Fraunhofer Institut Biomedizinische Technik

SmartHEALTH

Smart Integrated Biodiagnostic Systems for Cancer Diagnosis and Recurrence Monitoring

EU FP6-2004-IST-NMP-2-016817

Fraunhofer-Institut Biomedizinische Technik

Prof. Dr. G. Fuhr
Ensheimer Straße 48
D-66386 St. Ingbert
Germany

Dept. Telemedicine/Telematics

http://www.ibmt.fraunhofer.de
http://www.topcare.info/

Contact

Dipl.-Inform. Stephan Kiefer
Phone +49 (0) 6894/980-156
Fax +49 (0) 6894/980-400
stephan.kiefer@ibmt.fraunhofer.de

In Germany over 400 000 people fall ill with cancer every year, approx. 360 000 of them for the first time. Although today many patients are cured permanently, about 42% of the affected women and 54% of the male patients do not survive the next five years. Hence, it is of utmost importance to detect tumors as early as possible with screening procedures to increase the chance of a permanent cure, or to reduce and control tumor growth by suitable long-term therapies in not completely curable cases, in order to maintain a patient's lifetime and quality of life. Long-term therapy of chronic cancers requires close and individualized monitoring, if possible outside a hospital. Likewise, successful early diagnosis needs reliable and powerful biodiagnostic systems at the socalled point of care. New molecular and protein-based cancer markers, progress in microsystems technology and nanobiotechnology linked with information and communication technologies create the basis for developing a new generation of intelligent, integrated, biodiagnostic systems for the diagnosis and monitoring of cancer diseases. These all fall within the framework of the EU-funded integrated Research & Development project SmartHEALTH (project number FP6-2004-IST-NMP-2-016817).

Task:
Prevention, early diagnosis, and targeted and effective therapies form the cornerstones of an efficient health system. Therefore, new diagnostic cancer tests have to deliver precise and reliable results for therapy decisions and be optimally integrated into the healthcare process to avoid unnecessary treatment and stress for the patients. SmartHEALTH addresses these challenges and is developing a new generation of intelligent, biodiagnostic systems that allow, or support and complement optimized disease management and screening programs in health services.

Driven by three key applications in cancer diagnosis (breast, intestinal and cervical cancers) the project is developing intelligent, linked, prototypical diagnosis systems for multi-parametric cancer marker analysis for the point of care.

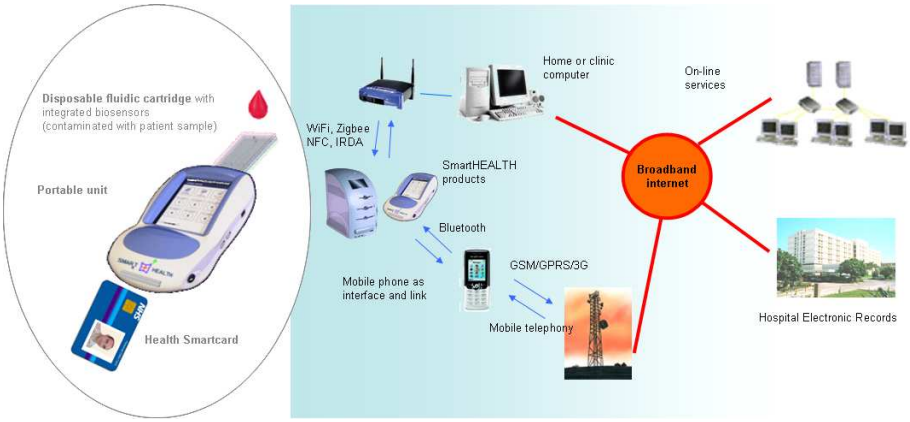
The objectives of SmartHEALTH include:

- Implementation of new sensor systems for biomarker analysis integrated into future healthcare services to improve current healthcare concepts.
- Clinical validation of the systems for target applications (breast, intestinal and cervical cancers).
- Demonstrating the usefulness of "ambient intelligence" technologies in medical diagnostic systems and coupled online services for "pervasive" healthcare.
- Development of new production technologies to achieve uniform sensor solutions that integrate microfluid components, transducers and biological assays.

Solution:
Driven by clinical oncological applications, micro- and nanobiotechnology and information and communication technologies, the Integrated Project SmartHEALTH is developing an open, integrated system platform for novel biodiagnostic devices to support the industry in exploiting bioassays and new application concepts for cancer diagnosis. The initial system comprises a disposable microfluidics chip. The chip is loaded with the biosample and connected to a desktop reader device, which integrates dynamically into the surrounding e-health infrastructure and allows wireless communication with other instruments. Subsequently, this system concept will be cost-optimized and miniaturized, eventually leading to various portable and easily accessible products. The system plat-

form will allow simultaneous measurements and analyses of several analytes based on nucleic acids and proteins and can process different types of biological samples. The results will be interpreted using artificial neural networks and further analysis tools. The adaptive systems will know their user, the patient and the current context. Based on medical standards they will maintain wireless communication with patient records at the respective laboratory, hospital or online information system, strictly complying with data protection regulations. In addition, they will support public key infrastructures.

The project was initiated in December 2005 with 25 European R&D partners and promises to improve medical cancer diagnosis by earlier and more precise cancer marker analysis. This will improve the quality of life of the patients and strengthen the competitiveness of the European industry in the area of in vitro diagnostics. The tasks for the IBMT include the integration of microfluidics and sensor components (workgroup Miniaturized Systems), and particularly pioneering the development of software that integrates the system with technologies such as "Ambient Intelligence", "Ubiquitous Computing" and the "Semantic Web" with the goal of making biodiagnostic devices more intelligent so they can be easily integrated into the surrounding IT infrastructure.



Results of IBMT:

The IBMT department Telematics/Telemedicine has developed a promising software architecture, the so-called "**Semantic Medical Device Space (SMDS)**", to integrate system intelligence into biodiagnostic devices so that they adapt to changes in their environment, dynamically recognize and use offered services and/or supply services to their surroundings, and auto-adapt to communicate with existing medical information systems or other devices. The SMDS is a pervasive software concept that uses semantic web and web service technologies to equip medical devices with intelligence and communication abilities, allowing semantic interoperability with other information systems and devices.
To take into account data privacy issues and to consider adequate data safety measures in the SMDS concept, we performed a safety analysis according to the Common Criteria Standard, derived a socalled Protection Profile for intelligent biodiagnostic medical devices and incorporated this into the SMDS.

In an initial step, the SMDS concept will be integrated into the initial SmartHEALTH instrument and evaluated by users. For this, communication standards such as HL7 V2.3 and POCT1A will be implemented on the basis of web service technologies. In addition, the department is developing a SmartHEALTH information system that is meant to support the clinical validation of cancer markers and offers new online services for the interpretation of analysis results.

Potential:

The "Semantic Medical Device Space (SMDS)" concept is an exemplary model for the design of intelligent and interoperable medical diagnostic devices. Reusable software components will allow the transfer to, and adaptation of medical devices of the medical technology industry. The first demonstration setups are expected to be completed in 2008. Further applications of the SMDS middleware are:

- Medical device interoperability with health information systems.
- Medical device communication in operating theatres.
- Asset management in hospitals.
- Ambient assisted living and smart homes.