IEC 60601-2-50(E)
(First edition – 2000)

Medical electrical equipment –

Part 2-50: Particular requirements for the safety of infant phototherapy equipment

CORRIGENDUM 1

Page 15

*34 Ultraviolet radiation

Replace the existing text by the following new text:

This clause of the General Standard applies, except as follows:

Replacement:

Effective ultraviolet irradiance shall not exceed

for 180 nm < $\lambda \leq$ 400 nm $\leq 1{,}0 \times 10^{-5}$ mW/cm² ($1{,}0 \times 10^{-4}$ W/m²)

at any point of the EFFECTIVE SURFACE AREA.

Compliance with this requirement is checked by testing.

Page 22

Annex AA
(informative)

Guidance and rationale for particular subclauses

*Addition to Item **34**, page 23:*

See also IRPA Guidelines on protection against non-ionizing radiation, edited by A.S. Duchéne *et al.* Pergamon Press: Chapter 3: Guidelines on limits of exposure to ultraviolet radiation of wavelengths between 180 nm and 400 nm (incoherent optical radiation), pages 42-52.

In this publication the exposure limits (EL) were given for the near-ultraviolet UV-A spectral region (315 nm – 400 nm). The total radiant exposure incident on the unprotected skin should not exceed the values given in table AA.1.

Values for the relative spectral effectiveness, S_λ, are given up to 400 nm to expand the action spectrum into the UV-A for determining the EL for skin exposure.

To determine the effective irradiance of a broadband source weighted against the peak of the spectral effectiveness curve (270 nm), the following weighting formula should be used:

$$E_{\text{eff}} = \sum E_\lambda \times S_\lambda \times \Delta_\lambda$$

where:

E_{eff} = effective irradiance in W/m² normalized to a monochromatic source at 270 nm

E_λ = spectral irradiance from measurements in W/m²

S_λ = relative spectral effectiveness (unitless)

Δ_λ = bandwidth in nanometers of the calculation or measurement intervals

These ELs should be used as guides in the control of exposure to UV sources and as such are intended as upper limits for non-therapeutic and non-elective exposure. The ELs were developed by considering lightly pigmented populations (i.e. Caucasian) with greatest sensitivity and genetic predisposition.

It has been considered that these limits can also be used for the phototherapy of babies, when the above limits are calculated to a 3-day (72-hour) exposure (dividing the 30 J/m² by 72 h) and calculated to a constant power of irradiance in watts (W/m²) (dividing by 3 600 s). This calculation results in a reduced limited spectrum for the UV-A irradiation and respects the uninterrupted phototherapy exposition time of between 24 h and 3 days.