

DECISION SHEET

Standard(s)- (year and edition): IEC 60601-1:1988 Ed.2 Am1+Am2	Sub clause(s): 42, 42.3	Sheet n°: DSH-422
Subject: Temperature limit applied part	Key words: Temperature limit, applied part, ambient.	Confirmed by CTL at its 39th meeting, in Cologne
<p>Question:</p> <p>It is not clear at what ambient temperature the limit of 41 °C should be applied. The temperature range of 10 °C to 40 °C stated in Sub-clause 10.2 applies to Table Xa and would appear to apply in this instance. Is a 1 °C temperature difference correct or realistic?</p> <p>Decision:</p> <p>When not otherwise specified by the manufacturer, the limit of 41 °C at an ambient temperature of 40 °C must be applied in NORMAL CONDITION or SINGLE FAULT CONDITION except where there is a medical justification for a higher limit/temperature rise. This requirement should be addressed in Particular Standards.</p> <p>Explanatory notes:</p> <p>It may be possible to consider a reduced maximum ambient temperature for operational use, say 35°C, if that is stated by the manufacturer in the Instruction for use, but the applied part shall still be safe and tested according to 42.3 and a ambient temperature of 40 °C.</p>		