



Prezados(as) Senhores(as),

A ABNT gostaria de contar com a sua participação na 6ª **Reunião/2024** 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: 02.08.2024

Horário: 09:00 às 13:00

Modalidade: remota

Local: não aplicável

Link: <https://zoom.us/join/joinMeeting/register/tJ0kc-CvqzouEtX0s5BFLkjdU6oDMsPFwqVu>

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 Comissões;
6. Documentos recebidos da IEC e ISO:

TC 62 - Medical equipment, software, and systems	
Referência	Título
62/514/DA	Draft agenda for the meeting to be held in Edinburgh, Scotland, on 25 October 2024 (starting time: 13:30) (approximate finishing time: 17:30)

TC 62A - Common aspects of medical equipment, software, and systems	
Referência	Título
62A/1600/INF	Results of the ISO Systematic Review of: ISO/TR 80001-2-6:2014, Application of risk management for IT-networks incorporating medical devices - Part 2-6: Application guidance - Guidance for responsibility agreements
62A/1601/INF	Results of the ISO Systematic Review of: ISO/TR 80001-2-7:2015, Application of risk management for IT-networks incorporating medical devices Application guidance Part 2-7 - Guidance for healthcare delivery organizations (HDOs) on how to self-assess their conformance with IEC 80001-1
62A/1602/RQ	Results of Questionnaire (62A/1595/Q) - National Committee approval to: Convert project PWI TR 62A-1, IEC 60601-4-7, Medical electrical equipment - Part 4-7: Guidance and interpretation - Essential performance fault safety to IEC PAS 60601-4-7, Medical electrical equipment - Part 4-7: Guidance and interpretation - Essential performance fault safety and convert PT 62A-1 into a PT 60601-4-7, keeping its members and project leader
62A/1603/RQ	Result of Questionnaire on 62A/1596/Q: Nomination of the Convenor for SC 62A/WG 40: Material hazards
62A/1605/DA	Draft agenda for the meeting to be held in Edinburgh, Scotland on 2024-10-23 (starting time: 9:30 am to approximate finishing time: 12:30 pm)

TC 62D - Particular medical equipment, software, and systems	
Referência	Título
62D/2063A/RVC	Revised Result of Voting on 62D/2019/CDV - IEC 60601-2-40 ED3: Medical electrical equipment - Part 2-40: Particular requirements for the basic safety and essential performance of electromyographs and evoked response equipment
62D/2141/RVD	Result of Voting on 62D/2125/FDIS - ISO 80369-2 ED1: Small-bore connectors for liquids and gases in healthcare applications - Part 2: Connectors for breathing systems and driving gases
62D/2142/RVC	Result of Voting on 62D/2038/CDV - ISO 80369-20 ED2: Small-bore connectors for liquids and gases in healthcare applications - Part 20: Common test methods
62D/2143/INF	Revised Compilation of Comments on Committee Draft (CC) for IEC 60601-2-23 ED4, Medical electrical equipment - Part 2-23: Particular requirements for the basic safety and essential performance of transcutaneous partial pressure monitoring equipment (62D/1627/CD)
62D/2147/CC	Compilation of Comments on 62D/2129/CD - 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/2148/RVC	Result of Voting on 62D/2114/CDV - IEC 80601-2-52 ED1: Medical electrical equipment - Part 2-52: Particular requirements for the basic safety and essential performance of medical beds
62D/2149/RVC	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
62D/2151/DA	Draft agenda for the meeting to be held in Edinburgh, Scotland on 2024-10-23 (starting time: 13:30) (approximate finishing time: 17:30)
62D/2152/RVD	Result of Voting on 62D/2134/FDIS - ISO 80601-2-79 ED2: Medical electrical equipment - Part 2-79: Particular requirements for basic safety and essential performance of ventilatory support equipment for ventilatory impairment
62D/2153/RVD	Result of Voting on 62D/2135/FDIS - ISO 80601-2-80 ED2: Medical electrical equipment - Part 2-80: Particular requirements for basic safety and essential performance of ventilatory support equipment for ventilatory insufficiency
62D/2154/RQ	Result of Questionnaire on 62D/2140/Q: Nomination of convenor for IEC/SC 62D/JWG 22, Electromedical diagnostic and patient monitoring equipment

TC 76 - Optical radiation safety and laser equipment	
Referência	Título

TC 87 - Ultrasonics	
Referência	Título
87/842A/RVC	Revised Result of Voting on 87/836/CDV - IEC 61846 ED2: Ultrasonics – Therapeutic focused short pressure pulse sources – Characteristics of fields
87/852A/RVC	Revised Result of Voting on 87/840/CDV - IEC 62127-2 ED2: Ultrasonics - Hydrophones - Part 2: Calibration for ultrasonic fields
87/871/RVD	Result of Voting on 87/851/FDIS - IEC 63412-1 ED1: Ultrasonics - Shear-wave elastography - Part 1: Specifications for the user interface
87/872/RVN	Result of Voting on 87/849/NP - PNW TS 87-849 ED1: Ultrasonics Field characterization Measurement-based simulation in water and other media
87/873/RVN	Result of Voting on 87/848/NP - PNW TS 87-848 ED1: Ultrasonics Field characterization Specification and measurement of field parameters at high pressure therapeutic levels in water
87/874/RR	Review Report on IEC 62127-3:2022 ED 2 - Ultrasonics - Hydrophones - Part 3: Properties of hydrophones for ultrasonic fields

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
	62/513/Q	Questionnaire regarding the establishment of an Ad-Hoc Group 11 "Establishing the credibility of computational modelling in the field of medical devices through verification, validation, and uncertainty quantification" and call for experts	2024-06-14	2024-07-26
	62/515/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")	2024-07-12	2024-08-23

SC 62A - Common aspects of electrical equipment used in medical practice				
GT/GTC	Referência	Título	Data de Circulação	Data de Encerramento
	62A/1604/Q	Appointment of a Vice-Chair of SC 62A	2024-06-28	2024-08-09
	62A/1606/NP	PNW 62A-1606 ED1: Packaging for non-sterile medical devices – Requirements for packaging systems	2024-07-05	2024-09-27

SC 62D - Electromedical equipment				
GT/GTC	Referência	Título	Data de Circulação	Data de Encerramento
	62D/2132/CD	IEC TR 63577 ED1: Design principles and validation methods for the maintenance of microbial control for non-disposable fluid paths of dialysis equipment	2024-04-19	2024-07-12
JWG 22	62D/2133/CDV	IEC 80601-2-23 ED1: Medical electrical equipment - Part 2-23: Particular requirements for the basic safety and essential performance of transcutaneous partial pressure monitoring equipment	2024-06-07	2024-08-30
JWG 3	62D/2136/CDV	IEC 80601-2-31 ED1: Medical electrical equipment - Part 2-31: Particular requirements for the basic safety and essential performance of external cardiac pacemakers with internal power source	2024-06-28	2024-09-20
	62D/2140/Q	Nomination of convenor for IEC/SC 62D/JWG 22, Electromedical diagnostic and patient monitoring equipment	2024-05-24	2024-07-05

	62D/2144/Q	Nomination of co-convenor of SC 62D/JWG 1, Critical Care Ventilators (joint with ISO/TC 121/SC 3) for a term of 3 years	2024-06-07	2024-07-19
JWG 10	62D/2145/FDIS	ISO 80369-20 ED2 - Small-bore connectors for liquids and gases in healthcare applications - Part 20: Common test methods	2024-06-14	2024-07-26
JWG 22	62D/2146/FDIS	IEC 80601-2-49/AMD1 ED1: Amendment 1 - Medical electrical equipment - Part 2-49: Particular requirements for the basic safety and essential performance of multifunction patient monitors	2024-06-21	2024-08-02
JWG 22	62D/2146(F)/FDIS	IEC 80601-2-49/AMD1 ED1: Amendment 1 - Medical electrical equipment - Part 2-49: Particular requirements for the basic safety and essential performance of multifunction patient monitors (idêntico ao 62D/2146/FDIS na versão francesa)	2024-06-28	2024-08-02
JWG 11	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	2024-06-21	2024-08-16
JWG 22	62D/2155/FDIS	IEC 60601-2-34 ED4: Medical electrical equipment - Part 2-34: Particular requirements for the basic safety and essential performance of invasive blood pressure monitoring equipment	2024-07-12	2024-08-23

TC 76 - Optical radiation safety and laser equipment				
GT/GTC	Referência	Título	Data de Circulação	Data de Encerramento

TC 87 - Ultrasonics				
GT/GTC	Referência	Título	Data de Circulação	Data de Encerramento
	87/875/NP	PNW 87-875 ED1: Ultrasonics – Intraluminal short pressure pulse therapy sources – Characteristics of fields	2024-07-05	2024-09-27

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 Comissões 026:020:001 e 026:020:002;
 - a. Consulta nacional: PROJETO ABNT NBR IEC 81000-5-1 - Segurança, eficácia e cibersegurança de software para saúde e sistemas de TI para saúde - Parte 5-1: Cibersegurança — Atividades no ciclo de vida do produto
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
02	01	05	03	07	05	02	06	04	01	06

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, 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!