

DECISION SHEET

Standard(s)- (year and edition): 60601-1:1988 Ed.2 Am1+Am2	Sub clause(s): 2.1.5	Sheet n°: DSH-425
Subject: Temperature limit applied part	Key words: Applied part, temperature limit	Confirmed by CTL at its 39th meeting, in Cologne

Question:

The EQUIPMENT worn by the patient, such as AMBULATORY ECG SYSTEM or AMBULATORY RECORDER is now considered as a APPLIED PART in addition to the associated ELECTRODES and cables. Clause 42.3 does not allow surface temperature exceeding 41 °C for an APPLIED PART and according to clause 3.1 EQUIPMENT shall cause no safety hazard in NORMAL CONDITION and in SINGLE FAULT CONDITION. Very often the EQUIPMENT exceeds the temperature limit of 41 °C under the above testing conditions.

Decision:

The instructions for use shall advise that the recorder is not to be worn in contact with the skin. The ENCLOSURE is therefore not considered as an APPLIED PART and should comply with Table Xa "Equipment parts which may in normal use have a brief contact with a patient 50°C".

Explanatory notes:

The special temperature limits have been set for patient contact.