

Prezados(as) Senhores(as),

A ABNT gostaria de contar com a sua participação na **1ª 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:** 07.02.2025

**Horário:** 09:00 às 13:00

**Modalidade:** remota

**Local:** não aplicável

**Link:** [https://zoom.us/meeting/register/oOA5e-r2T26crtJffoSBEA](https://zoom.us/join/zoom/register/oOA5e-r2T26crtJffoSBEA)

**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:
  - a) Calendário de reuniões de 2025.
  - b) PNS 2025.
6. Documentos recebidos da IEC e ISO:

TC 62 - Medical equipment, software, and systems	
Referência	Título
<a href="#">62/538/RM</a>	Unconfirmed minutes of the meeting in Edinburgh, Scotland, on 25 October 2024
<a href="#">62/539/MTG</a>	Meeting documents - Plenary meeting in Edinburgh, Scotland, on 25 October 2024
<a href="#">62/541/RQ</a>	Result of Questionnaire on 62/537/Q: Nomination for the Chair of 62C: Equipment for radiotherapy, nuclear medicine and radiation dosimetry
<a href="#">62/542/RVN</a>	Result of Voting on 62/531/NP - PNW PAS 62-531 ED1: Data management and data quality assessment for medical devices

TC 62A - Common aspects of medical equipment, software, and systems	
Referência	Título
<a href="#">62A/1627/INF</a>	Information to the National Committees of IEC/SC 62A and the P-members of the IEC committees participating in the development of IEC 60601-1 Ed. 4 (IEC/TC 62, SC 62B, SC 62C, SC 62D, IEC/TC 76, IEC/TC 87)
<a href="#">62A/1633/RQ</a>	Result of Questionnaire on 62A/1623/Q: Approval of the SC 62A Outgoing Liaisons
<a href="#">62A/1635/CC</a>	Compilation of Comments on 62A/1559/CD - IEC TS 81001-2-2 ED1: Health software and health IT systems safety, effectiveness and security - Part 2-2: Guidance for the implementation, disclosure and communication of security needs, risks and controls
<a href="#">62A/1636/CC</a>	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
<a href="#">62A/1637/CC</a>	Compilation of Comments on 62A/1619/CD - IEC TR 60601-4-9 ED1: Medical electrical equipment - Part 4-9: Guidance and interpretation - essential performance fault safety
<a href="#">62A/1638/RVDTS</a>	Result of Voting on 62A/1617/DTS - ISO TS 81001-2-1 ED1: Health software and health IT systems safety, effectiveness and security - Part 2-1: Coordination - Guidance for the use of assurance cases for safety and security

TC 62D - Particular medical equipment, software, and systems	
Referência	Título
<a href="#">62D/2149A/RVC</a>	Revised Result of Voting on 62D/2113/CDV - 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
<a href="#">62D/2196/RVD</a>	Result of Voting on 62D/2169/FDIS - IEC 80601-2-71 ED2: Medical electrical equipment - Part 2-71: Particular requirements for the basic safety and essential performance of functional near-infrared spectroscopy (NIRS) equipment
<a href="#">62D/2197/RM</a>	Unconfirmed report of the meeting held in in Edinburgh, Scotland on 2024-10-23
<a href="#">62D/2198/MTG</a>	Meeting documents - Plenary meeting held in in Edinburgh, Scotland on 2024-10-23

<a href="#">62D/2203/RVN</a>	Result of Voting on 62D/2192/NP - PNW 62D-2192 ED1: Medical devices — Sleep apnoea breathing therapy — Masks and application accessories
<a href="#">62D/2204/RVN</a>	Result of Voting on 62D/2175/NP - PNW 62D-2175 ED1: Non-invasive sphygmomanometers -- Part 7: Part 7: Clinical performance verification of intermittent or repeated intermittent cuffless measurement type
<a href="#">62D/2205/RR</a>	Review report of IEC TR 61289:2019 ED2: High frequency surgical equipment and high frequency surgical accessories - Operation and maintenance
<a href="#">62D/2206/CC</a>	Compilation of Comments on 62D/2150/CD - 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

TC 76 - Optical radiation safety and laser equipment	
Referência	Título
<a href="#">76/753A/CC</a>	Revised Compilation of Comments on 76/732/CD - ISO 11553-2 ED2: Safety of machinery — Laser processing machines — Part 2: Safety requirements for hand-held or hand-operated laser processing machines

TC 87 - Ultrasonics	
Referência	Título
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## 7. Análise de Votos dos seguintes documentos Internacionais:

TC 62 - Electrical equipment in medical practice				
GT/GTC	Referência	Título	Data de Circulação	Data de Encerramento
	<a href="#">62/540/NP</a>	PNW 62-540 ED1: Post-market surveillance of machine learning-enabled medical device	2024-12-20	2025-03-14

SC 62A - Common aspects of electrical equipment used in medical practice				
GT/GTC	Referência	Título	Data de Circulação	Data de Encerramento
	<a href="#">62A/1621/Q</a>	Questionnaire: Systematic review of ISO 14971:2019	2024-10-25	2025-02-28
GT 37	<a href="#">62A/1628/CD</a>	IEC 60601-1/FRAG1 ED4: Medical electrical equipment - Part 1: General requirements for basic safety and essential performance - General requirements (Fragment 1)	2024-12-06	2025-02-28
GT 47	<a href="#">62A/1629/CD</a>	IEC 60601-1/FRAG11 ED4: Medical electrical equipment - Part 1: General requirements for basic safety and essential performance - Electromagnetic exposure hazards (Fragment 11)	2024-12-06	2025-02-28
GT 38	<a href="#">62A/1630/CD</a>	IEC 60601-1/FRAG2 ED4: Medical electrical equipment - Part 1: General requirements for basic safety and essential performance - Physical environment hazard (Fragment 2)	2024-12-06	2025-02-28
GT 39	<a href="#">62A/1631/CD</a>	IEC 60601-1/FRAG3 ED4: Medical electrical equipment - Part 1: General requirements for basic safety and essential performance - User interface hazards (Fragment 3)	2024-12-06	2025-02-28
GT 40	<a href="#">62A/1632/CD</a>	IEC 60601-1/FRAG4 ED4: Medical electrical equipment - Part 1: General requirements for basic safety and essential performance - Materials hazards (Fragment 4)	2024-12-06	2025-02-28
	<a href="#">62A/1634/Q</a>	Approval of SC 62A Outgoing Liaisons	2024-12-20	2025-01-31
Gt 49	<a href="#">62A/1639/CD</a>	IEC 62304 ED2: Health software – Software life cycle processes	2025-01-17	2025-03-14
	<a href="#">62A/1640/Q</a>	Nomination of the Convenor for 62A/MT 62353, <i>Medical electrical equipment – Recurrent test and test after repair of medical electrical equipment</i>	2025-01-17	2025-02-28
	<a href="#">62A/1641/Q</a>	Development of the preliminary work item (PWI) entitled 81001-3-1	2025-01-17	2025-02-28

SC 62D - Electromedical equipment				
GT/GTC	Referência	Título	Data de Circulação	Data de Encerramento
GTC 5	<a href="#">62D/2178/CDV</a>	ISO 80601-2-61 ED3: Medical electrical equipment - Part 2-61: Particular requirements for basic safety and essential performance of pulse oximeter equipment	2024-11-22	2025-02-14
GT 41	<a href="#">62D/2183/CDV</a>	IEC 60601-2-91 ED1: Particular requirement for basic safety and essential performance of non-thermal plasma wound treatment equipment	2024-12-13	2025-02-07
GT 29	<a href="#">62D/2185/CDV</a>	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	2024-12-13	2025-03-07
GTC 12	<a href="#">62D/2188/CDV</a>	ISO 80601-2-74 ED3: Medical electrical equipment - Part 2-74: Particular requirements for basic safety and	2024-12-06	2025-02-28

		essential performance of respiratory humidifying equipment		
GTC 12	<a href="#">62D/2189/CDV</a>	ISO 80601-2-90 ED2: Medical electrical equipment - Part 2-90: Particular requirements for basic safety and essential performance of respiratory high-flow therapy equipment	2024-12-06	2025-02-28
GTC 12	<a href="#">62D/2190/CDV</a>	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	2025-01-03	2025-03-28
	<a href="#">62D/2200/DC</a>	Request for comments on the interpretation sheet concerning IEC 60601-2-2 Ed.6.1: 2023	2024-12-13	2025-01-24
GTC 8	<a href="#">62D/2202/CDV</a>	ISO 12487 ED1: Respiratory equipment -- Clinical investigation of clinical thermometers	2025-01-10	2025-04-04
GTC 12	<a href="#">62D/2207/CDV</a>	ISO 17510 ED1: Medical devices — Sleep apnoea breathing therapy — Masks and application accessories	2025-01-17	2025-04-11

TC 76 - Optical radiation safety and laser equipment				
GT/GTC	Referência	Título	Data de Circulação	Data de Encerramento
	<a href="#">76/762/CD</a>	IEC TS 60825-21 ED1: Safety of Laser Products - Part 21: Automatic Emission Control (AEC)	2024-12-13	2025-02-21
	<a href="#">76/763/CDV</a>	ISO 11553-2 ED2: Safety of machinery — Laser processing machines — Part 2: Safety requirements for hand-held or hand-operated laser processing machines	2025-01-17	2025-04-11

TC 87 - Ultrasonics				
GT/GTC	Referência	Título	Data de Circulação	Data de Encerramento

8. Estruturação de GTs/GTCs da CE-026:020:001 e CE-026:020:002. Relatórios relativos aos GTs e GTCs;
9. Apresentação da situação atual das normas trabalhadas pelas CEs 026:020:001 e 026:020:002;
10. Outros assuntos;
11. Planejamento dos próximos trabalhos;
12. Ações para a próxima reunião;
13. Próxima reunião:

Fevereiro	Março	Abril	Mai	Junho	Julho	Agosto	Setembro	Outubro	Novembro	Dezembro
07	07	04	09	06	04	01	05	03	07	05

14. Encerramento da reunião.

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

1. **Cadastre-se** em [www.abntonline.com.br/normalizacao](http://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](mailto:cb-026@abnt.org.br)) solicitando seu descadastramento.

**Junte-se a nós e faça a diferença!**