

Prezados(as) Senhores(as),

A ABNT gostaria de contar com a sua participação na **6ª Reunião/2025 da Comissão de Estudo de Aspectos Comuns de Segurança para Equipamentos Eletromédicos (CE-026:020.001) e Comissão de Estudo de Equipamento Eletromédico (CE-026:020.002)**, do Comitê Brasileiro Odonto-Médico-Hospitalar (ABNT/CB-026), a ser realizada conforme a programação a seguir.

Data: 04.07.2025

Horário: 9h às 13h

Modalidade: remota

Local: não aplicável

Link: <https://zoom.us/meeting/register/VLIHYSVZR-29LXe-IZwbYQ>

Pauta da reunião:

1. Abertura;
2. Identificação dos membros presentes;
3. Análise, correção e aprovação da Minuta de Ata da Reunião anterior;
4. Aceitação da pauta proposta (ou modificação);
5. Comunicados do Coordenador das CEs;
6. Documentos para conhecimento recebidos da IEC e ISO:
 - 6.1. [TC 62 – Medical equipment, software, and systems](#)

Referência	Título
62/550/RQ	Result on 62/547/Q: Questionnaire regarding the membership of AG SNAIG (Aprovado)
62/552/RR	Review report of IEC 60050-881 ED1: International Electrotechnical Vocabulary (IEV) - Part 881: Radiology and radiological physics

6.2. [SC 62A – Common aspects of medical equipment, software, and systems](#)

Referência	Título
62A/1643A/CC	Revised Compilation of Comments on 62A/1620/CD - ISO TS 24971-2 ED1: Medical devices – Guidance on the application of ISO 14971 - Part 2: Machine learning in artificial intelligence
62A/1657A/CC	Revised Compilation of Comments on 62A/1629/CD - IEC 60601-1/FRAG11 ED4: Medical electrical equipment - Part 1: General requirements for basic safety and essential performance - Electromagnetic exposure hazards (Fragment 11)
62A/1667/RVN	Result of Voting on 62A/1648/NP - PNW TS 62A-1648 ED1: Medical devices – Part 3: Guidance on the application of usability engineering to medical devices using artificial intelligence and machine learning technology

6.3. [SC 62D – Particular medical equipment, software, and systems](#)

Referência	Título
62D/2148A/RVC	Revised Result of Voting on 62D/2114/CDV - IEC 80601-2-52 ED1: Medical electrical equipment - Part 2-52: Particular requirements for the basic safety and essential performance of medical beds
62D/2229A/RVC	Revised Result of Voting on 62D/2207/CDV - ISO 17510 ED1: Medical devices — Sleep apnoea breathing therapy — Masks and application accessories
62D/2230/RVC	Result of Voting on 62D/2202/CDV - ISO 12487 ED1: Respiratory equipment -- Clinical investigation of clinical thermometers
62D/2231/RVC	Result of Voting on 62D/2057/CDV - ISO 80369-1 ED3: Small-bore connectors for liquids and gases in healthcare applications - Part 1: General requirements
62D/2232/RVC	Result of Voting on 62D/2190/CDV - ISO 80601-2-70 ED3: Medical electrical equipment - Part 2-70: Particular requirements for the basic safety and essential performance of sleep apnoea breathing therapy equipment
62D/2232A/RVC	Revised Result of Voting on 62D/2190/CDV - ISO 80601-2-70 ED3: Medical electrical equipment - Part 2-70: Particular requirements for the basic safety and essential performance of sleep apnoea breathing therapy equipment
62D/2233/RVC	Result of Voting on 62D/2165/CDV - ISO 80601-2-67 ED3: Medical electrical equipment - Part 2-67: Particular requirements for basic safety and essential performance of oxygen-conserving equipment

62D/2234/RVC	Result of Voting on 62D/2166/CDV - ISO 80601-2-69 ED3: Medical electrical equipment - Part 2-69: Particular requirements for the basic safety and essential performance of oxygen concentrator equipment
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6.4. [TC 76 – Optical radiation safety and laser equipment](#)

Referência	Título
76/776/RVDTS	Result of Voting on 76/766/DTS - IEC TS 60825-20 ED1: Safety of Laser Products - Part 20: Safety requirements for products intentionally exposing face or eyes to laser radiation

6.5. [TC 87 – Ultrasonics](#)

Referência	Título
87/905/DA	Draft agenda for the face to face meeting of TC 87 to be held in Arlington, United States of America on 2025-10-17
87/906/RQ	Result of Questionnaire 87/898/Q: Proposal for maintenance to IEC 61161:2013 Ed 3
87/907/AC	Registration - Next face to face meeting of TC 87, and its working groups to be held in Arlington, United States of America from 2025-10-13 to 2025-10-17
87/908/RVN	Result of Voting on 87/895/NP - PNW 87-895 ED1: Ultrasonics - Shear-wave elastography - Part 2: Preparation and characterization of phantoms for performance and constancy testing

7. Documentos para voto de documentos internacionais recebidos da IEC e ISO:

7.1. [TC 62 – Medical equipment, software, and systems](#)

Referência	Título	Data de circulação	Data de conclusão
62/545/CD	IEC 63521 ED1: Machine learning-enabled medical device – Performance evaluation process	2025-05-02	2025-07-25
62/546/Q	Priorities for future SNAIG reports	2025-05-02	2025-07-25
62/551/Q	Questionnaire regarding updating IEC 60050-880, International Electrotechnical Vocabulary (IEV) – Part 880: Electrical equipment, electrical systems and software used in healthcare with an amendment	2025-06-20	2025-08-01

7.2. [SC 62A – Common aspects of medical equipment, software, and systems](#)

Referência	Título	Data de circulação	Data de conclusão
62A/1666/CD	IEC 60601-1/FRAG11 ED4: Medical electrical equipment - Part 1: General requirements for basic safety and essential performance - Electromagnetic exposure hazards (Fragment 11)	2025-06-06	2025-08-29
62A/1668/DTS	IEC TS 81001-2-2 ED1: Health software and health IT systems safety, effectiveness and security - Part 2-2: Coordination - Guidance for the implementation, disclosure and communication of security needs, risks and controls	2025-06-13	2025-08-08
62A/1669/Q	Withdrawal of: IEC TR 80001-2-9:2017, Application of risk management for IT-networks incorporating medical devices - Part 2-9: Application guidance - Guidance for use of security assurance cases to demonstrate confidence in IEC TR 80001-2-2 security capabilities	2025-06-13	2025-07-25
62A/1670/Q	Revision of: IEC 81001-5-1:2021, Health software and health IT systems safety, effectiveness and security — Part 5-1: Security — Activities in the product life cycle	2025-06-13	2025-07-25
62A/1671/CD	IEC 60601-1/FRAG10 ED4: Medical electrical equipment - Part 1: General requirements for basic safety and essential performance - Ionizing radiation hazards (Fragment 10)	2025-06-06	2025-09-05
62A/1672/CD	IEC 60601-1/FRAG12 ED4: Medical electrical equipment - Part 1: General requirements for basic safety and essential performance - Electromagnetic disturbances hazards (Fragment 12)	2025-06-13	2025-09-05
62A/1673/CD	IEC 60601-1/FRAG8 ED4: Medical electrical equipment - Part 1: General requirements for basic safety and essential performance - Thermal and fire hazards (Fragment 8)	2025-06-20	2025-09-12
62A/1674/Q	Nomination of a co-convenor for IEC/SC 62A/WG 45, Optical radiation (visible, UV and IR) hazards	2025-06-20	2025-08-01
62A/1675/CD	IEC 60601-1/FRAG5 ED4: Medical electrical equipment - Part 1: General requirements for basic safety and essential performance - PEMS related hazards (Fragment 5)	2025-06-20	2025-09-12

62A/1676/CD	IEC 60601-1/FRAG6 ED4: Medical electrical equipment - Part 1: General requirements for basic safety and essential performance - Electrical hazards (Fragment 6)	2025-06-20	2025-09-12
62A/1677/CD	IEC 60601-1/FRAG7 ED4: Medical electrical equipment - Part 1: General requirements for basic safety and essential performance - Mechanical hazards (Fragment 7)	2025-06-20	2025-09-12

7.3. [SC 62D – Particular medical equipment, software, and systems](#)

Referência	Título	Data de circulação	Data de conclusão
62D/2235/Q	IEC 60601-1/FRAG12 ED4: Medical electrical equipment - Part 1: General requirements for basic safety and essential performance - Electromagnetic disturbances hazards (Fragment 12)	2025-06-13	2025-07-25
62D/2237/Q	Proposal to start the revision of ISO 81060-3:2022, Non-invasive sphygmomanometers - Part 3: Clinical investigation of continuous automated measurement type	2025-06-13	2025-07-25
62D/2238/FDIS	ISO 80369-1 ED3: Small-bore connectors for liquids and gases in healthcare applications - Part 1: General requirements	2025-06-20	2025-08-01

7.4. [TC 76 – Optical radiation safety and laser equipment](#)

Referência	Título	Data de circulação	Data de conclusão
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7.5. [TC 87 – Ultrasonics](#)

Referência	Título	Data de circulação	Data de conclusão
87/897/CDV	IEC 62127-3/AMD1 ED2: Amendment 1 - Ultrasonics - Hydrophones - Part 3: Properties of hydrophones for ultrasonic fields	2025-05-30	2025-08-22
87/899/CD	IEC 63612 ED1: Ultrasonics – Intraluminal short pressure pulse therapy sources – Characteristics of fields	2025-05-09	2025-08-01
87/902/CD	IEC TS 63588 ED1: Ultrasonics – Field characterization – Specification and measurement of field parameters at high pressure therapeutic levels in water	2025-05-16	2025-08-08
87/903/CD	IEC TS 63587 ED1: Ultrasonics – Field characterization – Measurement-based simulation in water and other media	2025-05-23	2025-08-15

8. Deliberação de Projeto de Norma para Consulta Nacional:

8.1. Projeto de Emenda de Norma

8.1.1. ISO 81060-2:2018 - Esfigmomanômetros não invasivos -- Parte 2: Investigação clínica de tipo de medição automatizada intermitente – Emenda 1.

Relator: Rafael Feldmann Farias – DIMEL/INMETRO

9. Estruturação e relatórios de GTs/GTCs da CE 026:020:001 e CE 026:020:002;

9.1. Avaliação de Fragmentos de Proposta de Norma (CD) – 4ª Edição IEC 60601-1

9.2. Indicação de Participação – Rafael Feldmann Farias (INMETRO) – [62D/2214/NP](#)
PNW 62D-2214 ED1: non-invasive arterial tonometer equipment

10. Apresentação da situação atual das normas trabalhadas pelas CEs 026:020:01 e 026:020:02;

10.1. Projeto – ABNT NBR ISO 80601-2-85 – Equipamento eletromédico - Parte 2-85: Requisitos particulares para a segurança básica e desempenho essencial de oxímetros de tecido cerebral. Publicação ABNT.

11. Outros assuntos;

12. Planejamento dos próximos trabalhos;

13. Ações para a próxima reunião;

14. Próximas reuniões – Ano 2025:

Fev	Mar	Abr	Mai	Jun	Jul	Ago	Set	Out	Nov	Dez
07	07	04	09	06	04	01	05	03	07	05

15. Encerramento da reunião.

Para contribuir com os trabalhos de Normalização, é necessário seguir estes passos:

1. **Cadastre-se** em www.abntonline.com.br/normalizacao, preencha o formulário de inscrição, selecione a(s) Comissão(ões) de Estudo de seu interesse e aceite os termos de confidencialidade e de consentimento.
2. **Acesse os documentos** destas Comissões de Estudos em:
[CE-026:020.001](#) e [CE-026:020.002](#)
3. **Participe** das reuniões, debates e [Consultas Nacionais](#), contribuindo com seu conhecimento e expertise.
4. **Indique novos participantes**, compartilhando o [link de inscrição](#).

Ressaltamos que:

- Não é permitido aos participantes fotografar, gravar ou filmar a reunião sem autorização.
- As reuniões poderão ser gravadas pela Coordenação, para fins de elaboração de ata de reunião.
- Caso não tenha mais interesse em participar desta Comissão de Estudo, envie um e-mail para a Secretaria do Comitê Técnico (cb-026@abnt.org.br) solicitando seu descadastramento.

Junte-se a nós e faça a diferença!