

Prezados(as) Senhores(as),

A ABNT gostaria de contar com a sua participação na **7ª 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: 01.08.2025

Horário: 9h às 13h

Modalidade: remota

Local: não aplicável

Link: <https://zoom.us/meeting/register/n0GzYCuTTQWS-QAekY2ojA>

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
62/554/DA	Draft agenda for the face to face meeting of TC 62 to be held in Milan, Italy on 2025-11-14

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

Referência	Título
62A/1625A/RM	Confirmed report of the meeting held in Edinburgh on 23 October 2024
62A/1636A/CC	Revised Compilation of Comments on 62A/1612/CD - IEC TS 62366-2 ED1: Medical devices - Part 2: Guidance on the application of usability engineering to medical devices
62A/1655B/INF	Updated IEC/SC 62A National Committee comments on 62A/1647/DC: IEC 81001-5-1:2021-12 - Draft Interpretation Sheet - Health software and health IT systems safety, effectiveness and security – Part 5-1: Security – Activities in the product life cycle principles
62A/1678/DA	Draft agenda for the face to face meeting of SC 62A to be held in Milan, Italy on 2025-11-11
62A/1679/INF	Cancellation of ISO/PWI 81001-3-1, Health software and health IT systems safety, effectiveness and security — Part 3-1: Healthcare Delivery Organization guidance

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

Referência	Título
62D/2236/RQ	Result of Questionnaire on 62D/2227/Q: Nomination of convenor for MT 20: Haemodialysis equipment
62D/2241/RVC	Result of Voting on 62D/2183/CDV - IEC 60601-2-91 ED1: Particular requirement for basic safety and essential performance of non-thermal plasma wound treatment equipment
62D/2242/RVC	Result of Voting on 62D/2209/CDV - IEC 80601-2-60/AMD1 ED2: Amendment 1 - Medical electrical equipment - Part 2-60: Particular requirements for the basic safety and essential performance of dental equipment
62D/2243/RQ	Result of Questionnaire on 62D/2228/Q: Nomination of co-convenor for IEC/SC 62D/JWG 8, Clinical thermometers (Joint with ISO/TC 121/SC 3)
62D/2244/INF	Committee Draft: Proposed IEC 60601-2-36 ED3, Medical electrical equipment – Part 2-36: Particular requirements for the basic safety and essential performance of therapy equipment for extracorporeally induced focused pressure pulses (redline/strike out version attached for information only)
62D/2245/DA	Draft agenda for the face to face meeting of SC 62D to be held in Milan, Italy on 2025-11-12

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

Referência	Título
76/778/RVN	Result of Voting on 76/771/NP - PNW TS 76-771 ED1: Safety of laser products - Part 22: Laser lamp products
76/779/CD	IEC 60825-18 ED1: Safety of laser products - Part 18: Guided beam delivery systems

6.5. [TC 87 – Ultrasonics](#)

Referência	Título
87/909/INF	INF document to support circulation of 62D/2240/CD on IEC 60601-2-36 ED3 'Medical electrical equipment – Part 2-36: Particular requirements for the basic safety and essential performance of therapy equipment for extracorporeally induced focused pressure pulses'

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
62/551/Qv	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
62/553/CD	IEC 60050-881 ED2: International Electrotechnical Vocabulary (IEV) - Part 881: Radiology and radiological physics	2025-07-04	2025-09-26

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/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-converter 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/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

62D/2239/FDIS	IEC 80601-2-89 ED1: Medical electrical equipment - Part 2-89: Particular requirements for the basic safety and essential performance of medical beds for children	2025-07-04	2025-08-15
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	2025-07-04	2025-08-29

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

Referência	Título	Data de circulação	Data de conclusão
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	2025-07-04	2025-09-26
76/777/Q	Nomination of a Convenor for TC 76/JWG 12: Eye and face protection against laser radiation linked to ISO/TC94/SC6	2025-07-11	2025-08-22
76/779/CD	IEC 60825-18 ED1: Safety of laser products - Part 18: Guided beam delivery systems	2025-07-18	2025-09-26

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. Convite de indicação de membros para participação em WGs para 4ª Edição IEC 60601-1

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!