

**COLLECTION OF THE CTL DECISIONS
DECISION SHEET**

Standard(s)- (year and edition): IEC 60601-1:1988 Ed.2 Am1+Am2	Sub clause(s): 6.8.1	Sheet n°: 532
Subject: Accompanying documents	Key words: Manuals, CD-ROM, Accompanying documents	Decision taken at the 40 th meeting 2003
<p>Question:</p> <ol style="list-style-type: none"> 1) Is it required that accompanying documents shall be provided as hard copy? 2) What if accompanying documents are provided either on CD-ROM or Electronic File Format ? <p>Decision:</p> <ol style="list-style-type: none"> 1) Accompanying documents may be in electronic format if acceptable to the USER.. 2) Please note that at least that part of documentation concerned with safety precautions shall be readable with the equipment in normal use and without interrupting a clinical procedure. A risk analysis will indicate whether hard copy is necessary to cover emergency procedures e.g. resulting from power failures. <p>Explanatory notes:</p> <p>None</p>		