



# iCARDEA

“An Intelligent Platform for Personalized Remote Monitoring of the Cardiac Patients with Electronic Implant Devices”

## SPECIFIC TARGETED RESEARCH PROJECT

**PRIORITY Objective ICT-2009.5.1: Personal Health Systems - a) Minimally invasive systems and ICT-enabled artificial organs: a1) Cardiovascular diseases**

### iCARDEA – D.7.1.1 Personalized Follow-up Parameter Assistant

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**Table of contents**

<b>1</b>	<b>Introduction</b> .....	5
1.1	Purpose .....	5
1.2	Scope .....	5
1.3	Definitions, acronyms and abbreviations.....	5
<b>2</b>	<b>OVERALL DESCRIPTION of iCARDEA Project</b> .....	5
2.1	iCARDEA System Architecture and the Role of Patient Parameter Role in this Architecture .....	7
<b>3</b>	<b>PERSONALIZED FOLLOW-UP PARAMETER ASSISTANT</b> .....	9
3.1	Requirements for PATIENT PARAMETER ASSISTANT Tool .....	9
3.2	Parameters for analysis.....	10
<b>4</b>	<b>Implementation of Patient Parameter Monitoring</b> .....	25
4.1	Architectural Design of the Patient Parameter Monitor .....	25
4.1.1.1	<i>Interactions between Design Objects</i> .....	26
4.1.1.2	<i>Design of the Patient Parameter Monitor function block</i> .....	27
4.1.1.3	<i>The Patient Parameter Monitor component</i> .....	28
4.1.1.4	<i>The PPM Data Exposure component</i> .....	29
4.2	Data extraction through Standard Interfaces .....	31
4.2.1.1	<i>ISO/IEEE 11073 Nomenclature</i> .....	31
4.2.1.2	<i>HL7v2.x Standard</i> .....	33
4.2.1.3	<i>IHE Profiles</i> .....	33
4.2.1.4	<i>iCARDEA Extensions to IHE IDCO Profile</i> .....	34
4.3	PPM User Interfaces.....	35
<b>5</b>	<b>CONCLUSION</b> .....	43
<b>6</b>	<b>REFERENCES</b> .....	43

## 1 Introduction

### 1.1 PURPOSE

This document describes the personalized follow up parameter assistant developed for the cardiac arrhythmia patients with an implanted cardiovascular implantable electronic device (CIED) in order to provide relevant information to the health care professional for achieve optimum standards of medical care.

This is achieved by analyzing patient data from CIEDs, Electronic Healthcare Records and Personal Health Records, such as history of illness, surgeries, medications, and then graphically presenting these data in an intelligent way by correlating the fields from separate sources.

### 1.2 SCOPE

This document provides detailed information about the personalized follow up parameter assistant developed within the scope of “Task 7.1.1. Determining on Patient Parameters to be monitored for Personalized Follow-up” and will contribute to the milestone “M5: “iCARDEA Patient Empowerment Framework, Interoperability Layer and Personalized Follow-up Parameter Assistant””.

### 1.3 DEFINITIONS, ACRONYMS AND ABBREVIATIONS

**Table 1 List of Abbreviations and Acronyms**

Abbreviation/Acronym	DEFINITION
CIED	Cardiovascular implantable electronic device
EHRA	European Heart Rhythm Association
EP	Electrophysiology
ESC	European Society of Cardiology
ER	Emergency department
HF	Heart failure
HIS	Hospital information System
ICD	Implantable Cardioverter Defibrillator
PHR	Personal Health Records
PM	Pacemaker
SCD	Sudden cardiac death

## 2 OVERALL DESCRIPTION of iCARDEA Project

Management of cardiac arrhythmia abnormalities that are not transient or reversible require constant clinical monitoring as a chronic condition. Delays on diagnosis or medical assistance increase risks of adverse outcomes such as heart failure (HF), stroke or sudden cardiac death. Therefore, CIEDs have become a part of the standard therapy in patients who are at the risk of life-threatening cardiac arrhythmias.

CIEDs with remote monitoring capabilities can store and transmit cardiac status and device function data. Remote sensor devices are located in patients’ homes to transfer stored data from the cardiac implant to a remote monitoring service centre. These remote monitoring service centres, operated by device manufacturers, receive, store, analyze and translate transmitted data into patient-specific reports and allow healthcare professionals to access patient data or to receive alerts in case of unusual persisting data variations. These systems are also capable of providing this valuable information in machine processable form. iCARDEA

project has set out to use this information to semi-automate the follow-up of cardiac arrhythmia patients with the care plans based on computer interpretable clinical guideline models by also personalizing the guidelines with the data obtained from patient EHRs.

Clinical guidelines include plans for treatment and aim to reduce inter-practice variations and the cost of the medical services, improve the quality of care and standardize clinical procedures. A variety of government and professional organizations are producing and disseminating clinical guidelines<sup>1,2</sup>. Several computer interpretable models of Clinical Guidelines have also been proposed such as GLIF<sup>3</sup>, ASBRU<sup>4</sup>, and ARDEN<sup>5</sup>. Additionally, there are several guideline execution engines processing these models, such as GLEE<sup>6</sup>, GLARE<sup>7</sup> and DeGel<sup>8</sup> demonstrating that the guideline definitions can be executed to automate the decision making process. In the iCARDEA system, GLIF is used for the definition of the care plans and an engine is developed to execute them. In this respect, the care plans presented in this deliverable are defined using GLIF Notation.

Currently the CIED data is available from two different sources. The patient may be at the clinic during an in-clinic follow-up, so the data from the CIED can be directly accessed using the CIED Programmer of the vendor. The CIED Programmer is able to export the data into PDF file(s) stored in a configurable directory. Alternatively, the patient may be at home and the data is transmitted (semi-) automatically into the CIED Data Centre of the vendor for a remote follow-up. The physicians then can access the CIED Portal of the vendor that functions as frontend of the CIED Data Centre. It is also possible to export the CIED Data to the clinic, however right now this export has to be triggered manually in the CIED Portal. The data is then either exported using the IHE IDCO/HL7 v2.5 message or it is exported to a vendor system that has to be installed in the clinic. Currently the v2.5 messages transferred by the CIED Vendors usually contain limited information; however the PDF reports that contain the detailed data are embedded in the message. The vendor system in the clinic then automatically stores the data in a single PDF file using a configurable filename and the filename includes additional information such as the Patient name, Patient ID, and the timestamp.

iCARDEA uses "IHE Implantable Device Cardiac Observation Profile (IDCO)"<sup>9</sup> to automatically expose the CIED data from different vendors in a machine processable format to be used in the care plan of the patients. There are different CIED vendors each with its own device and data centre interfaces. On the other hand, IHE has defined this profile in order to standardize transferring information from an interrogated implantable cardiac device to the healthcare enterprise information management systems. The implant device is

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<sup>1</sup> US National Guideline Clearinghouse, <http://www.guideline.gov/>

<sup>2</sup> National Institute for Clinical Excellence- England/Wales (NICE) Published Guidelines, <http://www.nice.org.uk/page.aspx?o=guidelines.completd>

<sup>3</sup> Boxwala AA, Peleg M, Tu S et al. GLIF3: a representation format for sharable computer-interpretable clinical practice guidelines. *Journal of Biomed Inform.*, 2004, 37(3), 147-61

<sup>4</sup> Shahar, Y., Miksch, S., and Johnson, P. The Asgaard project: A task-specific framework for the application and critiquing of time-oriented clinical guidelines. *Artificial Intelligence in Medicine*, 1998, 14: 29-51.

<sup>5</sup> Jenders RA, Corman R, Dasgupta B. Making the standard more standard: a data and query model for knowledge representation in the Arden syntax. *Proceedings of AMIA Annual Symp.*, 2003, 323-30.

<sup>6</sup> Wang D, Shortliffe EH. GLEE - a model-driven execution system for computer-based implementation of clinical practice guidelines. *Proceedings of AMIA Symp.*, 2002, 855-9.

<sup>7</sup> Terenziani P, Montani S, Bottrighi A et al. The GLARE approach to clinical guidelines: main features. *Studies in Health Technology and Informatics*, 2004. 101, 162-6.

<sup>8</sup> Shahar Y, Young O, Shalom E, Mayaffit A, Moskovitch R, Hessian A, and Galperin M. DeGeL: A Hybrid, Multiple-Ontology Framework for Specification and Retrieval of Clinical Guidelines. *Proceedings of the 9th Conference on Artificial Intelligence in Medicine*, Springer-Verlag Heidelberg, 2003, 122 - 131.

<sup>9</sup> IHE Implantable Device - Cardiac - Observation Profile, [http://www.ihe.net/Technical\\_Framework/upload/IHE\\_PCD\\_TF\\_Supplement\\_IDCO\\_2009-08-10.pdf](http://www.ihe.net/Technical_Framework/upload/IHE_PCD_TF_Supplement_IDCO_2009-08-10.pdf)

interrogated in clinic or home environment using vendor proprietary equipment and the information is transferred to clinic system as structured HL7 v2.5 ORU message using IEEE 11073 IDC nomenclature<sup>10</sup>.

In iCARDEA, a care plan is personalized to a patient by also accessing his medical history from the EHR systems. For example, in executing iCARDEA care plans for monitoring CIED patients with Atrial Fibrillation (AF), the history of the non-cardiac conditions, detailed information about severity of each condition (e.g., record of prior hospitalizations or specifics of therapy for the condition), the medications being taken at the time of spontaneous arrhythmia occurrence or the non-cardiac conditions denoting contraindications to the proposed therapies need to be accessed from the patient EHRs. The major challenge addressed in accessing the EHR systems is the interoperability problem of communicating with very many heterogeneous EHR systems. It should be noted that the care plans in this deliverables are generic in that they are not personalized to a specific patient.

To be able to avoid routinely monitoring a wide variety of clinical data from disparate systems, and developing ad hoc interfaces to access heterogeneous systems, IHE has specified the "Care Management Profile"<sup>11</sup> and this profile is used in the iCARDEA system.

## **2.1 ICARDEA SYSTEM ARCHITECTURE AND THE ROLE OF PATIENT PARAMETER ROLE IN THIS ARCHITECTURE**

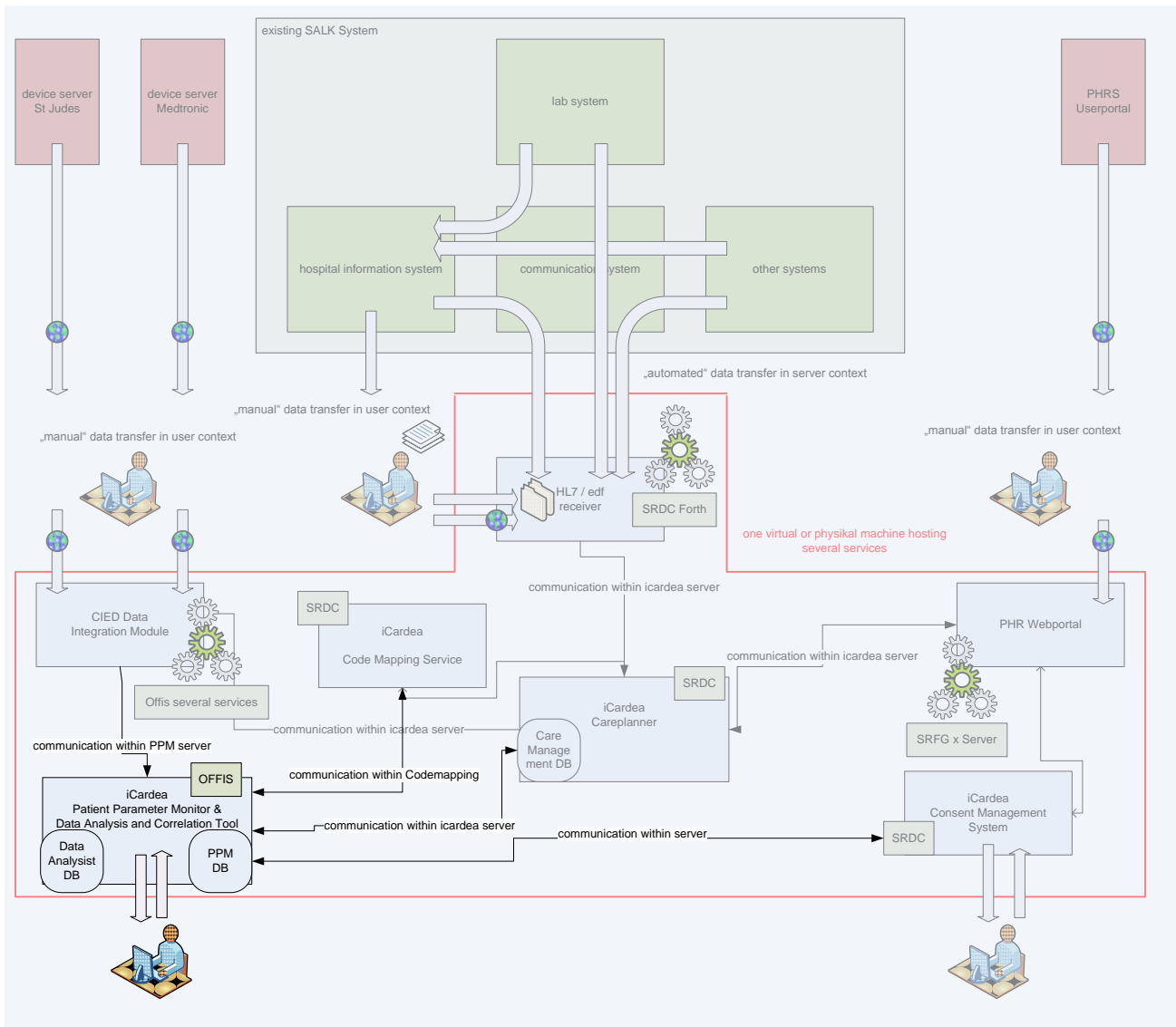
The iCARDEA system aims to automate and personalize the follow-up of cardiac arrhythmia patients with implanted CIED devices with computer interpretable clinical guideline models using standard device interfaces and integrating patient EHRs. Figure 1 shows the overall architecture and the environment in which iCARDEA needs to provide interoperation services. The major components of the system are as follows:

1. Care Planner: In the iCARDEA project, the personalized follow-up of CIED patients is coordinated through a "care plan" which is an executable definition of computer interpretable clinical guideline models. The care plans are represented in GLIF, and the Care Plan Engine is capable of semi-automatically executing the care plan by processing its machine processable definition. The control flow of the care plan is dynamically adapted based on the patient's context derived from the data coming from CIEDs and the medical context obtained from the EHRs. Through a graphical monitoring tool, the physicians are allowed to follow the execution of the care plan in detail, and coordinate the flow of actions when consultations to physicians are required.
2. The CIED Data Integration Module uses "IHE Implantable Device Cardiac Observation Profile (IDCO)" to expose the CIED data from different vendors in a machine processable format to be used in the care plan of the patients. For this, it has a component that allows accessing the CIED Portal of the vendor and triggers the CIED data export automatically from the CIED Data Centre (periodically every x hours or each morning at a defined time). The CIED Data Listener Component waits for the exported data. For this it either scans a configurable directory in case of the data is exported directly to a vendor system in the clinic, alternatively it listens a pre-configured port for the exported data using the IHE IDCO/HL7 v2.5 protocol in case of direct network retrieval. In both cases the PDF file(s) need to be processed to extract the CIED data and the Data Translation Service sub-system creates a valid IHE IDCO format (HL7 v2.5 ORU Message) and makes the CIED data available to the iCARDEA Adaptive Care Planner through PCD-09 Send Observation message.

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<sup>10</sup> ISO/IEEE 11073-10101:2004, Point-of-care medical device communication -- Part 10101: Nomenclature, [http://www.iso.org/iso/catalogue\\_detail.htm?csnumber=37890](http://www.iso.org/iso/catalogue_detail.htm?csnumber=37890)

<sup>11</sup> IHE Patient Care Coordination (PCC) Technical Framework Supplement, 2008-2009, Care Management (CM), Draft for Trial Implementation, August 22, 2008



**Figure 1 iCARDEA System Architecture and the Role of Patient Parameter Role in this Architecture**

3. EHR Interoperability Infrastructure: To execute the clinical guidelines, it is also necessary to have access to medical history of the patients in the EHR systems. Considering that there are very many EHR systems with proprietary interfaces, in iCARDEA, “IHE Care Management (CM) Profile” is used. In our system, the proprietary hospital information systems export “Discharge Summary” and also “Laboratory Report Summary” reports, which are processed by HER Interoperability System and uploaded in conformance to IHE CDA Document templates<sup>12</sup> to an EHR Server which is implemented as an IHE XDS Repository<sup>13</sup>. This EHR Server also acts as a “Clinical Data Source” by implementing the IHE CM Profile. In this way, Adaptive Care Manager can subscribe to receive update notifications for the clinical data that is necessary to execute the care plans.
4. Additionally, iCARDEA includes the Patient Empowerment Framework, namely PHR System aiming to provide an active and informed involvement of patients in management of their own health.

<sup>12</sup> IHE Care Coordination Framework, Content Modules, [http://wiki.ihe.net/index.php?title=1.3.6.1.4.1.19376.1.5.3.1.1#Medical Documents Specification 1.3.6.1.4.1.19376.1.5.3.1.1.1](http://wiki.ihe.net/index.php?title=1.3.6.1.4.1.19376.1.5.3.1.1#Medical_Documents_Specification_1.3.6.1.4.1.19376.1.5.3.1.1.1)

<sup>13</sup> IHE Cross Enterprise Document Sharing (XDS) Profile, [http://www.ihe.net/Technical\\_Framework/index.cfm#IT](http://www.ihe.net/Technical_Framework/index.cfm#IT)

Through this PHR portal patients are able to have an overview about their own health data and to add additional personal health data such as the daily recorded blood pressure, body weight or upcoming problems related to their heart disease. Another important feature of the PHR portal is recording medication compliance indicating changes in e.g. dosage or change of drugs. Finally, the PHR portal allows the patient to have access to the education material provided by iCARDEA project.

As explained through the standard based interfaces, CIED, EHR and PHR data are continuously sent to iCARDEA Care Planners system, which are stored in Care Management Database. These stored clinical data are used while previously defined care plans are being executed to guide the medical professionals in guideline based care of the patient. Care Planner Monitoring interfaces, present relevant patient data retrieved from EHR, PHR and CIED of patient in each step of care plan step as a summary, however it is also required to have a single interface from which the medical professionals can check the current status of the patient independent of the care plan execution, by also checking the information sources when necessary. Such a single interface is also required especially during regular remote monitoring follow-ups. This is necessary, because execution of care plans are more oriented to check the treatment plan after an alert is detected by CIEDs. Based on these requirements, the iCARDEA Patient Parameter Assistant Tool is developed. As presented in Figure 1, the information source of Patient Parameter Assistant Tool is Care Management Database hosted by Care Planner, alternatively, the tool is also capable to directly communicating with EHR Interoperability System, PHR System and CIED Integration Module to collect most recent patient medical status as well as medical history.

### 3 PERSONALIZED FOLLOW-UP PARAMETER ASSISTANT

The aim is to provide assistant software for healthcare professionals to help in determining the critical patient parameters to be monitored and analyzed for better personalization of the automated follow-up. This is achieved by analyzing patient data from CIEDs, Electronic Healthcare Records and Personal Health Records, such as history of illness, surgeries, medications, and then graphically presenting these data in an intelligent way by correlating the fields from separate sources.

In Section 3.1, the requirements for Patient Parameter Assistant Tool will be revisited, which was previously presented in D3.4.1. In Section 3.2, the selected parameters to be presented through this tool will be elaborated in different views.

#### 3.1 REQUIREMENTS FOR PATIENT PARAMETER ASSISTANT TOOL

In Deliverable 3.4.1, Annex II, the requirements for Patient Parameter Assistant Tool is presented through the following use case definition:

		Patient Parameter Monitor
<b>Description</b>		The Patient Monitor prepares all available data of a patient for an easy and harmonized view of all available data. Thereby it enables the Physician to gather information needed to define the follow up process.
<b>Actors</b>		Healthcare Actor and Patient Mapping Service
<b>Assumptions</b>	<b>Preconditions</b>	1. Healthcare Actor have sufficient access-rights for the patient

	<b>Post conditions</b>	<ol style="list-style-type: none"> <li>1. Changed documentation is saved</li> <li>2. Patient specific view is saved</li> </ol>
<b>Steps</b>		<ol style="list-style-type: none"> <li>1. Healthcare Actor logs in to the system.</li> <li>2. Select an “owned” patient.</li> <li>3. System gathers all available information about Patient from CIED-Agent, EHR-Agent, PHR-Agent and HIS-Agent.</li> <li>4. The data (already harmonized by the agents) is visualized.</li> <li>5. The Healthcare Actor can Add/ Edit/ Delete patient specific data.</li> <li>6. The Healthcare Actor can edit the View-Preferences for the Patient.</li> <li>7. All changes are saved.</li> <li>8. Healthcare Actor logs out from the system.</li> </ol>
<b>Variations</b>		<ol style="list-style-type: none"> <li>1. If the connection is closed or a time limit has expired, the Healthcare Actor is logged of automatically.</li> </ol>
<b>Non-Functional Requirements</b>		<ol style="list-style-type: none"> <li>1. “Easy to use” for Healthcare Actor</li> </ol>

### 3.2 PARAMETERS FOR ANALYSIS

The Patient Monitor prepares all available data of a patient for an easy and harmonized view of all available data. Thereby it enables the physician to gather information needed to define the follow up process. For this purpose, a list of all necessary parameter for the personalized and thorough evaluation of patients with CIEDs is decided on with medical practitioners. The following list is organized in five main groups; as follow:

- Entry page: general information of the patient and device, measured parameters, arrhythmia episodes, programmed parameters.
- AT/AF episode: arrhythmia episode information, patient’s relevant information, patient’s objective data.
- VT/VF episode: arrhythmia episode information, patient’s relevant information, patient’s objective data.
- Patient information: clinical data, device information, healthcare practitioners’ information (doctor, nurse, contact data, etc.).
- Programmed parameters: bradycardia, tachycardia.

In the following subsections, these parameters will be presented together with the type of the variable, format of the variable, and possible validation measures if there are any.

### 3.1.1 Entry page:

This page aims to analyze the general state of the patient and the device at a single glance, including the patient clinical status, the battery, lead parameters and the occurrence of events. The table 1 show the parameters and their characteristics.

Start page				
PARAMETER	EXPLANATION	TYPE OF VARIABLE	FORMAT	VALIDATION
Name	Name of the patient	Text		
ID	Hospitals ID number	Numeric	F8.0	Depends on each institution, but usually it has >3 digits and <9
Age	Age of the patient at the time of interrogation	Numeric	F3.0	>2 and <110
Diagnosis	Main diagnosis of the patient	Text		
Date of implantation		Date	DD-MM-YYYY	> Date of birth
Date of battery exchange		Date	DD-MM-YYYY	> Date of implantation
Type of device	PM / ICD / CRT-P / CRT-D	Categoric	Nominal	
CIED manufacturer	Medtronic / SJM	Categoric	Nominal	
Model	for types - ASK Medtronic & SJM	Categoric	Nominal	
MEASURED PARAMETERS				
Battery Voltage	(volts) SHOW IN PARANTHESES (ERI and EOL limits for the	Numeric	F3.2	>1.00 and <4.00 - Check the exact

Start page				
PARAMETER	EXPLANATION	TYPE OF VARIABLE	FORMAT	VALIDATION
	specific model - Ask Medtronic & SJM)			limits with Medtronic & SJM
Battery Impedance		Numeric		Check limits with Medtronic & SJM
Magnet rate	for pacemakers (b.p.m)	Numeric	F3.0	<110 and >50
Charge time	for ICDs (seconds)	Numeric	F3.1	>6.0 and <35 seconds
Date of last capacitor charge	Date that the above variable was measured	Date	DD-MM-YYYY	> Date of implantation
RA lead impedance	Impedance of the atrial lead	Numeric	F4.0	For valid limits, ask Medtronic & SJM
RA lead P wave amplitude	Amplitude of the atrial lead signal	Numeric	F2.1	<15.0 and >0.1
RA lead pacing	Pacing threshold of the atrial lead	Numeric	F2.1	<5.0
RV lead defibrillation impedance	Defibrillation impedance of the right ventricular lead	Numeric	F2.0	For valid limits, ask Medtronic & SJM
RV lead pacing impedance	Pacing impedance of the right ventricular lead	Numeric	F4.0	For valid limits, ask Medtronic & SJM
RV lead R wave amplitude	Amplitude of the right ventricular lead signal	Numeric	F2.1	<15.0 and >0.1
RV lead pacing threshold	Pacing threshold of the right ventricular lead	Numeric	F2.1	<5.0
LV lead pacing impedance	Pacing impedance of the left ventricular lead	Numeric	F4.0	For valid limits, ask Medtronic & SJM
LV lead R wave amplitude	Amplitude of the left ventricular lead signal	Numeric	F2.1	<15.0 and >0.1
LV lead pacing threshold	Pacing threshold of the left ventricular lead	Numeric	F2.1	<5.0
Percentage of AS	% of atrial sensing	Numeric	F3.0	0 - 100

Start page				
PARAMETER	EXPLANATION	TYPE OF VARIABLE	FORMAT	VALIDATION
Percentage of AP	% of atrial pacing	Numeric	F3.0	0 - 100
Percentage of RVS	% of right ventricular sensing	Numeric	F3.0	0 - 100
Percentage of RVP	% of right ventricular pacing	Numeric	F3.0	0 - 100
Percentage of LVS	% of left ventricular sensing	Numeric	F3.0	0 - 100
Percentage of LVP	% of left ventricular pacing	Numeric	F3.0	0 - 100
ARRHYTHMIA EPISODES				
SVT	Number of episodes classified as SVT	Numeric	F3.0	
AF / AT	Number of episodes classified as AF / AT	Numeric	F3.0	
VT	Number of episodes classified as VT / VF	Numeric	F3.0	
PMT	Number of episodes classified as pacemaker mediated tachycardia	Numeric	F3.0	
SVT treated	Number of episodes classified as SVT treated	Numeric	F3.0	
VT treated	Number of episodes classified as VT / VF treated	Numeric	F3.0	
ALERTS & OTHER MEASUREMENTS				
Safety alerts	Safety alerts detected by the device	Text		

**Start page**

PARAMETER	EXPLANATION	TYPE OF VARIABLE	FORMAT	VALIDATION
<b>PATIENTS CLINICAL STATUS</b>				
NYHA functional class	Functional class according to the New York Heart Association Classification (I -IV)	Categorical	Ordinal	I, II, III or IV
QOL score	Quality of Life test score	Numeric	F3.0	0 - 105
Hospital admissions	Any hospital admissions since prior visit	Numeric	F1.0	
Medications	Current medical treatment of the patient	List		

### 3.1.2 AT/AF episode:

AF event is detected by the CIED indicating that the AF daily burden has exceeded the specified threshold. Whenever such an event is detected, the physician is notified automatically through an SMS or through email depending on the capabilities of the CIED Vendor by the CIED system. The page shows all the relevant parameters in case of atrial arrhythmias such as symptoms, clinical characteristics of the arrhythmia, treatment and the presence of cardio embolic or bleeding risk factors. It provides guidance to the physician for a reliable and fast decision on whether to start anticoagulation by checking the alerts provided by the CIED devices, together with the patient's medical history, his current medications, his recent lab results, and the possible contraindications. (Table 2).

AF/AT			
PARAMETER	EXPLANATION	TYPE OF VARIABLE	FORMAT
# of episodes	Number of episodes	Numeric	F3.0
date of episode	Date of each episode	Date	DD-MM-YYYY
time of episode	Time of each episode	Time	hh:mm:ss
duration of episode	Duration of each episode	Time	hh:mm:ss
vt zone	Programmed zone to which each episode is classified	Categorical	Nominal
cycle length	If stable, the mean cycle length (ms) of the tachycardia	Numeric	F3.0
onset	Onset of the tachycardia (%)	Numeric	F2.0
stability	Stability of tachycardia's cycle length (%)	Numeric	F2.0
VA relationship	In patients with atrial lead, VA relationship (V>A, V=A, V<A)	Categorical	Nominal
Morphology criteria	% QRS concordance between baseline electrogram and the electrogram during the tachycardia	Numeric	F2.0

AF/AT			
PARAMETER	EXPLANATION	TYPE OF VARIABLE	FORMAT
ATP	Number of ATP delivered for each episode	Numeric	F3.0
Shock	Number of shocks delivered for each episode	Numeric	F1.0
electrogram	Intracardiac electrogram registered by the device for each episode	Image	
PATIENT'S RELEVANT INFORMATION			
Diagnosis	Main diagnosis of the patient	Text	
symptoms	Patient's reported symptoms (palpitations, dizziness, syncope, chest pain, shortness of breath, etc.)	List	
Anticoagulation	Oral chronic anticoagulation (YES / NO)	Categorical	Binary
Medications	Current medical treatment of the patient	List	
Medication compliance	Patient's reported compliance to medication	List	
treatment changes	Changes in treatment	Text	
reports	Recent hospital admission reports	Text	
CHADS2 Score	Prior congestive heart failure / Hypertension / Age >75 years / Diabetes mellitus / Stroke (table 7 D.4.2.1)	Numeric	F1.0
CHADS2-Vasc Score	Table 9 D.4.2.1	Numeric	F1.0
HAS-BLED Score	Table 11 D.4.2.1	Numeric	F1.0
Contraindications for anticoagulation	List of possible contraindications for oral chronic anticoagulation (see flowchart 10 of D.4.1.1)	List	

AF/AT			
PARAMETER	EXPLANATION	TYPE OF VARIABLE	FORMAT
patient's comments	any other comment that the patient wants to resgister (like his diary)	Text	
PATIENT'S OBJECTIVE DATA			
lab results	Table showing the patient's laboratory results	Numeric	
electrocardiogram	Electrocardiogram	Image	
echocardiogram	Table showing the patient's echocardiography results, report and images	Text, image	

### 3.1.3 VT/VF episode:

This page shows the presence of VT events, including characteristics, episodes and frequency. If the case is VT, then the Medical Professional controls the number of episodes within 24 hours and the care plan engine guides the Medical Professional whether the case is single/rare episode case or frequent episode case (table 3)

VT/VF			
PARAMETER	EXPLANATION	TYPE OF VARIABLE	FORMAT
# of episodes	Number of episodes	Numeric	F3.0
date of episode	Date of each episode	Date	DD-MM-YYYY
time of episode	Time of each episode	Time	hh:mm:ss
duration of episode	Duration of each episode	Time	hh:mm:ss
vt zone	Programmed zone to which each episode is classified	Categoric	Nominal
cycle length	If stable, the mean cycle length (ms) of the tachycardia	Numeric	F3.0
onset	Onset of the tachycardia (%)	Numeric	F2.0
stability	Stability of tachycardia's cycle length (%)	Numeric	F2.0
VA relationship	In patients with atrial lead, VA relationship (V>A, V=A, V<A)	Categoric	Nominal
Morphology criteria	% QRS concordance between baseline electrogram and the electrogram during the tachycardia	Numeric	F2.0
ATP	Number of ATP delivered for each episode	Numeric	F3.0
Shock	Number of shocks delivered for each episode	Numeric	F1.0
electrogram	Intracardiac electrogram registered by the device for each episode	Image	

VT/VF			
PARAMETER	EXPLANATION	TYPE OF VARIABLE	FORMAT
<b>PATIENT'S RELEVANT INFORMATION</b>			
Diagnosis	Main diagnosis of the patient	Text	
symptoms	Patient's reported symptoms (palpitations, dizziness, syncope, chest pain, shortness of breath, etc.)	List	
Medications	Current medical treatment of the patient	List	
Medication compliance	Patient's reported compliance to medication	List	
treatment changes	Changes in treatment	Text	
reports	Recent hospital admission reports	Text	
patient's comments	any other comment that the patient wants to register (like his diary)	Text	
<b>PATIENT'S OBJECTIVE DATA</b>			
lab results	Table showing the patient's laboratory results	Numeric	
INR	Patient's anticoagulation status	Numeric	F2.1
electrocardiogram	Electrocardiogram	Image	
echocardiogram	Table showing the patient's echocardiography results, report and images	Text, image	

### 3.1.4 Patient information:

This page summarizes the patient sociodemographic data, the diagnosis and the type of device and electrodes implanted. The following table explains the patient and device data.

PATIENT INFORMATION				
PARAMETER	EXPLANATION	TYPE OF VARIABLE	FORMAT	VALIDATION
Date of birth		Date	DD-MM-YYYY	>01-01-1900 and <interrogation date
Diagnosis	Main diagnosis of the patient	Text		
NYHA functional class at implant	Functional class according to the New York Heart Association Classification (I -IV) at implant	Categoric	Ordinal	I, II, III or IV
EF	Ejection fraction	Numeric	F2.0	>8 and <95
Date of EF	Date of EF shown	Date	DD-MM-YYYY	
DEVICE PARAMETERS				
Date of implantation		Date	DD-MM-YYYY	> Date of birth
Date of battery exchange		Date	DD-MM-YYYY	> Date of implantation
Type of device	PM / ICD / CRT-P / CRT-D	Categoric	Nominal	
CIED manufacturer	Medtronic / SJM	Categoric	Nominal	
Model	for types - ASK Medtronic & SJM	Categoric	Nominal	
CIED serial number		Numeric	ASK Medtronic & SJM	
RA lead model	Right atrial lead model	Categoric	Nominal	

PATIENT INFORMATION				
PARAMETER	EXPLANATION	TYPE OF VARIABLE	FORMAT	VALIDATION
RA lead serial number	Right atrial lead serial number	Numeric		
RA lead impedance at implant	Impedance of the atrial lead at implant	Numeric	F4.0	
RA lead P wave amplitude at implant	Amplitude of the atrial lead signal at implant	Numeric	F2.1	<15.0 and >0.1
RA lead pacing threshold at implant	Pacing threshold of the atrial lead at implant	Numeric	F2.1	<5.0
RV lead model	Right ventricular lead model	Categoric	Nominal	
RV lead serial number	Right ventricular lead serial number	Numeric		
RV lead defibrillation impedance at implant	Defibrillation impedance of the right ventricular lead at implant	Numeric	F2.0	
RV lead pacing impedance at implant	Pacing impedance of the right ventricular lead at implant	Numeric	F4.0	
RV lead R wave amplitude at implant	Amplitude of the right ventricular lead signal at implant	Numeric	F2.1	<15.0 and >0.1
RV lead pacing threshold at implant	Pacing threshold of the right ventricular lead at implant	Numeric	F2.1	<5.0
LV lead model	Left ventricular lead model	Categoric	Nominal	
LV lead serial number	Left ventricular lead serial number	Numeric		
LV lead pacing impedance at implant	Pacing impedance of the left ventricular lead at implant	Numeric	F4.0	

PATIENT INFORMATION				
PARAMETER	EXPLANATION	TYPE OF VARIABLE	FORMAT	VALIDATION
LV lead R wave amplitude at implant	Amplitude of the left ventricular lead signal at implant	Numeric	F2.1	<15.0 and >0.1
LV lead pacing threshold at implant	Pacing threshold of the left ventricular lead at implant	Numeric	F2.1	<5.0

### 3.1.5 Programmed parameters:

This page allows to the medical care personal check the device function and programmed the CIED in the best way for the safety and comfort for the patient.

PROGRAMMED PARAMETERS				
PARAMETER	EXPLANATION	TYPE OF VARIABLE FORMAT		VALIDATION
<b>Bradycardia parameters</b>				
Pacing mode	DDD / DDDR / VVI / VVIR / AAI / AAIR / VDD	Categorical	Nominal	
LRL	Lower rate limit	Numeric	F2.0	LRL < ULR; LRL >35
URL	Upper rate limit	Numeric	F3.0	LRL < ULR; URL >95
MSR	Maximal rate of the sensor	Numeric	F3.0	MSR ≥ URL
AV sensed	AV interval sensed	Numeric	F3.0	60 - 350
AV paced	AV interval paced	Numeric	F3.0	60 - 350
VP mode	RV only / LV only / Biventricular	Categorical	Nominal	
VV	VV interval	Numeric	F3.0	
<b>Tachycardia parameters</b>				
Number of zones programmed	1, 2 or 3	Categorical	Ordinal	
VT1 limit	Rate at what VT1 zone is considered	Numeric	F3.0	VT1 limit < VT2 limit
VT2 limit	Rate at what VT2 zone is considered	Numeric	F3.0	VT2 limit < VF limit
VF limit	Rate at what VF zone is considered	Numeric	F3.0	VF limit > VT1 or VT2 limit

PROGRAMMED PARAMETERS			
PARAMETER	EXPLANATION	TYPE OF VARIABLE FORMAT	VALIDATION
VT1 therapy	VT1 therapy programmed		
VT2 therapy	VT2 therapy programmed		
VF therapy	VF therapy programmed		

## 4 Implementation of Patient Parameter Monitoring

### 4.1 ARCHITECTURAL DESIGN OF THE PATIENT PARAMETER MONITOR

As shown in Figure 2 the Patient Parameter Monitor consists as three components. The graphical user interface and control is grouped at the PatientParameterMonitorSubSystem. The PatientParameterMonitorSubSystem retrieves data from two other subsystems namely PPM Data Exposure Service and the Patient Parameter Monitor Data Base Service.

1. The PatientParameterMonitorSubSystem that encapsulates the visible Patient Parameter Monitor functionalities has following tasks:
  - a. Obtain the electronically available EHR, PHR and CIED Data of iCARDEA patients for presentation to an authorised healthcare actor
  - b. Enable the healthcare actor to choose from different visualisation templates
  - c. Make potential data conflicts visible to the healthcare actor
2. The PPM Data Exposure Service is designed to obtain the data of a patient from the EHR, PHR and CIED sources that are available to the healthcare actor. It provides a list of the available patients, retrieves in which sources data about these patients are available and on request provides the data about the patient. The PPM Data Exposure Service therefore is designed to access all available data sources including Care Management DB hosted by iCARDEA Care Planner. Which data from what source will be accessed has to be decided by the medical domain experts and can partly configured in PPM.
3. The data sources that are considered are as follows:
  - a. Care management DB to retrieve structured patient data and registered healthcare actors using the Care Management DB Interface
  - b. EHR Data using the EHR Interoperability Framework to obtain IHE-CM messages for a specific patient
  - c. CIED Data using the CIED Data Exposure Service Interface to obtain the IHE IDCO messages including PDF-Documents
  - d. PHR Data using the provided PHR Interoperability System to obtain IHE-CM messages for a specific patient
4. The PPM Database Service provides functions to store Patient Parameter Monitor specific data like visualisation templates persistently into a database and make them available for later use.

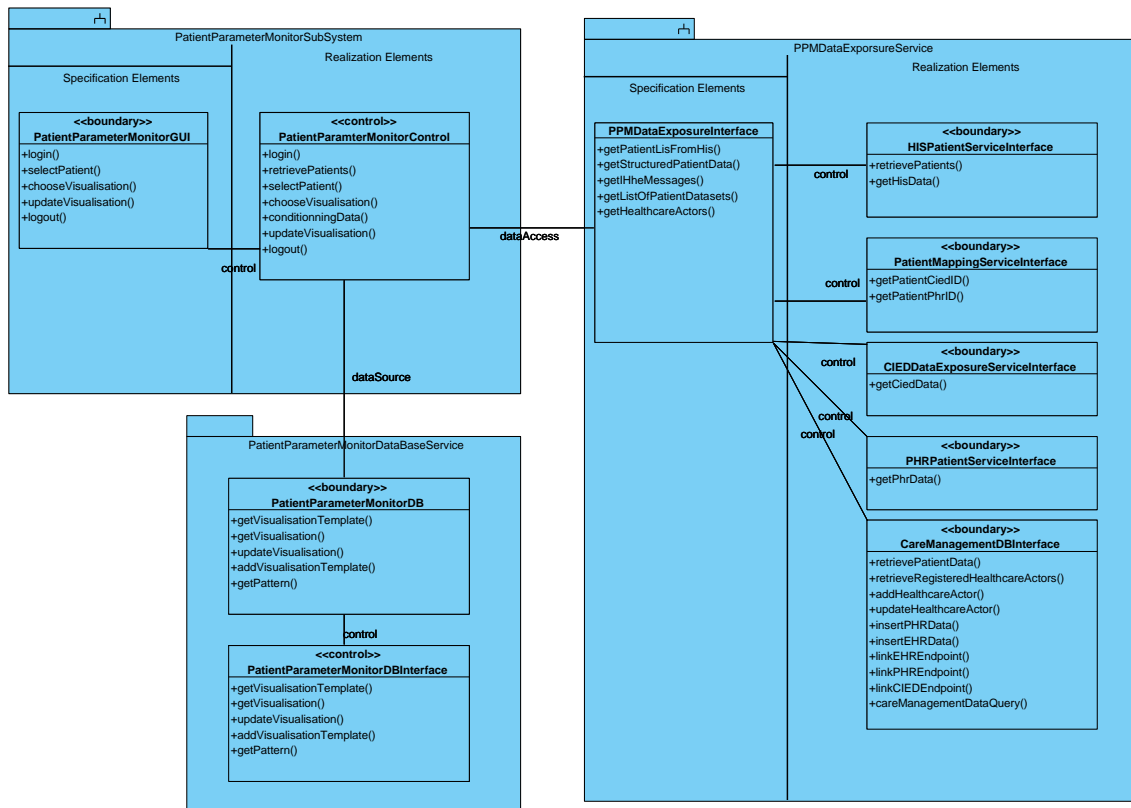


Figure 2 Subsystem and Packages identified for the Patient Parameter Monitor

4.1.1.1 Interactions between Design Objects

The interaction diagram for the Patient Parameter Monitor is shown in Figure 3. In this use case the Patient Parameter Monitor asks all potential data sources about available patients for the health care actor and provides the data in dependency of the chosen visualization template.

The interaction is as follows:

First the healthcare actor is asked from the front end to enter his login data. The login is checked by the *Patient Parameter Monitor Control*. Therefore it obtains the registered healthcare actors from the *PPM Data Exposures Interface*, which retrieves the data from the *Care management DB*. If the Login fails, no data is provided to the use. Otherwise the *Patient Parameter Monitor Control* request a list of all available patients with electronically available records for the healthcare actor from the *PPM Data Exposure Service*. This information should be retrieved from the *HIS Patient Service Interface*. It is possible that this information is also or exclusively stored at the *Care Management DB*. In that case the information will be requested from the *Care Management DB Interface*.

The available Patients will be presented to the logged in healthcare actor to choose one of the patients by the *Patient Parameter Monitor GUI*. After the healthcare actor has chosen one specific patient, the *PPM Data Exposures Interface* will create a list of all available records of the patient by queering the four available data sources:

1. The *HIS Patient Service Interface* to retrieve EHR related data. It is possible to retrieve to the data as IHE-CM messages.
2. The *CIED Data Exposure Service Interface* to retrieve patient records obtained from the CIED-Data centre or programmer via IHE IDCO messages.
3. The *PHR Patient Service Interface* to retrieve PHR related data. It is possible to retrieve to the data as IHE-CM messages.

4. The *Care Management DB Interface* to retrieve iCARDEA specific patient data and potentially structured data form the EHR, PHR and CIED that isn't available at the other data sources. It is possible to retrieve to the data as database result sets.

After all patient records including there Meta information like creation date and time is collected, the *Patient Parameter Monitor Control* accesses the *Patient Parameter Monitor DB* to receive predefined visualization templates. The templates hold information, which parameters from what type of source (CIED, EHR, PHR) should be presented in what way.

After all this data is collected, the *Patient Parameter Monitor GUI* presents a start screen to the healthcare actor with a summary of the available patient records together with a time stamp and brief information about the patient. It is thought to present the chosen contradictory parameters at this point.

The healthcare actor now can click the shown patient's records. Depending on the chosen visualization template the data will be prepared.

After exploring the patient data the healthcare actor can log off. The Figure 3 shows an optional update of the visualisation. This can be an assignment of the chosen visualisation template to the selected patient so that the next time the healthcare actors chose the patient the visualisation will be preselected.

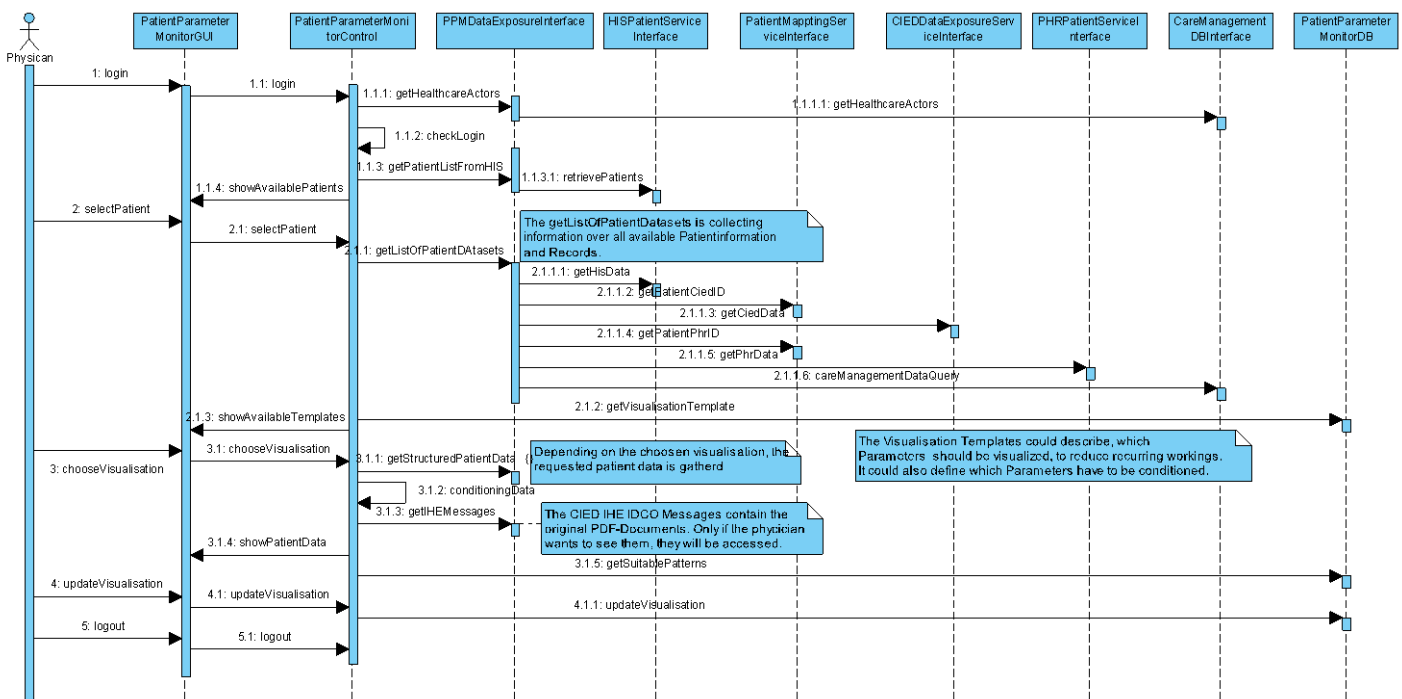


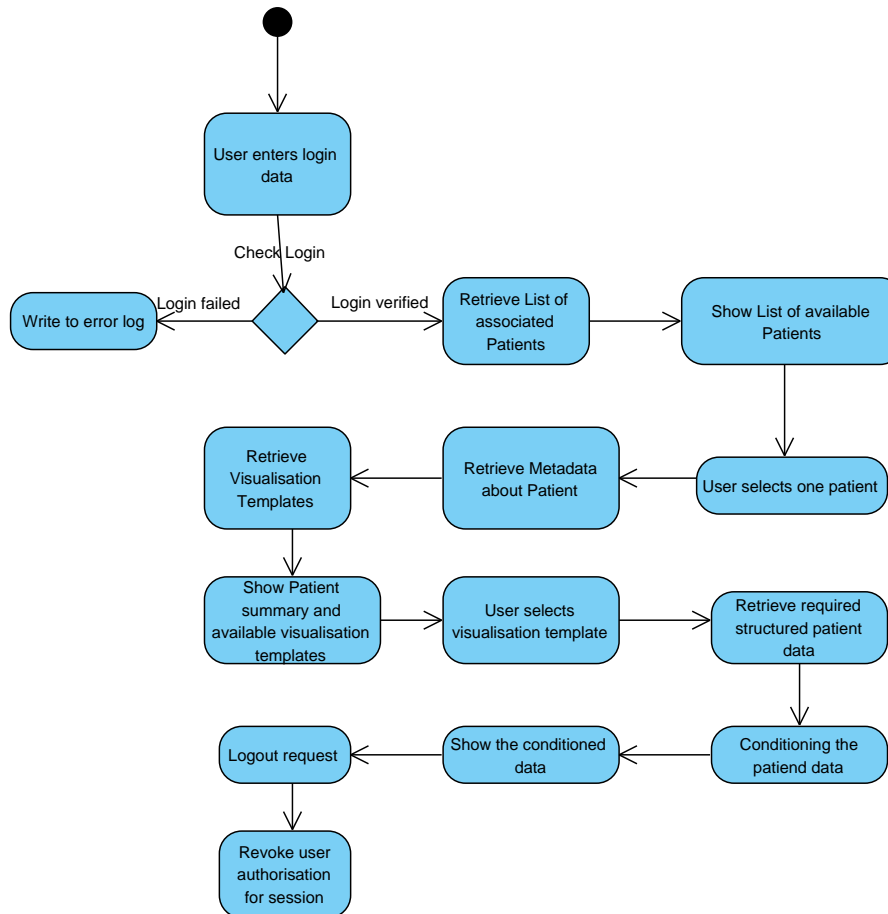
Figure 3 Interaction diagram showing the retrieval of Patient Data for Presentation

#### 4.1.1.2 Design of the Patient Parameter Monitor function block

The following subsections describes the function blocks that are used to visualize the patient data obtained from EHR, PHR, CIED and Care management DB using the Patient Parameter Monitor.

#### 4.1.1.3 The Patient Parameter Monitor component

The Patient Parameter Monitor consists of the two classes *Patient Parameter Monitor GUI* and *Patient Parameter Monitor Control* as shown in Figure 2 . The state chart for the common use case of the tool is shown in Figure 4.



**Figure 4 State Chart for the Patient Parameter Monitor for User interaction**

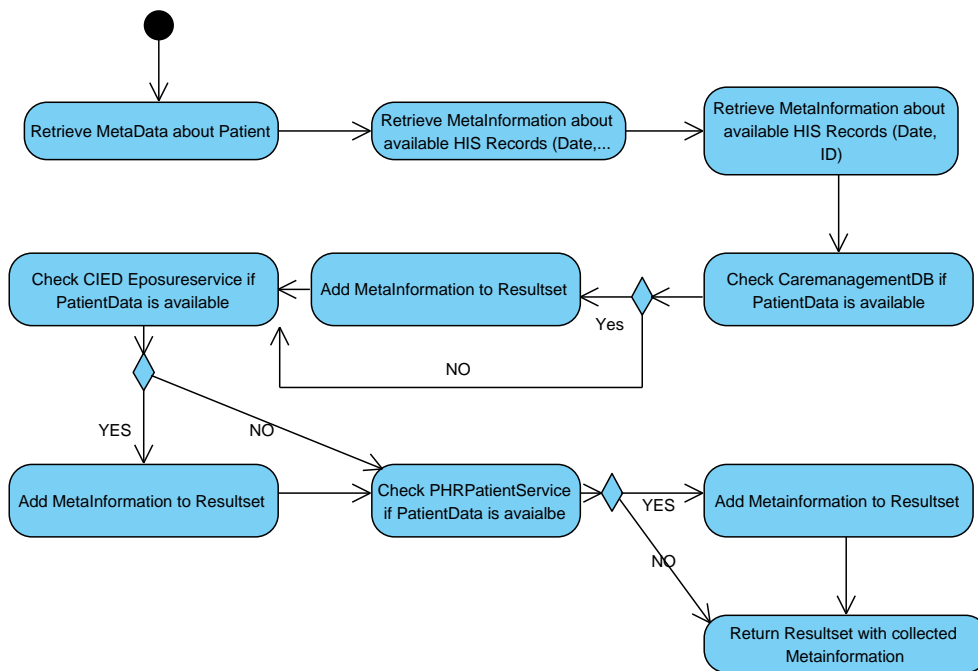
1. The user enters his Login-Information at the *Patient Parameter Monitor GUI* and sends a login request
2. The login request is checked by the *Patient Parameter Monitor Control*. If the login could not be verified, an entry to a error log is written together with information about the failed login for security and legal reasons
3. If the login is verified, a list of all patients who is associated to the healthcare actor is retrieved from the *Patient Parameter Monitor Data Exposure Service*
4. The Patient list is presented to the healthcare actor by the *Patient Parameter Monitor GUI*
5. The healthcare actor chooses one patient using *Patient Parameter Monitor GUI*
6. The *Patient Parameter Monitor Control* request from *Patient Parameter Monitor Data Exposure Service* a list of Metadata (List of available records with timestamps) about the selected Patient
7. The *Patient Parameter Monitor Control* also request visualisation templates from the *Patient Parameter Monitor DB Interface*
8. The *Patient Parameter Monitor GUI* presents the available records together with the available visualisation templates to the healthcare actor. If a visualisation template was previously stored to the patient this will be preselected
9. The User selects one visualisation template at the *Patient Parameter Monitor GUI*

10. The *Patient Parameter Monitor Control* will trigger the *Patient Parameter Monitor Data Exposure Service* for the requested data
11. After the Data is provided by the *Patient Parameter Monitor Data Exposure Service* the *Patient Parameter Monitor Control* will conditioning the data as required by the visualisation template
12. *Patient Parameter Monitor GUI* shows the patient data to the healthcare actor
13. The healthcare user sends a Logout request using the *Patient Parameter Monitor GUI*.
14. The *Patient Parameter Monitor Control* revokes all authorisation for this session and removes all cached patient data

**4.1.1.4 The PPM Data Exposure component**

The *PPM Data Exposure* consists of the class *PPM Data Exposure Interface* which uses the classes *HIS Patient Service Interface*, (*PatientMappingServiceInterface*, only required if the CIED-Exposure Service doesn't provide HIS-PatientID), *CIED Data Exposure Service Interfac*, *PHR Patient Service Interface* and *CareManagementDBInterface* as shown in Figure 2. The main operations are providing Metadata or data about patients from the EHR, PHR, CIED and CaremanagementDB sources. Figure 5 shows the retrieving of Metainformation for a patient and Figure 6 shows retrieving data from patient records.

**Retrieving Metainformation about a patient**

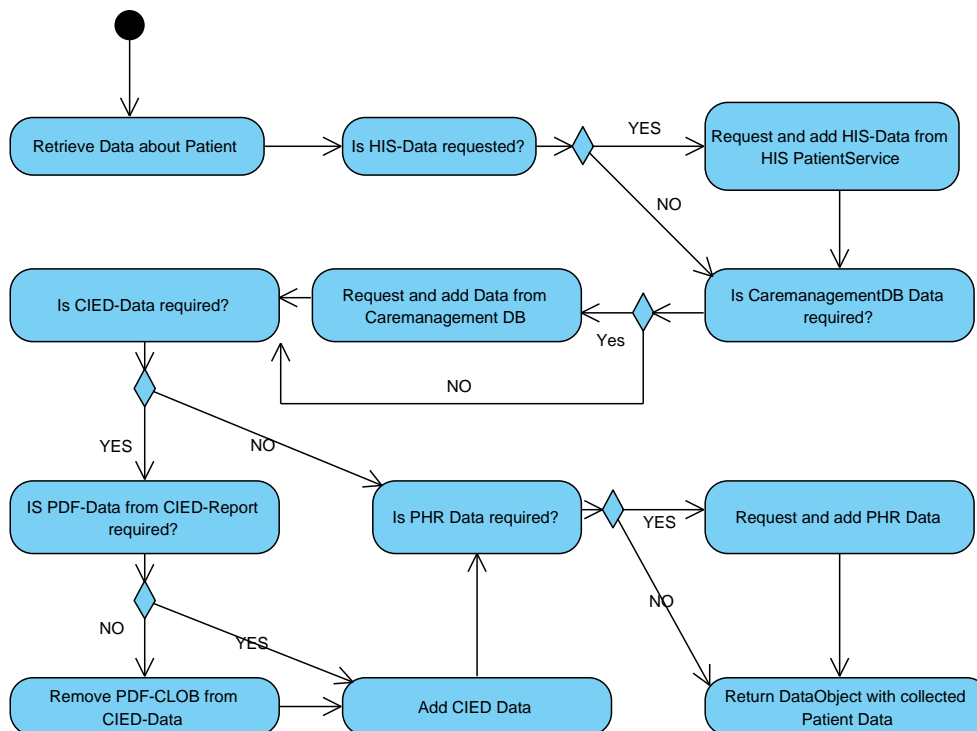


**Figure 5 Patient Parameter Monitor Data Exposure retrieving Metainformation**

1. First the *PPMDataExposureInterface* receives a request to retrieve Metainformation for a PatientID
2. The *PPMDataExposureInterface* access the *HISPatientServiceInterface* and sends a request for the available patient's record and expects the recordID and timestamp as result. All patients must have an entry at the HIS, otherwise a fatal error occurs
3. Then the *CareManagementDBInterface* is triggered for information about the patient.
4. If there is information for the PatientID it is added to the Metainformation.

5. Then the *CIEDDataExposureServiceInterface* is interrogated for the patientID. If the *CIEDDataExposureServiceInterface* doesn't support patientID the *PatientMappingServiceInterface* is used to obtain the needed IDs.
6. The obtained information is added to the Metainformation
7. At last the *PHRPatientServiceInterface* is accessed for information about the patientID and available information added to the Metainformation.
8. Finally the collected Metainformation consisting of a list of available records together with their timestamps is returned by the *PPMDataExposureInterface*

### Retrieving Data about a patient



**Figure 6 Patient Parameter Monitor Data Exposure retrieving Patientdata**

1. First the *PPMDataExposureInterface* receives a request to retrieve medical records for a PatientID together with a specification of the required data.
2. If HIS Data is required, the *PPMDataExposureInterface* access the *HISPatientServiceInterface* and sends a request for the patient recordID and expects IHE CM Message as a result that will be added to the DataObject storing the patient data
3. Then the *CareManagementDBInterface* is triggered for information about the patient if such data is requested. This data is expected to be a resultset to a SQL-Query.
4. If CIED Data is requested the *CIEDDataExposureServiceInterface* is interrogated for the recordIDs and expected to provide IHE IDCO Messages.
5. If only structured data is required, the PDF-Documents will be removed from the CIED-Data messages
6. At last the *PHRPatientServiceInterface* is accessed for data of the patient.
7. Finally the requested data is provided as a DataObject.

## 4.2 DATA EXTRACTION THROUGH STANDARD INTERFACES

The sharing of updated reports and parameter assessment, as offered by the data servers and networks connections implemented by many vendors, is helpful for healthcare providers to gain a better understanding of the progress in rehabilitation and the overall effects of medical treatment. Furthermore, emergency alarms and potential problems can be reported and addressed immediately.

Due to heterogeneous data and communication standards in various eHealth systems, many aspects should be taken into consideration, such as consistent nomenclature, data access, data transmission, data formats and storage. The following presented standards and profile aspects play an essential role in integration of CIED data.

In the iCARDEA project, CIED Information Integration System employs standards specifications from ISO/IEEE 11073 (Health Informatics, Point-of-care Medical Device Communication) and HL7v2.x in the context of Integrating the Healthcare Enterprise (IHE) profiles (in particular, IHE IDCO Profile) to deliver telemonitoring report data sources to the patient parameter monitoring database. During the implementation of Patient Parameter Assessment Tool, we realized that the parameters identified by IDCO profile from the ISO/IEEE 11073 nomenclature are not adequate to represent all of the data requested to be visualized by medical professionals. For this reason, we needed to do some extensions to the parameter list. In the following sections, a brief information about ISO/IEEE 11073 nomenclature, and IHE IDCO profile will be presented, then our proposed extensions will be listed.

### 4.2.1.1 ISO/IEEE 11073 Nomenclature

Standardization begins with the vocabulary used for describing the concepts referred. Many concepts may all mean one and the same observation, but are often labeled differently by different manufacturers. The ISO/IEEE 11073 nomenclature concerns all aspects of cardiac rhythm disease management measurement devices, aggregators, electronic patient records, electronic health records, etc [1]. The nomenclature was especially developed for remote monitoring [2]. It enables communication between medical, health care and wellness devices and with external computer systems. This increasingly harmonized nomenclature facilitates automatic and detailed electronic data capture of client-related and vital signs information [3], and of device operational data from the ISO/IEEE 11073 domain such as 11073-10102 for annotated ECGs, 11073-10103 for implantable cardiac devices, etc.

#### ***Current IDCO Complaint Parameters:***

PARAMETER	Reference ID
Date of implantation	720901^MDC_IDC_PG_IMPLANT_DT^MDC
Type of device	720897^MDC_IDC_PG_TYPE^MDC
CIED manufacturer	720900^MDC_IDC_PG_MFG^MDC
Model	720898^MDC_IDC_PG_MODEL^MDC
Battery Voltage	721344^MDC_IDC_MSMT_BATTERY_VOLTAGE^MDC
Battery Impedance	721408^MDC_IDC_MSMT_BATTERY_IMPEDANCE^MDC
Charge time	721728^MDC_IDC_MSMT_CAP_CHARGE_TIME^MDC
Date of last capacitor charge	721664^MDC_IDC_MSMT_CAP_CHARGE_DTM^MDC
RA lead impedance	722432^MDC_IDC_MSMT_LEADCHNL_RA_IMPEDANCE_VALUE^MDC

RA lead pacing	722176^MDC_IDC_MSMT_LEADCHNL_RA_PACING_THRESHOLD_AMPLITUDE^MDC
RV lead pacing impedance	722433^MDC_IDC_MSMT_LEADCHNL_RV_IMPEDANCE_VALUE^MDC
RV lead pacing threshold	722177^MDC_IDC_MSMT_LEADCHNL_RV_PACING_THRESHOLD_AMPLITUDE^MDC
LV lead pacing impedance	722435^MDC_IDC_MSMT_LEADCHNL_LV_IMPEDANCE_VALUE^MDC
LV lead pacing threshold	722179^MDC_IDC_MSMT_LEADCHNL_LV_PACING_THRESHOLD_AMPLITUDE
SVT	739568^MDC_IDC_EPISODE_TYPE^MDC (SVT)
AF / AT	739568^MDC_IDC_EPISODE_TYPE^MDC (AT/AF)
VT	739568^MDC_IDC_EPISODE_TYPE^MDC (VT)
Nr of episodes	737952^MDC_IDC_STAT_EPISODE_TYPE^MDC (AT/AF)
Date of episode	739552^MDC_IDC_EPISODE_DTM^MDC (AT/AF)
Time of episode	739552^MDC_IDC_EPISODE_DTM^MDC (AT/AF)
Duration of episode	739712^MDC_IDC_EPISODE_DURATION^MDC (AT/AF)
ATP	737888^MDC_IDC_STAT_TACHYTHERAPY_ATP_DELIVERED_RECENT^MDC
Shock	737824^MDC_IDC_STAT_TACHYTHERAPY_SHOCKS_DELIVERED_RECENT^MDC
Electrogram	18750-0^Cardiac Electrophysiology Report^LN
Nr of episodes	737952^MDC_IDC_STAT_EPISODE_TYPE^MDC (VT/VF)
Date of episode	739552^MDC_IDC_EPISODE_DTM^MDC (VT/VF)
Time of episode	739552^MDC_IDC_EPISODE_DTM^MDC (VT/VF)
Duration of episode	739712^MDC_IDC_EPISODE_DURATION^MDC (VT/VF)
ATP	737888^MDC_IDC_STAT_TACHYTHERAPY_ATP_DELIVERED_RECENT^MDC
Shock	737824^MDC_IDC_STAT_TACHYTHERAPY_SHOCKS_DELIVERED_RECENT^MDC
Electrogram	18750-0^Cardiac Electrophysiology Report^LN
Date of implantation	720901^MDC_IDC_PG_IMPLANT_DT^MDC
Type of device	720897^MDC_IDC_PG_TYPE^MDC
CIED manufacturer	720900^MDC_IDC_PG_MFG^MDC
Model	720898^MDC_IDC_PG_MODEL^MDC
CIED serial number	720899^MDC_IDC_PG_SERIAL^MDC
RA lead model	720961^MDC_IDC_LEAD_MODEL^MDC

RA lead serial number	720962^MDC_IDC_LEAD_SERIAL^MDC
RA lead impedance at implant	722432^MDC_IDC_MSMT_LEADCHNL_RA_IMPEDANCE_VALUE^MDC
RA lead pacing threshold at implant	at722176^MDC_IDC_MSMT_LEADCHNL_RA_PACING_THRESHOLD_AMPLITUDE^MDC
RV lead model	720961^MDC_IDC_LEAD_MODEL^MDC
RV lead serial number	720962^MDC_IDC_LEAD_SERIAL^MDC
RV lead pacing impedance at implant	722433^MDC_IDC_MSMT_LEADCHNL_RV_IMPEDANCE_VALUE^MDC
RV lead pacing threshold at implant	at722177^MDC_IDC_MSMT_LEADCHNL_RV_PACING_THRESHOLD_AMPLITUDE^MDC
LV lead model	720961^MDC_IDC_LEAD_MODEL^MDC
LV lead serial number	720962^MDC_IDC_LEAD_SERIAL^MDC
LV lead pacing impedance at implant	722435^MDC_IDC_MSMT_LEADCHNL_LV_IMPEDANCE_VALUE^MDC
LV lead pacing threshold at implant	at722179^MDC_IDC_MSMT_LEADCHNL_LV_PACING_THRESHOLD_AMPLITUDE^MDC
Pacing mode	730752^MDC_IDC_SET_BRADY_MODE^MDC
Maximal rate of the sensor	731200^MDC_IDC_SET_BRADY_MAX_SENSOR_RATE^MDC
AV sensed	731266^MDC_IDC_SET_BRADY_SAV_DELAY_LOW^MDC
AV paced	731330^MDC_IDC_SET_BRADY_PAV_DELAY_LOW^MDC
VT1 therapy	739680^MDC_IDC_EPISODE_DETECTION_THERAPY_DETAILS^MDC
VT2 therapy	739680^MDC_IDC_EPISODE_DETECTION_THERAPY_DETAILS^MDC
VF therapy	739680^MDC_IDC_EPISODE_DETECTION_THERAPY_DETAILS^MDC

#### 4.2.1.2 HL7v2.x Standard

As soon as terms (“words”) are found to describe medical findings, a standard for how to combine these words into “sentences” is needed. These aspects are covered by HIT (Healthcare Information Technology) messaging standards. Messages are sent in between all partners of cardiac rhythm disease management [2]. HL7v2.x is the most commonly used HIT messaging standard worldwide. It has the aim to support hospital workflows by enabling different systems to communicate with each another. Early HL7v2.x messages use a textual, non-XML based syntax based on delimiters. Since HL7v2.5, an equivalent XML format is also available.

#### 4.2.1.3 IHE Profiles

Integrating the Healthcare Enterprise (IHE) is an international voluntary collaboration of vendors, healthcare providers, regulatory agencies, and independent experts working on improving medical data interoperability in a number of subject areas (domains) [1]. The IHE domain concerned with electronic medical devices is the Patient Care Devices domain (PCD). As one of IHE PCD domain integration profiles, IDCO (Implantable

Device Cardiac Observation) has been defined for an intermediary system to send device data from an implantable device such as ICD to an enterprise system in HL7v2.x messages. The IHE PIX profile has been developed to enable correlation of patient identifiers from different sources, e.g. the hospital information system (HIS), the implant, or the personal health record system.

#### 4.2.1.4 ICARDEA Extensions to IHE IDCO Profile

Due to the fact, that the IDCO Standard is currently work in progress, we could not represent all currently needed patient parameters through IDCO complaint nomenclature. As a result of the iCARDEA work, we implemented and defined further parameters in an iCARDEA Nomenclature and we will discuss these extensions with the IHE IDCO community.

##### ***New defined Parameters:***

PARAMETER	Reference ID
Date of battery exchange	180101^ICARDEA_IDC_PG_BATTERY_EXCHANGE_DTM^ICARDEA
Magnet rate	180201^ICARDEA_IDC_MSMT_MAGNET_RATE^ICARDEA
RA lead P wave amplitude	180202^ICARDEA_IDC_MSMT_LEADCHNEL_RA_PWAVE_AMPLITUDE^ICARDEA
RV lead defibrillation impedance	180203^ICARDEA_IDC_MSMT_LEADCHNEL_RV_DEFIBRILLATION_IMPENDENCE^ICARDEA
RV lead R wave amplitude	180204^ICARDEA_IDC_MSMT_LEADCHNEL_RV_RWAVE_AMPLITUDE^ICARDEA
LV lead R wave amplitude	180205^ICARDEA_IDC_MSMT_LEADCHNEL_LV_RWAVE_AMPLITUDE^ICARDEA
Percentage of AS	180206^ICARDEA_IDC_MSMT_AS_PERCENT^ICARDEA
Percentage of AP	180207^ICARDEA_IDC_MSMT_AP_PERCENT^ICARDEA
Percentage of RVS	180208^ICARDEA_IDC_MSMT_RVS_PERCENT^ICARDEA
Percentage of RVP	180209^ICARDEA_IDC_MSMT_RVP_PERCENT^ICARDEA
Percentage of LVS	180210^ICARDEA_IDC_MSMT_LVS_PERCENT^ICARDEA
Percentage of LVP	180211^ICARDEA_IDC_MSMT_LVP_PERCENT^ICARDEA
PMT	180301^ICARDEA_IDC_EPISODE_PMT^ICARDEA
SVT treated	180302^ICARDEA_IDC_EPISODE_TREATED_SVT^ICARDEA
VT treated	180303^ICARDEA_IDC_EPISODE_TREATED_VT^ICARDEA
Safety alerts	180304^ICARDEA_IDC_EPISODE_SAFETY_ALERTS^ICARDEA
VT zone	180305^ICARDEA_IDC_EPISODE_VT_ZONE^ICARDEA
Cycle length	180306^ICARDEA_IDC_EPISODE_CYCLE_LENGTH^ICARDEA
Onset	180307^ICARDEA_IDC_EPISODE_ONSET^ICARDEA

Stability	180308^iCARDEA_IDC_EPISODE_STABILITY^iCARDEA
VA relationship	180309^iCARDEA_IDC_EPISODE_VA_RELATIONSHIP^iCARDEA
Morphology criteria	180310^iCARDEA_IDC_EPISODE_MORPHOLOGY_CRITERIA^iCARDEA
VT zone	180305^iCARDEA_IDC_EPISODE_VT_ZONE^iCARDEA
Cycle length	180306^iCARDEA_IDC_EPISODE_CYCLE_LENGTH^iCARDEA
Onset	180307^iCARDEA_IDC_EPISODE_ONSET^iCARDEA
Stability	180308^iCARDEA_IDC_EPISODE_STABILITY^iCARDEA
VA relationship	180309^iCARDEA_IDC_EPISODE_VA_RELATIONSHIP^iCARDEA
Morphology criteria	180310^iCARDEA_IDC_EPISODE_MORPHOLOGY_CRITERIA^iCARDEA
Date of battery exchange	180101^iCARDEA_IDC_PG_BATTERY_EXCHANGE_DTM^
RA lead P wave amplitude at implant	180202^iCARDEA_IDC_MSMT_LEADCHNEL_RA_PWAVE_AMPLITUDE^iCARDEA
RV lead defibrillation impedance at implant	180203^iCARDEA_IDC_MSMT_LEADCHNEL_RV_DEFIBRILLATION_IMPEDENCE^iCARDEA
RV lead R wave amplitude at implant	180204^iCARDEA_IDC_MSMT_LEADCHNEL_RV_RWAVE_AMPLITUDE^iCARDEA
LV lead R wave amplitude at implant	180205^iCARDEA_IDC_MSMT_LEADCHNEL_LV_RWAVE_AMPLITUDE^iCARDEA
Lower rate limit	180401^iCARDEA_IDC_SET_RATE_LIMIT_LOWER^iCARDEA
Upper rate limit	180402^iCARDEA_IDC_SET_RATE_LIMIT_UPPER^iCARDEA
VP mode	180403^iCARDEA_IDC_SET_VP_MODE^iCARDEA
VV	180404^iCARDEA_IDC_SET_VV^iCARDEA
Number of zones programmed	180405^iCARDEA_IDC_SET_ZONE_NUM^iCARDEA
VT1 limit	180406^iCARDEA_IDC_SET_LIMIT_VT1^iCARDEA
VT2 limit	180407^iCARDEA_IDC_SET_LIMIT_VT2^iCARDEA
VF limit	180408^iCARDEA_IDC_SET_LIMIT_VF^iCARDEA

### 4.3 PPM USER INTERFACES

PPM View

General Information

Patient: Mayr, Jane (04.08.1973)  
 Diagnosis: Sudden Cardiac Death  
 Implantation: 02.12.2008  
 ICD: Medtronic

Welcome Nurse Allan 30.09.2011  
 Choose View: Overview Logout DACT

PPM Main

Description	Current Values	Subitems
Name	Mayr, Jane	
ID	model:Maximo/serial:D284DRG	
Age	38	
Diagnosis	Sudden Cardiac Death	
Date of implantation	02.12.2008	
Type of device	ICD	
CIED manufacturer	Medtronic	
Model	Maximo	
Battery Voltage	3,2 V	
Battery Impedance	40 Ohm	
Magnet rate	100 bpm	
Charge time	9 s	
RA lead impedance	478 Ohm	
RA lead P wave amplitude	2,8 mV	
RA lead pacing	1,0 V / 0,4 ms	
RV lead defibrillation impedance	45 Ohm	
RV lead pacing impedance	543 Ohm	
RV lead R wave amplitude	15 mV	
RV lead pacing threshold	0,6V/0,4ms	
LV lead pacing impedance	544 Ohm	
LV lead R wave amplitude	15 mV	
LV lead pacing threshold	2,0V/0,4ms	
Percentage of AS	95%	
Percentage of AP	5%	
Percentage of RVS	1%	
Percentage of RVP	99%	
Percentage of LVS	1%	
Percentage of LVP	99%	
SVT	0	
AF / AT	0	

Figure 7 Overview including General Information

Description	Current Values	Subitems
Name	Mayr,Jane	
ID	model:Maximo/serial:D284DRG	
Age	38	
Diagnosis	Sudden Cardiac Death	
Date of implantation	02.12.2008	
Type of device	ICD	
CIED manufacturer	Medtronic	
Model	Maximo	
Battery Voltage	3,2 V	
Battery Impedance	40 Ohm	
Magnet rate	100 bpm	
Charge time	9 s	
RA lead impedance	478 Ohm	
RA lead P wave amplitude	2,8 mV	
RA lead pacing	1,0 V / 0,4 ms	
RV lead defibrillation impedance	45 Ohm	
RV lead pacing impedance	543 Ohm	
RV lead R wave amplitude	15 mV	
RV lead pacing threshold	0,6V/0,4ms	
LV lead pacing impedance	544 Ohm	
LV lead R wave amplitude	15 mV	
LV lead pacing threshold	2,0V/0,4ms	
Percentage of AS	95%	
Percentage of AP	5%	
Percentage of RVS	1%	
Percentage of RVP	99%	
Percentage of LVS	1%	
Percentage of LVP	99%	
SVT	0	
AF / AT	0	
VT	5	
PMT	0	
SVT treated	0	
VT treated	3	
Safety alerts	3	
NYHA functional class	ICD	
QOL score	35	
Hospital admissions	2	

Figure 8 Overview full screen.

PPM View

General Information

Patient: Mayr, Jane (04.08.1973)  
 Diagnosis: Sudden Cardiac Death  
 Implantation: 02.12.2008  
 ICD: Medtronic

Welcome Nurse Allan  
 Choose View: Overview  
 Logout  
 DACT

30.09.2011

PPM Main

Overview | VT/VF | AF/AT | PatInfo | ProPara

Description	Current Values	Subitems
Nr of episodes	3	
Date of episode	10.05.2011	
Time of episode	12:00	
Duration of episode	65 s	
VT zone	184 bpm	
Cycle length	325 ms	
Onset	9%	
Stability	40 ms	
VA relationship	V>A	
Morphology criteria	60%	
ATP	3	
Shock	1	
Diagnosis	Sudden Cardiac Death	
Symptoms	Feeling Well	Symptoms
Medications	Psychopax (Diazepam) 1 mg	Medications
Medication compliance	Concor taken 5 mg prescribed 7.5 mg	Compliance

Figure 9 VT Sheet information view

PPM View

PPM Main

Overview	VT/VF	AF/AT	PatInfo	ProPara	
Description				Current Values	Subitems
Date of birth				04.08.1973	
Diagnosis				Sudden Cardiac Death	
NYHA functional class at implant				II	
EF				Inductibilit of VT	
Date of EF				2.3.2008	
Date of implantation				02.12.2008	
Date of battery exchange				2 years	
Type of device				Implantable Cardioverter-Defibrillator	
CIED manufacturer				Medtronic	
Model				Maximo	
CIED serial number				D284DRG	
RA lead model				ISOFLEX 52	
RA lead serial number				SN PO88764	
RA lead impedance at implant				450 Ohm	
RA lead P wave amplitude at implant				3,2 mV	
RA lead pacing threshold at implant				0,8 V/ 0,4 ms	
RV lead model				ISOFLEX 58	
RV lead serial number				YU6544	
RV lead defibrillation impedance at implant				50 Ohm	
RV lead pacing impedance at implant				600 Ohm	
RV lead R wave amplitude at implant				18 mV	
RV lead pacing threshold at implant				0,5V/0,4ms	
LV lead model				LADE60	
LV lead serial number				TR888889	
LV lead pacing impedance at implant				650 Ohm	
LV lead R wave amplitude at implant				18 mV	
LV lead pacing threshold at implant				1,5V/0,4ms	
Doctor				Smith	
Doctor s contact details				00549326518	
Systolic blood pressure				--	SystolicBlood
Diastolic blood pressure				--	DiastolicBlood
Heart rate				--	HeartRate
Body weight				53 kg	BodyWeight
Medications				Psychopax (Diazepam) 1 mg	Medications
Symptoms				Feeling Well	Symptoms

Figure 10 Patient Information View

The screenshot shows a web browser window titled 'PPM Data View'. The address bar shows the URL 'http://127.0.0.1:10101/view?startup=de.offi'. The browser's menu bar includes 'Datei', 'Bearbeiten', 'Ansicht', 'Favoriten', and 'Extras'. The page content is organized into two main sections: 'PPM View' and 'PPM Main'.

**PPM View Section:**

- General Information:** Patient: Mayr, Jane (04.08.1973); Diagnosis: Sudden Cardiac Death; Implantation: 02.12.2008; ICD: Medtronic.
- User and Date:** Welcome Nurse Allan; Date: 30.09.2011.
- Actions:** Choose View: Overview (selected); Logout; DACT.

**PPM Main Section:**

Navigation tabs: Overview | VT/VF | AF/AT | PatInfo | **ProPara**

Description	Current Values	Subitems
Pacing mode	DDDR	
Lower rate limit	45 bpm	
Upper rate limit	130 bpm	
Maximal rate of the sensor	150 bpm	
AV sensed	100 ms	
AV paced	130 ms	
VP mode	RV+LV	
VV	30 ms	
Number of zones programmed	3	
VT1 limit	150 bpm	
VT2 limit	180 bpm	
VF limit	200 bpm	
VT1 therapy	Monitor zone	
VT2 therapy	ATP x3 + CV 36J/40J X2	
VF therapy	CV 40J x 6	

The browser's status bar at the bottom right shows a magnification level of 100%.

Figure 11 Programmed Parameter View

The screenshot shows a web browser window titled 'PPM Data View' with the URL 'http://127.0.0.1:10101/view?startup=de.offi'. The browser's menu bar includes 'Datei', 'Bearbeiten', 'Ansicht', 'Favoriten', and 'Extras'. The main content area is titled 'PPM View' and contains a sub-window 'PPM Main' with a tabbed interface. The 'Medications' tab is active, displaying a table with the following data:

From	Until	Description
10.10.1999	10.06.2011	Concor 7.5 mg
10.10.1980	10.06.2011	Convulex 300 mg
01.01.2009	10.06.2011	Ebetrexat(Methotrexate) 20 mg
01.01.2009	10.06.2011	Folsan(Folic Acid) 10 mg
10.10.1999	10.10.2010	Magnosolv(Magnesium) 1 mg
24.01.2011	10.06.2011	Nexium 40 mg
01.12.2008	24.01.2011	Pantoprazole (Pantoloc) 40 mg
01.12.2008	10.06.2011	Prednisone 5 mg
10.10.1999	10.10.2010	Psychopax (Diazepam) 1 mg

Figure 12 Medication Sub Item view

PPM View

General Information

Patient: Mayr, Jane (04.08.1973)  
 Diagnosis: Sudden Cardiac Death  
 Implantation: 02.12.2008  
 ICD: Medtronic

Welcome Nurse Allan 30.09.2011  
 Choose View: Logout  
 Overview DACT

PPM Main

From	Until	Description
15.06.2010	10.07.2010	Anxiety
15.06.2010	10.07.2010	Shortnes of Breath
20.08.2010	07.10.2010	Sick to Stomach
20.08.2010	07.10.2010	Unable to Eat
07.10.2010		Feeling Well

Figure 13 Symptoms Sub Item View

## 5 CONCLUSION

The healthcare professionals identified the need for a single tool to display all required parameters instead of accessing multiple different tools. This is achieved by analyzing patient data from CIEDs, Electronic Healthcare Records and Personal Health Records, such as history of illness, surgeries, medications, and then graphically presenting these data in an intelligent way by combining the fields from separate sources. Furthermore, predefined sets of values to be examined for the treatment of different complications were identified as useful and are presented in an optimized view. Several different visualization views have been implemented to present the selected patient parameters and interfaces to clinical data information sources are implemented in conformance to the selected iCARDEA standards to collect the parameters to be visualized.

## 6 REFERENCES

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