

DECISION SHEET

Standard(s)- (year and edition): IEC 60601-1:1988 Ed.2 Am1+Am2	Sub clause(s): 16	Sheet n°: DSH-404
Subject: ENCLOSURES and PROTECTIVE COVERS	Key words: ENCLOSURES, PROTECTIVE COVERS, SIP/SOP	Confirmed by CTL at its 39th meeting, in Cologne
<p>Question:</p> <p>In practice, many standard SIP/SOPs are constructed so that live parts of the SIP/SOPs are accessible with the standard test finger or, alternatively, the air clearances and/or creepage distances between these live parts and the standard test finger are too short. This means that these live parts of SIP/SOPs are to be considered as part of the enclosure and therefore the corresponding enclosure leakage currents shall be measured, and hence, many existing standard SIP/SOPs fail to comply with the standard.</p> <p>Should, for instance, concession be granted for SIP/SOPs with accessible live parts with a voltage (to earth) not exceeding 25V AC or 60V DC?</p> <p>Decision:</p> <p>Include SIP/SOP in the list of sub-clause 16e)1. Instructions for use must contain the warning given in 16a)5.</p> <p>Explanatory notes:</p> <p>For the operator, access to parts at potentials not exceeding 25V AC or 60V DC is consider not to present a hazard, provided that simultaneous contact between operator and patient is avoided.</p>		