ISO 15189 and Point-of-care testing: Thromboelastometry"full" electronization

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Introduction

- ROTEM (rotational thromboelastometry) - fast and comprehensive information about the state of haemostasis
- acute diagnosis of coagulation disorders
    - perioperative monitoring
    - postoperative monitoring
    - other conditions affecting haemostasis (polytrauma, severe bleeding conditions, sepsis, obstetric haemorrhage, etc.)
- determining the causes of bleeding and early detection of thrombotic risk
- the comprehensive nature of the output cannot be replaced by methods in haematology laboratories

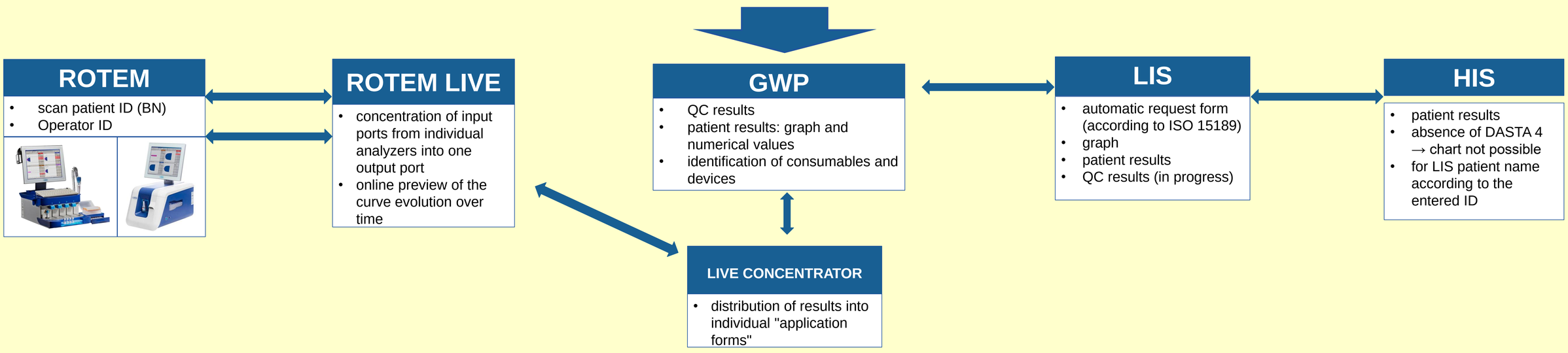
Methods

Application of the ISO 15189 standard to the POCT process based on the full computerization of the POCT process, namely the linking of instruments to the laboratory information system (LIS) via the GemWeb Plus (GWP) middleware and the transfer of results to the hospital information system (HIS). The installation of ROTEM *live* and the addition of the GWP with the Live concentrator middleware enabled bidirectional communication with all analyzers (1x Sigma, 2x Delta).

Objective

Maximum possible use of electronization of the Point-of-care testing (POCT) process in relation to the ISO 15189 standard.

Results



With the introduction of ROTEM *live* and the extension of the GemWeb Plus middleware with the additional embedded middleware *Live* concentrator, we have maintained two-way communication and extended the online view of the evolution of results over time from any location in FNO. After entering the patient's birth number and department into the analyzer (manually or by scanning a generated barcode), the analyzer will pull up the patient's first and last name. From the analyzers, all the data flows into ROTEM *live*, which concentrates it into a single channel so that the *Live* concentrator can receive it and sort it again for reception into the GWP, where it passes to the LIS and then to the HIS.

Fig. 1: Meeting the requirements of ISO 15189 for the identification of instrumentation and consumables - **internal quality control (QC) at GWP**

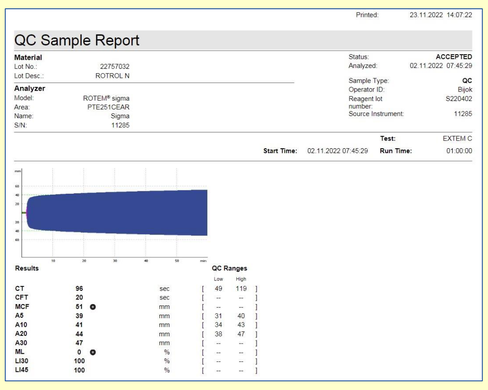


Figure 2: Meeting the requirements of ISO 15189 for identification of instrumentation and consumables - **patient sample in GWP**

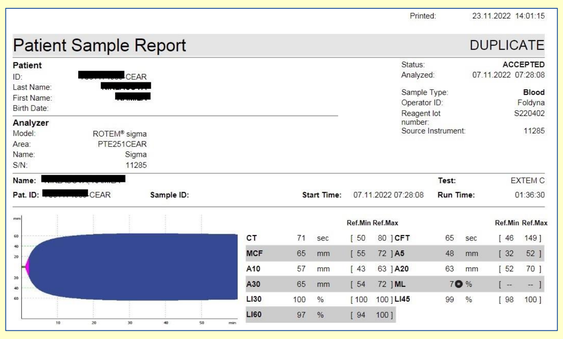


Fig. 3: ISO 15189 requirements fulfilment - **application in LIS** (Open Lims)

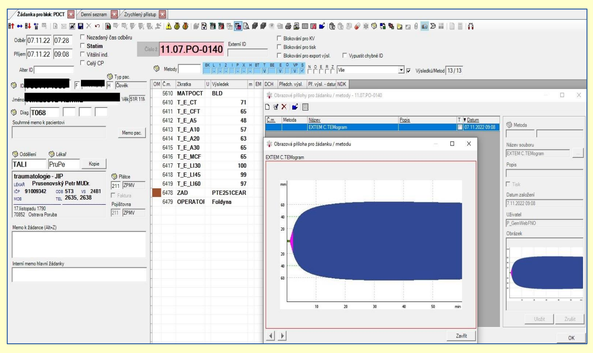
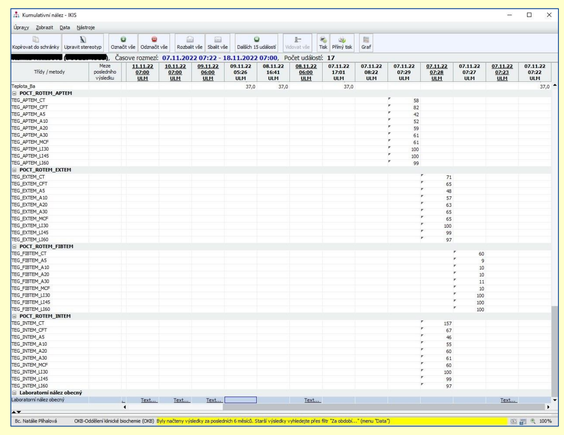


Fig. 4: Display of numerical values of **patient measurement results in HIS** (IKIS)



Application of ISO 15189 in practice. The ROTEM *live* ↔ *Live* concentrator ↔ GWP ↔ LIS ↔ HIS link allows us to look back via GWP to controls and patient samples to see all the details related to the control (QC name, Lot, instrument name, instrument serial number, location, date, time, operator ID, QC result status, QC numerical results including units and control limits, graphical display of results) and patient samples (patient ID, instrument name, instrument serial number, location, date, time, operator ID, test name, result status, numerical results including units and reference limits, time of curve development, graphical display of results). LIS shall cooperate with HIS. The application form in LIS meets the standard's requirements and, in addition to the numerical values, includes a graphical view of the entire curve for the test, the operator ID and the instrument ID (name). The results in HIS are numerical values without the possibility of previewing the graph (absence of DASTA 4). The graph is archived in LIS, GWP or by printout at the department. The graph is available for clinicians from the analyzer screen, online preview or printout.

ROTEM *live* → online preview of the waveform evolution over time at the patient's point of care allows different departments remote from the POCT device to view the up-to-date results and thus accelerate therapeutic intervention

Fig. 5: Login window to ROTEM *live*

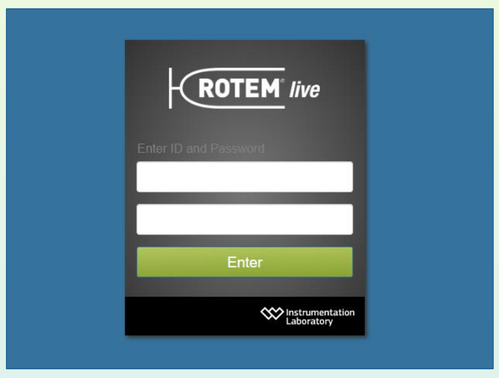


Fig. 6: Prompt to enter a patient ID (BN) or sample to view the online preview

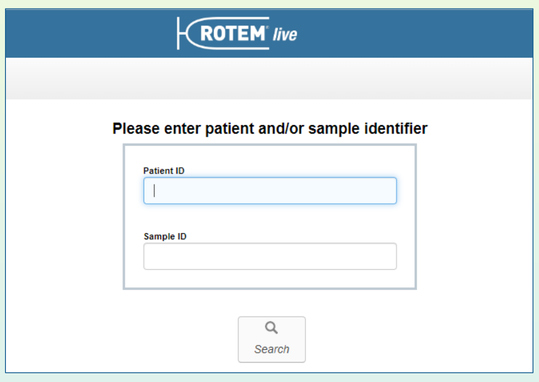
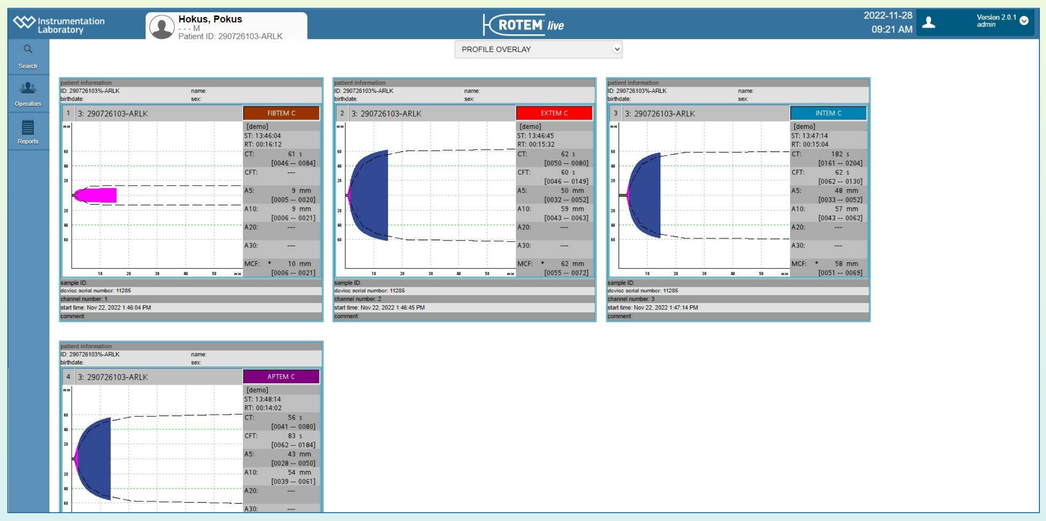


Fig. 7: Online preview of the curves over time on the ROTEM sigma® analyzer - experimental patient samples



Conclusion

Our workplace became the first in the Czech and Slovak Republic to implement full electronic data transmission from analyzers measuring on the principle of rotational thromboelastometry. The result is the display of all required data in GWP, LIS, HIS and, at the same time, an online preview of the currently measured results from any predefined computer in the University Hospital in Ostrava. Combined with the hospital-wide POCT management document, this process fully ensures the application of ISO 15189 requirements for records and identification, reducing Turn Around Time (TAT) as much as possible while saving human resources.