Fraunhofer Institut
Integrierte Schaltungen

POCT1-A

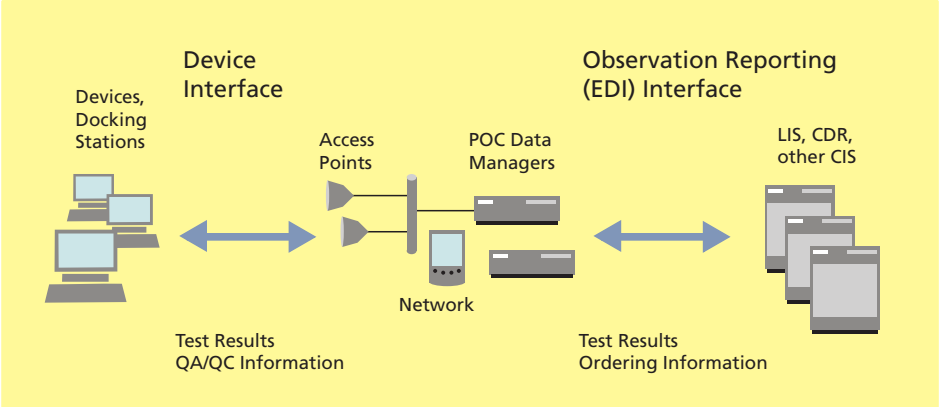

Figure 1: The connectivity system components

POCT1-A - a new standard for diagnostic device management

A new class of diagnostic devices has enabled advances in microfluidic and other miniaturization technologies. This new device class – Point-of-Care diagnostic – supports a wide diversity of diagnostic testing directly at the point of care. Tests that had been previously limited to the domain of central laboratory analyzers are now available in a variety of care settings. Sophisticated tests are possible at the hospital bedside, during patient encounters in primary- and secondary-care clinics, and even at home. This new Point-of-Care diagnostic device class offers the advantages of fast turnaround times for test results and quite possibly cost reduction for some types of tests.
In general, a diagnostic test is not differentiated on where the test is performed. Someone in the institution must be able to show that the test was performed in compliance with the policies of an overall diagnostic testing quality system for the institution. Hence it is compulsory for Point-of-Care diagnostic device vendors to offer mechanisms by which their devices may be integrated into an institution's diagnostic information management system. It is this requirement for integration that drives the need for standardization.
For the purposes of this specification, Point-of-Care testing defines all testing conducted at the site of patient care. This encompasses many different environments including hospital-based testing, near-patient testing, physician's-office testing, and patient self-testing. A Point-of-Care Connectivity specification must be applicable to all of these settings.

Our Technology

As shown in figure 1, the POCT1-A standard defines two interfaces: a "Device Interface" which governs the flow of information between Point-of-Care devices and "Observation Reviewers" (Point-of-Care Data Managers), and an "Observation Reporting (EDI) Interface" describing messaging between Observation Reviewers and an "Observation Recipient", typically a Laboratory Information System (LIS) or

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Clinical Data Repository (CDR). The Device Interface communication is done by exchanging short messages which are based on XML (extensible markup language). A fragment of such a so-called observation message is presented in figure 2, describing a measurement of hemoglobine. The values, ranges and units are coded as attributes of an observation which is sent to an observation reviewer. The Observation Reporting interface (figure 1 on the right) defines messages in the HL7 (Health Level 7) format to exchange the reviewed information with the hospital information system.

Benefit for the Producer

POCT1-A offers clear advantages for producers of medical devices such as:

- Shorter specification and development times
- Less coordination efforts among development sites (i.e. for data management systems)
- Easier product maintenance and support (life cycle management)
- Development cost savings (less specialized resources needed)
- Lower complexity: Easier trouble-shooting and technical support (interoperability of components)
- Reduced instrument implementation and installation cost (less customization of interfaces)

Benefit for the User

The user will benefit from POCT1-A as well:

- Reduced costs for interfacing: e.g. device to data manager or LIS
- Re-usable connectivity infrastructure and hardware (i.e. access points) in case of vendor change
- Faster implementation and installation (reduced need for specialists)
- Easier and faster trouble shooting and support (faster exchange of components - plug&play)
- Purchase decision based on functionality and innovation rather than connectivity

What We Offer

The Fraunhofer IIS offers a wide range of customized support for manufacturers of medical devices and information systems to provide and enhance connectivity and interoperability. Connectivity building blocks based on e.g. CEN/IEEE/ISO "VITAL" or NCCLS POCT-1 communication standards are available on a license agreement basis. Using our expertise in software development and integrated circuit design, we offer engineering and system integration services, implementation of customer applications in standard and embedded platforms as well as procedures and tools for compliance and interoperability testing.

```
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    <OBS.status_cd V="A"/>
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Figure 2: XML-observation message fragment