

# VERIFICATION OF THE THERMAL PROPERTIES OF THE ELECTRONIC SKIN

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**Abstract:** The “electronic skin” of the swaroTEST device replaces volunteer tests for the thermal performance of neutral electrodes. The conformity with the human skin was validated with 70 experiments on volunteers. For the verification of the temperature measurement itself heating via a water basin is used to prove an accuracy of 0,4°C.

**Keywords:** electrosurgery, neutral electrode, volunteer tests, electronic skin, thermal measurement.

## Introduction

In electrosurgery the hf current is lead to the operation site by means of the electric knife (active electrode); for the return path to the generator a large-area self-adhesive neutral electrode is used. According to the respective Standard EN 60601-2-2:2009 [1] the thermal properties of the neutral electrodes have to be tested with volunteers by means of a thermo camera. As an alternative to these very laborious measurements a device with an “electronic skin” [2] was designed and developed in order to replace such volunteer tests (Figure 1).

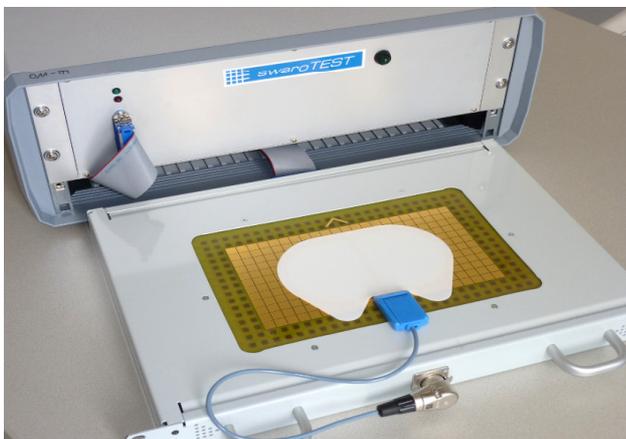


Fig. 1: swaroTEST device with a neutral electrode adhering to the gold-plated surface of the „electronic skin“ for the test to be performed

## Conformity with volunteer tests

According to Standard EN 60601-2-2 (Item 201.15.101.5) it must be proved for the electronic skin as a „surrogate medium“ that the temperature increase under standard load does not yield temperatures that are below those in at least 20 volunteer tests.

To fulfill this requirements the results of 70 volunteer tests were compared with the respective equivalent measurements at the swaroTEST device [3].

The results of the comparison of volunteer measurements with measurements at the test device swaroTEST are given in figure 2.

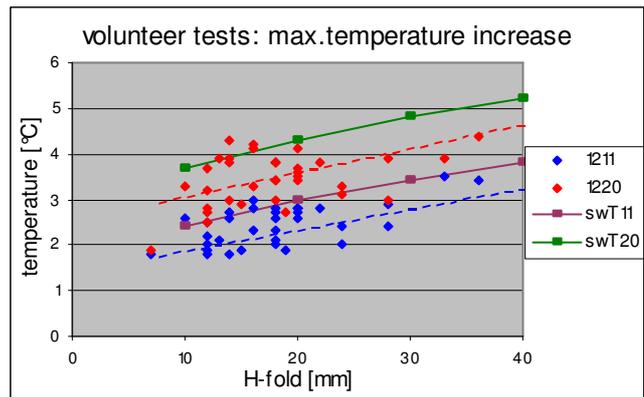


Fig. 2: Comparison of volunteer tests with equivalent measurements on the electronic skin in the swaroTEST device

The measurements were conducted with two frequently applied sizes of neutral electrodes (type 1211, 144 cm<sup>2</sup> active area und type 1220, 105 cm<sup>2</sup>). The different skin types (thickness of the hypodermis) are taken into account by the thickness of the skin fold (H-fold in mm). The results of the temperature increase in the volunteer tests (red and blue dots in figure 2) are by 0,5°C on an average lower (dashed lines) than the respective measurements with the electronic skin (solid lines).

**Result:** The electronic skin in the test device swaroTEST fulfills the requirements of Standard EN 60601-2-2, Item 201.15.101.5 and is therefore admitted and approved to replace volunteer tests.

## Thermal verification of the electronic skin

**Measurement assembly:** The measurement of the temperature increase in the electronic skin is done with one sensor each per cm<sup>2</sup> of the measurement area. The Standard stipulates a measurement accuracy of 0,5°C for the temperature measurement. To prove the measurement accuracy the temperature increase is not measured via the current flow through neutral electrode and electronic skin, but instead it is produced in a water basin on the measurement area. (see assembly in figure 3).

**Realization:** For the verification, „cold“ water (about 23°C) is filled in the water basin, the thermo measurement is started after thermal equilibrium has been reached and the water temperature is correspondingly increased by stirring in hot water. In the beginning (cold) and at the end (warm) of the measurement time, the temperature is

measured and the difference is the quantity to be measured for the verification.



Fig. 3: Water bath with calibrated thermometer for the thermal calibration of the electronic skin

The problem lies in the fact that at the current passage over the neutral electrodes the heat is produced in those electronic components that simulate the corium, whereas in the verification by means of the water bath the heat needs first to migrate through the test board from the contact side (gold-plated surface) to the component side with the temperature sensors.

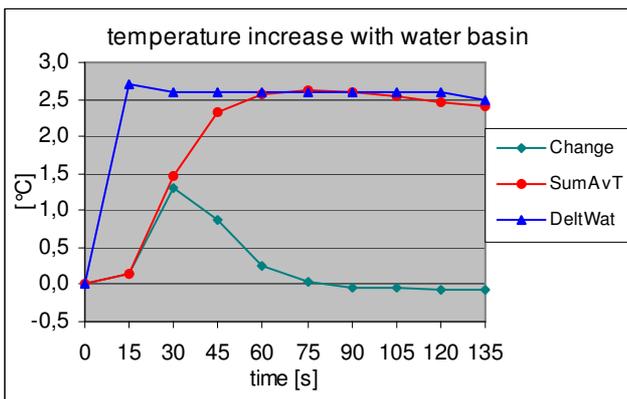


Fig. 4: typical warming-up process with the water bath (explanation in the text)

Figure 4 shows a typical process of warming in the water basin and of the sensors in the test board. In the beginning of the measurement the water temperature is increased for instance by 2,6°C by stirring in hot water. The curve **DeltWat** (blue) shows this temperature increase starting at the beginning of the measurement. The water temperature remains about the same during the total measurement time. With a delay of 15s to 45s the temperature increases at the sensors **SumAvT** (red). As of about 60s the temperature at the sensors remains approximately equal. As of 90s we observe cooling. **Change** (green) is a relative measure for the temperature increase and decrease, respectively, at the sensors.

**Result:** The optimal measurement time for the verification is 60s, which is at the same time equal to the measurement time for the standard load for the test of neutral electrodes according to the Standard.

**Measurement accuracy:** The judgment of the measurement accuracy takes place in two steps: (1) Uniformity (ripple) of the temperature(difference)values of the indi-

vidual sensors and (2) deviation of the mean value of all temperature measurements from the temperature increase of the water bath.

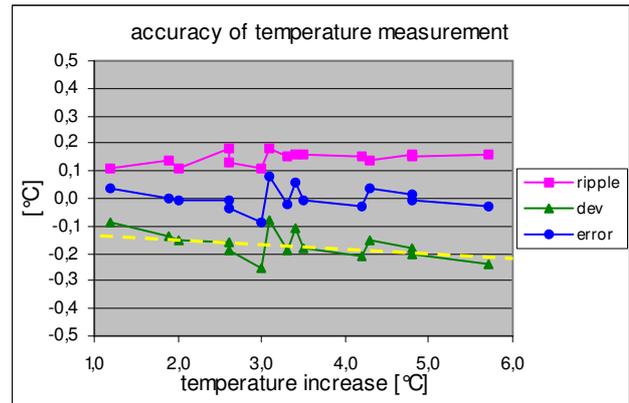


Fig. 5: Accuracy of temperature verification

Figure 5 shows the test of several devices with different temperature increase. **Ripple** (red) represents the uniformity of all temperature sensors in the test boards, with ripple being half of the difference between highest and lowest temperature value among all sensors. A defective sensor would significantly increase this value. **Dev** (green) is the uncorrected deviation between temperature difference in the water bath and the mean value of the temperature increase of all sensors. If the systematic error due to heat loss during the passage through the test board is taken into account (yellow line), then the true **error** (blue) is within  $\pm 0,1^{\circ}\text{C}$ . The specification of the measurement accuracy of  $0,4^{\circ}\text{C}$  (Standard  $0,5^{\circ}\text{C}$ ) for the test board (electronic skin) of the swaroTEST device is therefore justified.

## Discussion

The basic agreement of the „electronic skin“ of the swaroTEST device with the electrical and thermal properties of the skin of a patient was confirmed by comparison with 70 volunteer tests according to the requirements of Standard EN 60601-2-2:2009.

Verification of the temperature measurement by means of a water bath yielded without additional correction a measurement accuracy in the range of  $0,3^{\circ}\text{C}$  and an error of only  $0,1^{\circ}\text{C}$  under consideration of the heat losses in the test board. This justifies the specification of  $0,4^{\circ}\text{C}$  measurement accuracy for the electronic skin of the swaroTEST device.

## Bibliography

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