

PATIENT HEART SIGNAL EXTRACTION FROM DIALYSIS SESSIONS PRESSURE DATA

Authors: P. Rovatti ¹, E. Grandi ¹, D. Stefani ¹, M. Ruffo ¹, K. Solem ², B. Olde ², A. Santoro ³ and G. Sterner ⁴.

1, Gambro Dasco, Medolla, Italy, 2, Gambro Lundia, Lund, Sweden, 3, Malpighi Hospital, Bologna, Italy and 4, University Hospital, Malmö, Sweden.

Objectives:

Failure of identification of Venous Needle Dislodgement (VND) is one of the major issues of modern dialysis machines (1,2).

Current detection (3) is based on measurement of venous pressure's variation in case of dislodgement, but efficacy and reliability of this method are poor. Venous needle slipping is estimated to occur every 20000 treatments, and undetected VND is believed to cause hundreds of deaths yearly worldwide (4). Home and nocturnal dialysis, which numbers are increasing, are particularly exposed to this problem (4).

Analysis of clinical dialysis pressure data was performed, in order to study the possibility of heart pulse extraction and supervision, transmitted from the patient to pressure transducers of the dialysis system via the blood access. The ultimate purpose is to design a Venous Needle Monitoring (VNM) system able to detect a VND in real time, with high sensitivity and specificity. A VND alert is expected as the heart pressure signal disappears from the venous side, since the connection between patient and machine is interrupted.

Methods:

A multicentric data collection was arranged, aimed at recording patient's pressure data from clinical dialysis sessions, followed by an off-line analysis for VNM application (algorithm definition and fine tuning).

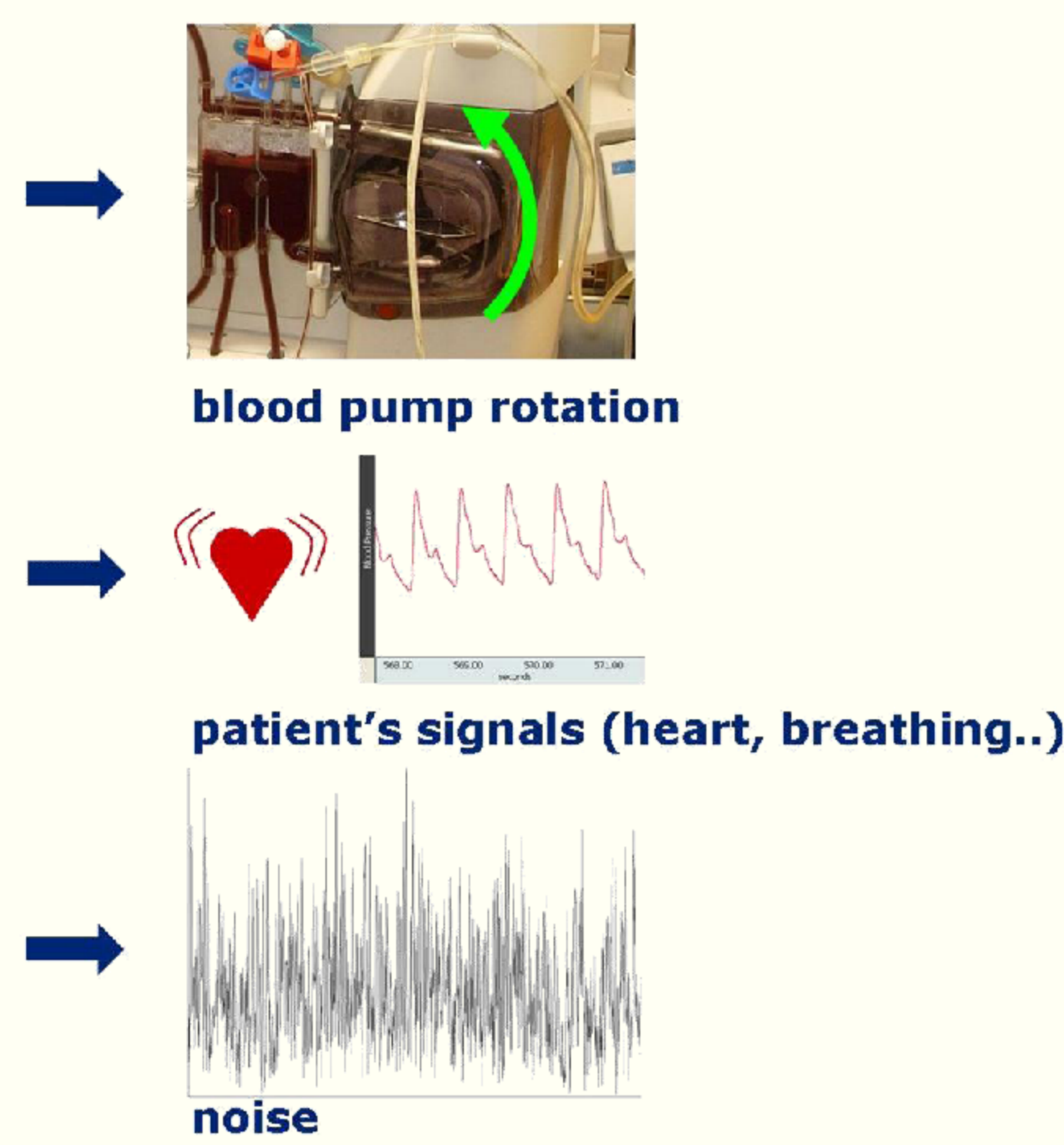
The study sites were identified in:

- Sant'Orsola-Malpighi Clinic, Bologna, Italy;
- Malmö University Hospital, Malmö, Sweden.

Dedicated Gambro Artis® dialysis machines were used, with custom-built acquisition software for fast and accurate recordings of pressure values. Pressure data recorded by Arterial and Venous chamber sensors, composed by blood pump pressure variations, signals originating from patient (such as heart pressure) and noise, have been analyzed using algorithms for biological signal extraction and denoising (5). The MATLAB toolsuite has been used for analysis of selected data.



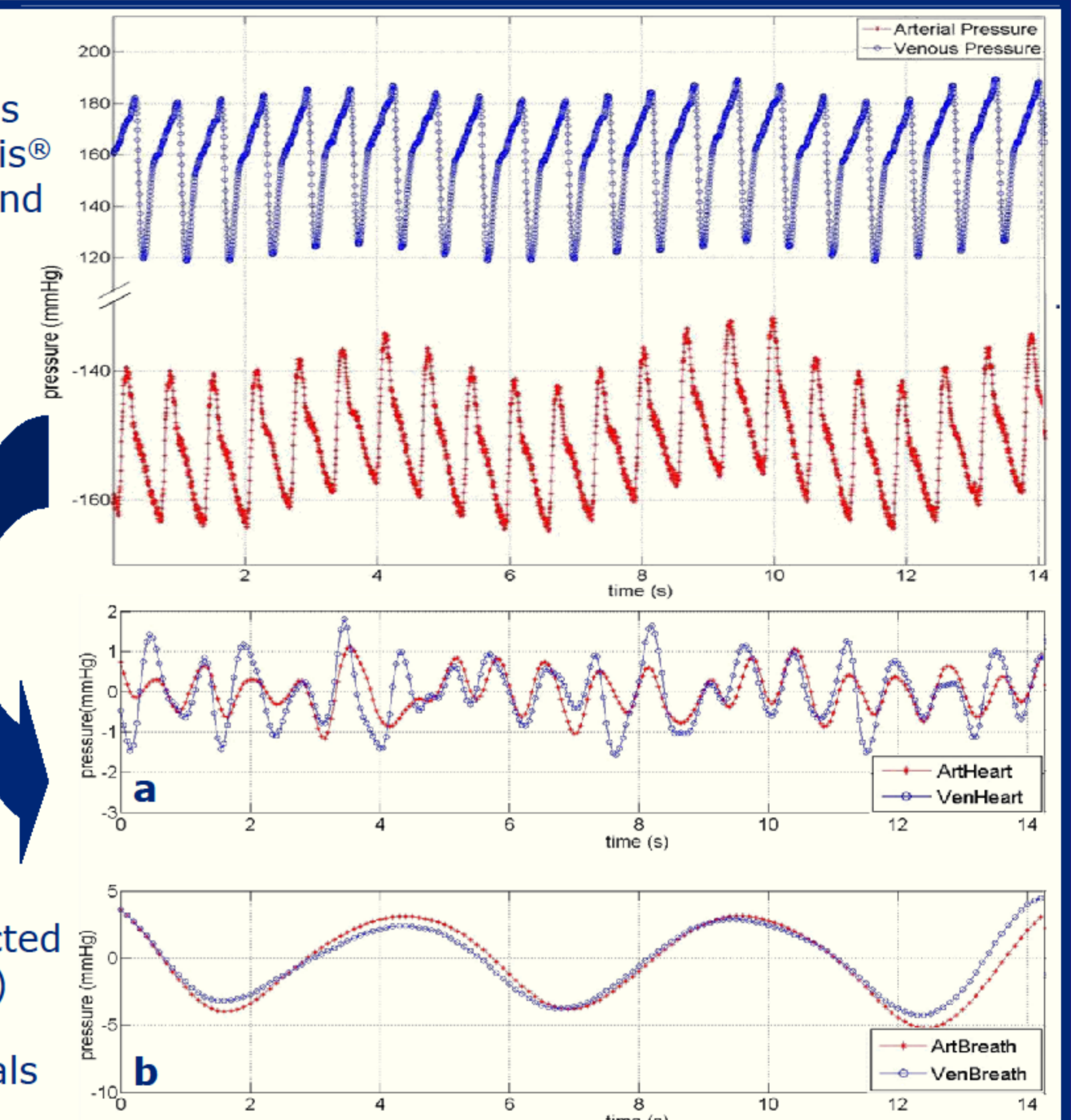
Pressure signals measured by the sensors placed in Art and Ven Artis® chambers are composed by:



Example of pressure signals recorded in Artis® Arterial (red) and Venous (blue) chambers

Off-line data processing

Patient's extracted heart (graph a) and breathing (graph b) signals

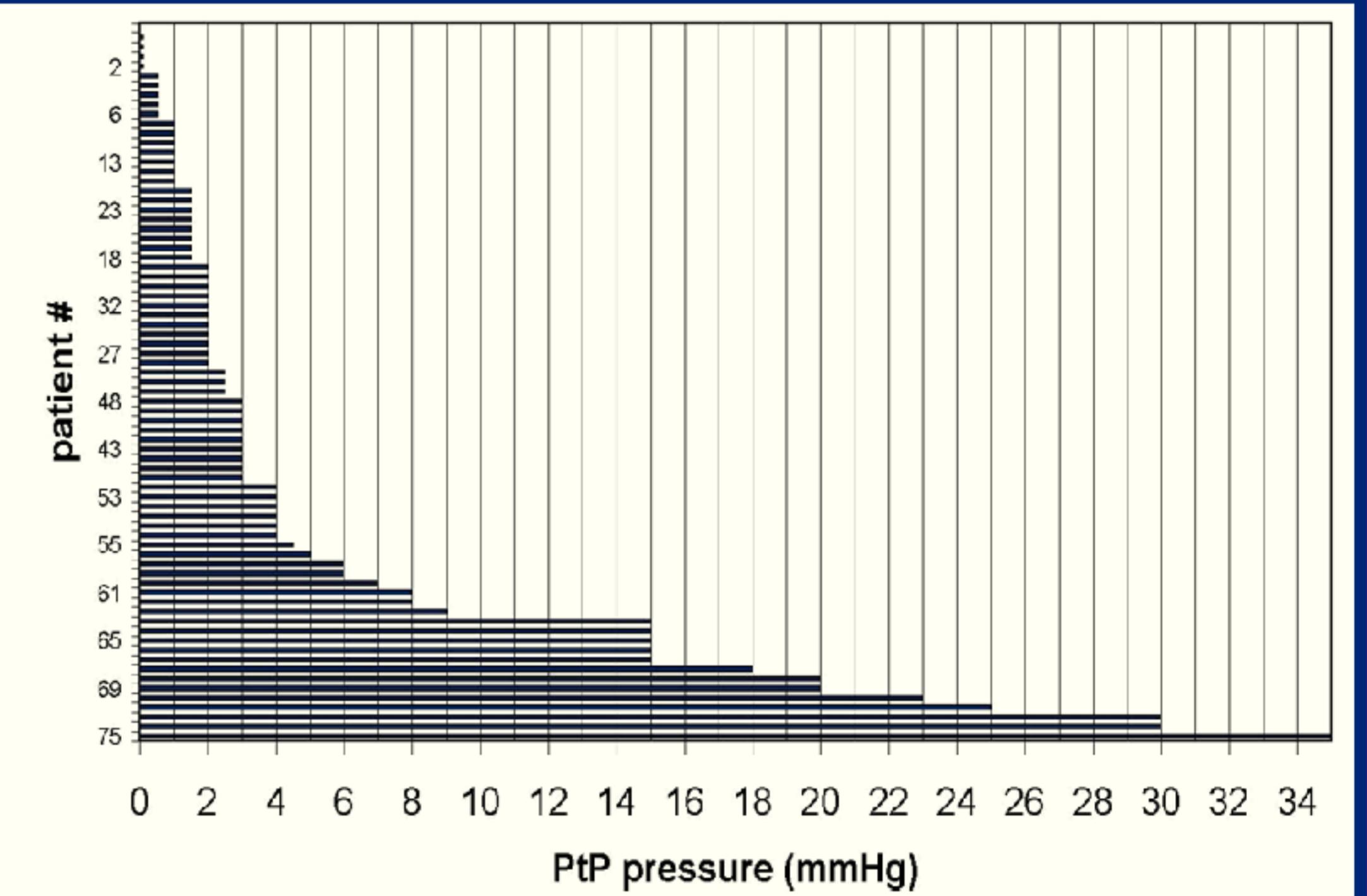


Results:

Preliminary results on a data subset (75 patients, HemoDialysis treatments, vascular access: arteriovenous fistula) show that it is possible to separate and extract patient's heart signals if the corresponding pressure oscillation has a peak to peak (PtP) amplitude $> \sim 1$ mmHg as measured by machine's sensors. Heart intensity is strongly patient-dependent but it has been shown to be quite reproducible in different dialysis sessions for the same patient. Arterial heart amplitudes at the beginning of treatment for the analyzed patients are shown in figure; they were obtained during a short blood pump stop at patient connection. A common finding is a decrease of heart PtP intensity in the course of treatment, due to fluid removal in the patient's body.

For very weak hearts, the signal could be too small to be successfully extracted, with respect either to pressure variations due to blood pump (usually around 30-100 mmHg PtP amplitude), or even to background noise.

Another cause of poor heart detection is a possible overlap between the frequency band of heartbeats and blood pump rotations. In addition to heart, other patient-related signals (e.g. breathing) are often present in the data set, and can be extracted and used to be able of monitoring most patients.



Conclusions:

An off-line analysis of clinical data showed the described system to be a promising tool to provide safe and reliable heart supervision and Venous Needle Monitoring for patients performing dialysis on Gambro Artis® system, without the use of any external/additional device.

Moreover, this system could pave the way to the possibility of developing further features such as heart rate estimation, cardiac arrest identification, reverse needles detection, hypotension prediction, continuous measurement of fistula pressure.

References:

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3. IEC 60601-2-16:1998, 2nd ed
4. "Catastrophic Hemorrhage from Venous Needle Dislodgement during Hemodialysis: Continued Risk of Avoidable Death and Progress toward a Solution". S. Sandroni, T. Sherockman & K. Hayes-Leight, ASN Renal Week 2008 abstract
5. "On-line Heart Rate Monitoring Using Pressure Sensors of the Dialysis Machine". M. Holmer, E. Grigonyte, B. Olde, M. Segelmark, L. Sörnmo, J. Sternby & K. Solem, ESAO 2012, Rostock, Germany

