Manual for ROLLTEMP II

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Version 02 EN 2017-03-27

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For cleaning you should not use detergents containing abrasives, as this would scratch the surface of the Rolltemp base unit. Do also avoid using solvents, like alcohol, for cleaning, as they may dissolve the text on the Rolltemp base unit or produce toxic and/or flammable fumes.

For cleaning the base unit, disconnect it from the mains power supply. Then use a soft cloth with a minimal amount of detergent.

The rollers shall also be kept clean. If necessary, the actual roller can be taken out of the handle and heat sterilised, but in most cases it would be sufficient to either wipe it off with a cloth or sterilize with a chemical solution (like Cidex) where the roller does not need to be disassembled from the handle.

It is recommended to clean the rollers rather before they are placed back into the respective compartments instead of just prior to use to avoid that they are moist during use, as this may give false readings.

DAILY CARE

No particular maintenance is required, except to keep the base unit and the rollers clean.

TECHNICAL DESCRIPTION

Two stainless steel rollers are kept in a box with two separate compartments. The compartments are thermostatically regulated to 25 oC and 40 oC. With a normal skin temperature of 32 oC, this corresponds to temperatures that are 7 oC lower and 8 oC higher than normal skin temperature. These temperatures are selected as relevant to screen between normal and abnormal temperature sensibility. Thermoelectric pumps, based on Peltier elements are used to create the 25oC and 40oC compartments.

Transducers detect the temperatures in both of the compartments, their signals are compared with reference levels and the difference used to control the electrical drive signal to the two systems.

The Rolltemp is designed to be continuously connected to the mains supply. As soon as the switch is turned on, it starts to "warm up". A green light emitting diode (LED) indicates that power is applied to the Rolltemp, by starting to flash at a rate of 1 flash per 2 seconds as soon as power is applied. When the temperature in both of the compartments are within one degree of their final temperatures, the LED switches from flashing to be lit by a steady green light.

The thermal mass of both the compartments in the Rolltemp base unit, as well as the mass of the rollers, makes this into a system that requires some time before it has acquired the correct temperatures. In practice, proper temperatures are obtained within 5 minutes from the moment the Rolltemp is switched on. The thermal mass is also the reason why the rollers can be used for some time, while still keeping the right temperatures. Obviously, this time can not be very long, but normal practice has shown that the mass of the rollers is sufficient to keep the temperature levels during most types of examinations. Here the mass of the roller (110 gram) has to be a compromise. A larger mass would make it possible to keep the temperatures for a longer period of time, but this would also make the roller heavier, giving higher pressure stimuli to the skin as well as making it more difficult to handle the roller. When the roller is returned to the Rolltemp base unit, the thermal mass of the compartment contributes to the "recharging" of the roller.

READ THIS BEFORE USE OF THE ROLLTEMP

The green indicator light on the front panel of the Rolltemp indicates the temperatures of the rollers. During the initial warming-up period, this indicator is normally flashing, indicating incorrect temperature for any or both of the rollers. Correct temperatures are indicated by a steady green light. If, during normal operation, this indicator light starts to flash, then the rollers shall be returned to their slots and not be used until the indicator lamp again is lit with a steady light.

DANGER ! RISK OF THERMAL BURN !

The rollers may have improper temperatures and shall not be used if the indicator

The use of the ROLLTEMP in operating theatres and other areas where flammable anaesthetics may be used is not recommended and the following warning is issued:

DANGER ! EXPLOSION HAZARD !

The ROLLTEMP produces a possible explosion hazard if used in the presence of

To preserve the safety of the ROLLTEMP, it is important that in the case of repairs of the electrical circuits, all components, and particularly the fuses, are replaced with their exact replacements.

WARNING !

For continued protection against fire, use only fuses of the specified type.

Do not open the case of the ROLLTEMP. Service and repairs should only be handled by qualified technical personnel.

CAUTION ! !

Hazardous potentials inside cover. Refer servicing to qualified service personnel.

DECLARATION OF CONFORMITY

According to the Medical Device Directive, 93/42/EEC

The undersigned, representing the following manufacturer, established within the EEA

Registered name	Somedic SenseLab AB
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hereby declares that the following product is CE-marked 2014

Brand name/Trade mark	Rolltemp II
Type of equipment	The Rolltemp II is a non-invasive active medical device, for transient diagnostic use, classified Class I.

This Declaration of Conformity is given in accordance with Addendum 7, to Directive 93/42/EEC and the Swedish implementation LVFS 2003:11. By signing this document, the undersigned declares as representative for the manufacturer, that the product complies with the requirements of the harmonized standard stated above.

Place of issue:	Sösdala
Date of issue:	March 27th, 2017
Authorized by:	Bo G. Johansson
Signature:	
Title of authority:	CEO, Somedic SenseLab AB

INTRODUCTION

ROLLTEMP is designed to allow determination of temperature sensibility over large body areas. It uses two rollers, one warm and one cold that get their respective temperatures from a base unit with a thermo-electric regulation system, where they are placed in-between investigations. In normal use, the roller is removed from the base unit and moved over the skin of a patient. The patient then determines the corresponding sensation and areas with normal/abnormal sensibility can rapidly be mapped out.

USE

Verify that the rollers are inserted in their corresponding slots at the top side of the **ROLLTEMP**. The slot marked **25°C** shall have a roller with a **blue** handle and the slot marked **40°C**, a roller with a **red** handle.

Connect the power cord of the **ROLLTEMP** to a proper mains supply and turn on the switch. Verify that the green **On** indicator on the front starts to flash.

Wait until the indicator on the front of the **ROLLTEMP** is lit with a steady green light (takes normally 5 - 15 minutes). This indicates that the rollers have reached the correct temperatures.

Explain the test procedure for the patient. If possible, use a location with normal sensibility on the patient's skin to demonstrate the difference between the warm and the cold roller and point out that it is not the weight of the roller, but the temperature sensation which should be reported. Instruct the patient to further focus on changes in sensation. Be prepared that the range of sensations, that the patient can report, may go from total lack of sensation to intense pain.

Select one of the rollers, usually the blue (25° C). Hold the roller such that it is resting with its own weight on the patient's skin. Start the mapping outside of the area where an abnormal sensibility is expected. Move the roller along the skin with a speed of 1 to 5 cm per second. Move it from a normal area into the abnormal and then out again. Determine the total area with abnormal sensibility, as well as the type(s) of abnormality, by moving the roller from several different directions into the area with sensory abnormality. Mark out this area on a sketch of the patient's body, or directly on the patient's skin.

Repeat the investigation with the other roller.

Correlate the area of the sensory alterations with the neuroanatomical distribution of relevant nerve fibres, which gives an indication of the nerve(s) involved. Be prepared that if the sensory alterations have been present for long time, there may be a spread of the area involved outside the area originally considered.

A more detailed Quantitative Sensory Test (QST) may give further possibilities to follow the effects of therapy. The initial investigation with the ROLLTEMP may then serve as a basis for the selection of where to perform the QST.