

Prezados(as) Senhores(as),

A ABNT gostaria de contar com a sua participação na **8ª Reunião/2026 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: 04.09.2026

Horário: 9h às 12h

Modalidade: remota

Local: não aplicável

Link: https://zoom.us/join/zoom/register/qiHz8NzfT4yg-NMt_-VX_g

Pauta da reunião:

1. Abertura e identificação dos membros presentes;
2. Análise, correção e aprovação da Minuta de Ata da Reunião anterior;
3. Aceitação da pauta proposta (ou modificação);
4. Comunicados do Coordenador das CEs;
5. Documentos para conhecimento recebidos da IEC e ISO:

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

Referência	Título
62/597/RVN	Result of Voting on 62/590/NP - PNW 62-590 ED1: Evaluation of pre-trained AI models for use within a medical device
62/598/RQ	Result on 62/594/Q: Questionnaire regarding the nomination of the Convenor of ad hoc group (ahG) "Telemedicine and IoT"

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

Referência	Título
62A/1736A/CC	Revised Compilation of Comments on 62A/1725/CD - ISO 81001-1 ED2: Health software and health IT systems safety, effectiveness and security - Part 1: Principles and concepts
62A/1656A/CC	Revised Compilation of Comments on 62A/1628/CD - IEC 60601-1/FRAG1 ED4: Medical electrical equipment - Part 1: General requirements for basic safety and essential performance - General requirements (Fragment 1)
62A/1766/RQ	Result of Questionnaire on 62A/1749/Q: Extension of the term of office for Convenor of 62A/JWG 3: Medical device software
62A/1667A/RVN	Revised 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

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

Referência	Título
62D/2296A/RVC	Revised Result of Voting on 62D/2280/CDV - ISO 80601-2-56 ED3: Medical electrical equipment - Part 2-56: Particular requirements for basic safety and essential performance of clinical thermometers for body temperature measurement
62D/2321/RQ	Result of Questionnaire on 62D/2315/Q: Appointment of a New Project Leader for ISO 27427, Anaesthetic and respiratory equipment - Nebulizing systems and components
62D/2322/RVD	Result of Voting on 62D/2294/FDIS - 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/2323/CC	Compilation of Comments on 62D/2251/CD - ISO 81060-7 ED1: Non-invasive sphygmomanometers -- Part 7: Clinical performance verification of intermittent or repeated intermittent cuffless measurement type

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

Referência	Título
76/781A/CC	Revised Compilation of Comments on 76/769/CD - ISO TS 19818-2 ED1: Eye and face protection — Protection against laser radiation — Part 2: Guidance on the selection and use of laser eye and face protection related to ISO 19818-1
76/800/RR	Review Report for IEC 60825-12:2022 ED3 - Safety of laser products - Part 12: Safety of free space optical communication systems used for transmission of information

76/801/AC	Registration - Next plenary meeting of TC 76, and its working groups to be held in Didcot, United Kingdom with remote participation from 2026-10-25 to 2026-10-30
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5.5. [TC 87 – Ultrasonics](#)

Referência	Título
87/946/RVDISH	Result of Voting on 87/941/DISH - IEC 62127-1/ISH1 ED2: Interpretation Sheet 1 - Ultrasonics - Hydrophones - Part 1: Measurement and characterization of medical ultrasonic fields

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

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

Referência	Título	Data de circulação	Data de conclusão
62/591/NP	PNW 62-591 ED1: Artificial intelligence enabled medical devices - Data management	2026-06-19	2026-09-11
62/596/AC	Nomination of a TC 62 representative in the Advisory Committee on Information security and data privacy (ACSEC)	2026-07-24	2026-09-11

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

Referência	Título	Data de circulação	Data de conclusão
62A/1745/CD	IEC 60601-1/FRAG2 ED4: Medical electrical equipment - Part 1: General requirements for basic safety and essential performance - Physical environment hazard (Fragment 2)	2026-07-03	2026-09-25
62A/1746/CD	IEC 60601-1/FRAG4 ED4: Medical electrical equipment - Part 1: General requirements for basic safety and essential performance - Materials hazards (Fragment 4)	2026-07-03	2026-09-25
62A/1751A/CD	ISO TS 24971-3 ED1: Medical devices – Guidance on the application of ISO 14971 – Part 3: Combination products	2026-07-10	2026-09-25
62A/1752/CD	IEC 60601-1/FRAG10 ED4: Medical electrical equipment - Part 1: General requirements for basic safety and essential performance - Ionizing radiation hazards (Fragment 10)	2026-07-03	2026-09-25
62A/1753/CD	ISO 81001-4-1 ED1: Health software and health IT systems safety, effectiveness and security - Part 4-1 Application of risk management in the Implementation and Clinical Use	2026-07-10	2026-09-04
62A/1754/CD	IEC TS 63738 ED1: Medical electrical equipment - Requirements for assessment of electromagnetic exposure hazards	2026-07-10	2026-10-02
62A/1756/CD	ISO 81001-5-2 ED1: Health software and health IT systems safety, effectiveness and security - Part 5-2: Security Risk Management for Manufacturers	2026-07-17	2026-09-11
62A/1757/Q	Draft application for designation of a Group Safety Function and associated Group Safety Publications development	2026-07-17	2026-09-11
62A/1759/CD	IEC 60601-1/FRAG1 ED4: Medical electrical equipment - Part 1: General requirements for basic safety and essential performance - General requirements (Fragment 1)	2026-07-24	2026-10-16
62A/1760/Q	Nomination of Co-convenors for SC 62A/WG 42: <i>Electrical hazards</i>	2026-07-31	2026-09-11
62A/1761/CD	IEC 62304 ED2: Health software – Software life cycle processes	2026-08-07	2026-11-27
62A/1762/CD	IEC TS 62366-3 ED1: Medical devices – Part 3: Guidance for artificial intelligence-enabled medical devices	2026-08-14	2026-12-04
62A/1764/Q	Nomination of the convenor for SC 62A/WG 14: Testing to General Safety Standard	2026-08-21	2026-10-02
62A/1765/AC	Proposal for the extension of the term of office for the working group convenors listed in Annex A	2026-08-21	2026-10-02

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

Referência	Título	Data de circulação	Data de conclusão
62D/2309/CDV	ISO 81060-2 ED4: Non-invasive sphygmomanometers - Part 2: Clinical investigation of intermittent automated measurement type	2026-06-26	2026-09-18
62D/2310/CDV	IEC 80601-2-86 ED1: Medical electrical equipment - Part 2-86: Particular requirements for the basic safety and essential performance of	2026-07-10	2026-10-02

	electrocardiographs, including diagnostic equipment, monitoring equipment, ambulatory equipment, electrodes, cables and leadwires		
62D/2311/CDV	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	2026-07-10	2026-10-02
62D/2324/Q	Proposal for Full Revision of ISO 80601-2-55:2018/AMD1:2023, Medical electrical equipment - Part 2-55: Particular requirements for the basic safety and essential performance of respiratory gas monitors	2026-08-21	2026-10-02
62D/2325/CD	ISO 27427 ED1: Anaesthetic and respiratory equipment — Nebulizing systems and components	2026-08-21	2026-10-16

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

Referência	Título	Data de circulação	Data de conclusão
76/802/CD	IEC 60825-1 ED4: Safety of laser products - Part 1: Equipment classification and requirements	2026-07-24	2026-10-02

6.5. [TC 87 – Ultrasonics](#)

Referência	Título	Data de circulação	Data de conclusão
87/942/CD	IEC 63612 ED1: Ultrasonics – Intraluminal short pressure pulse therapy sources – Characteristics of fields	2026-07-10	2026-10-02
87/944/CD	IEC TS 63587 ED1: Ultrasonics – Field characterization – Measurement-based simulation in water and other media	2026-07-24	2026-10-16
87/945/CD	IEC 61161 ED4: Ultrasonics - Power measurement - Radiation force balances and performance requirements	2026-08-07	2026-10-30

7. Estruturação e relatórios de GTs/GTCs da CE-026:020:001 e CE-026:020:002;
8. Apresentação da situação atual das normas trabalhadas pela CE-026:020:001 e CE-026:020:002;
9. Outros assuntos;
 - 9.1. Dúvidas técnicas - Anexo K do IEC TR 62354 – Questionamento TÜV Rheinland
10. Planejamento dos próximos trabalhos;
11. Ações para a próxima reunião;
12. Próximas reuniões – Ano 2026:

Fev	Mar	Abr	Mai	Jun	Jul	Ago	Set	Out	Nov	Dez
06	06	10*	08*	12*	03	07	04	02	06	04

13. 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:
 - a. [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!