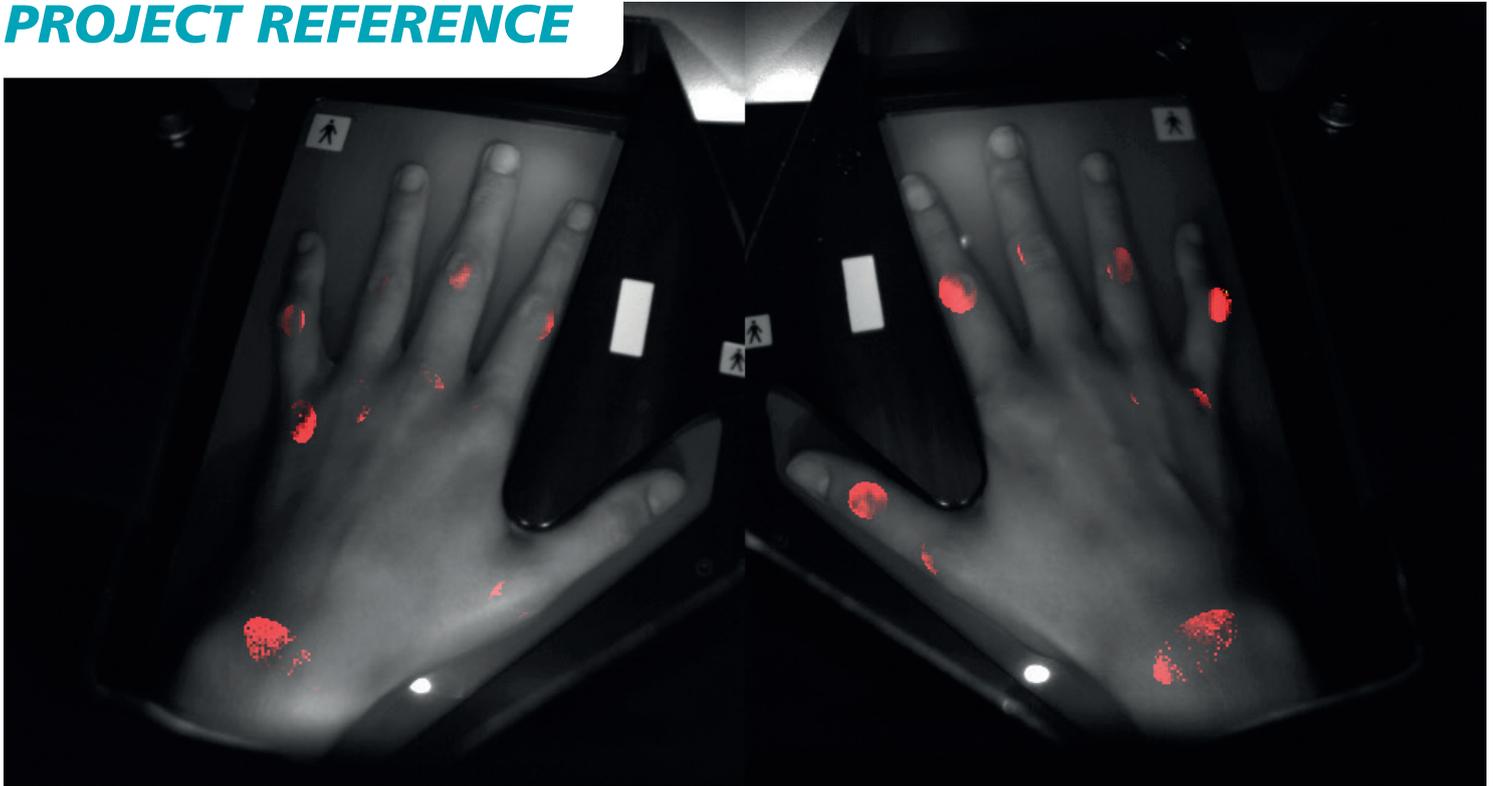


PROJECT REFERENCE



Hemics HandScan

A network module for connectivity

The HandScan is based on the patented Optical Inflammation Detection technology, a non-invasive, fast and objective method that supports rheumatologists in the quantification of inflammation, a key parameter in the treatment of patients with rheumatoid arthritis (RA). The HandScan incorporates both a DICOM and HL7 interface.

Inflammation of tissue is characterized by redness, swelling and increased temperature; symptoms which are all caused by vascular changes, including vasodilation (widening) and increased permeability (leakage) of blood vessels. An inflammation is easily recognized, but it's the level of inflammation that is difficult to quantify. The patented Optical Inflammation Detection technology of Hemics B.V. supports physicians in establishing the level of inflammation of RA patients by visualizing the hemodynamic response to an applied stimulus.

How it works

A pressure cuff around the lower arm is inflated for a short time to modify the blood flow in the hands. The venous

backflow is hindered whereas the arterial flow continues, resulting in the pooling of blood in the hands. Due to the vascular changes associated with inflammation, the speed and magnitude of blood pooling in inflamed and healthy tissue differ. To accomplish seamless integration with the existing hospital workflow, excellent HL7 / DICOM interoperability is essential for operating the HandScan. ICT has a great track record with similar solutions.

A Network module for connectivity

So Hemics asked ICT Healthcare to develop the Network module, which will take care of the HandScan connectivity within the hospital. It needs to be embedded in the application software using a dedicated software interface. The Network module supports the following forms of connectivity:

- HL7 query (to be able to receive patient information from a Hospital Information System)
- DICOM Verification (to be able to verify the DICOM connection)
- DICOM file storage (to be able to view the measurements in a DICOM viewer)

- DICOM Modality Worklist (IHE based, to be able to receive the scheduled work items)
- DICOM Storage (IHE based, to be able to store the measurements to PACS)

Role of ICT Healthcare

ICT Healthcare was responsible for the complete HL7 / DICOM connectivity. The project started with an initial consultancy to investigate possible forms of connectivity within the hospital, specific for the HandScan.

As the HandScan is a medical device, the Network module needs to comply to the IEC 62304 standard. This resulted in the following tasks:

- map customer user requirements into specific software HL7 / DICOM / IHE requirements
- as part of the architecture, agree on a common software interface
- use these requirements as input for the design and C# coding, making use of a lower level DICOM library: an advice by ICT Healthcare
- create test cases for the requirements, some of them must use the DICOM Validation Toolkit (see www.dvtk.org). ICT Healthcare is a main contributor
- take care of the traceability between requirements, design and test cases
- participate in FMEA sessions for the HandScan.

As the Network module implements a DICOM and HL7 interface for the HandScan, a system level DICOM Conformance Statement and HL7 Integration Statement were created. ICT Healthcare took care of translating hospital requirements into new software requirements, as well as analysing actual HL7 / DICOM communication taking place in the hospital.

Keywords

Windows Embedded 7, .Net, C#, DICOM, HL7, Mirth Connect, DicomObjects (native .Net DICOM library from Medical Connections), SVN, Requirements, Design, Testing, DICOM Conformance Statement, DVTK (DICOM Validation Toolkit), FMEA, Service, IEC 62304, ISO 13485.

PROJECT RESULT

The Network module is developed according to the HL7 and DICOM standards. Verification took place in one of Hemics' customer's hospitals. Seamless integration within the hospital workflow was realized to full satisfaction of Hemics. The software is developed according to IEC 62304. ICT Healthcare has supplied the Design History File for the Network module, enabling Hemics to obtain CE certification for the complete solution. Hemics and ICT Healthcare look back on a great collaboration. To guarantee further support for Hemics' customers, both parties have agreed a service contract to keep the solution up-to-date according to the latest regulations. ICT Healthcare is responsible for management and maintenance of the software.



About Hemics

Hemics is a medical device company active in the field of rheumatoid arthritis (RA). They aim to improve the quality of life of RA-patients by creating imaging devices that support rheumatologists in monitoring and treatment of this disease. Hemics started as a LabVenture within Philips Research. After the realization of a clinical prototype and a successful clinical trial, the venture raised sufficient money for a spin-out of Philips in September 2011.

www.hemics.com