notes: | | | |

| Device Category | Manufacturer | Document ID | Document Release Date | |
|--|-------------------|-----------------------|---------------------------------|--------|
| Device Model | Software Revision | Software Release Date | | |
| SECURITY CAPABILITIES | | | | |
| Refer to Section 2.3.2 of this standard for the proper interpretation of information requested in this form. | | | Yes, No, N/A, or See Note | Note # |
| <p>1 AUTOMATIC LOGOFF (ALOF) The device's ability to prevent access and misuse by unauthorized users if device is left idle for a period of time.</p> <p>1-1 Can the device be configured to force reauthorization of logged-in user(s) after a predetermined length of inactivity (e.g., auto-logoff, session lock, password protected screen saver)? _____</p> <p>1-1.1 Is the length of inactivity time before auto-logoff/screen lock user or administrator configurable? (Indicate time [fixed or configurable range] in notes.) _____</p> <p>1-1.2 Can auto-logoff/screen lock be manually invoked (e.g., via a shortcut key or proximity sensor, etc.) by the user? _____</p> <p>ALOF notes:</p> | | | | |
| <p>2 AUDIT CONTROLS (AUDT) The ability to reliably audit activity on the device.</p> <p>2-1 Can the medical device create an audit trail? _____</p> <p>2-2 Indicate which of the following events are recorded in the audit log:</p> <p>2-2.1 Login/logout _____</p> <p>2-2.2 Display/presentation of data _____</p> <p>2-2.3 Creation/modification/deletion of data _____</p> <p>2-2.4 Import/export of data from removable media _____</p> <p>2-2.5 Receipt/transmission of data from/to external (e.g., network) connection _____</p> <p>2-2.5.1 Remote service activity _____</p> <p>2-2.6 Other events? (describe in the notes section) _____</p> <p>2-3 Indicate what information is used to identify individual events recorded in the audit log:</p> <p>2-3.1 User ID _____</p> <p>2-3.2 Date/time _____</p> <p>AUDT notes:</p> | | | | |
| <p>3 AUTHORIZATION (AUTH) The ability of the device to determine the authorization of users.</p> <p>3-1 Can the device prevent access to unauthorized users through user login requirements or other mechanism? _____</p> <p>3-2 Can users be assigned different privilege levels within an application based on 'roles' (e.g., guests, regular users, power users, administrators, etc.)? _____</p> <p>3-3 Can the device owner/operator obtain unrestricted administrative privileges (e.g., access operating system or application via local root or admin account)? _____</p> <p>AUTH notes:</p> | | | | |

| | | | |
|---|-------------------|-----------------------|---------------------------------|
| Device Category | Manufacturer | Document ID | Document Release Date |
| Device Model | Software Revision | Software Release Date | |
| Refer to Section 2.3.2 of this standard for the proper interpretation of information requested in this form . | | | Yes, No, N/A, or See Note |
| | | | Note # |
| <p>4 CONFIGURATION OF SECURITY FEATURES (CNFS) The ability to configure/re-configure device security capabilities to meet users' needs.</p> <p>4-1 Can the device owner/operator reconfigure product security capabilities? _____</p> <p>CNFS notes:</p> | | | |
| <p>5 CYBER SECURITY PRODUCT UPGRADES (CSUP) The ability of on-site service staff, remote service staff, or authorized customer staff to install/upgrade device's security patches.</p> <p>5-1 Can relevant OS and device security patches be applied to the device as they become available? _____</p> <p>5-1.1 Can security patches or other software be installed remotely? _____</p> <p>CSUP notes:</p> | | | |
| <p>6 HEALTH DATA DE-IDENTIFICATION (DIDT) The ability of the device to directly remove information that allows identification of a person.</p> <p>6-1 Does the device provide an integral capability to de-identify private data? _____</p> <p>DIDT notes:</p> | | | |
| <p>7 DATA BACKUP AND DISASTER RECOVERY (DTBK) The ability to recover after damage or destruction of device data, hardware, or software.</p> <p>7-1 Does the device have an integral data backup capability (i.e., backup to remote storage or removable media such as tape, disk)? _____</p> <p>DTBK notes:</p> | | | |
| <p>8 EMERGENCY ACCESS (EMRG) The ability of device users to access private data in case of an emergency situation that requires immediate access to stored private data.</p> <p>8-1 Does the device incorporate an emergency access ("break-glass") feature? _____</p> <p>EMRG notes:</p> | | | |
| <p>9 HEALTH DATA INTEGRITY AND AUTHENTICITY (IGAU) How the device ensures that data processed by the device has not been altered or destroyed in an unauthorized manner and is from the originator.</p> <p>9-1 Does the device ensure the integrity of stored data with implicit or explicit error detection/correction technology? _____</p> <p>IGAU notes:</p> | | | |

| Device Category | Manufacturer | Document ID | Document Release Date | |
|---|--|-----------------------|---------------------------------|--------|
| Device Model | Software Revision | Software Release Date | | |
| Refer to Section 2.3.2 of this standard for the proper interpretation of information requested in this form . | | | Yes, No, N/A, or See Note | Note # |
| 10 MALWARE DETECTION/PROTECTION (MLDP) The ability of the device to effectively prevent, detect and remove malicious software (malware). | | | | |
| 10-1 | Does the device support the use of anti-malware software (or other anti-malware mechanism)? | | _____ | ___ |
| 10-1.1 | Can the user independently re-configure anti-malware settings? | | _____ | ___ |
| 10-1.2 | Does notification of malware detection occur in the device user interface? | | _____ | ___ |
| 10-1.3 | Can only manufacturer-authorized persons repair systems when malware has been detected? | | _____ | ___ |
| 10-2 | Can the device owner install or update anti-virus software ? | | _____ | ___ |
| 10-3 | Can the device owner/ operator (technically/physically) update virus definitions on manufacturer-installed anti-virus software ? | | _____ | ___ |
| MLDP notes: | | | | |
| 11 NODE AUTHENTICATION (NAUT) The ability of the device to authenticate communication partners/nodes. | | | | |
| 11-1 | Does the device provide/support any means of node authentication that assures both the sender and the recipient of data are known to each other and are authorized to receive transferred information? | | | _____ |
| NAUT notes: | | | | |
| 12 PERSON AUTHENTICATION (PAUT) Ability of the device to authenticate users | | | | |
| 12-1 | Does the device support user/operator -specific username(s) and password(s) for at least one user ? | | _____ | ___ |
| 12-1.1 | Does the device support unique user/operator -specific IDs and passwords for multiple users ? | | _____ | ___ |
| 12-2 | Can the device be configured to authenticate users through an external authentication service (e.g., MS Active Directory, NDS, LDAP, etc.)? | | _____ | ___ |
| 12-3 | Can the device be configured to lock out a user after a certain number of unsuccessful logon attempts? | | _____ | ___ |
| 12-4 | Can default passwords be changed at/prior to installation? | | _____ | ___ |
| 12-5 | Are any shared user IDs used in this system? | | _____ | ___ |
| 12-6 | Can the device be configured to enforce creation of user account passwords that meet established complexity rules? | | _____ | ___ |
| 12-7 | Can the device be configured so that account passwords expire periodically? | | _____ | ___ |
| PAUT notes: | | | | |
| 13 PHYSICAL LOCKS (PLOK) Physical locks can prevent unauthorized users with physical access to the device from compromising the integrity and confidentiality of private data stored on the device or on removable media . | | | | |
| 13-1 | Are all device components maintaining private data (other than removable media) physically secure (i.e., cannot remove without tools)? | | | _____ |
| PLOK notes: | | | | |

| Device Category | Manufacturer | Document ID | Document Release Date | |
|---|-------------------|-----------------------|---------------------------|--------|
| Device Model | Software Revision | Software Release Date | | |
| Refer to Section 2.3.2 of this standard for the proper interpretation of information requested in this form . | | | Yes, No, N/A, or See Note | Note # |
| 14 ROADMAP FOR THIRD PARTY COMPONENTS IN DEVICE LIFE CYCLE (RDMP) Manufacturer's plans for security support of 3rd party components within device life cycle. | | | | |
| 14-1 In the notes section, list the provided or required (separately purchased and/or delivered) operating system(s) - including version number(s). | | | _____ | ___ |
| 14-2 Is a list of other third party applications provided by the manufacturer available? | | | _____ | ___ |
| RDMP notes: | | | | |
| 15 SYSTEM AND APPLICATION HARDENING (SAHD) The device's resistance to cyber attacks and malware . | | | | |
| 15-1 Does the device employ any hardening measures? Please indicate in the notes the level of conformance to any industry-recognized hardening standards. | | | _____ | ___ |
| 15-2 Does the device employ any mechanism (e.g., release-specific hash key, checksums, etc.) to ensure the installed program/update is the manufacturer-authorized program or software update? | | | _____ | ___ |
| 15-3 Does the device have external communication capability (e.g., network, modem, etc.)? | | | _____ | ___ |
| 15-4 Does the file system allow the implementation of file-level access controls (e.g., New Technology File System (NTFS) for MS Windows platforms)? | | | _____ | ___ |
| 15-5 Are all accounts which are not required for the intended use of the device disabled or deleted, for both users and applications? | | | _____ | ___ |
| 15-6 Are all shared resources (e.g., file shares) which are not required for the intended use of the device , disabled? | | | _____ | ___ |
| 15-7 Are all communication ports which are not required for the intended use of the device closed/disabled? | | | _____ | ___ |
| 15-8 Are all services (e.g., telnet, file transfer protocol [FTP], internet information server [IIS], etc.), which are not required for the intended use of the device deleted/disabled? | | | _____ | ___ |
| 15-9 Are all applications (COTS applications as well as OS-included applications, e.g., MS Internet Explorer, etc.) which are not required for the intended use of the device deleted/disabled? | | | _____ | ___ |
| 15-10 Can the device boot from uncontrolled or removable media (i.e., a source other than an internal drive or memory component)? | | | _____ | ___ |
| 15-11 Can software or hardware not authorized by the device manufacturer be installed on the device without the use of tools? | | | _____ | ___ |
| SAHD notes: | | | | |
| 16 SECURITY GUIDANCE (SGUD) The availability of security guidance for operator and administrator of the system and manufacturer sales and service. | | | | |
| 16-1 Are security-related features documented for the device user ? | | | _____ | ___ |
| 16-2 Are instructions available for device /media sanitization (i.e., instructions for how to achieve the permanent deletion of personal or other sensitive data)? | | | _____ | ___ |
| SGUD notes: | | | | |

| Device Category | Manufacturer | Document ID | Document Release Date | |
|---|-------------------|-----------------------|---------------------------------|--------|
| Device Model | Software Revision | Software Release Date | | |
| Refer to Section 2.3.2 of this standard for the proper interpretation of information requested in this form . | | | Yes, No, N/A, or See Note | Note # |
| 17 HEALTH DATA STORAGE CONFIDENTIALITY (STCF) The ability of the device to ensure unauthorized access does not compromise the integrity and confidentiality of private data stored on device or removable media . | | | | |
| 17-1 Can the device encrypt data at rest? | | | _____ | ___ |
| STCF notes: | | | | |
| 18 TRANSMISSION CONFIDENTIALITY (TXCF) The ability of the device to ensure the confidentiality of transmitted private data . | | | | |
| 18-1 Can private data be transmitted only via a point-to-point dedicated cable? | | | _____ | ___ |
| 18-2 Is private data encrypted prior to transmission via a network or removable media ? (If yes, indicate in the notes which encryption standard is implemented.) | | | _____ | ___ |
| 18-3 Is private data transmission restricted to a fixed list of network destinations? | | | _____ | ___ |
| TXCF notes: | | | | |
| 19 TRANSMISSION INTEGRITY (TXIG) The ability of the device to ensure the integrity of transmitted private data . | | | | |
| 19-1 Does the device support any mechanism intended to ensure data is not modified during transmission? (If yes, describe in the notes section how this is achieved.) | | | _____ | ___ |
| TXIG notes: | | | | |
| 20 OTHER SECURITY CONSIDERATIONS (OTHR) Additional security considerations/notes regarding medical device security. | | | | |
| 20-1 Can the device be serviced remotely? | | | _____ | ___ |
| 20-2 Can the device restrict remote access to/from specified devices or users or network locations (e.g., specific IP addresses)? | | | _____ | ___ |
| 20-2.1 Can the device be configured to require the local user to accept or initiate remote access? | | | _____ | ___ |
| OTHR notes: | | | | |

Annex
COMPARISON OF PREVIOUS (2008) AND CURRENT (2013) MDS² (Informative)

Table A-1
MDS² question number changes cross-reference: HN 1-2008 vs. HN 1-2013

| 2013 | | 2008 |
|-------|---|------|
| A | Can this device display, transmit or maintain private data (including electronic Protected Health Information (ePHI))? | 1 |
| B | Types of private data elements that can be maintained by the device : | 2 |
| B.1 | Demographic (e.g., name, address, location, unique identification number)? | 2a |
| B.2 | Medical record (e.g., medical record #, account #, test or treatment date, device identification number)? | 2b |
| B.3 | Diagnostic/therapeutic (e.g., photo/radiograph, test results, or physiologic data with identifying characteristics)? | 2c |
| B.4 | Open, unstructured text entered by device user/operator ? | 2d |
| B.5 | Biometric data ? | ... |
| B.6 | Personal financial information? | ... |
| C | Maintaining private data - Can the device : | 3 |
| C.1 | Maintain private data temporarily in volatile memory (i.e., until cleared by power-off or reset)? | 3a |
| C.2 | Store private data persistently on local media? | 3b |
| C.3 | Import/export private data with other systems? | 3c |
| C.4 | Maintain private data during power service interruptions? | 17 |
| D | Mechanisms used for the transmitting, importing/exporting of private data – Can the device : | 4 |
| D.1 | Display private data (e.g., video display, etc.)? | 4a |
| D.2 | Generate hardcopy reports or images containing private data ? | 4b |
| D.3 | Retrieve private data from or record private data to removable media (e.g., disk, DVD, CD-ROM, tape, CF/SD card, memory stick, etc.)? | 4c |
| D.4 | Transmit/receive or import/export private data via dedicated cable connection (e.g., IEEE 1073, serial port, USB, FireWire, etc.)? | 4d |
| D.5 | Transmit/receive private data via a wired network connection (e.g., LAN, WAN, VPN, intranet, Internet, etc.)? | 4e |
| D.6 | Transmit/receive private data via an integrated wireless network connection (e.g., WiFi, Bluetooth, infrared, etc.)? | 4f |
| D.7 | Import private data via scanning? | ... |
| D.8 | Other? | 4g |
| 1-1 | Can the device be configured to force reauthorization of logged-in user(s) after a predetermined length of inactivity (e.g., auto-logoff, session lock, password protected screen saver)? | 14 |
| 1-1.1 | Is the length of inactivity time before auto-logoff/screen lock user or administrator configurable? (Indicate time [fixed or configurable range] in notes.) | ... |
| 1-1.2 | Can auto-logoff/screen lock be manually invoked (e.g., via a shortcut key or proximity sensor, etc.) by the user ? | ... |
| 2-1 | Can the medical device create an audit trail ? | 15 |
| 2-2 | Indicate which of the following events are recorded in the audit log: | 15 |
| 2-2.1 | Login/logout | 15a |

Table continues on next page

Table A-1 Continued

| 2013 | | 2008 |
|---------|---|------|
| 2-2.2 | Display/presentation of data | 15b |
| 2-2.3 | Creation/modification/deletion of data | 15c |
| 2-2.4 | Import/export of data from removable media | 15d |
| 2-2.5 | Receipt/transmission of data from/to external (e.g., network) connection | |
| 2-2.5.1 | Remote service activity | 11b |
| 2-2.6 | Other events? (describe in the notes section) | ... |
| 2-3 | Indicate what information is used to identify individual events recorded in the audit log: | ... |
| 2-3.1 | User ID | ... |
| 2-3.2 | Date/time | ... |
| 3-1 | Can the device prevent access to unauthorized users through user login requirements or other mechanism? | ... |
| 3-2 | Can users be assigned different privilege levels within an application based on 'roles' (e.g., guests, regular users , power users , administrators, etc.)? | ... |
| 3-3 | Can the device owner/ operator obtain unrestricted administrative privileges (e.g., access operating system or application via local root or admin account)? | 12d |
| 4-1 | Can the device owner/ operator reconfigure product security capabilities ? | ... |
| 5-1 | Can relevant OS and device security patches be applied to the device as they become available? | 12a |
| 5-1.1 | Can security patches or other software be installed remotely? | 11c |
| 6-1 | Does the device provide an integral capability to de-identify private data ? | ... |
| 7-1 | Does the device have an integral data backup capability (i.e., backup to remote storage or removable media like tape, disk)? | 8 |
| 8-1 | Does the device incorporate an emergency access ("break-glass") feature? | 16 |
| 9-1 | Does the device ensure the integrity of stored data with implicit or explicit error detection/correction technology? | 19 |
| 10-1 | Does the device support the use of anti-malware software (or other anti-malware mechanism)? | ... |
| 10-1.1 | Can the user independently re-configure anti-malware settings? | ... |
| 10-1.2 | Does notification of malware detection occur in the device user interface? | ... |
| 10-1.3 | Can only manufacturer-authorized persons repair systems when malware has been detected? | ... |
| 10-2 | Can the device owner install or update anti-virus software ? | 12b |
| 10-3 | Can the device owner/ operator (technically/physically) update virus definitions on manufacturer-installed anti-virus software ? | 12c |
| 11-1 | Does the device provide/support any means of node authentication that assures both the sender and the recipient of data are known to each other and are authorized to receive transferred information? | 11a |
| 12-1 | Does the device support user/operator -specific username(s) and password(s) for at least one user ? | 13 |
| 12-1.1 | Does the device support unique user/operator -specific IDs and passwords for multiple users? | ... |
| 12-2 | Can the device be configured to authenticate users through an external authentication service (e.g., MS Active Directory, NDS, LDAP, etc.)? | ... |
| 12-3 | Can the device be configured to lockout a user after a certain number of unsuccessful logon attempts? | ... |
| 12-4 | Can default passwords be changed at/prior to installation? | ... |

Table continues on next page

Table A-1 Continued

| 2013 | | 2008 |
|--------|--|------|
| 12-5 | Are any shared user IDs used in this system? | ... |
| 12-6 | Can the device be configured to enforce creation of user account passwords that meet established complexity rules? | ... |
| 12-7 | Can the device be configured so that account passwords expire periodically? | ... |
| 13-1 | Are all device components maintaining private data (other than removable media) physically secure (i.e., cannot remove without tools)? | 7 |
| 14-1 | In the notes section, list the provided or required (separately purchased and/or delivered) operating system(s) - including version number(s). | 6 |
| 14-2 | Is a list of other third party applications provided by the manufacturer available? | ... |
| 15-1 | Does the device employ any hardening measures? Please indicate in the notes the level of conformance to any industry-recognized hardening standards. | ... |
| 15-2 | Does the device employ any mechanism (e.g., release-specific hash key, checksums, etc.) to ensure the installed program/update is the manufacturer-authorized program or software update? | ... |
| 15-3 | Does the device have external communication capability (e.g., network, modem, etc.)? | ... |
| 15-4 | Does the file system allow the implementation of file-level access controls (e.g., New Technology File System (NTFS) for MS Windows platforms)? | ... |
| 15-5 | Are all accounts which are not required for the intended use of the device disabled or deleted, for both users and applications? | ... |
| 15-6 | Are all shared resources (e.g., file shares) which are not required for the intended use of the device , disabled? | ... |
| 15-7 | Are all communication ports which are not required for the intended use of the device closed/disabled? | ... |
| 15-8 | Are all services (e.g., Telnet, File Transfer Protocol [FTP], Internet Information Server [IIS], etc.), which are not required for the intended use of the device deleted/disabled? | ... |
| 15-9 | Are all applications (COTS applications as well as OS-included applications, e.g., MS Internet Explorer, etc.) which are not required for the intended use of the device deleted/disabled? | ... |
| 15-10 | Can the device boot from uncontrolled or removable media (i.e., a source other than an internal drive or memory component)? | 9 |
| 15-11 | Can software or hardware not authorized by the device manufacturer be installed on the device without the use of tools? | 10 |
| 16-1 | Are security-related features documented for the device user ? | 5 |
| 16-2 | Are instructions available for device /media sanitization (i.e., instructions for how to achieve the permanent deletion of personal or other sensitive data)? | ... |
| 17-1 | Can the device encrypt data at rest? | ... |
| 18-1 | Can private data be transmitted only via a point-to-point dedicated cable? | 18a |
| 18-2 | Is private data encrypted prior to transmission via a network or removable media ? (If yes, indicate in the notes which encryption standard is implemented.) | 18b |
| 18-3 | Is private data transmission restricted to a fixed list of network destinations? | 18c |
| 19-1 | Does the device support any mechanism intended to ensure data is not modified during transmission? (If yes, describe in the notes section how this is achieved.) | ... |
| 20-1 | Can the device be serviced remotely? | 11 |
| 20-2 | Can the device restrict remote access to/from specified devices or users or network locations (e.g., specific IP addresses)? | 11a |
| 20-2.1 | Can the device be configured to require the local user to accept or initiate remote access? | ... |

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