Proposal Form –
Standards Development Projects

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Please click here for guidance on the proposal submission process.

Proposal title	Amendment to ISO 80601-2-12
Your name	Saurabh Sapre
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Name of employer	Therapeutic Goods Administration (TGA)
Job title or position	Electromedical Engineer
Postal address	136 Narrabundah Ln
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State	ACT
Postal code	2609
Web address	https://www.tga.gov.au/

If you are submitting on behalf of an organisation that is different than your current employer, please fill out the information below.	
Nominating organisation	N/A
Primary contact name	N/A
Primary contact position	N/A
Primary contact email	N/A
Primary contact phone	N/A

Section 1: Scope

1A: Provide details of the proposed documents				
#	**Title** *(e.g. Masonry cement)*	**Project type** *(e.g. revision, amendment[1] or new[2])*	**Designation** *(e.g. AS 1316:2003)*[3]	**Product type** *(e.g. AS, AS Int, SA TS, etc...)* [4]
	Medical electrical equipment — Part 2-12: Particular requirements for basic safety and essential performance of critical care ventilators	Australian Modified ISO/IEC Standard (MOD)	ISO 80601-2-12	AS -
2				

1 An amendment is usually only possible for small changes to recently created documents. See Section 4 of Standardisation Guide SG-003: Standards and Other Publications for more details.

[2] If you are proposing to create a new document, please provide a suggested Title.

[3] Use the SAI Global website to obtain the full designation and name of existing documents.

[4] Standards Australia mainly develops Australian Standards (AS) but it also develops the following Product types: Australian Interim Standard (AS Int), Australian Technical Specification (SA TS), Australian Technical Report (SA TR), Handbook (SA HB), Miscellaneous Publication (SA MP), Supplement (Normative), Supplement (Informative), Australian Standard Certified Reference Material (ASCRM). For guidance, see Standardisation Guide SG-003: Standards and Other Publications.

1B: Write a clear and concise statement of the nature of the issue to be addressed by your proposal.

Describe who is affected e.g. businesses, community organisations or individuals affected by the problem. What are the consequences of no action?

The Therapeutic Goods Administration (TGA) has recently tested the performance of universal critical care ventilators using ISO 80601-2-12 as a reference and has found several deficiencies in this standard. The deficiencies in this standard means that manufacturers of critical care ventilators that comply with ISO 80601-2-12:2011 do not comply with the Essential Principles (Schedule 1 of *Therapeutic Goods (Medical Devices) Regulations 2002*). Compliance with the Essential Principles is required by the *Therapeutic Goods Act 1989*.

TGA has also been conducting a post-market review of compliance of the universal ventilator market with Australian regulations. Current information from this review shows that manufacturers have been working to the ISO 80601-2-12 standard, expecting it to be sufficient to demonstration compliance with Australian regulations. Unfortunately, the TGA's experience has been that many manufacturers have not conducted sufficient testing of their ventilator/s to prove that their device will perform as intended, because ISO 80601-2-12 falls short of the requirements in the Australian regulations.

Failure to improve the Standard in this case would mean that the performance of ventilators used in Australia are not validated sufficiently, which could lead to compromised health and safety. It will also mean that international ventilator manufacturers will continue to hit unexpected barriers to entering the Australian market, and find themselves with insufficient data to demonstrate compliance with Australian regulations when approached by the TGA.

This project will affect critical care ventilator sponsors, manufacturers and the regulator (TGA). Addressing these deficiencies will provide clear expectations for the evidence required to demonstrate that critical ventilators do not compromise health and safety, are suitable for their intended purpose, and comply with Australian legislation.

1C: Write a clear and concise proposed scope that will outline how to address the identified issue(s). **Unless this is a proposal for a new document, this should not be a scope of the document, but a scope of the work which you propose to undertake.** Include what is going to be changed from the status quo and summarise the specific intent of the change. *If you wish to include proposed revisions as tracked changes in the standard, or an outline of a new standard, please summarise the scope and note the attachment here, and include the document as an appendix to this form.*
The project scope will include additions and modifications to ISO 80601-2-12:2011 to insure that ventilators are tested for performance and safety over their entire performance range. The changes suggested are a small part of the standard found within 201.12.1.101 and 201.12.1.2 as well as some additional requirements. These additions and modifications are aimed to raise the minimum level of ventilators in Australia to be consistent with the requirements of the Essential Principles. The scope of this project is: • to ensure that all measured/displayed data is to specification. The specifications between displayed values, measured values and ventilation settings are known, tested (where applicable) and reported to users of the device (e.g. in the Instructions for Use). • Test over the full ventilation range (e.g. ISO 80601-2-12 only requires that delivered volume be tested over the range of 5 – 500 mL, but many modern ventilators deliver below 5 mL or up to 2500 mL). • Include a statement that ventilator manufacturers publish the specifications for, or specific models of, Ventilation Breathing System (VBS; a.k.a. breathing circuits) that are safe to use with their ventilator (e.g. acceptable diameters, compliance and resistance). Validation of justified/demonstrated worst cases may be sufficient and reduce the burden of testing on manufacturers. Publishing VBS specifications will help users choose a breathing circuit that has been validated with the ventilator. • Add a statement that every mode of ventilation be validated for performance over its range of operation. Validation of justified/demonstrated worst cases may be sufficient and reduce the burden of testing on manufacturers. For example, a universal ventilator shall have each of its patient modes validated over the full range (e.g. neonatal 1ml-30ml, paediatric 25ml-350ml and adult 150ml-2500ml), and each mode of delivery (e.g. pressure controlled, volume targeted, volume controlled, etc.) shall be tested over the full range. • Include content for useability testing of the device to ensure that all intended users are able to use the device as intended. It may be sufficient to reference IEC 62366-1:2015 and AAMI-HE75.

1D: Are you proposing an adoption of an International Standard (i.e. ISO or IEC)? **If so answer the following:**[5]	
Is it a Modified or Identical Adoption? Note: if Identical use the Proposal Form – Identical Adoption	Modified
What is the designation? **e.g. ISO 10303.212-2004**	IEC 80901-2-12:2011

[5] Use the SAI Global website to obtain the full designation and name of existing documents.

1E: Is the existing document referenced in Australian State, Territory or Commonwealth legislation or regulatory framework? **For joint documents, also consider New Zealand legislation.**[6]	
*Yes (*List all legislation or regulation that refer to the existing document.[7]*)* ***Note**: For National Construction Code (NCC) and WaterMark proposals, the Australian Building Codes Board (ABCB) needs to be consulted prior to submission.*	
No (Go to 1F)	X

[6] To search for standards in Australasian legislation, use our search function here.

[7] Use the full formal designation for the relevant legislation, e.g. Explosives Regulation 2013 (NSW). If more than four items of legislation are affected, provide a list as an attachment to this proposal form.

Note: All relevant regulatory authorities must be consulted in the stakeholder consultation.

1F: Is there an ISO/IEC document that also covers the issues in question?	
Yes (Go to 1G)	
No (Go to 1G)	X

1G: Will the proposed document include any conformity assessment requirements?[8]	
Yes	
No	X

[8] See Standardisation Guide SG-006: Rules for the structure and drafting of Australian Standards. Note that conformity assessment requirements are rarely permitted in a standard. If you selected "yes," please discuss with the relevant National Sector Manager prior to submission.

Section 2: Net benefit

2A: What will be the impact of the proposed project in the below categories? Explain this in terms of a positive or negative impact on the following "Net Benefit" criteria.[9]
Public health and safety (max 200 words)
Clinicians expect critical care ventilators to be accurate and work as intended when delivering therapy. It is therefore essential that these ventilators meet specifications appropriate for their intended use. Critical care ventilators also require accessories to be used including filters, humidifiers, temperature probes, flow meters and breathing circuits. Addition of these accessories will change the ventilator's performance, including the accuracy of ventilation delivery. Ventilators are not perfect devices and deliver ventilation within a specified tolerance. Clarity of the meaning of these tolerances, and the underlying assumptions, is required if clinicians are to understand the impact of particular ventilation modes and ventilator accessories on their patients. Clinicians base clinical decisions on their assumptions about the accuracy of ventilators, and the accuracy of the information reported by ventilators. Therefore it is important that clinicians are provided with accurate and complete information that is easy to understand quickly. Neonatal and paediatric patients are the most vulnerable, and can also be subject to the most inaccurate ventilation (up to 70 % error for some products). This should be clear to the physicians using the devices. This project is expected to improve the safety of patients requiring critical care ventilation in Australia.
Social and community impact (max 200 words)
The community expects that devices used in intensive care are fit for purpose and will not compromise the health and safety of critically ill Australians. The current standard does not cover all of the important performance criteria for these devices. The community expects that Standards Australia and the TGA are monitoring and improving standards when deficiencies are identified and that specific Australian requirements will be introduced when required to protect Australians.
Environmental impact (max 200 words)
Nil
Competition (max 200 words)
Currently the requirements for critical care ventilators in Australia are not clear. Detailed information is only obtainable directly from the regulator or regulatory specialists. This gives a competitive advantage to those companies who interact with the regulator frequently, or who have access to experienced (and expensive) regulatory consultants. Innovation will not be impacted as the amendments will focus on the minimum requirements for performance, safety and useability of critical care ventilators. Manufacturers are encouraged to innovate and exceed the requirements of the standard, but must meet minimum requirements to supply to the Australian market. This standard will make the requirements of entering, and remaining on, the Australian market more transparent. This is a net improvement on competition because all manufacturers have access to the same information about the requirements.
Economic impact (max 200 words)

Introduction of this standard would have a short term negative impact on ventilator manufacturers who will be required to do additional work to conform to an Australian specific standard. This will be a cost to manufacturers currently in, or planning to enter, the Australian market.

However, more importantly the standard removes a current barrier to market, which is the opaque Australian legislative requirement for critical care ventilators. Many manufacturers are unaware that ISO 80601-2-12 is not sufficient to meet the requirements of Australian legislation. This project will make the requirements clearer which will make it easier for manufacturers to enter the market, and reduce the burden on the regulator.

A net positive economic impact is expected in the long term.

[9] Add specific facts and examples if possible. Refer to the Guide to Net Benefit. Not all categories may be affected, in which case, leave these blank.

Section 3: Evidence of support — Stakeholder support

3A: Describe the process taken to gain stakeholder support for your proposal (max 100 words)

Relevant medical colleges, the Medical Technology Association of Australia (MTAA) and the Australian Commission for Safety and Quality in Healthcare(ACSQHC) were approached directly and asked to review the proposal and provide support, and any additional requirements that they wanted included in the proposal and consider the impact on communities they represent. Members of HE-017 *Medical Gas Systems* and other relevant stakeholder groups have also been consulted.

Under the legislation, the manufacturers and the regulators are responsible for the testing requirements of the standard**.**

3B: Identify the Australian stakeholder organisations that you have consulted with.
Evidence of stakeholder support MUST be provided in a letter (on company letterhead) or email (company email only).

At least two New Zealand-based stakeholders must be included for projects relating to joint AS/NZS standards. Include those that do, and those that do not, support the proposal.

Key stakeholder groups	Organisation Name	Contact name	Position	Letter or email evidence is attached: Y/N	Interested in membership of standards committee: Y/N
Research and academic organisations					
Manufacturer associations					
Testing bodies					
Certification and auditing bodies					
Supplier associations					
User and purchaser associations					
Employer and industry associations					
Professional and technical bodies					
Unions and employee associations					
Consumer and community groups					
Government and regulatory agencies					

Independent experts					
New Zealand stakeholders					
Other					

Section 4: Declaration

Please check that your proposal is complete and all fields have been filled out. Read and complete the declaration, then forward this proposal and any attached documents to Standards Australia at mail@standards.org.au. The named proponent is deemed to have approved the information contained within this proposal and this declaration.

This declaration is a mandatory requirement and proposals will not be considered without it.

I consent to Standards Australia making information relating to Standards development projects public, including information contained within a proposal form I have submitted in part or in full. In the event that Standards Australia publishes proposals on its website, proponent details at page 1 and stakeholder contact details provided at Section 3 will not be included. However, with prior agreement, my contact details may be provided to interested parties wishing to contribute or comment on the proposal or the proposed project.

The information provided in this application is complete, true and accurate to the best of my knowledge. I believe the proposed document will result in Net Benefit[10] to Australia. I have consulted with, and have the support of, national organisations with a relevant interest in this project.

Name of proponent	
Date of declaration	

[10] As defined in the Guide to Net Benefit

Section 5: Instructions and notices

To submit this proposal for Standards Australia consideration:

1. You must complete every section of this form and then submit your initial proposal draft to a National Sector Manager. Use simple, non-technical and concise language and do not use jargon of any kind. For additional information, visit the "Proposing a Project" page on our website.

2. The National Sector Manager will conduct the preliminary review of this form and then guide you as to the next steps.

3. Final submissions, along with evidence of stakeholder support, have to be provided electronically to Standards Australia (mail@standards.org.au) before the closing date of each Prioritisation Round. Please note: you should allow sufficient time to circulate your proposal to stakeholders and collect evidence of support before the Prioritisation Round deadline.

If you have any trouble with the form, you can contact us on (02) 9237 6170, 1800 035 822, or email us at mail@standards.org.au.

For identical adoptions of International Standards please complete the Proposal Form – Identical Adoptions.

Privacy notice: Standards Australia reserves the right to make information relating to Standards development projects public, including information contained within submitted proposal forms in part or in full. In the event that Standards Australia publishes proposals on its website, proponent details at page 1 and stakeholder contact details provided at Section 3 will not be included. However, with prior agreement, your contact details may be provided to interested parties wishing to contribute or comment on the proposal or the proposed project.