

Prezados(as) Senhores(as),

A ABNT gostaria de contar com a sua participação na **7ª 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: 07.08.2026

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;
 - 4.1. [62A/1748/INF](#) – Update on the IEC 60601-1 fourth edition Project – Extensão de prazo para os trabalhos da 4ª Edição da IEC 60601-1
5. Documentos para conhecimento recebidos da IEC e ISO:
 - 5.1. [TC 62 – Medical equipment, software, and systems](#)

Referência	Título
62/502B/INF	Standards suitable to be used for the development of AI/ML standards in the medical area (confirmed by IEC TC 62 "Medical equipment, software and systems")
62/593/RQ	Result on 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") (LISTA APROVADA)
62/595/DA	Draft agenda for the plenary meeting of TC 62 to be held in Hamburg, Germany on 2026-11-20

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

Referência	Título
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/1664A/RVN	Revised Result of Voting on 62A/1644/NP - PNW TS 62A-1644 ED1: Risk Management for Combination Products (APROVADO)
62A/1693B/CC	Revised 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/1705A/CC	Revised Compilation of Comments on 62A/1680/CD - IEC TS 62366-2 ED1: Medical devices - Part 2: Guidance on the application of usability engineering to medical devices
62A/1741A/RVN	Revised Result of Voting on 62A/1727/NP - PNW TS 62A-1727 ED1: Medical electrical equipment - Requirements for assessment of electromagnetic exposure hazards (APROVADO)
62A/1748/INF	Update on the IEC 60601-1 fourth edition project
62A/1750/RVN	Result of Voting on 62A/1735/NP - PNW TS 62A-1735 ED1: Medical devices -- Guidance on the application of ISO 14971 -- Part 1: General (APROVADO)
62A/1755/CCDC	Compilation of comments on 62A/1730/DC: Draft application for a Group Safety Function and associated Group Safety Publications development
62A/1758/DA	Draft agenda for the plenary meeting of SC 62A to be held in Hamburg, Germany on 2026-11-17

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

Referência	Título
62D/2316/RQ	Result of Questionnaire (62D/2220/Q) - Questionnaire regarding the proposal for an Amendment to IEC 60601-2-41:2021, Medical electrical equipment - Part 2-41: Particular requirements for the basic safety and essential performance of surgical luminaires and luminaires for diagnosis (APROVADO PROPOSTA POR PROCESSO ABREVIADO DE NOVA EMENDA)

62D/2318/RR	Review report of IEC 60601-2-41 ED3: Medical electrical equipment - Part 2-41: Particular requirements for the basic safety and essential performance of surgical luminaires and luminaires for diagnosis (NOVA EMENDA)
62D/2319/INF	Revised Compilation of Comments on Committee Draft (CC) for IEC 80601-2-86 ED1, Medical electrical equipment - Part 2-86: Particular requirements for the basic safety and essential performance of electrocardiographs, including diagnostic equipment, monitoring equipment, ambulatory equipment, electrodes, cables and leadwires (62D/1975/CD)
62D/2320/DA	Draft agenda for the plenary meeting of SC 62D to be held in Hamburg, Germany on 2026-11-18

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

Referência	Título
76/799/DA	Draft agenda for the face to face meeting of TC 76 to be held in Didcot, United Kingdom from 2026-10-25 to 2026-10-30. Meeting times for the Plenary: Monday and Friday 9am - 12pm. Meeting times for WGs/JWGs: 9am - 12:30pm (AM session), 14:00pm - 17:30pm (PM session).
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 (NOVA EDIÇÃO)
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

5.5. [TC 87 – Ultrasonics](#)

Referência	Título
87/937A/CC	Revised Compilation of Comments on 87/903/CD - IEC TS 63587 ED1: Ultrasonics – Field characterization – Measurement-based simulation in water and other media
87/943/DA	Draft agenda for the plenary meeting of TC 87 to be held in Hamburg, Germany on 2026-11-20
87/922A/CC	Revised Compilation of Comments on 87/899/CD - IEC 63612 ED1: Ultrasonics – Intraluminal short pressure pulse therapy sources – Characteristics of 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
62/590/NP	PNW 62-590 ED1: Evaluation of pre-trained AI models for use within a medical device	2026-05-22	2026-08-14
62/591/NP	PNW 62-591 ED1: Artificial intelligence enabled medical devices - Data management	2026-06-19	2026-09-11
62/594/Q	Questionnaire regarding Convenor of ad hoc group (ahG) "Telemedicine and IoT"	2026-07-03	2026-08-14
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/1747/AC	Call for a convener for IEC/SC 62A/WG 14, Testing to General Safety Standard	2026-07-03	2026-08-14
62A/1749/Q	Extension of the term of office for Convenor of 62A/JWG 3: Medical device software	2026-07-03	2026-08-14
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

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

Referência	Título	Data de circulação	Data de conclusão
62D/2299/CDV	IEC 80601-2-77 ED2: Medical electrical equipment - Part 2-77: Particular requirements for the basic safety and essential performance of robotically assisted surgical equipment	2026-06-05	2026-08-28
62D/2302/CDV	IEC 60601-2-18 ED4: Medical electrical equipment - Part 2-18: Particular requirements for the basic safety and essential performance of endoscopic equipment	2026-06-05	2026-08-28
62D/2304/CDV	IEC 80601-2-78 ED2: Medical electrical equipment - Part 2-78: Particular requirements for basic safety and essential performance of medical robots for rehabilitation, assessment, compensation or alleviation	2026-06-05	2026-08-28
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 62D/2310(F)/CDV	IEC 80601-2-86 ED1: Medical electrical equipment - Part 2-86: Particular requirements for the basic safety and essential performance of electrocardiographs, including diagnostic equipment, monitoring equipment, ambulatory equipment, electrodes, cables and leadwires	2026-07-10	2026-10-02
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/2312/CD	IEC 60601-2-24 ED3: Medical electrical equipment - Part 2-24: Particular requirements for the basic safety and essential performance of infusion pumps and controllers	2026-05-29	2026-08-21
62D/2317/FDIS 62D/2317(F)/FDIS	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	2026-07-10	2026-08-21

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
87/941/DISH	IEC 62127-1/ISH1 ED2: Interpretation Sheet 1 - Ultrasonics - Hydrophones - Part 1: Measurement and characterization of medical ultrasonic fields	2026-07-03	2026-08-14
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

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-026:020:02;
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!