MANAGEMENT OF ELECTRONIC PROTECTED HEALTH INFORMATION (ePHI) As defined by HIPAA Security Rule, 45 CFR Part 164

1. Can this device transmit or maintain electronic Protected Health Information (ePHI)?
   - Yes
   - No
   - N/A

2. Types of ePHI data elements that can be maintained by the device:
   - a. Demographic (e.g., name, address, location, unique identification number)?
   - Yes
   - No
   - N/A
   - b. Medical record (e.g., medical record #, account #, test or treatment date, device identification number)?
   - Yes
   - No
   - N/A
   - c. Diagnostic/therapeutic (e.g., photo/radiograph, test results, or physiologic data with identifying characteristics)?
   - Yes
   - No
   - N/A
   - d. Open, unstructured text entered by device user/operator?
   - Yes
   - No
   - N/A

3. Maintaining ePHI: Can the device
   - a. Maintain ePHI temporarily in volatile memory (i.e., until cleared on by power-off or reset)?
   - Yes
   - No
   - N/A
   - b. Store ePHI persistently on local media?
   - Yes
   - No
   - N/A
   - c. Import/export ePHI with other systems?
   - Yes
   - No
   - N/A

4. Mechanisms used for the transmitting, importing/exporting of ePHI: Can the device
   - a. Display ePHI (e.g., video display)?
   - Yes
   - No
   - N/A
   - b. Generate hardcopy reports or images containing ePHI?
   - Yes
   - No
   - N/A
   - c. Retrieve ePHI from or record ePHI to removable media (e.g., disk, DVD, CD-ROM, tape, CF/SD card, memory stick)?
   - Yes
   - No
   - N/A
   - d. Transmit/receive or import/export ePHI via dedicated cable connection (e.g., IEEE 1073, serial port, USB, FireWire)
   - Yes
   - No
   - N/A
   - e. Transmit/receive ePHI via a network connection (e.g., LAN, WAN, VPN, intranet, Internet)?
   - Yes
   - No
   - N/A
   - f. Transmit/receive ePHI via an integrated wireless connection (e.g., WiFi, Bluetooth, infrared)*
   - Yes
   - No
   - N/A
   - g. Other?
   - Yes
   - No
   - N/A

ADMINISTRATIVE SAFEGUARDS

5. Does manufacturer offer operator and technical support training or documentation on device security features?
   - Yes
   - No
   - N/A

6. What underlying operating system(s) (including version number) are used by the device?
   - Microsoft XP Embedded SP2

PHYSICAL SAFEGUARDS

7. Are all device components maintaining ePHI (other than removable media) physically secure (i.e., cannot remove without tools)?
   - Yes
   - No
   - N/A

8. Does the device have an integral data backup capability (i.e., backup onto removable media such as tape, disk)?
   - Yes
   - No
   - N/A

9. Can the device boot from uncontrolled or removable media (i.e., a source other than an internal drive or memory component)?
   - Yes
   - No
   - N/A

TECHNICAL SAFEGUARDS

10. Can software or hardware not authorized by the device manufacturer be installed on the device?
    - Yes
    - No
    - N/A

11. Can the device be serviced remotely (i.e., maintenance activities performed by service person via network or remote connection)?
    - Yes
    - No
    - N/A
    - a. Can the device restrict remote access to specific devices or network locations (e.g., specific IP addresses)?
      - Yes
      - No
      - N/A
    - b. Can the device log provide an audit trail of remote-service activity?
      - Yes
      - No
      - N/A
    - c. Can security patches or other software be installed remotely?
      - Yes
      - No
      - N/A

12. Level of owner/operator service access to device operating system: Can the device owner/operator
    - a. Apply device manufacturer-validated security patches?
      - Yes
      - No
      - N/A
    - b. Install or update antivirus software?
      - Yes
      - No
      - N/A
    - c. Update virus definitions on manufacturer-installed antivirus software?
      - Yes
      - No
      - N/A
    - d. Obtain administrative privileges (e.g., access operating system or application via local root or admin account)?
      - Yes
      - No
      - N/A

13. Does the device support user/operator specific ID and password?
    - Yes
    - No
    - N/A

14. Are access sessions terminated after a predetermined length of inactivity (e.g., auto logoff)?
    - Yes
    - No
    - N/A

15. Events recorded in device audit log (e.g., user, date/time, action taken): Can the audit log record
    - a. Login and logout by users/operators?
      - Yes
      - No
      - N/A
    - b. Viewing of ePHI?
      - Yes
      - No
      - N/A
    - c. Creation, modification or deletion of ePHI?
      - Yes
      - No
      - N/A
    - d. Import/export or transmittal/receipt of ePHI?
      - Yes
      - No
      - N/A

16. Does the device incorporate an emergency access (“break-glass”) feature that logs each instance of use?
    - Yes
    - No
    - N/A

17. Can the device maintain ePHI (e.g., by internal battery) during power service interruptions?
    - Yes
    - No
    - N/A

18. Controls when exchanging ePHI with other devices:
    - a. Transmitted only via a physically secure connection (e.g., dedicated cable)?
      - Yes
      - No
      - N/A
    - b. Encrypted prior to transmission via a network or removable media?
      - Yes
      - No
      - N/A
    - c. Restricted to a fixed list of network addresses (i.e., host-based access control list)?
      - Yes
      - No
      - N/A

19. Does the device ensure the integrity of the ePHI data with implicit or explicit error detection/correction technology?
    - Yes
    - No
    - N/A

* Recommend use of ECRI’s Universal Medical Device Nomenclature System (UMDNS).
Manufacturer Disclosure Statement for Medical Device Security – MDS²

RECOMMENDED SECURITY PRACTICES

EXPLANATORY NOTES (from questions 1 – 19):

IMPORTANT: Refer to Instructions for the Manufacturers Disclosure Statement for Medical Device Security for the proper interpretation of information provided in this form.

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ACCE – the American College of Clinical Engineering; ECRI – formerly the Emergency Care Research Institute.