Subclause 201.101.2.1 – Minimum temperature imaging range of the FACE

This requirement is intended to ensure that a complete thermogram of the FACE will exist. An incomplete thermogram of the FACE caused by out-of-range values can affect the ability of the SCREENING THERMOGRAPH to determine the TARGET.

Subclause 201.101.2.2 – Minimum radiometric temperature LABORATORY ACCURACY

The committee decided that this is the minimum radiometric LABORATORY ACCURACY that will permit the separation of febrile and afebrile individuals.

Table AA.1 illustrates some of the elements of uncertainty of the measurement of temperature using the CALIBRATION SOURCE with the SCREENING THERMOGRAPH. Table AA.1 includes examples of how to treat them in the estimation of overall uncertainty. Table AA.1 is for illustrative purposes only. Not all uncertainty components are necessarily included.

Table AA.1 – Example of relevant uncertainty terms for a SCREENING THERMOGRAPH

Component of uncertainty	Type	Uncertainty estimate	Distribution normal or rectangular and resulting divisor	Standard uncertainty
EXTERNAL TEMPERATURE REFERENCE SOURCE, u_{ER}	A	0,3	2	0,15
Maximum permissible drift of the SCREENING THERMOGRAPH, u_D	B	0,2	2√3	0,06
Maximum permissible measurement non-uniformity of the SCREENING THERMOGRAPH, u_U	B	0,2	2√3	0,06
Maximum permissible instability of the SCREENING THERMOGRAPH,u_S	B	0,2	2√3	0,06
MRTD of the SCREENING THERMOGRAPH, u_{MRTD}	B	0,1	2√3	0,03
Uncertainty of the CALIBRATION SOURCE, u_{CS}	A	0,2	2	0,10
Combined standard uncertainty, u (k = 1, a one-sigma confidence factor)				0,21
Expanded uncertainty, U (k = 2 , a two-sigma confidence factor)				0,42
Type A are evaluated by statistical methods and type B are evaluated by other means. The coverage factor, k, is chosen on the basis of the desired level of confidence. [42] NOTE The drift of the SCREENING THERMOGRAPH includes that of the EXTERNAL TEMPERATURE REFERENCE SOURCE.				

Subclause 201.101.3 – EXTERNAL TEMPERATURE REFERENCE SOURCE

These requirements are designed to ensure that the EXTERNAL TEMPERATURE REFERENCE SOURCE can be used:

– to determine whether or not the LABORATORY ACCURACY or stability is sufficient to permit reliable detection of the TARGET temperature;

– to correct the readings of the infrared camera; or

– to establish the accuracy of the SCREENING THERMOGRAPH.

To meet these objectives, the actual temperature of the EXTERNAL TEMPERATURE REFERENCE SOURCE needs to be known and should be constant.

The size of the EXTERNAL TEMPERATURE REFERENCE SOURCE relative to its distance from the DETECTOR of the SCREENING THERMOGRAPH needs to be such that there are a sufficient number of IMAGE PIXELS to permit an accurate measurement.

Subclause 201.101.3.1 – Performance

The EXTERNAL TEMPERATURE REFERENCE SOURCE should be set at a value near the THRESHOLD TEMPERATURE. The minimum temperature range of the EXTERNAL TEMPERATURE REFERENCE SOURCE was chosen to be slightly broader than the minimum temperature range of the THRESHOLD TEMPERATURE.

Subclause 201.101.3.2 – Size

The EXTERNAL TEMPERATURE REFERENCE SOURCE is required to be sufficiently large so that the SCREENING THERMOGRAPH'S measurement is not affected by its small size and to allow a clear identification of the display colour within the WORKABLE TARGET PLANE. The EXTERNAL TEMPERATURE REFERENCE SOURCE should not be larger than 10 % of the FACE so as to not adversely affect the infrared camera.

Subclause 201.101.4 – Measurement of drift and stability

This requirement is intended to ensure that the EXTERNAL TEMPERATURE REFERENCE SOURCE can be used to determine whether or not the LABORATORY ACCURACY is sufficient to permit reliable detection of the TARGET temperature and detection of a TARGET temperature that exceeds the THRESHOLD TEMPERATURE. In operational use, RESPONSIBLE ORGANIZATIONS will want the time interval between CALIBRATIONS to be as long as practicable since the SCREENING THERMOGRAPH has to be taken out of service for CALIBRATION.

Subclause 201.101.5 – Minimum resolvable temperature difference (MRTD)

This requirement is intended to ensure that the EXTERNAL TEMPERATURE REFERENCE SOURCE can be used to determine whether or not the LABORATORY ACCURACY is sufficient to permit reliable determination of the TARGET temperature and detection of a TARGET temperature that exceeds the THRESHOLD TEMPERATURE.

For a SCREENING THERMOGRAPH to be effective, a small MRTD is needed. This reflects the sensitivity of the SCREENING THERMOGRAPH when distinguishing between two close temperature values. A small MRTD permits fine adjustment of the THRESHOLD TEMPERATURE setting to optimize the effectiveness of the screening operation.

Subclause 201.101.6 – Uniformity of WORKABLE TARGET PLANE

This requirement is intended to ensure that the EXTERNAL TEMPERATURE REFERENCE SOURCE can be used to determine whether or not the LABORATORY ACCURACY is sufficient to permit reliable detection of the TARGET temperature and detection of a TARGET temperature that exceeds the THRESHOLD TEMPERATURE. The SCREENING THERMOGRAPH should have adequate uniformity in terms of the response of the DETECTOR across the whole field of view, e.g. all sensors in the DETECTOR should respond to the same electromagnetic energy emitted by an object as a consequence of its temperature in a similar way.

Subclause 201.101.7 – FACE position

SCREENING THERMOGRAPHS are used to screen the general population. The committee chose a minimum range of TARGET positions that permit ambulatory individuals to be screened, including very tall individuals, as well as ambulatory small children and individuals in wheelchairs.

Subclause 201.101.8 – SCREENING THERMOGRAPH start-up

Some infrared cameras (i.e. DETECTORS) and the EXTERNAL TEMPERATURE REFERENCE SOURCE exhibit significant drift during an initial period of stabilization. The LABORATORY ACCURACY of measurements during this period is suspect. Figure AA.3 [34] shows the actual drift of some infrared cameras and DETECTORS following start-up. Four examples of the change in measured temperature are shown. The square symbols are from an infrared camera with a single element cooled DETECTOR. The other symbols are from three different focal-plane array DETECTORS over time. The triangular symbols show the temperature readings from a cooled DETECTOR that does not indicate temperature until stability is achieved. None of these DETECTORS fulfill the LABORATORY ACCURACY requirements of this document without correction. This requirement is intended to ensure that the entire SCREENING THERMOGRAPH as a whole is ready to operate.

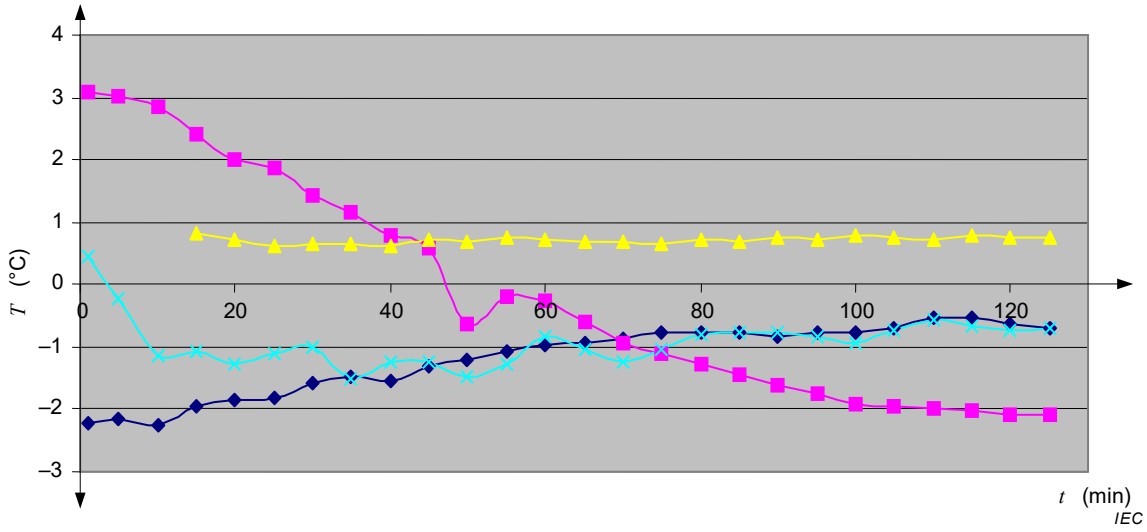

Figure AA.3 – Relative drift of 4 DETECTORS as a function of time

Subclause 201.101.9 – Spatial resolution

This spatial resolution was chosen to ensure that there is sufficient resolution to measure the temperature of the TARGET. Heated resolution charts can be used to perform this test. [27] [43] [44].

Subclause 201.101.10 – EMISSIVITY setting

Published sources have reported human skin EMISSIVITY is in the range from 0,96 to 0,98. The measurement of EMISSIVITY is difficult and the uncertainty of the measurement could typically be 2 % to 5 % (k = 2). Varying the EMISSIVITY setting in the calculation of temperature changes the reported temperature and would otherwise cause errors. As a result, this document specifies a fixed EMISSIVITY value for use in a SCREENING THERMOGRAPH.

Since the TARGET is required to include the region medially adjacent to the inner canthus, which is shaped like the entrance to a cavity, its shape can cause an enhancement in EMISSIVITY compared to flat surfaces. Sweating does cause surface cooling of the skin and changes its temperature. The committee has not found evidence to indicate that sweating skin has an effect on skin EMISSIVITY. The document requires disclosures to the RESPONSIBLE ORGANIZATION to remind them that controlled environmental conditions are needed to achieve specified performance.

The principle work on establishing the EMISSIVITY of human skin in the living body was carried out by Professor Hardy in the 1930s. [35] He demonstrated that human skin has a high value of EMISSIVITY of 0,98 regardless of skin colour. The only significant work since that time has been published by Professor Togawa, [31] whose results using a reflectance radiometric technique have confirmed the data from Hardy. [35] There are no credible references to indicate that healthy skin deviates in its EMISSIVITY value. Most authors cite 0,98 or 0,97 as the value, [45] [46] [47] which at the temperatures of the human body surface do not show significant differences in temperature whichever value is used.

Subclause 201.102.1 – Start-up ALARM CONDITION

This requirement ensures that the OPERATOR is aware when the SCREENING THERMOGRAPH is not capable of performing to specification.

Subclause 201.102.2 – Exceeding the THRESHOLD TEMPERATURE ALARM CONDITION

This requirement represents the ESSENTIAL PERFORMANCE of a SCREENING THERMOGRAPH. The THRESHOLD TEMPERATURE ALARM CONDITION is used to discriminate febrile from afebrile persons. The algorithms chosen by the MANUFACTURER to determine THRESHOLD TEMPERATURE affect the performance of the SCREENING THERMOGRAPH. The RESPONSIBLE ORGANIZATION needs to understand the algorithm (e.g. single IMAGE PIXEL, average of 4 IMAGE PIXELS, average of 16 IMAGE PIXELS) used to make this THRESHOLD TEMPERATURE determination.

Annex BB
(normative)

CALIBRATION SOURCE

The CALIBRATION SOURCE is used as a known temperature reference for characterizing the SCREENING THERMOGRAPH. As such, it is important that radiance temperature is traceable to ITS-90 [48] through a national temperature standard. The CALIBRATION of the CALIBRATION SOURCE should be performed by a laboratory that is accredited to ISO 17025 [49] for that purpose. The radiance temperature of the CALIBRATION SOURCE shall have an expanded uncertainty not greater than 0,2 °C and a combined stability and drift better than ± 0,05 °C at the operating wavelength of the SCREENING THERMOGRAPH.

The CALIBRATION SOURCE shall have a known EMISSIVITY equal to or greater than 0,998. [34] [38] [50].

Annex CC
(informative)

Reference to the essential principles

This document has been prepared to support the essential principles of safety and performance of SCREENING THERMOGRAPHS as medical devices according to ISO 16142-1:2016. [51] This document is intended to be acceptable for conformity assessment purposes.

Compliance with this document provides one means of demonstrating conformance with the specific essential principles of ISO 16142-1:2016. Other means are possible. Table CC.1 maps the clauses and subclauses of this document with the essential principles of ISO 16142-1:2015.

Table CC.1 – Correspondence between this document and the essential principles *(1 of 3)*

Essential principle of ISO 16142-1:2016, Annex B	Corresponding clause(s)/subclause(s) of this document	Qualifying remarks/notes
1	all	The part relating to manufacturing is not addressed.
a)	206	
b)	206	
2	201.4	The part relating to manufacturing is not addressed.
a)	all	
b)	201.4	The part relating to manufacturing is not addressed.
c)	201.1.3, 201.7	
d)	201.7	
3	all	The part relating to manufacturing is not addressed.
4	all	
5	201.4, 201.15	
6	201.4	
8.1	—	
a)	201.11	
b)	201.4, 201.11	
c)	201.9, 201.15	
8.3	201.11	
8.4	201.11	
12.1	201.7, 201.14, 201.16	
12.2	—	
a)	206	
b)	206	
c)	201.5, 202	
d)	201.11	
e)	201.14, 201.16	
f)	201.11	

Table CC.1 *(2 of 3)*

Essential principle of ISO 16142-1:2016	Corresponding clause(s)/subclause(s) of this document	Qualifying remarks/notes
g)	202	
12.4	201.11	
12.5	201.7, 201.8	
12.6	201.1.3	
13.1	201.101	
13.2	201.7	
13.3	206	
13.4	201.7	
15.1	201.14	
15.2	201.14	
16.1	201.4, 201.13	
16.5	202	
16.6	202	
16.7	201.8	
17.1	201.9	
17.2	201.9	
17.3	201.9	
17.4	201.15	
17.5	201.15	
17.6	201.11	
19.1	201.7	
19.2	206	
21.1	201.7	
21.2	201.7	
21.3	201.7	
21.4	201.7	
21.5	—	
a)	201.7.2.2	
b)	201.7.2.2	
d)	201.7.2.2	
k)	201.7	
l)	201.7.2.2	
21.6	201.7.2.2	
21.7	—	
a)	201.7.9.1	
b)	201.7.9.1	
h)	201.7.9.2.9	
i)	201.7.9.2.9	
k)	201.14, 201.16	
l)	201.7	

Table CC.1 *(3 of 3)*

Essential principle of ISO 16142-1:2016	Corresponding clause(s)/subclause(s) of this document	Qualifying remarks/notes
p)	201.11	
q)	201.7	
21.8	201.7	

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