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RE: The Consolidated Health Informatics Multimedia Workgroup final report on Standards Adoption Recommendation for Multimedia Information in Patient Records – support for adoption of DICOM.

Dear Ms. Freedman

Mortara Instrument, Inc. is a leading producer of diagnostic ECG equipment including resting 12-lead electrocardiographs, 12-lead exercise stress systems, and 12-lead Holter recorders and analysis workstations. Mortara Instrument, Inc. is also the FDA's industry partner for the ECG Warehouse that is used by the FDA for the archival and review of all drug trial ECGs.

Mortara Instrument, Inc. enthusiastically supports the adoption of the DICOM standard for the storage and communication of multimedia data in the healthcare environment. More specifically, Mortara supports the requirement to use the DICOM standard for the storage and communication of all diagnostic ECG information. Mortara also supports the recommendation that the HL7 Annotated ECG standard required by the FDA for all clinical trials remain in place.

Standardization in the diagnostic ECG domain has a long history of resistance from device manufacturers. The usage of proprietary communication to electrocardiographs, stress, and Holter systems keeps healthcare providers locked into purchasing specialized data management systems and devices from the same manufacturer. Standardizing the communication protocol to these devices eliminates the need for any particular manufacturer's expensive, proprietary data management system. The use of DICOM will allow healthcare providers to purchase "best in class" devices that can all "plug and play" with a healthcare provider's existing (or choice of) ordering, scheduling, and multimedia archival systems.

Mortara chose to implement the DICOM standard in its diagnostic ECG devices because it is a well-understood, easily implemented, widely adopted data communications standard in the healthcare industry. All device manufacturers offering imaging products already have DICOM implementations today. Any diagnostic ECG product that doesn't already include a DICOM interface can easily be enhanced to include it. The DICOM standard has included waveform support since the year 2000. The waveform objects are well engineered and support all the important aspects of ECG waveforms. Stress and Holter reports are supported today by the encapsulated PDF object. Currently, IHE is talking about defining a DICOM SR template for stress reports. DICOM SR is a natural solution for resting, stress, and Holter reports.

The DICOM standard not only specifies the format of the waveform data and exam reports, but it also specifies how the devices communicate. The DICOM standard supports important workflow events such as:

- Modality work list - requested and scheduled diagnostic ECG exams.
- Storage of multimedia objects - ECG waveforms, PDF and SR reports for resting, stress, and Holter.
- Storage commitment - gives the device positive feedback that ECGs and reports have been securely archived and can be deleted from the device.
- Event communication - echo, exam in progress, exam completed, exam canceled.

In summary, Mortara Instrument, Inc. strongly endorses the use of the DICOM standard for storage and communication of multimedia data in the healthcare environment. We believe the expanded use of this standard will uniquely enable facilities to integrate clinical data from diverse modalities while placing minimum burden on industry to enable this integration.

Sincerely,

Justin L. Mortara, Ph.D.   Barry D. Brown
Vice President   Product Integration Manager