g) Aftercare should include 5 min to15 min pressure, pressure bandage >1 h, instructions for limited activity and Principal Investigator's contact information.

The committees believe evidence indicates that with the use of PROCEDURES as described in presentations in the October 5-6, 2015 meeting, the RESIDUAL RISK inherent in a controlled hypoxia study and arterial line placement in healthy adult volunteers, after suitable mitigation by following these additional PROCEDURES, can be reduced to a non-significant level.

Subclause 201.12.1.101.3 — Data analysis for determination of SpO_2 ACCURACY

CO-OXIMETERS have an inherent inaccuracy that will influence SpO_2 ACCURACY assessment[14]. To reduce PULSE OXIMETER EQUIPMENT inaccuracy, the inaccuracy of the reference CO-OXIMETER'S measurement of SaO_2 needs to be controlled.

The committees are not aware of a practical or traceable PROCEDURE that allows a MANUFACTURER or RESPONSIBLE ORGANIZATION to VERIFY SaO_2 ACCURACY of a CO-OXIMETER. To minimize the influence of the CO-OXIMETER inaccuracy in the A_{rms} measurement, careful attention should be paid to ensure that the CO-OXIMETER is performing within its specified performance capability. VERIFICATION of correct operation by use of the CO-OXIMETER MANUFACTURER'S recommended maintenance PROCEDURES is necessary, but is not sufficient to ensure a traceable, accurate measurement. Further quality assurance PROCEDURES for VERIFYING CO-OXIMETER ACCURACY are needed.

EXAMPLE 1 CLSI[4]

EXAMPLE 2 College of American Pathologists[31]

Subclause 201.12.4.101 — DATA UPDATE PERIOD

PULSE OXIMETER EQUIPMENT is required to provide an indication that the displayed SpO_2 value is not current if the DATA UPDATE PERIOD of SpO_2 exceeds 30 s. Subclause 201.7.9.2.1.101 includes a requirement to disclose the DATA UPDATE PERIOD in the ACCOMPANYING DOCUMENTS. However, there is no requirement that limits the duration of the DATA UPDATE PERIOD. The additional requirement that "there shall be an indication that the displayed value is not current" was added by the committees based on potentially significant delays that can occur between an event that activates an ALARM CONDITION, and the actual generation of the ALARM SIGNALS. The displayed SpO_2 value does not reflect changes in the measured SpO_2 value until completion of each update period. If an event that activates an ALARM CONDITION, such as PATIENT desaturation, occurs just after the display is updated, a significant delay could occur between the event and the generation of the ALARM SIGNALS. This could create a HAZARDOUS SITUATION for the PATIENT if the DATA UPDATE PERIOD is long.

To mitigate this potentially HAZARDOUS SITUATION, the committees believe it is important for the PULSE OXIMETER EQUIPMENT to provide an indication to the OPERATOR when the displayed SpO_2 value has not been updated in the last 30 s, and as such, can be invalid. This provides the OPERATOR timely information to assess the PATIENT'S condition and take appropriate action, if necessary.

Subclause 201.12.4.102 — Signal inadequacy

Clinicians assume that SpO_2 ACCURACY degrades under various physiological and environmental conditions, and they wish to see an indicator of performance degradation. They generally assume that the plethysmographic display will reveal performance degradation due to motion and poor pulsatile signal strength. Consequently, clinicians would like to require the display of the non-NORMALIZED plethysmogram. (It is also generally assumed that the plethysmograms that are NORMALIZED in amplitude will hide significant changes in signal strength, the time-varying component of the infrared waveform.)

In fact, many factors contribute to degradation of signal adequacy with potential loss of ACCURACY. Changes of the plethysmogram can be sensitive to noise and changes in signal strength, but plethysmographic changes are not specific to factors that degrade ACCURACY versus factors that corrupt the plethysmogram but do not degrade ACCURACY. These factors can include, but are not limited to: signal strength, noise frequency and

amplitude, source of noise, plethysmographic morphology, ambient light intensity and sensor positioning and alignment.

Ideally, it would be beneficial to provide a means for assessment of signal adequacy as it relates to general performance, including confidence in measurement ACCURACY. Although this would best be accomplished by a comprehensive real-time assessment of signal adequacy and a visual indication of said status, it can also be accomplished in a clinically acceptable manner, e.g. with an appropriately scaled plethysmographic display.

A non-scaled plethysmographic display can lack the resolution to reveal clinically significant changes in signal strength in the low range[32][33][34]. Therefore, scaling of the plethysmographic display to increase resolution in the low signal-strength range can enhance the utility of the plethysmogram for assessing changes in signal strength.

Subclause 201.15.3.5.101 — Additional requirements for rough handling

ME EQUIPMENT, including PULSE OXIMETER EQUIPMENT, in NORMAL USE, used for professional transport of a PATIENT outside a professional healthcare facility will be subjected to these mechanical stresses (e.g. vibration, shock, bump, and drop) and could randomly be subjected to additional stresses. Therefore, ME EQUIPMENT intended to be used for professional transport of a PATIENT outside a professional healthcare facility needs to be robust enough to withstand the mechanical strength testing described by IEC 60721-3-7, class 7M3[35]. IEC 60721-3-7 indicates that in addition to the conditions covered by class 7M2, class 7M3 applies to use at and direct transfer between locations with significant vibrations, or with high-level shocks. Rough handling and transfer of ME EQUIPMENT is expected in these environments.

There are no established generalized test programmes that exactly reproduce the variety of vibration and shock conditions that ME EQUIPMENT can meet when installed in a range of land vehicles and aircraft. Therefore the dynamic tests specified in this subclause have been chosen because ME EQUIPMENT tested to these levels are likely to withstand the dynamic disturbances routinely seen during use in the range of vehicles and aircraft (including helicopters) likely to be used to transport PATIENTS.

The use of ME EQUIPMENT in road ambulances, fixed-wing and rotary wing aircraft, naval vessels, etc. can require additional tests and VERIFICATION of safety when used in these different environments.

For free-fall testing described in IEC 60068-2-31, the committees used the rationale for the various levels to gauge the severity of the test based on Table AA.1 of this rationale. The category of the test level chosen for PORTABLE ME EQUIPMENT was PORTABLE cases. The committees agreed that PULSE OXIMETER EQUIPMENT should be required to meet a level of drop testing for the professional transport environment. The committees also agreed that much PULSE OXIMETER EQUIPMENT is likely to be supplied with a protective or carrying case for use in transport environments. The committees agreed that it would be an adequate test for PORTABLE ME EQUIPMENT to be dropped while in their carrying cases, as this would be most like the real world environment. For MOBILE ME EQUIPMENT, a less severe level was chosen since wheeled ME EQUIPMENT is typically heavier.

In selecting the requirements, the committees reviewed other sources for material related to these tests (e.g. FDA Reviewers Guidance[36] for premarket notification submissions, Mil Std 810) but found the best fit was with IEC 60721-3-7:2002[35] and its companion IEC/TR 60721-4-7:2001[17]. This document mapped well to the requirements defined in Table AA.1. The aforementioned document specifies 3 classes of mechanical conditions: 7M1, 7M2 and 7M3. The committees found that classes 7M2 and 7M3 best represent the conditions seen during transport of a PATIENT within a professional healthcare facility and professional transport of a PATIENT outside a professional healthcare facility, respectively. The committees agreed that different tests and test levels should be applied to ME EQUIPMENT intended for use in a professional healthcare facility versus ME EQUIPMENT intended for use during professional transport of a PATIENT outside the professional healthcare facility.

Table AA.1—Qualitative assessment of PULSE OXIMETER EQUIPMENT shock and vibration environment

ME EQUIPMENT category	Location											
	Standard environments						Transport vehicles					
	Home			Healthcare facility			Wheels			Wings/Rotary		
MOBILE	D1	S1	V1	D1	S2	V1	D1	S3	V2	D1	S3	V3
PORTABLE	D1	S2	V0	D1	S2	V1	D1	S3	V2	D1	S3	V3
HAND-HELD	D3	S1	V0	D3	S2	V1	D3	S3	V2	D3	S3	V3
STATIONARY	None			None			Not applicable					
S = shock; V = vibration; D = drop Rating: 0 = no test, 1 = least severe or 7M1[a]; 2 = moderate severity or 7M2; 3 = most severe or 7M3												
[a] The 7Mx designations are defined in IEC 60721-3-7:2002[35].												

VERIFYING that the ME EQUIPMENT is functioning within the MANUFACTURER'S specifications while the vibration (random and sinusoidal) tests are being conducted was not believed necessary. This line of thought was considered and it was decided that the test done in this manner would be overly burdensome and would only add a minimum additional level of safety to the ME EQUIPMENT that would not outweigh the costs. VERIFYING proper functioning after completion of the tests is believed adequate.

Subclause 201.15.3.5.101.1 — Shock and vibration

ME EQUIPMENT, including PULSE OXIMETER EQUIPMENT, in NORMAL USE, used within a professional healthcare facility will be subjected to these mechanical stresses (e.g. vibration, shock) and could randomly be subjected to additional stresses. Therefore, ME EQUIPMENT intended to be used in the professional healthcare facility needs to be robust enough to withstand the vibration and shock testing described by IEC 60721-3-7 level 7M2[35]. IEC 60721-3-7 indicates that this class applies to use at, and direct transfer between, locations with only low-level vibrations, or with medium-level shocks. Careful handling and transfer of products is expected in these environments.

The committees chose the duration of 10 min for the random vibration test even though the duration recommended by IEC 60721-3-7 is 30 min to maintain testing compatibility with ISO 80601-2-61:2011[1]. As was indicated in the previous edition[1], the committees increased the duration to 30 min.

Subclause 201.101 — PULSE OXIMETER PROBES and PROBE CABLE EXTENDERS

PULSE OXIMETER PROBES and PROBE CABLE EXTENDERS are as important in establishing the safety and ACCURACY of the complete PULSE OXIMETER EQUIPMENT as is the PULSE OXIMETER MONITOR itself. Subclause 201.101 establishes that the MANUFACTURER of the PULSE OXIMETER PROBE or PROBE CABLE EXTENDER (including a MANUFACTURER of a REPROCESSED PULSE OXIMETER PROBE or PROBE CABLE EXTENDER) is responsible for the separately testable properties (e.g. biocompatibility) of their components as well as for the affected combined properties. This MANUFACTURER is responsible for testing the affected combined properties for their PULSE OXIMETER PROBE or PROBE CABLE EXTENDER when used with any PULSE OXIMETER EQUIPMENT they have specified as compatible. The affected combined properties include at least ACCURACY, EMC, electrical safety, and protection against excessive temperature at the PULSE OXIMETER PROBE-tissue interface. As an example of a possible effect of REPROCESSING on biocompatibility, some surface-cleaning agents can result in impregnation of the material with solvent that, if not sufficiently removed by subsequent processing, can cause a chemical burn when that PROCESS is not described (and therefore VALIDATED) in the ACCOMPANYING DOCUMENTS.

Subclause 201.103.2 — Connection to electronic health record

The Society for Technology in Anesthesia (STA) proposed the following horizontal guidance:

A medical device electronic data interface (EDI) shall be capable of communicating the following.

– Medical device identification data including manufacturer, model number, device serial number and software/firmware version number.

– All data available for display to the operator, including numeric values, waveforms and alarm conditions.

– The mode of operation and the state of operator-configurable equipment settings (e.g. signal filters, signal averaging time, alarm limits).

– Medical device clock time and last clock time update, time zone.

– Patient ID if stored in the medical device.

This document applies these general requirements to PULSE OXIMETER EQUIPMENT.

PULSE OXIMETER EQUIPMENT should be equipped with a FUNCTIONAL CONNECTION that permits integration into an integrated clinical environment. If the PULSE OXIMETER EQUIPMENT is equipped with data transmission, Annex HH contains requirements regarding the data transmission.

The transmission of PULSE OXIMETER EQUIPMENT data to other ME EQUIPMENT, ME SYSTEMS or health software systems for purposes including decision support, control and data logging is problematic due to the use of proprietary interfaces and protocols. It is the intent of this document, as a safety and performance standard, to define a minimum set of measured parameters, equipment identification parameters and equipment settings that should be available for transmission if the PULSE OXIMETER EQUIPMENT'S external data interface is intended to be incorporated into an integrated clinical environment (ICE). The standardization of a minimum set of parameters and settings allows greater interoperability between PULSE OXIMETER EQUIPMENT and ME SYSTEMS, thus enabling new applications and paradigms that can increase PATIENT SAFETY and improve PATIENT care such as part of an infusion delivery system.

It is not intended to define a specific device information model for PULSE OXIMETER EQUIPMENT communication. The ISO/IEEE 11073 family of standards defines one such model and includes for specific equipment, such as PULSE OXIMETER EQUIPMENT, a device specialization document (ISO 11073-10404)[37]. Another approach, divides the healthcare space into domains. One such domain, the IHE Patient Care Device (PCD)[2] domain through the use of existing standards such as HL7 and clinical language vocabularies such as LOINC, is described as providing a framework for integrating medical devices into the healthcare enterprise. ASTM F2761-14 on the Integrated Clinical Environment (ICE) describes the need for an "ICE" model to take into consideration interactions with the connected ME EQUIPMENT, workflow, and PATIENT state to support the coordinated use of medical devices for improved PATIENT SAFETY[18].

PULSE OXIMETER EQUIPMENT in clinical use has provided parameters, identification data and settings through the FUNCTIONAL CONNECTION. However, that data has been transmitted primarily using proprietary interfaces and protocols. To help foster interoperability of PULSE OXIMETER EQUIPMENT in the medical device ecosystem, increased standardization of this interface is desirable. This document has sought logically to categorize the data that can be transmitted or received as parameters, identification data, settings data, configuration data, specification data, service monitoring data and ALARM SYSTEM-related data. In addition to these categories and types of data, MANUFACTURERS are encouraged to leverage the FUNCTIONAL CONNECTION to allow the PULSE OXIMETER EQUIPMENT greater capabilities, including the use of intelligent algorithms that can reside in the PULSE OXIMETER EQUIPMENT and which can adjust their algorithm or display settings based upon information received externally. This includes, for example, location, status and data from other sensors, such as the sphygmomanometer to indicate inflation if the cuff and PULSE OXIMETER SENSOR are on the same limb.

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2 Available at https://www.ihe.net/Patient_Care_Devices/.

With the proliferation of PULSE OXIMETER EQUIPMENT with varying performance and features, it is becoming increasing important for clinical care to determine the PULSE OXIMETER EQUIPMENT'S suitability for a particular clinical application. At the moment, this is solely determined by caregivers based on their knowledge of the equipment and requirements of the application. Given that the requirements for an application such as closed-loop control (whether it be autonomous or with a clinician providing the titration) depends on PULSE OXIMETER EQUIPMENT specifics such as averaging time, ACCURACY of attached PULSE OXIMETER PROBE, time response and delays in the PULSE OXIMETER EQUIPMENT, the determination of applicability of the PULSE OXIMETER EQUIPMENT can be challenging for the average caregiver. However, if the PULSE OXIMETER EQUIPMENT provides this information through the FUNCTIONAL CONNECTION, the determination of applicability can be made by querying the equipment settings, configuration and specifications.

Subclause 208.6.1.2.101 — Additional requirements for ALARM CONDITION priority

The language in the previous versions of this document is similar, except that the introductory phrase is "If intended for continuous monitoring…". This language led to extended discussions among committee members and their advisors as to just what were the circumstances in which low SpO_2 attended monitoring" are sufficiently ambiguous to require extensive clarification, and might be interpreted to include sleep studies, which do not require PHYSIOLOGICAL ALARM CONDITIONS at all. The committees finally agreed that OPERATORS and RESPONSIBLE ORGANIZATIONS should know when they require a PULSE OXIMETER MONITOR to have PHYSIOLOGICAL ALARM CONDITIONS, so that a useful contribution of this document would be to ensure that PULSE OXIMETER MONITORS having no PHYSIOLOGICAL ALARM CONDITIONS are labelled appropriately (see 201.7.2.101 and 201.7.9.2.1.101 f)), and that if such ALARM CONDITIONS are included, there is an ALARM CONDITION for the parameter that is usually most important, i.e. low SpO_2.

Some PULSE OXIMETER MONITORS can have TECHNICAL ALARM CONDITIONS for PULSE OXIMETER EQUIPMENT-related variables, such as low battery, but no PHYSIOLOGICAL ALARM CONDITIONS. Such PULSE OXIMETER MONITORS are not required to have a low SpO_2 level ALARM CONDITION.

Subclause 208.6.5.4.101 – Additional requirements for DEFAULT ALARM PRESET

An 85 % SpO_2 is a generally accepted lower ALARM LIMIT for most clinical situations; however lower ALARM LIMITS can be desirable in particular clinical conditions. The OPERATOR is permitted to set lower ALARM LIMITS during NORMAL USE.

In selecting 85 % SpO_2 as the minimum MANUFACTURER-configured default ALARM LIMIT for the low SpO_2 level ALARM CONDITION, the committees made a compromise between two clinical requirements. One requirement was that PULSE OXIMETER EQUIPMENT should act as an early indicator of distress in a PATIENT with relatively normal oxygenation. In this situation, it would be good clinical practice to select a default ALARM LIMIT above the "knee" of the oxyhaemoglobin dissociation curve that provides as much margin of safety as is practical. The second requirement is to avoid frequent ALARM SIGNALS not necessarily requiring clinical intervention, which might "desensitize" caregivers to ALARM SIGNALS (i.e. cause 'alarm fatigue'). In this case, one might argue for a default ALARM LIMIT low enough to guarantee that most ALARM CONDITIONS would be meaningful by anyone's measure. It was acknowledged that in both clinical situations, many, if not most, OPERATORS were likely to rely on the default low SpO_2 ALARM LIMIT.

Another factor that the committees considered is that many examples of PULSE OXIMETER EQUIPMENT intended for continuous monitoring allow RESPONSIBLE ORGANIZATION-configured or OPERATOR-configured default ALARM LIMITS and that for specific monitoring settings, default ALARM LIMITS that were more closely tailored to the needs of the PATIENT and OPERATOR in that setting could be selected. Given these considerations, a lower limit of 85 % SpO_2 for the MANUFACTURER-configured default ALARM LIMIT was felt to be an acceptable compromise that best met both clinical requirements.

Annex BB
(informative)

Skin temperature at the PULSE OXIMETER PROBE

BB.1 Summary

A literature review relating to temperature requirements leads to the conclusion that it is appropriate and conservative to retain the 41 °C limit for infants (PATIENTS up to 1 year of age) and to apply the limits of 42 °C for 8 h and 43 °C for 4 h for older PATIENTS.

BB.2 Literature review

The committees have taken the use of *external* heat to produce a 35 °C surface temperature, in the absence of strong peripheral circulation, as being worst case. Although strong local perfusion can lead to a skin temperature of 35 °C or above, forced convective heat transfer by blood increases the effective thermal conductivity of the skin. Thus, if the 35 °C temperature is endogenously produced, a given heat input from the PULSE OXIMETER PROBE will produce less temperature rise.

In this document, the committees have adopted the FDA's 35 °C rule for the test environment, and made explicit an interpretation that "ambient" temperature, as used in the FDA guidance[36], can be taken as local skin temperature when the PULSE OXIMETER PROBE is not energized. Heat generated by the light-emitting diodes of a PULSE OXIMETER PROBE primarily dissipates through the skin of the PATIENT, not to the surrounding air. Thus the PATIENT'S skin temperature (without the PULSE OXIMETER PROBE) is much more important in determining the temperature to which the PULSE OXIMETER PROBE/skin interface eventually rises than is the temperature of the surrounding air. It is therefore appropriate for skin temperature, rather than air temperature, to be specified.

The same 35 °C maximum skin temperature appears in this document for neonates as for adults. 35 °C is a sufficient maximum, even though infant incubators can be adjusted to raise abdominal skin temperature as high as 37 °C. In the absence of strong local perfusion, the skin of the extremities is several degrees cooler than the skin of the abdomen, as indicated in the following literature:

– Templeman and Bell[38] showed mean heel temperatures near 33 °C, when abdominal temperature was regulated in the 36 °C to 37 °C range, in both air-heated incubators and radiant warmers;

– Malin and Baumgart[39] showed, in a radiant warmer environment, mean heel temperatures were 4,5 °C below mean rectal temperature when the abdominal wall temperature was 35,5 °C, but only about 2 °C below at 37,5 °C;

– Topper and Stewart[40] studying the use of heated water pads to supplement radiant warmers, found back and abdomen temperatures were nearly equal, but mean foot temperature was about 2,1 °C lower (heating pad on) and 2,6 °C lower (heating pad off);

– Seguin[41] studied the distorting effects on incubator servo control of heated transcutaneous sensors. During the control phase, with the transcutaneous sensor not in use, mean foot temperature was 33,4 °C, for an oesophageal temperature of 36,9 °C. This work was with radiant warmers, servo-controlled for an abdominal skin probe temperature of 36,5 °C to 37 °C;

– Harpin *et al.*[42] studying the responses of newborns to overheating, in air-heated incubators, showed a consistent pattern in which hand temperature was 1,5 °C to 5 °C below rectal

temperature when the baby was at the low end of the "thermoneutral" range, to about 0,5 °C below rectal temperature when the baby was overheated. The authors interpreted the higher hand temperatures as consistent with stronger local circulation.

– Greenhalgh, *et al.*[43] studied PATIENTS scheduled for removal of redundant skin (abdominoplasty, breast reduction surgery). PULSE OXIMETER PROBES were applied and left in place for 8 h (or less if significant pain was noted) and set at 42,5 °C, 43 °C, 43,5 °C, and 44 °C. They found that PULSE OXIMETER PROBES were safe up to a temperature of 43 °C for at least 8 h on well-perfused skin.

Additional published reviews and case reports confirm these findings. [44][45][46][47][48][49][50][51][52].

There is little experimental evidence supporting the possibility that the natural damage-repair mechanism of skin is weaker when circulation is poor and whether that could lead to a lower threshold temperature for thermal injury[53]. An early direct experiment[54] done on pigs showed no effect of local perfusion on injury threshold. More recent experiments, also on pigs[55][56], showed that in the presence of high local pressure (100 mmHg) over a large area (51 mm to 57 mm diameter) it is hard to define a threshold temperature for injury. Greater injury occurred at 35 °C than at 25 °C, but some injury occurred at 25 °C. Any recommended safe temperature threshold for PULSE OXIMETER PROBES should be accompanied by the usual caution that PULSE OXIMETER PROBES need to be applied so as to avoid excessive pressure[57]. Given this precaution, the recommended temperature thresholds appear safe in view of the most pessimistic literature values. In this way, the effects of poor perfusion that probably existed in some of the experimental subjects who were studied have been included.

Table BB.1 shows the committee's best estimates of the safe skin temperature thresholds implied by each of many reports in the clinical literature. The inconsistencies among these reports arise from at least two causes.

– All the available data for neonates come from studies of transcutaneous blood gas monitoring, in which the observed variable is usually the temperature of the transcutaneous sensor core. Skin temperature is an uncontrolled variable, which the committees have estimated as being 1 °C below the transcutaneous sensor core temperature, but which can actually vary more widely[48][58][59][60].

– Important variables, including the ACCURACY of temperature measurements and the varying physiology of PATIENTS, were not addressed consistently in many of these experiments.

To interpret each report, the threshold safe temperature was taken to be the level at which no blisters were observed. Erythema, which might imply heat-induced hyperaemia, or might imply thermal damage to part of the thickness of the epidermis (commonly called a first-degree burn), was taken as marginally acceptable, since recovery from simple reddened skin is typically rapid. Blisters are unambiguously recognizable as injuries and imply damage to basal cells in the epidermis (a second-degree burn). If the duration of exposure was less than 8 h, the committees arrived at the safe 8 h temperature using the rule of thumb of Moritz and Henriques[49][54] that doubling exposure time reduces the safe temperature by 1 °C.

Table BB.1—PULSE OXIMETER PROBE safe application time and source

Reference	Safe skin temperature for *n* h	Safe skin temperature for 8 h
Neonates		
Boyle, 1980[46]	43 °C for 4 h to 7 h	>42 °C
Bucher, 1986[62]	41 °C for 24 h	>42 °C
Cabal, 1981[48]	42,5 °C for 4 h	>41,5 °C
Eberhard, 1975[63]	41 °C for up to 84 h	>42 °C
Eberhard, 1976[58]	43 °C for 4 h "eliminate[d] the risk of blister formation *almost* entirely". 42 °C was "tolerated well [for] up to 24 h."	42 °C
Fanconi, 1996[64]	41 °C for up to 24 h, in the absence of eugenol	>41 °C
Golden, 1981[65]	<42 °C for 2 h	<40 °C
Huch, 1981[59][66]	44 °C for 1 h (appears to be a purposely conservative guess. No data presented)	41 °C
Laptook, 1981[67]	43 °C for 4 h	42 °C
Löfgren, 1983[68]	<43 °C for 8 h	42 °C
Monaco, 1981[69]	43 °C, 3 h to 4 h	42 °C
Rimdeika, 2005[70]	≤ 42°C, burns noted after 15 min contact with water warmer	≤ 42°C,
Schachinger, 1983[71]	<43 °C, 2 h. No original data presented	<41 °C
Venus, 1981[72]	44 °C, up to 6 h	43 °C
Intermediate ages		
Poler, 1992[50]	43 °C for period of application of pulse oximeter	43 °C
Adults		
Greenhalgh, 2004[43]	43 °C for 8 h	43 °C
Manzinger, 1990[73]	Rats, not humans. Water baths at 60 °C, 75 °C, and 90 °C, for 4 s, 10 s, or 15 s	Results generally support Moritz
Moncrief, 1979[74]	44 °C for 6 h (this is a review article, not an experimental report, and might actually be based on Moritz[51][56]	>43 °C
Moritz, 1947[49][54]	44 °C for 5 h	>43 °C
Poler, 1992[50]	43 °C for period of application of pulse oximeter	43 °C
Vyas, 1988[75]	43 °C for 8 h	43 °C
Wienert, 1983[53]	<43 °C for 8 h	<43 °C

The literature references fall, for the most part, into two groups. There are many citations of work with transcutaneous monitors, which apply for the most part to neonates. Another group of documents represent burn threshold studies with adult volunteers. Only a few references apply to subjects in the intermediate age group.

Reviewing the estimates in Table BB.1 led to the following conclusions:

– 42 °C should be safe for infants (including neonates), but there are enough conflicting results to warrant caution. For this reason, it is recommended that the traditional 41 °C limit for infant applications not be increased and that the default setting of 41 °C be retained.

– 43 °C for 8 h should be safe for adults, but there have been few studies since the classic work of Moritz *et al.;* and the results of Wienert *et al.* suggest caution. For that reason, it was concluded that the justifiable limit for adults is 42 °C for 8 h, and (using Moritz's rule), 43 °C for 4 h.

It is appropriate and conservative to retain the 41 °C limit for infants (PATIENTS up to 1 year of age) and to apply the limits of 42 °C for 8 h and 43 °C for 4 h for older PATIENTS, based on the observation that dermal circulation is immature before 1 y of age[51] and that in other structural respects the skin is adult-like by this age[61].

BB.3 Test methods

This document does not require a particular method of measuring the skin temperature beneath the PULSE OXIMETER PROBE. There are many different widely known and accepted methods of measuring surface temperatures. Different PULSE OXIMETER PROBE MANUFACTURERS have evolved their own methods of measuring temperature, using either human test subjects or thermo-mechanical simulators. It would be impractical today to find a single universally acceptable test method, and the excellent thermal safety record of pulse oximetry suggests that such a method is not necessary. PULSE OXIMETER PROBE designers who wish to take advantage of the higher temperatures should keep the following cautions in mind.

– Measurement tolerances are required to be evaluated carefully. The MANUFACTURER should know the true ACCURACY of temperature measurement when designing PULSE OXIMETER PROBES for use at temperatures above 41 °C since a higher temperature reduces the margin of safety.

– Temperature sensors are required to be small enough so as not to distort the measurement. The largest temperature sensors that have been found acceptable have characteristic dimensions near 0,5 mm (e.g. the bead of a thermocouple welded from 0,25 mm wire). Often still smaller temperature sensors are used.

– The temperature sensor is required to not reduce the measured peak temperature by conducting a significant amount of heat away from the measurement region. Thus, it would usually be inappropriate to use the copper-constantan type T thermocouples that are common in medical investigation, since the high thermal conductivity of the copper wire could cause a falsely low temperature measurement.

– Experimental methods are required to be adequate to ensure that recommended temperature limits are met under "reasonable worst case" conditions. As an example, reasonable worst case for neonatal PULSE OXIMETER PROBES might include the following conditions.

  – The PATIENT has poor peripheral circulation. There is therefore little forced-convection heat transfer by blood to increase the effective thermal conductivity of surface tissue.
  – The light-emitting diodes (LEDs) in the PULSE OXIMETER PROBE are driven at the maximum current which the PULSE OXIMETER MONITOR is capable of providing during normal operation (this condition can occur when the PATIENT has very dark skin or a thick foot).
  – An active heat source is in use to raise the baby's abdominal skin temperature artificially to 37 °C.

It is not the intention to require that every model of PULSE OXIMETER PROBE be tested directly on "worst-case" PATIENTS. The MANUFACTURER should select methods for evaluation of the thermal performance of the PULSE OXIMETER PROBE that lead to confident prediction of thermal safety on such PATIENTS.

Annex CC
(informative)

Determination of ACCURACY

CC.1 General

This annex discusses both the formulae used to evaluate the quality of PULSE OXIMETER EQUIPMENT measurements, and the names that are assigned to those formulae.

It has been common for the SpO_2 ACCURACY specifications of PULSE OXIMETER EQUIPMENT to be stated in terms such as "±2 %, one standard deviation." In this document, the committees have chosen a different name for the recommended SpO_2 ACCURACY measure, while retaining essentially the same formula (a value of n − 1 is replaced with n) that has been in common use. The committees recommend definitions of LOCAL BIAS, MEAN BIAS, and PRECISION that are consistent with common engineering usage, but slightly different from the meanings of these terms, as they have sometimes been used in the pulse oximetry literature. The reasons for the recommendations are explained in this annex. The committees also discuss the term "ambiguity," which was introduced by Severinghaus et al.[14], and explain the committees belief that the term ACCURACY can perform a similar function.

— CC.2 ACCURACY, bias and PRECISION

— CC.2.1 Definitions

The terms ACCURACY, bias and PRECISION have all been used in a variety of ways. *The compilation of ASTM standard definitions* (ASTM, 7th ed., 1990)[76] assembles 11 definitions of ACCURACY, 9 of bias, and 19 of PRECISION, all taken from ASTM documents. The committees have chosen specific definitions that are consistent with the general definitions appearing in ASTM E456[13]. These definitions, with their associated notes, are as follows:

accuracy
the closeness of agreement between a test result and an accepted reference value

NOTE 1 The term accuracy, when applied to a set of test results, involves a combination of a random component and of a common systematic error or bias component.

bias
the difference between the expectation of the test results and an accepted reference value

NOTE 2 Bias is the total systematic error as contrasted to random error. There can be one or more systematic error components contributing to the bias. A larger systematic difference from the accepted reference value is reflected by a larger bias value.

NOTE 3 Expectation is a statistical term which can be interpreted approximately as the mean of the values that would be obtained if the measurement were made many times.

precision
the closeness of agreement between independent test results obtained under stipulated conditions

NOTE 4 Precision depends on random errors and does not relate to the true value or the specified value.

NOTE 5 Precision is usually expressed in terms of imprecision and computed as a standard deviation of the test results. Less precision is reflected by a larger standard deviation.