

# Therapy monitoring and personalised medicine

Intravenous catheters infuse drugs into the body and can send back information about the effects of the infusion so that the drug therapeutic index can be increased by controlling infusion parameters. Alexandre Tsoukalis, **Micrel Medical Devices**, describes an alternative way to trial phases of a drug where its dose prescription depends on the feedback reading, not on age and weight.

**T**oday's practice is to infuse drugs unattended, based on an early clinical study that specified a 'blind' prescription rule. There is no real time reported feedback on therapy results or side effects, so it is necessary for doctors to change the protocol or drug as early as possible. It is obvious that if the side effects can be observed/measured by a return route while a drug is infused:

- casualties caused by medication error can be prevented
- the side effects of a patient who is borderline for the drug can be prevented by reducing or stopping infusion before the side effects become dangerous and so the toxic limit for the patient's genotype can be found
- drugs that have metabolic effects depending on living conditions (like insulin) can be administered safely.

Micrel Medical Devices' Rythmic pump has the ability to let the nurse, automatic pump process or distant server change certain infusion parameters within predefined limits. These parameters can also be changed by the doctor over the internet by using a safe telemetry process. The method used by medical personnel is the automatic process of 'trimming within limits' preset by the doctor. The pump, being a class IIb medical device, is considered reliable to observe these limits and so excessive over or under-infusion can be prevented.

Side effects can be identified by placing sensors in the implantable catheter tip used in many chronic diseases in the bloodstream (to read states such as temperature, blood pressure, glucose, oxygen and ions) or by the pump asking the user about conditions such as diarrhoea, vomiting and nausea.

Should an automatic process correct the pump dosage, if the pharmaceutical company needs to keep the closed loop algorithm proprietary, the algorithm can be located in a server under its control and output communicated to the pump through telemetry.

## Telemedicine service

MicrelCare™ is a telemedicine service based on GSM/GPRS telemetry connecting Micrel's ambulatory Rythmic Connect pump and sensors to its micrelcare server. The server web pages are used by the home-care provider/hospital service and



The Rythmic Connect pump allows infusion parameters to be changed within predefined limits.

have data about patients treated and nurse personnel organised in groups. So a nurse who is in charge of a patient will receive an SMS describing the problem encountered with the pump or the treatment, or be informed that in a given time the drug reservoir must be replaced. From a list of patients, doctors and paramedics can watch the infusion (events and graphs) and therapy progress of each patient in real time on the web, with alarms in red popping up in the list.

Technically, this is possible as follows: the Rythmic Connect pump is connected serially with Micrel's IP-Connect proprietary mobile GSM/GPRS data phone, which is permanently connected with the micrelcare server, while communicating by a radio link (such as Bluetooth but ultra-low power), to other personal health devices on the patient, in the form of a personal area sensor network. Micrel Medical Devices holds European and US patents for this technology.

## Web-programmable ambulatory pump

Micrel's new Rythmic i-PCEA, the first CE Marked web-programmable ambulatory pump, is an example of feedback used for therapy enhancement. Regional analgesia uses a catheter placed adjacent to a nerve block. Pump programming has a lot to do with the distance of the catheter to the nerve and the elapsed time. The doctor rarely knows the correct programming of a regional analgesia pump, so many patients stay at the hospital until the doctor finds a working protocol. With the Micrel solution, doctors can send the patient home, the patient answers questions about the motor block or analgesia results and then the doctor trims the protocol through the internet.

The system is completely ambulatory acting as an ICU for working and 'normal-living' patients. It has the power to change the way drugs are registered, and even revitalise drugs rejected from the clinical trial process in a personalised medicine approach. The system also adds compliance and validity on clinical trials processing. ■

## Further information

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