Remote Access: A Vision for Mobile Medical Devices

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***Abstract*—During the Symposium for Remote Engineering and Virtual Instrumentation held at Brasov in early July 2005 an outlook was presented regarding the future potential of remote engineering for mobile medical devices. It is the intention of this article to recapitulate the content of the initiated discussions and to stimulate work in this complex and until now largely neglected field of application.**

***Index Terms*—Remote sensing, Remote handling, Medical Devices, Diagnostics, Therapeutics**

I. Introduction

Medical device technology deals with a vast range of applications covering diagnostics and therapeutics. The term diagnostics encompasses applications that have to do with the detection of medically relevant parameters – anything from blood pressure down to full blood parameters. Therapeutics on the other hand describes all forms of treatment measures - covering anything from physical training down to the application of drugs.

As can easily be understood diagnostics and therapeutics are closely linked to each other, a suggested therapy being the conclusion of a corresponding diagnosis. The linkage between the two is largely controlled by physicians. The delay between measurement and therapy is indicative for the quality- and often also for the outcome of a treatment. Hence it is necessary to minimize delays by bringing diagnostics and therapeutics as close to each other as possible. Optimally diagnostic and therapeutic devices are interlinked directly at a patient for the entire duration of a treatment. In some cases the latter can cover a whole lifetime. Such an approach requires that the associated devices are fully mobile to allow the patient to live as normal a life as possible.

Going a step further - looking into the future potential of remote engineering - diagnostic and therapeutic devices should be linked to each other in a closed loop system and at the same time allow external monitoring and manipulation of their performance, e.g. by physicians or device technicians. Obviously the latter would be located at a certain distance to the patient for the majority of the treatment. Both, the physician and the technician, will be responsible to determine the effect of the therapy and to suggest potential changes. Optimally this could be done purely via remote control.

The advantage of such a constellation lies in the patient comfort and – even more importantly - in the continuous process of monitoring patient and device, which strongly facilitates both a technical and a medical learning process. Last but not least such an approach does allow a reduction of health care related costs by improving the efficiency of treatments and limiting the patient visits to the physician's office or hospital to a minimum. A disease may thus become "remotely controllable", or at least "remotely monitorable".

What of the above is actually technically possible today? The available technical subsystems are manifold and are able to fulfill the majority of the individual requirements. The actual problem of the approach lies in the complexity of the required system integration and control mechanisms. This requires highly interdisciplinary approaches. In turn this demands development efforts that initially should be driven by the most relevant medical topics. Probably one of the most relevant diseases is diabetes, so let us take this as an example.

II. Case study - Diabetes

Generally speaking diabetes is a disease related to the failure of the blood sugar (glucose) level control mechanism, thus endangering the body's control over its primary energy supply. The applicable therapy used to manually maintain a stable blood sugar level requires a repeated measurement of the sugar level and appropriate measures to adapt the sugar level, either by uptake of sugar or through sugar binding by uptake of a hormone called insulin.

Figure 1: Handheld, teststrip based blood sugar meters, left: Glucometer from Bayer AG, right: Accu-Chek from Roche AG

The most common mode of measurement of the sugar level uses a test-strip onto which a drop of fresh blood is applied, typically taken from the patient's finger tip. The test strip is then inserted into a handheld analyzer unit as shown in Figure 1 which - either optically or electro-chemically - reads the test strip and outputs the sugar concentration to the user via a display. Typically in between 2 to 5 tests are done per day. Some of the more complex systems store the read value together with the time of the measurement and later allow the consulting physician to download a set of data from the device. The latter requires the patient to physically visit the physician and hand over the device.

A more advanced mode of measurement allows continuous monitoring of the body sugar level. The associated sensors are implanted subcutaneously, i.e. positioned under the skin, where they remain for the duration of the measurement. The collected data is then stored in a handheld device as shown in Figure 2. Similar to the analyzers shown in Figure 1 the stored data can be downloaded from the device allowing an analysis of the patient's blood sugar level over time. For reliability reasons the continuous meter is not yet able to replace the test strip measurements. It is merely used as a supplementary measurement to establish a better understanding of the sugar gradients over time, making its data available only to the treating physician, but not to the patient. Hence this type of device seems most promising for use as a remote data monitoring functionality.

Figure 2: Continuous blood sugar meter CGMS System Gold sold by Medtronic Inc.

As mentioned above insulin is used to actively counteract high sugar levels. Most commonly insulin is delivered via injection under the skin (subcutaneous injection). Other routes of delivery such as oral or nasal delivery are also possible but as of yet less common. For the subcutaneous delivery semi automated, handheld pumps are available (see Figure 3). Being patient specifically programmable, these pumps are able to continuously deliver a base amount of insulin, typically few milliliters per day. Extra doses are delivered upon manual request by the patient, e.g. prior to uptake of food. The delivery rates are stored in the pump and are accessible via an electronic interface. The amount of insulin that a patient may require is determined by the patient. The patient is still required to monitor the own sugar level, typically using test strips, before manually entering a required insulin dose into the pump.

There in fact are manifold reasons why no closed loop systems are available on the market at this time. One of the prime issues is reliability and thus safety. Today science and medicine simply do not understand the connection between the human metabolism, the patient specific detection site, and required therapeutic algorithms well enough. One way to gain the required data is to monitor and analyze as many different cases as possible under conditions that are as realistic as possible. Optimally this process should also allow an online manipulation of the involved diagnostic and therapeutic parameters to help investigate the corresponding effects.

Figure 3: Insulin pump H-Tron from Dissetronic AG

For the given example the practical remote engineering approach could involve the following scenario: A series of patients carry the currently available mobile diagnostic and therapeutic devices - as is done today! In extension to the current practice the devices send information on their status as well as that of the patient to a central data processing center. At the center the data is analyzed and divided into clinically-, pharmaceutically- and mechanically relevant data. Patient specific information is forwarded to the practitioner while anonymized data is used for statistical evaluation and improvement of the general therapy and the involved equipment. Using this procedure a gradual patient specific integration of diagnosis and therapeutic equipment can be achieved, eventually leading to a closed loop system. At the same time the general understanding of correlations relating to the disease is improved. The continuous monitoring process guarantees an individual patient's safety during the procedure and allows remote interaction in the case of problems.

Remote engineering needs to provide the platform as well as the network to achieve the above mentioned. It needs to drive the process. The difficulty clearly is the interdisciplinary character involving pharmaceutical-, medical- and system- "engineering".

III. Conclusion

Far more diseases require and/or could greatly profit from remote engineering, respectively initially of remote monitoring, to learn more about physiological backgrounds, metabolisms and system characteristics.

Gathering data and deriving conclusions thereof is the approach that has allowed mankind to reach the technical level that we see today. For medicine this is even more the case than for most other disciplines. The problem that we encounter nowadays with gathering data is the level of complexity involved with getting to see what we would like to understand, such as in the exemplary case described above. This complexity is reaching levels that demand highly coordinated development efforts of different technologies and disciplines to further the system capabilities. Not alone with the technical advances in wireless communication, have the possibilities provided by remote engineering added to the potential solutions for the coordination of various disciplines. The latter is done by granting various disciplines, and groups of scientists, clinicians and engineers, direct access to data they would otherwise not be able to touch, and least manipulate. It is this coordinating character that forces a coordinating role onto engineering, requiring it to take a leading position.

Medicine, more than any other science, relies on statistics. The easier it is to obtain data the more data can be gathered, thus the better can a disease be understood and treated. Remote monitoring provides this means to allow easy access to patient data. On the long run this will be combined with therapeutic measures and lead to remote therapeutics (remote engineering on the human body). It is the intention of this article to motivate engineers to investigate the possibilities in medical applications and to initiate interdisciplinary activities in this field.

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