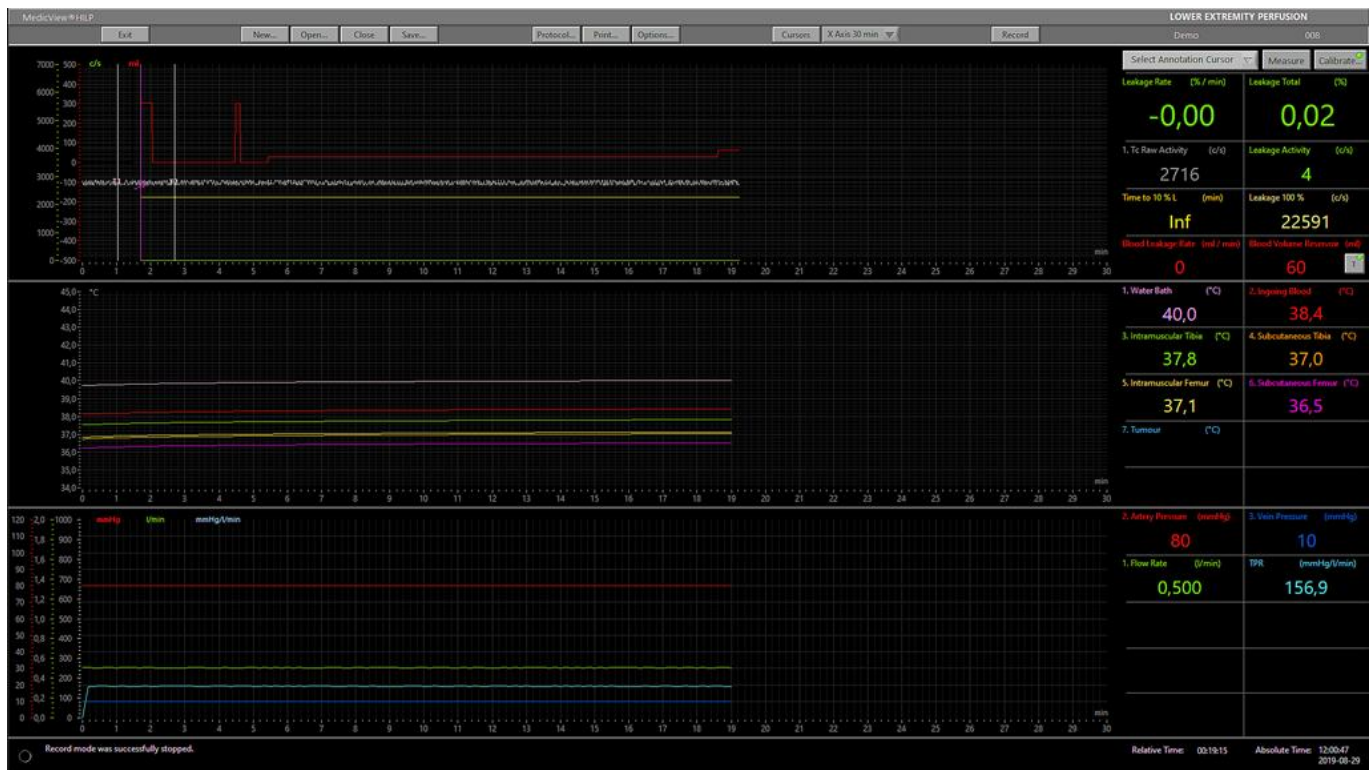


# MedicView®HILP



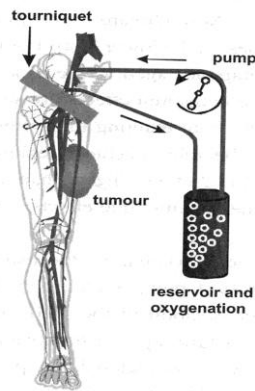
## Background

MedicView®HILP is a measurement system, especially developed for use during a surgical procedure called Hyperthermic Isolated Limb Perfusion (HILP).

HILP is a treatment method intended for an aggressive form of melanoma that occurs on the extremities known as in-transit metastases. The operation is performed under general anesthesia in which the main artery and vein of the affected extremity are connected to a perfusion circuit, to completely isolate the blood flow to and from the limb. The circuit uses a membrane oxygenator, a rotary pump and a heat exchanger to control oxygenation, temperature, and flow of the blood in the limb.

By having the affected limb connected to a perfusion circuit and with its blood completely isolated from that of the remainder of the body, it is possible to warm the blood and the extremity to a temperature of 39-40 °C without warming the entire body. High doses of cytotoxic chemotherapy agents, such as Melphalan only or in combination with Tumor Necrosis Factor-Alpha (TNF $\alpha$ ), can be administered into the extremity without exposing the entire body to the drug.

The combination of heat and high doses of Melphalan and TNF $\alpha$  circulated in the extremity for ninety minutes induces tumor regression and limb salvage in around 80% of the patients. The operation usually lasts a total of 3 to 4 hours and subsequent regression of tumor takes place over 2 - 10 weeks. High doses of cytostatics such as Melphalan or Adriamycin and TNF $\alpha$  (ten times MTD) generate considerable risk of toxic effects due to perfusate leakage into the systemic circulation. It is therefore very important that leakage can be continuously measured, in absolute terms and with high accuracy, during the entire operation. Local toxicity and tumor response also depend on tissue temperature. Therefore, continuous and accurate temperature registration is important as well.



## System Overview

MedicView®HILP consists of a medically certified all-in-one PC with a touch screen, a NaI(Tl) scintillation detector connected to a photomultiplier tube base for gamma-ray spectroscopy and, optionally, a collimator tripod for stable attachment of the detector to the operating table.

To facilitate accurate calculations of blood transfusion needs a specially designed electronic scale, on which the blood reservoir is attached, may optionally be ordered. This enables the operator to continuously monitor blood loss, from the systemic circulation to the perfusion circuit, on the computer screen. Since accuracy is better than  $\pm 5$  ml this method is far superior to the more common method of just watching the painted ml scale on the reservoir.

Apart from measuring leakage of chemotherapy agents and blood volume in the reservoir it is also desirable to be able to measure temperature, mean blood pressure and flow rate in the perfusion circuit during treatment. Therefore, several protocols from external devices such as heart-lung machines, thermometers and pressure monitors are supported.

## Leakage Measurement Methodology

Leakage calculation is based on the use of a small and big dose of a radioactive tracer. Nominal activity quotient of the doses is 10. During calibration the small dose is injected into the systemic circulation whereupon the activity, defined as baseline, is measured above the heart of the patient. With known activity and blood volume quotients the activity at 100% leakage can be calculated. Since accuracy of subsequent leakage calculations is strongly affected by the half-life of the tracer, effective half-life, where both physical and biological half-lives are taken into account, can be estimated by the built-in calibration function. This feature is especially practical if short-lived isotopes are used.

The big dose is then injected into the isolated extremity. With a ten times higher dose circulating in the perfusion circuit the system becomes very sensitive and even a smallest leakage will immediately be detected. After ensuring that there is no leakage the calibration is completed and the chemotherapy agents can safely be injected.

During treatment, data is continuously presented on the computer screen, both in graphs and in numerical fields, and alarms are generated if predefined levels are exceeded. A fully equipped system shows leakage rate, total leakage, time to 10% leakage, blood volume in the reservoir, proximal and distal subcutaneous and intramuscular temperatures, flow rate and mean blood pressure in the perfusion circuit.

## Conclusion

MedicView®HILP has been used during more than 2000 treatments and has proven to be an extremely accurate and reliable system. The easy-to-use software application has a nice "look and feel" and under the hood it is a powerful instrument capable of clearly visualizing events and coherencies that would otherwise be hidden. Therefore, it is the perfect tool for surgeons who want to have complete control during HILP treatments.