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ORIGINAL ARTICLE

The semantic extension and storage of EECP Hemodynamic Waveforms based on DICOM Standard

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Abstract Digital imaging and communications in medicine (DICOM) Standard has a detailed description on the Information Object Definition (IOD) of all kinds of medical images and waveforms. With the development and application of DICOM, all medical imaging and waveform devices will support the standard. This article describes the method and implementation on how to encapsulate the EECP Hemodynamic Waveforms data acquired from EECP device, integrating patient information, EECP physiological parameters, and diagnosis and treat information into DICOM Hemodynamic Waveform file. We define Private Data Elements to encode and represent EECP parameters which haven't been registered as Standard Data Elements. This is the semantic extension of DICOM applied in EECP. The paper introduces following parts in detail: the structure of DICOM waveform file, Data Element, Nesting of Data Sets, the Waveform IOD Modules and the specification of Private Data Element. Then the method and process of our program are analyzed in depth. According to object-oriented methodology, firstly, Data Element, Nesting of Data Sets and waveform IOD with their corresponding operations and services are respectively abstracted into classes. Then the waveforms data and other attributes are assigned to the corresponding Data Members of the waveform class. Finally, they are stored into a DICOM waveform file by invoking related functions.

Keywords DICOM · EECP · Waveform IOD · Private Data Element · Nesting of Data Sets

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1 Introduction

Enhanced external counterpulsation (EECP) is a new technology which has been used in the therapy of cardiovascular diseases. It is considered a safe, highly beneficial, low-cost, noninvasive treatment [4]. It can promote collateral circulation by increasing diastolic pressure during counterpulsation. The latest investigation shows that the flow shear stress were increased obviously during EECP, regulating a series of reaction of sheer stress responsive elements, inducing vascular endothelial cell (VEC) repair mechanism, improving VEC function, all of which contribute to the inhibition of development of atherosclerosis [11]. Nowadays, many countries such as America, Germany, Japan, Indonesia, England, India, Israel, and Saudi Arabia had established EECP medical study centers [9].

During EECP therapy, the EECP Hemodynamic Waveforms and important physiological parameters (such as the Heart Rate, the ratio of D/S peak value, the ratio of D/S area value, saturation of blood oxygen, systolic pressure and diastolic pressure) were monitored on the monitor of EECP device, which are required for data exchange and have significant clinical study and evaluation values in EECP therapy. Doctors expect they could review and analyze the waveforms and related data in EECP

Workstations. Fortunately, DICOM Standard provides us a new normative solution for the storage and communication of EECP waveforms and data.

Digital imaging and communications in medicine (DICOM) has been widely acknowledged as an important standard in medical imaging domain and medical informatics, which provides the software interface and communication protocol for medical imaging and waveform devices. DICOM can be used for all medical data [1]. On the basis of this standard, various medical devices with DICOM interfaces can be connected together by network, and then they can exchange data each other and share images and other information.

With the comprehensive application of DICOM, now not only do conventional medical imaging devices support DICOM, but the medical signal and waveform devices will also support it. Some researchers have contributed a lot to the DICOM interfaces of conventional electrocardiograph, dynamic electrocardiograph, electroencephalograph, sphygmograph and so on [3], while other experts have made an in-depth study on the integration of waveform data with DICOM images [1, 2, 8]. The ability to make clinical data available and exchangeable in a standardized fashion is of great importance. It has been a trend that all medical waveform devices will support DICOM for normative data interchange, which is also the clinical requirements; in addition, most medical device manufacturers are interested in the standardized data interchange, so it is very necessary to equip EECP devices with DICOM interface.

Information sharing is very important for the development of the medical industry. In order to share EECP therapy information, managing patient data and EECP waveforms conveniently and improving the functions and quality of EECP device, a LAN system for EECP medical center based on DICOM Communication Protocol has been established, which is being evaluated within the Key Laboratory on Assisted Circulation of Ministry and the EECP Medical Center of the First Affiliated Hospital of Sun Yat-sen University in Guangzhou [10]. The key technology of this system contains three parts: how to store the waveform data acquired from EECP device into DICOM waveform file, how to establish a database and a management information system (MIS) for EECP and how to construct a network communication system based on DICOM Protocol. This article focuses on the implementation of the first part. Through the technology described in this article, we provide EECP device a DICOM interface and it can store DICOM waveform file which is the encapsulation of EECP Hemodynamic Waveforms data, patient information, EECP physiological parameters, and diagnosis and treat information.

2 The structure of DICOM Waveform File

2.1 The structure of DICOM Waveform File and Data Element

DICOM waveform file is essentially the encapsulation of the DICOM File Meta Information and a SOP instance related to a DICOM waveform Composite IOD which is represented by a Data Set. A Data Set is constructed of a series of Data Elements. Data Elements contain the encoded values of attributes of that object. The DICOM File Meta Information includes identifying information of the encapsulated DICOM Data Set. It consists of a 128 bytes File Preamble, followed by a 4 bytes DICOM Prefix, followed by the File Meta Elements whose Group Number is 0002. The DICOM Data Set consists of related attributes of the Waveform Information Model and waveform sampling data values. Figure 1 shows the structure of DICOM waveform file and Data Element [5, 7].

The Data Element Tag consists of the Group Number followed by Element Number. According to the parity of the Group Number of Data Element Tag, two types of Data Elements are defined: Standard Data Elements and Private Data Elements. Standard Data Elements have an even Group Number except (0000, eeee), (0002, eeee), (0004, eeee) or (0006, eeee) (these are reserved for DIMSE Commands and DICOM File Formats). Private Data Elements have an odd Group Number except (0001, eeee), (0003, eeee), (0005, eeee), (0007, eeee) or (FFFF,eeee) [5]. Private Data Elements provide the conditions for implementors to extend the semantics of DICOM in certain application domains. In the following text, we will discuss the application of Private Data Elements in the storage of EECP Hemodynamic waveforms.

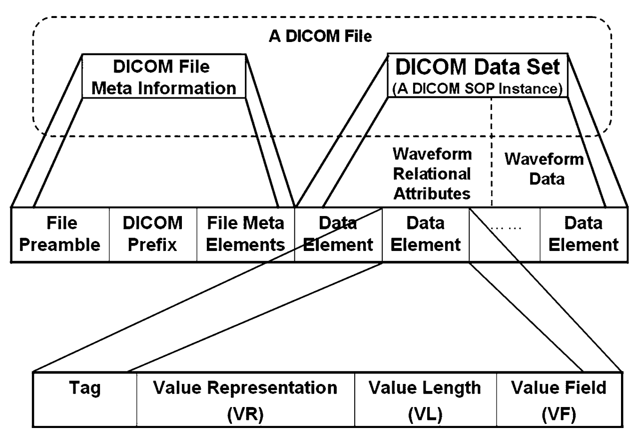

Fig. 1 The structure of DICOM waveform file and Data Element

2.2 The structure of Nesting of Data Sets

The encoding structure of DICOM waveform file, which is more complex than other DICOM files, usually contains a lot of Nesting of Data Sets and its multi-level nested structures. When the VR is identified “SQ” (Sequence of Items), it means that the Data Element is a Nesting of Data Sets with a Value Field consisting of a sequence of zero or more Items, where each Item contains a set of Data Elements. SQ Data Elements can also be used recursively to contain multi-level nested structures [5].

There are three special Data Elements related to SQ Data Elements:

2.2.1 Item

The Tag is (FFFE,E000).

2.2.2 Item Delimitation Item

The Tag is (FFFE,E00D). When the Value Length of Item is an Undefined Length, we use Item Delimitation Item with a Value Length of 00000000H to delimit the end of the Item.

2.2.3 Sequence Delimitation Item

The Tag is (FFFE,E0DD). When the Value Length of a Sequence of Items is an Undefined Length, we use Sequence Delimitation Item with a Value Length of 00000000H after the last Item in the Sequence to delimit the end of this Sequence.

The three special Data Elements shall be encoded as Implicit VR whatever the Transfer Syntax is.

In different Transfer Syntaxes or Value Representations, the encoding structures of Data Element (including the Nesting of Data Sets) are generally different. Figure 2 shows examples of encoding structures [5].

3 The design of system

3.1 Methods

The development tool is Visual C++ .Net (which is a Microsoft product; Version: 2003). According to object-oriented programming methodology, using C++ language, we build some specific classes and functions to provide DICOM interface for EECP device. On the base of the DICOM Hemodynamic Waveform IOD Modules, after having a detailed analysis of these modules and their related Data Elements, firstly, we abstract Data Element into a class (called *Data Element Class*), then build a simple *Nesting of Data Sets Class* on the foundation of Data Element Class, and then abstract Hemodynamic Waveform IOD with its operations and services into a class (call *Waveform Base Class*) that can store general DICOM Hemodynamic Waveform file. Finally, we build a class (called *EECP Waveform Class*) which is derived from the Waveform Base Class. In this class, we define Private Data Elements to represent the relational EECP physiological parameters and therapy information. This class can store EECP Waveform file in DICOM format by using a certain Member Function. Figure 3 shows the flow of the design methods.

3.2 Data Element Class

Value Representation (VR) specifies the data type and format of the value(s) contained in the Value Field of a Data Element. There are many different kinds of VR in Data Elements. In the encoding of Data Element, Data Elements with different kinds of VR may have different lengths of VR, and the limitations of Value Length (VL) are usually not the same. So it is very complex to build a class with a unified encoding of all kinds of Data Elements. To reduce the complexity of our program, we can build some special classes to encode some Data Elements with special kinds of VR. In many Data Elements, as the data types of their VF can be represented by corresponding base data types in C++ language, for example, US can be represented by unsigned short, UL can be represented by unsigned long and FL can be represented by float. And we build a class template to encode Data Elements with those types of VR, which makes our program more sententious. The definition of the class template *CDcmElement* is as follows:

```
template<class Type>        // The Class Parameter is Type
class CDcmElement
{
public:
    friend class CWaveForms ;      // CWaveForms is one Friend Class of CDcmElement
    friend class CWaveFormsECP ; // CWaveFormECP is a Friend Class of CDcmElement
    void SetData(Type data);              // Set VF
    void Write(fstream &filedcm);         // Store Data Element into a file
    unsigned short GetVFLength() ;        // Get VL
    char * GetVR();                       // Get VR
    unsigned int GetTag();                // Get Tag
    Type GetData();                       // Get VF
    CDcmElement(unsigned int tag,char *VRs,Type datas);   //the constructed function
private:
    unsigned int Tag;                     // Tag
    char VR[2];                           // VR
    unsigned short VFLength;              // VL
    Type Data;                            // VF
};
```

Fig. 2 The examples of the encoding structures of Data Element and Nesting of Data Sets. **a** Data Element with explicit VR of OB, OW, OF, SQ, UT or UN. **b** Data Element with implicit VR defined as a Sequence of Items of Undefined Length, containing two Items where one is of Explicit Length and the other is of Undefined Length

a

Tag		VR		VL	Value Field
Group Number (16-bit unsigned integer)	Element Number (16-bit unsigned integer)	VR (2 bytes character string:"OB", "OW", "OF", "SQ", "UT" or "UN")	Reserved (2 bytes, set to a value of 0000H)	32 bit unsigned integer	Even number of bytes, encoded according to the VR and Transfer Syntax. Delimited with Sequence Delimitation Item if of Undefined Length
2bytes	2bytes	2bytes	2bytes	4bytes	'Value length'bytes if of Explicit Length

b

Tag	VL	Data Element Value									
		First Item			Second Item					Sequence Delimitation Item	
(gggg, eeee) with VR of SQ	FFFFFFFFH (Undefined Length)	Item Tag (FFFE,E000)	Item Length 000017B6H	Item Value Data Set	Item Tag (FFFE,E000)	Item Length FFFFFFFFH	Item Value Data Set	Item Delim. Tag (FFFE,E00D)	Item Length 00000000H	Seq. Delim. Tag (FFFE,E0DD)	Item Length 00000000H
4 bytes	4 bytes	4 bytes	4 bytes	17B6H bytes	4 bytes	4 bytes	undefined	4 bytes	4 bytes	4 bytes	4 bytes

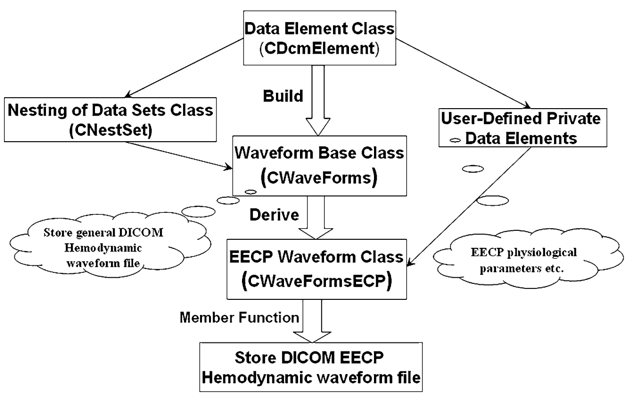

Fig. 3 The flow of the general design methods

IE	Module	Usage
Patient	Patient	M
	Clinical Trial Subject	U
Study	General Study	M
	Patient Study	U
	Clinical Trial Study	U
Series	General Series	M
	Clinical Trial Series	U
Frame of Reference	Synchronization	C – Required if Waveform Originality (003A,0004) is ORIGINAL;
Equipment	General Equipment	M
Waveform	Waveform Identification	M
	Waveform	M
	Acquisition Context	M
	Waveform Annotation	C – required if annotation is present
	SOP Common	M

Fig. 4 The Hemodynamic Waveform IOD Modules

3.3 Waveform Base Class

This class is the abstract of DICOM Hemodynamic Waveform IOD with its operations and services. In accordance with DICOM standard, Fig. 4 shows the Hemodynamic Waveform IOD Modules [6]. In this figure, if the Usage is 'M', it means that module is Mandatory Module (necessary) in the waveform IOD, and if the Usage is 'U', it means that module is User Option Module (optional), and if the Usage is 'C', it means that module is Conditional Module (necessary in certain situation).

In these modules, the most important one is Waveform Module. A waveform information object may contain several Multiplex Groups, each defined by digitization with the same clock whose frequency is defined for the group, and each encoded into an Item of waveform Sequence. Within each Multiplex Group there will be one or more Channels, each with a full technical definition. Finally, each Channel has its set of digital waveform Samples. Figure 5 shows the DICOM Waveform Information Model [7]. For different kinds of waveforms, they contain different amounts of Multiplex Groups, and each Multiplex Group may also contain different amount of Channels. In

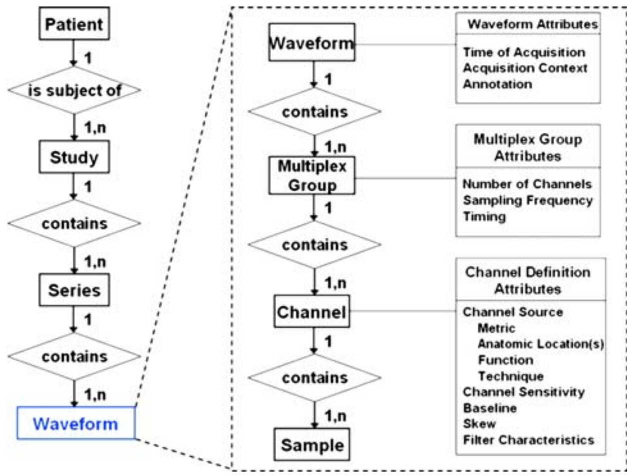

Fig. 5 The DICOM Waveform Information Model

the Waveform Module, it also contain the Data Elements which describe the attributes of Waveform IE, for instance, the Number of Channels, Sampling Frequency, Waveform Bits Allocated and attributes of Channels which contain the Channel Sensitivity, Channel Sensitivity Correction Factor, Channel Time Skew, Filter Low Frequency, Filter High Frequency and so on [6].

The major Data Elements of Waveform Module are shown by Table 1 as follows [6].

Based on the DICOM Hemodynamic Waveform IOD Modules and their related Data Elements, after designing the Data Element Class and the simple Nesting of Data Sets Class, we define Data Members including Data Elements and Nesting of Data Sets ordered by Tags inside the Waveform Base Class. Relative Member Functions are defined such as the functions to set the VF of some Data Elements frequently used, to get the VF of those Data Elements, to store a Data Elements into a file and the function to store waveform sampling data into a file, for example:

Table 1 The major Data Elements of Waveform Module

TAG	Attribute description	VR
(5400, 0100)	Waveform sequence	SQ
(5400, 1004)	Waveform bits allocated	US
(5400, 1006)	Waveform sample interpretation	CS
(5400, 100A)	Waveform padding value	OW
(5400, 1010)	Waveform data	OW
(003A, 0004)	Waveform originality	CS
(003A, 0005)	Number of waveform channels	US
(003A, 0010)	Number of waveform samples	UL
(003A, 001A)	Sampling frequency	DS
(003A, 0200)	Channel definition sequence	SQ
(003A, 0208)	Channel source sequence	SQ
(003A, 0210)	Channel sensitivity	DS
(003A, 0211)	Channel sensitivity units Sequence	SQ
(003A, 0212)	Channel sensitivity correction factor	DS
(003A, 0213)	Channel baseline	DS
(003A, 0214)	Channel time skew	DS
(003A, 021A)	Waveform bits stored	US

```
void SetPatientName(char *name)   //Set the Patient Name
char * GetPatientName()           // Get the Patient Name
void WriteWaveform()              // Store waveform sampling data into a file
```

Since the EECP Waveforms belong to Hemodynamic Waveform, according to the Data Dictionary of DICOM, we set the VF of SOP Class UID (the Data Element whose Tag is (0008,0016)) as "1.2.840.10008.5.1.4.1.1.9.2.1", and set the VF of Modality (a Data Element whose Tag is (0008,0060)) as "HD" in the waveform attributes.

3.4 EECP Waveform Class

The EECP Hemodynamic Waveforms contain one Multiplex Group with two Channels: one is the ECG waveform and the other is the Hemodynamic waveform (in the clinical practices, it is the photoplethysmography waveform which usually measured from maniphalanx or auricular lobule). The EECP Waveform Class is the inheritance of the Waveform Base Class. Besides, we define some other Data Elements as the Private Data Members of this class to represent the relational EECP Hemodynamic Waveform physiological parameters and therapy information, most of which can not be represented by Standard Data Elements registered in the Data Dictionary of DICOM. These important physiological parameters (such as the ratio of D/S peak value, the ratio of D/S area value, saturation of blood oxygen, systolic pressure, diastolic pressure etc.) are required for data exchange during EECP. So according to the specification of Private Data Element in DICOM, we define related Private Data Elements to represent and encode these important transferred data. This is the Semantic Extension of DICOM Standard applied in EECP. In the future, we will submit a Change Proposal about the addition of EECP Private Data Elements to NAME committee and make great efforts to the normalization of EECP data.

It is possible that multiple implementors may define Private Data Elements with the same (odd) group number. To avoid conflicts, DICOM reserves a block of Data Elements whose Tags are (gggg,0010-00FF) (gggg is odd) to tell the signification of Private Data Elements to the decoders of Private Data Elements. DICOM ordains: Private Creator Data Elements numbered (gggg,0010-00FF)

Table 2 Some Private Data Elements defined by creator

Tag	VR	Attribute description
(003B, 0010)	LO	Private Data Elements identification code
(003B, 1000)	US	Heart rate
(003B, 1001)	FL	The ratio of D/S peak value
(003B, 1002)	FL	The ratio of D/S area value
(003B, 1003)	US	Saturation of blood oxygen
(003B, 1004)	US	Systolic pressure
(003B, 1005)	US	Diastolic pressure
(003B, 1006)	LO	The effect of EECP therapy

shall be used to reserve a block of Elements with Group Number gggg for use by an individual implementor. The implementor shall insert an identification code in the first unused (unassigned) Element in this series to reserve a block of Private Elements. The VR of the private identification code shall be Long String (LO) and the VM shall be equal to 1. Private Creator Data Element (gggg,0010), is a Type 1 Data Element that identifies the implementor reserving elements (gggg, 1000-10FF), and Private Creator Data Element (gggg,0011) identifies the implementor reserving elements (gggg,1100-11FF), until Private Creator Data Element (gggg,00FF) identifies the implementor reserving elements (gggg,FF00-FFFF) [5].

Based on these regulations, we define a series of Private Data Elements whose Group Number is 003B to represent the EECP physiological parameters and therapy information. Table 2 shows some Private Data Elements defined by creator.

In the class, corresponding Private Data Members were defined:

```
CDcmElement <char *> *PrivateCode;                  // Identification Code
CDcmElement<unsigned short> *HeartRate;             //Heart rate
CDcmElement<float> *DSPSpecificValue;               // The ratio of D/S peak value
CDcmElement<float> *DSASpecificValue;               // The ratio of D/S area value
CDcmElement<unsigned short> *SpO2;                  // Saturation of blood oxygen
CDcmElement<unsigned short> *SystolicPressure;      // Systolic pressure
CDcmElement<unsigned short> *DiastolicPressure;     //Diastolic pressure
CDcmElement <char *> *TherapyEffect;                // The effect of EECP therapy
```

In the Data Dictionary of DICOM, There is also a Data Element that represents Heart Rate. Its Tag is (0018,1088) and VR is IS (Integer String), but Heart Rate is an

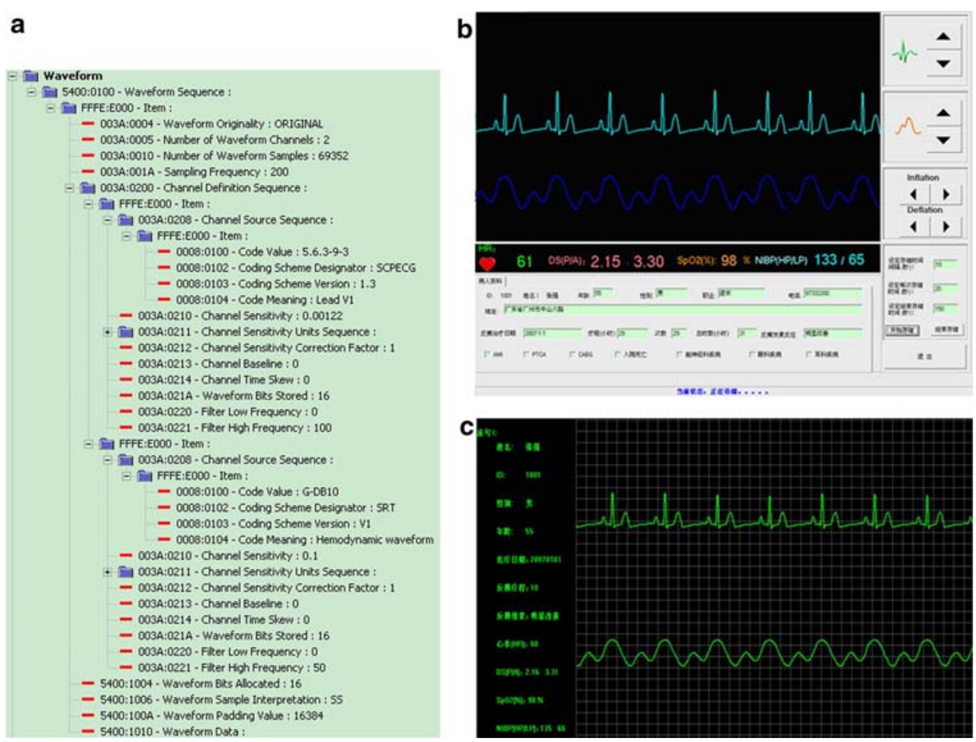

Fig. 6 The display of the results of our study. **a** The main Data Elements of the Waveform Module shown in the dendriform format by using the DICOM Waveforms Viewer of LEADTOOLS V14.5 (the product of LEADTOOLS Corporation) to open a DICOM waveform file stored by our program (This mainly shows the attributes of Multiplex Group and Channel especially the Channel Source Sequences of these two Channels). **b** A monitoring interface of EECP device in one of our testing programs. In this program, we set short durations at designated times, then during these designated times, EECP device stored waveforms and other data in DICOM waveform file format. **c** Use the EECP workstation application to open a DICOM waveform file stored by our program and display both the EECP Waveforms and other data.

important monitoring parameter which is required for data exchange during EECP, and it is also defined as a Private Data Element whose VR is US(Unsigned Short) and VM is 1-n.

4 Results

Figure 6 shows the results of our study. The DICOM waveform files stored by our program can be well read and displayed by most DICOM waveform viewers. Figure 6c shows the result of using our EECP workstation application to display a DICOM waveform file stored by our program. It displays both the EECP Waveforms and other data (some of the patient information, EECP physiological parameters and therapy information).

5 Conclusion and prospect

In this article, the technology of storing DICOM EECP Hemodynamic Waveforms has been discussed. Using this technology, we have designed the program to provide DICOM interface for EECP device, which is helpful for EECP information unification and sharing all over the world. This technology can be analogously applied to electrocardiograph, electroencephalograph and so on, which equips them with DICOM interfaces.

By now, we haven't applied a certain compression technology to the storage of DICOM waveform files. Although the byte count of waveform file is usually much less than image file, sometimes we may need to acquire long-playing waveforms, and the compression technology becomes more important at that time. For the further research, we will study an algorithm with high performance in the compression of the storage of DICOM waveform data, which will reduce the byte count of file and improve the storage efficiency and data transmission speed. The LAN system for EECP medical center can communicate with PACS, HIS and RIS, even Internet such as connection with the International EECP Patient Register Center (IEPR) in America.

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