

Prezados(as) Senhores(as),

A ABNT gostaria de contar com a sua participação na **10ª 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: 07.11.2025

Horário: 9h às 13h

Modalidade: remota

Local: não aplicável

Link: <https://zoom.us/meeting/register/3zahllwnRMOu1mizTBVZpw>

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
62/549A/AC	Registration - Next face to face meeting of TC 62, its subcommittees and its working groups to be held in Milan, Italy from 2025-11-03 to 2025-11-14 with possibility for remote connection
62/554A/DA	Revised draft agenda for the face-to-face meeting of TC 62 to be held in Milan, Italy on 2025-11-14
62/561/RVN	Result of Voting on 62/540/NP - PNW 62-540 ED1: Post-market surveillance of machine learning-enabled medical device
62/562/INF	Reports from TC 62 participation in Advisory Committees to IEC SMB to TC 62 for the meeting in Milan, Italy on 2025-11-14
62/563/INF	Reports from Liaisons to TC 62 for the meeting in Milan, Italy on 2025-11-14
62/563A/INF	Revised reports from Liaisons to TC 62 for the meeting in Milan, Italy on 2025-11-14
62/564/INF	Reports from Advisory and Working Groups to TC 62 to TC 62 for the meeting in Milan, Italy on 2025-11-14
62/565/INF	Review of Stability Dates of the publications of TC 62 for the meeting in Milan, Italy on 2025-11-14
62/566/INF	Seventh report of the IEC TC 62 Advisory Group SNAIG Software Network and Artificial Intelligence Advisory Group
62/567/CC	Compilation of Comments on 62/553/CD - IEC 60050-881 ED2: 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/1678A/DA	Revised draft agenda for the face-to-face meeting of SC 62A to be held in Milan, Italy on 2025-11-11
62A/1693/CC	Compilation of Comments on 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)
62A/1694/CC	Compilation of Comments on 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)
62A/1695/CC	Compilation of Comments on 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)
62A/1696/CC	Compilation of Comments on 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)

Referência	Título
62A/1697/CC	Compilation of Comments on 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)
62A/1698/CC	Compilation of Comments on 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)
62A/1698A/CC	Revised Compilation of Comments on 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)
62A/1699/INF	Results of the Document for Comment on ISO/CD 24973, <i>Health informatics — Digital therapeutics — Product requirements</i>
62A/1700/INF	Review of stability dates (Agenda Item 7)
62A/1701/INF	IEC/SC 62A liaison list and reports for the November 2025 subcommittee meeting held in Milan, Italy (Agenda item 9)
62A/1702/INF	Reports from the working groups, maintenance teams and joint working groups of IEC/SC 62A for the November 2025 Subcommittee meeting – Milan, Italy (Agenda item 6.2)
62A/1703/INF	Confirmation of working group conveners - (Agenda item 6.1)

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

Referência	Título
62D/2245A/DA	Revised draft agenda for the face-to-face meeting of SC 62D to be held in Milan, Italy on 2025-11-12
62D/2256/RVC	Result of Voting on 62D/2211/CDV - ISO 80601-2-13/AMD1 ED2: Amendment 1 - Medical electrical equipment - Part 2-13: Particular requirements for basic safety and essential performance of an anaesthetic workstation
62D/2257/RVC	Result of Voting on 62D/2185/CDV - IEC 60601-2-4/AMD2 ED3: Amendment 2 - Medical electrical equipment - Part 2-4: Particular requirements for the basic safety and essential performance of cardiac defibrillators
62D/2262/INF	Confirmation of working group conveners - (Agenda Item 9)
62D/2263/INF	Maintenance Cycle (Agenda Item 11)
62D/2264/INF	Reports from the liaisons of other committees and organizations for the October 2025 Subcommittee meeting in Milan (Agenda item 12.1)
62D/2265/INF	Report from the Maintenance Teams and Joint Working Groups of IEC/SC 62D for the November 2025 Subcommittee meeting in Milan - (Agenda item 10)
62D/2266/CC	Compilation of Comments on 62D/2240/CD - IEC 60601-2-36 ED3: Medical electrical equipment - Part 2-36: Particular requirements for the basic safety and essential performance of equipment for extracorporeally induced lithotripsy
62D/2267/RVN	Result of Voting on 62D/2214/NP - PNW 62D-2214 ED1: Medical electrical equipment -- Part 2-xx: Part 2-XX : Particular requirements for basic safety and essential performance of non-invasive arterial tonometer equipment (APROVADO)

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

Referência	Título
76/787/RQ	Result of Questionnaire on 76/777/Q: Nomination for Convenor of TC 76/JWG 12: Eye and face protection against laser radiation linked to ISO/TC94/SC6
76/788/RVC	Result of Voting on 76/774/CDV - IEC 60601-2-22/AMD1 ED4: Amendment 1 - Medical electrical equipment - Part 2-22: Particular requirements for basic safety and essential performance of surgical, cosmetic, therapeutic and diagnostic laser equipment (APROVADO)
76/789/DL	List of decisions taken at the Plenary Meeting of TC76, held in Le Barp, France on 2025-10-10

6.5. [TC 87 – Ultrasonics](#)

Referência	Título
87/905A/DA	Revised draft agenda for the plenary meeting of TC 87 to be held in Arlington, United States of America on 2025-10-17
87/920/INF	Working Group 14: Determination of Ultrasound Exposure Parameters
87/922/CC	Compilation of Comments on 87/899/CD - IEC 63612 ED1: Ultrasonics – Intraluminal short pressure pulse therapy sources – Characteristics of fields
87/923/INF	Report of liaison between IEC TC87 and ISO TC43 SC3 (Underwater Acoustics), October 2025.
87/924/INF	IEC/TC 29: Electroacoustics: Liaison Report – 05 October 2025
87/925/INF	WG15 Convenor's Report for IEC TC87 (October 2025)
87/926/DL	List of decisions taken at the plenary meeting of TC 87 held in Arlington, United States of America on 2025-10-17

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
62/559/DPAS	IEC PAS 63621 ED1: Artificial intelligence enabled medical devices - Data management	2025-09-12	2025-11-07
62/560/CD	IEC 60050-880/AMD1 ED1: International Electrotechnical Vocabulary (IEV) – Part 880: Electrical equipment, electrical systems and software used in healthcare	2025-09-12	2025-11-07
62/568/NP	PNW 62-568 ED1: Management systems - Guidelines for incorporating ecodesign in the medical device sector	2025-10-24	2026-01-16
62/569/Q	Questionnaire on “Supporting document listing the standards suitable to be used for development of AI/ML standards in the medical area (confirmed by IEC TC 62 “Medical equipment, software and systems”)”	2025-10-03	2025-11-14
62/570/CD	IEC TR 63691-1 ED1: Medical devices – In silico technologies – Part 1: Terminology and context	2025-10-24	2026-01-16
62/571/NP	PNW 62-571 ED1: Medical devices – In silico technologies – Part 2: Credibility assessment of first-principles based methods	2025-10-24	2026-01-16

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

Referência	Título	Data de circulação	Data de conclusão
62A/1704/DTR	IEC TR 60601-4-9 ED1: Medical electrical equipment - Part 4-9: Guidance and interpretation - Maintaining essential performance in single fault condition - Examples	2025-10-24	2025-12-19

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

Referência	Título	Data de circulação	Data de conclusão
62D/2248/NP	PNW 62D-2248 ED1: Anaesthetic and respiratory equipment — Nebulizing systems and components	2025-08-15	2025-11-07
62D/2258/CDV	ISO 80601-2-13/AMD1 ED2: Amendment 1 - Medical electrical equipment - Part 2-13: Particular requirements for basic safety and essential performance of an anaesthetic workstation	2025-09-26	2025-11-21
62D/2259/FDIS	ISO 80601-2-67 ED3: Medical electrical equipment - Part 2-67: Particular requirements for basic safety and essential performance of oxygen-conserving equipment	2025-10-10	2025-11-21
62D/2260/FDIS	ISO 80601-2-69 ED3: Medical electrical equipment - Part 2-69: Particular requirements for the basic safety and essential performance of oxygen concentrator equipment	2025-10-10	2025-11-21
62D/2261/AC	Call for outgoing liaison representatives from SC 62D - (Agenda item 12.2)	2025-09-26	2025-11-07

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

Referência	Título	Data de circulação	Data de conclusão
76/786/DTS	IEC TS 60825-13 ED1: Safety of laser products - Part 13: Measurements for classification of laser products	2025-09-19	2025-11-14

7.5. [TC 87 – Ultrasonics](#)

Referência	Título	Data de circulação	Data de conclusão
87/916/CDV	IEC 63440 ED1: Ultrasonics - Measurement of temperature rise produced by medical ultrasonic equipment	2025-10-24	2026-01-16
87/921/NP	PNW 87-921 ED1: Underwater acoustics—Calibration of interferometric fiber-optic hydrophones in the frequency range 10 Hz to 20 kHz	2025-09-26	2025-12-19

8. Deliberação de Projeto de Norma para Consulta Nacional:

- Nenhum documento

9. Estruturação e relatórios de GTs/GTCs da CE 026:020:001 e CE 026:020:002;
10. Apresentação da situação atual das normas trabalhadas pelas CEs 026:020:01 e 026:020:02;
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!