APPENDIX GG  
ADOPTION PROPOSAL FORM

**STA/SDV/OP/04/F1**

**KENYA BUREAU OF STANDARDS**

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| **Document Type:** | **Adoption proposal** | |
| **Dates:** | Circulation date | Closing date |
| 23-08-2019 | 22-09-2019 |
| **TC Secretary** | **This form shall be filled, signed and returned to Kenya Bureau of Standards for the attention of Oyoo T.O.** | |

The Kenya Bureau of Standards intends to adopt the International Standards as detailed here below .............................................................................................................................................

**Number.** ISO 80601-2-74:2017........................................................................................................................................

**Title.** Medical electrical equipment -- Part 2-74: Particular requirements for basic safety and essential performance of respiratory humidifying equipment

**Scope:** ISO 80601-2-74:2017 applies to the basic safety and essential performance of a humidifier, also hereafter referred to as me equipment, in combination with its accessories, the combination also hereafter referred to as me system.

ISO 80601-2-74:2017 is also applicable to those accessories intended by their manufacturer to be connected to a humidifier where the characteristics of those accessories can affect the basic safety or essential performance of the humidifier.

EXAMPLE 1 Heated breathing tubes (heated-wire breathing tubes) or me equipment intended to control these heated breathing tubes (heated breathing tube controllers).

NOTE 1 Heated breathing tubes and their controllers are me equipment and are subject to the requirements of IEC 60601‑1.

NOTE 2 ISO 5367 specifies other safety and performance requirements for breathing tubes.

ISO 80601-2-74:2017 includes requirements for the different medical uses of humidification, such as invasive ventilation, non-invasive ventilation, nasal high-flow therapy, and obstructive sleep apnoea therapy, as well as humidification therapy for tracheostomy patients.

NOTE 3 A humidifier can be integrated into other equipment. When this is the case, the requirements of the other equipment also apply to the humidifier.

EXAMPLE 2 Heated humidifier incorporated into a critical care ventilator where ISO 80601‑2-12[12] also applies.

EXAMPLE 3 Heated humidifier incorporated into a homecare ventilator for dependent patients where ISO 80601‑2-72[14] also applies.

EXAMPLE 4 Heated humidifier incorporated into sleep apnoea therapy equipment where ISO 80601‑2-70[13] also applies.

ISO 80601-2-74:2017 also includes requirements for an active hme (heat and moisture exchanger), me equipment which actively adds heat and moisture to increase the humidity level of the gas delivered from the hme to the patient. This document is not applicable to a passive hme, which returns a portion of the expired moisture and heat of the patient to the respiratory tract during inspiration without adding heat or moisture.

NOTE 4 ISO 9360‑1[5] and ISO 9360‑2[6] specify the safety and performance requirements for a passive hme.

If a clause or subclause is specifically intended to be applicable to me equipment only, or to me systems only, the title and content of that clause or subclause will say so. If that is not the case, the clause or subclause applies both to me equipment and to me systems, as relevant.

Hazards inherent in the intended physiological function of me equipment or me systems within the scope of this document are not covered by specific requirements in this document except in IEC 60601‑1:2005+AMD1:2012, 7.2.13 and 8.4.1.

NOTE 5 Additional information can be found in IEC 60601‑1:2005+AMD1:2012, 4.2.

ISO 80601-2-74:2017 does not specify the requirements for cold pass-over or cold bubble-through humidification devices, the requirements for which are given in ISO 20789:?.[8]

This document is not applicable to equipment commonly referred to as "room humidifiers" or humidifiers used in heating, ventilation and air conditioning systems, or humidifiers incorporated into infant incubators.

ISO 80601-2-74:2017 is not applicable to nebulizers used for the delivery of drugs to patients.

NOTE 6 ISO 27427[10] specifies the safety and performance requirements for nebulizers.

ISO 80601-2-74:2017 is a particular standard in the IEC 60601‑1 and the ISO/IEC 80601 series.

We are therefore seeking views from potential users in respect of the same. The Standard is available at the Kenya Bureau of Standards Information Centre. Please tick and fill your preference of the listed option. (If the spaces provided are not enough, please attach a separate sheet of paper).

Adoption acceptable as presented

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Adoption proposal not acceptable because of the reason(s) below

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Our Recommendations are as follows

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Name and Signature (of respondent): ................................................

Position (of respondent): .....................................

On behalf of ......................................................................................... (Name of organization)

Date .........................................................................

**NOTE:** Absence of any reply or comments shall be deemed to be an acceptance of the proposal for adoption and **shall constitute an approval vote**.