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Electrocardiograph papers — Specifications

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Foreword

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This Kenya Standard was prepared by Technical Committee KEBS/TC 136, Medical Tools, devices and Equipment.

During the preparation of this standard, reference was made to the following documents:


Acknowledgement is hereby made for the assistance derived from these sources.
Electrocardiograph papers — Specifications

1 Scope

This Kenya Standard prescribes the requirements and test methods for Electrocardiograph paper intended for use in electrocardiography.

2 Normative references

The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 186, Paper and board — Sampling to determine average quality
ISO 187, Paper, board and pulps — Standard atmosphere for conditioning and testing and procedure for monitoring the atmosphere and conditioning of samples
ISO 287, Paper and board — Determination of moisture content of a lot — Oven-drying method
ISO 11556, Paper and board — Determination of curl using a single vertically suspended test piece

3 Terms and definitions

For the purposes of this standard, the following definitions shall apply.

3.1 electrocardiograph
this is an instrument used in the detection and diagnosis of heart abnormalities that measures electrical potentials on the body surface and generates a record of the electrical currents associated with heart muscle activity.

3.2 electrocardiograph paper
is a paper impregnated or coated with materials sufficiently sensitive to make a permanent record of very faint tracings produced by electrocardiograph.

3.3 electrocardiogram
is a test that records the electrical activity of the heart.

3.4 electrocardiography
is a trans-thoracic (across the thorax or chest) interpretation of the electrical activity of the heart over a period of time.

3.5 grammage, actual
the average grammage obtained on a sample of paper under specified test conditions and that shall normally be within 5 percent of the nominal grammage

3.6 grammage, nominal
the designated grammage of paper that is used for reference purposes

3.7 long grain
the orientation when the machine direction of the paper is in the long direction of the sheet.
3.8
lot
one or more nominally identical boxes of paper, the paper having been made on the same equipment under essentially the same conditions, from one manufacturer, and submitted at any one time for inspection and testing.

3.9
surface resistivity
the electrical resistance between two straight edged electrodes of the same length positioned to form the opposite edges of a rectangle in contact with the surface on one side of a sheet of paper, multiplied by the electrode length and divided by the distance between them.

4  Requirements

4.1  General requirements

4.1.1  The paper shall be free from loose fibres, bits of loose paper, dust, wood splinters, dirt, creases and any other defects that shall impair its serviceability.

4.1.3  The edges of the paper shall be clearly cut and straight.

4.1.3  Designed side of the paper shall be smooth and accept machine plotting without undue signs of feathering or spread.

4.2  Material

4.2.1  The machine direction of the paper shall be in the longer direction of the sheet, i.e. the sheets shall be long grain.

4.2.2  The physical properties of the paper shall comply with the requirements given in Table 1.

<table>
<thead>
<tr>
<th>Sl No.</th>
<th>Property</th>
<th>Requirement</th>
<th>Test Method</th>
</tr>
</thead>
<tbody>
<tr>
<td>(i)</td>
<td>Grammage, nominal, g/m²</td>
<td>80</td>
<td>KS ISO 536:2012</td>
</tr>
<tr>
<td>(ii)</td>
<td>Grammage, actual, g/m², min.</td>
<td>76</td>
<td>KS ISO 536:2012</td>
</tr>
<tr>
<td>(iii)</td>
<td>Moisture content as packed, %</td>
<td>4.5 ± 1</td>
<td>KS ISO 287:2017</td>
</tr>
<tr>
<td>(iv)</td>
<td>Opacity, %, min.</td>
<td>85</td>
<td>KS 03-420, Clause 13</td>
</tr>
<tr>
<td>(v)</td>
<td>P.V brightness †, %, min.</td>
<td>90 ± 2</td>
<td>KS 03-420, Clause 14</td>
</tr>
<tr>
<td>(vi)</td>
<td>pH of aqueous extract, range</td>
<td>4.5 — 9.5</td>
<td>KS 03-420, Clause 7</td>
</tr>
<tr>
<td>(vii)</td>
<td>Thickness, mm, range</td>
<td>0.08 — 0.10</td>
<td>KS 03-420, Clause 17</td>
</tr>
<tr>
<td>(viii)</td>
<td>Roughness, max.</td>
<td>300</td>
<td>KS 03-420, Clause 15</td>
</tr>
<tr>
<td>(ix)</td>
<td>Cobb test, range g/m²/min.</td>
<td>18 — 24</td>
<td>KS 03-420, Clause 10.2</td>
</tr>
<tr>
<td>(x)</td>
<td>Infra red curl deflection, mm</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Top side: Positive, max.</td>
<td>15</td>
<td>KS ISO 11556:2005</td>
</tr>
<tr>
<td></td>
<td>Negative, max.</td>
<td>3</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Bottom side: Negative, min.</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Negative, max.</td>
<td>15</td>
<td></td>
</tr>
</tbody>
</table>

* Specification for substance of paper and boards.
† Methods of test for paper and board.
‡ Applicable to white paper only.
5 Dimensions and grids

5.1 The dimensions of the sheet of the paper shall be dependent on the electrocardiograph machine in use.

5.2 The grids shall be visible and shall have an inner measurement of 1 mm X 1 mm and the margin (outer) with a measurement of 5 mm X 5 mm.

6 Packaging and marking

6.1 Packaging

i) Sheets or rolls shall be wrapped and sealed in moisture resistant wrappers.

ii) The wrapping and sealing shall be adequate to ensure that during normal transportation, handling and storage, the moisture content of the paper remains within the limits specified in Table 1.

iii) No adhesive shall adhere to the ECG paper. The sheets or rolls of paper shall not adhere to one another. Reams shall only contain sheets that are nominally identical with respect to size, grammage and colour.

6.2 Marking

The following shall be marked legibly and indelibly on the wrapping of each ream and on each box:

i) The name and address of the manufacturer or local distributor and registered trade mark, if any;

ii) The name of the product as “ECG Paper”;

iii) The size designation of the paper depending on the machine;

iv) The number of rolls or “reams” in each box;

v) The grammage of the paper;

vi) The colour of the paper.

7 Sampling and compliance with the specification

7.1 Sampling

6.1.1 Sampling of boxes

To determine whether the packing and marking requirements of the standard with respect to boxes are met, take at random from the lot the number of boxes given in Table 3, appropriate to the lot size.

If the boxes are on pallets, take as nearly as possible the same number of boxes from each pallet to make up the total number of boxes required. Deem the samples so taken to represent the lot for the respective properties.

Table 2 — Selection of units

<table>
<thead>
<tr>
<th>Size of lot, number of units, n</th>
<th>Number of units selected</th>
<th>Method of selection</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 to 5</td>
<td>All</td>
<td>—</td>
</tr>
<tr>
<td>6 to 399</td>
<td>( \sqrt{(n + 20)} )</td>
<td>At random</td>
</tr>
<tr>
<td>400 or more</td>
<td>20</td>
<td>At random</td>
</tr>
</tbody>
</table>
In deciding the number of units to be selected round down to the nearest whole number.

6.1.2 Sampling of reams and paper

To determine whether the requirements of the standard with respect to reams and paper are met, after inspection of the boxes sampled in accordance with 6.1.1, take at random a ream from each of five of the boxes sampled; or if fewer than five boxes are sampled, take a ream from each of them and deem the samples so taken to represent the lot for the respective properties.

7.2 Compliance with the Specification

The lot shall be deemed to comply with the relevant requirements of the standard if

i) after inspection of boxes for packing and marking, not more than one defective is found,

ii) after inspection of the rolls or “reams” for packing and marking not more than one defective is found,

iii) after inspection of the paper for defects, not more than five defects are found, and,

iv) after testing in accordance with 3.2.2, no defect is found.

8 Inspection

7.1 Inspection of Boxes — Visually examine each of the corrugated board boxes sampled in accordance with 6.1.1 for compliance with the packing and marking requirements and report the results for each box.

7.2 Inspection of Reams/rolls — Visually examine each of the reams sampled in accordance with 6.1 and 6.2 for compliance with the packing and marking and report the results for each ream.

7.3 Inspection of Paper — Open a ream and immediately remove from about the centre of the ream, the number of sheets required for the determination of moisture content.

Take all reasonable precautions to avoid detectable change in moisture content of the sampled sheets. Afterwards count the remaining number of sheets in the ream, add the number removed, and report the total number of sheets in the ream. From the remaining sheets in the ream, take at random 50 consecutive sheets and inspect both sides for

(a) compliance with the requirements of 4.1,

(b) the machine direction.

Report the number of defects found. Repeat this procedure with the other ream samples. Report the total number of defects found.