



AC/32/2020

Administrative Circular

2020-09-18

To all:

National Committees

Technical committees, subcommittees, systems committees, and technical advisory committees
Officers of the IEC Conformity Assessment System National Committees

COVID-19: Key IEC and ISO Standards related to critical care ventilators to facilitate increase of production

Dear Sir/Madam,

As set out in [AC/12/2020](#), IEC and ISO have made several standards available free of charge to the extent that they support the fight against the COVID-19 pandemic. The initiative includes the ISO standards about medical ventilators to ease the development of such devices. IEC offers a package of standards which are required to properly use these ISO standards about medical ventilators.

The IEC package includes:

- **IEC 60601-1:2005+AMD1:2012 CSV**, *Medical electrical equipment - Part 1: General requirements for basic safety and essential performance*
- **IEC 60601-1-2:2014**, *Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic disturbances - Requirements and tests*
- **IEC 60601-1-6:2010+AMD1:2013 CSV**, *Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability*
- **IEC 60601-1-8:2006+AMD1:2012 CSV**, *Medical electrical equipment - Part 1-8: General requirements for basic safety and essential performance - Collateral Standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems*
- **IEC 60601-1-11:2015**, *Medical electrical equipment - Part 1-11: General requirements for basic safety and essential performance - Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment*

The ISO standards on medical ventilators include the above five **dated** normative references. The proper use of the ISO standards requires the use of the above **dated** references. IEC has now published amendments or new editions of the above listed standards which should however not be used in conjunction with the ISO standards about medical ventilators.

National Committees are invited to note that IEC CO will not change the package of free standards and will continue to provide the standards as per the dated normative references.

IEC CO recommends keeping the same list referencing when National Committees have set up their own packages of standards free of charge to support the fight against the COVID-19 pandemic with national adoptions.

Yours faithfully,

Philippe Metzger
General Secretary & CEO

PSE