



Prezados(as) Senhores(as),

A ABNT, como único Foro Nacional de Normalização, mediante a demanda de normalização no campo Odonto-Médico-Hospitalar, criou as Comissões de Estudo de Aspectos Comuns de Segurança para Equipamentos Eletromédicos (ABNT/CE-026:020.001) e de Equipamento Eletromédico (ABNT/CE-026:020.002) para discutir e estabelecer, por consenso, regras, diretrizes ou características para o referido assunto.

Desta forma, convidamos V.Sa. a participar da 3ª Reunião de 2024 da ABNT/CE-026:020.001 e ABNT/CE-026:020.002, a ser realizada conforme a programação a seguir:

Data: 05.04.2024

Horário: 09h00 às 13h00

Acesso Remoto Individual:

https://zoom.us/meeting/register/tJ0rdeyurTgoEtHvRmAL3R17tOXRjh2H_Obi

Pauta:

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 recebidos da IEC e ISO:

TC 62 - Electrical equipment in medical practice	
Referência	Título
62/507/CC	Compilation of Comments on 62/495/CD - IEC 60050-880 ED1: International Electrotechnical Vocabulary (IEV) ? Part 880: Electrical equipment, electrical systems and software used in healthcare
62/508/INF	Result on 62/501/DC: Feedback on IEC 63366 (TC 111) - Product category rules for life cycle assessment of electrical and electronic products and systems

TC 62A - Common aspects of electrical equipment used in medical practice	
Referência	Título
62A/1576/RQ	Results of Questionnaire (62A/1557/Q)Questionnaire regarding withdrawal of IEC TR 80001-2-1:2012, IEC TR 80001-2-3:2012 and. IEC TR 80001-2-4:2012
62A/1575/RQ	Result of Questionnaire on 62A/1552/Q: Nomination of experts and Co-convenors for SC 62A/WG 43
62A/1574/RQ	Result of Questionnaire on 62A/1555/Q: Nomination of experts and Co-convenors for SC 62A/MT 49
62A/1573/RQ	Result of Questionnaire on 62A/1554/Q: Nomination of experts and Co-convenors for SC 62A/WG 46
62A/1580/RR	Review report of IEC 80001-2-4 ED1: Application of risk management for IT-networks incorporating medical devices - Part 2-4: Application guidance - General implementation guidance for healthcare delivery organizations
62A/1579/RR	Review report of IEC TR 80001-2-3 ED1: Application of risk management for IT-networks incorporating medical devices - Part 2-3: Guidance for wireless networks
62A/1578/RR	Review report of IEC TR 80001-2-1 ED1: Application of risk management for IT-networks incorporating medical devices - Part 2-1: Step by step risk management of medical IT-networks - Practical applications and examples
62A/1582/RR	Review report of IEC 60601-1 ED3: Medical electrical equipment - Part 1: General requirements for basic safety and essential performance

TC 62D - Electromedical equipment	
Referência	Título
62D/2120/RR	Review report of IEC 80601-2-60 ED2: Medical electrical equipment - Part 2-60: Particular requirements for the basic safety and essential performance of dental equipment
62D/2119/RR	Review report if ISO 80601-2-70 ED2: Medical electrical equipment - Part 2-70: Particular requirements for the basic safety and essential performance of sleep apnoea breathing therapy equipment



TC 62D - Electromedical equipment	
Referência	Título
62D/2037A/RR	Review report of IEC 60601-2-23 ED3: Medical electrical equipment - Part 2-23: Particular requirements for the basic safety and essential performance of transcutaneous partial pressure monitoring equipment
62D/2035A/RVC	Revised Result of Voting on 62D/1992/CDV - IEC 60601-2-39 ED4: Medical electrical equipment - Part 2-39: Particular requirements for basic safety and essential performance of peritoneal dialysis equipment
62D/2031A/RVC	Revised Result of Voting on 62D/1988/CDV - IEC 60601-2-16 ED6: Medical electrical equipment - Part 2-16: Particular requirements for basic safety and essential performance of haemodialysis, haemodiafiltration and haemofiltration equipment
62D/2118/RVD	Result of Voting on 62D/2107/FDIS - ISO 81060-2/AMD2 ED3: Amendment 2 - Non-invasive sphygmomanometers - Part 2: Clinical investigation of intermittent automated measurement type
62D/2094A/CC	Revised Compilation of Comments on 62D/2060/CD - ISO 80601-2-74 ED3: Medical electrical equipment - Part 2-74: Particular requirements for basic safety and essential performance of respiratory humidifying equipment
62D/2089A/CC	Revised Compilation of Comments on 62D/2058/CD - 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
62D/2080A/RVC	Revised Result of Voting on 62D/2043/CDV - 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/1903A/RVC	Revised Result of Voting on 62D/1851/CDV - ISO 80369-2 ED1: Small-bore connectors for liquids and gases in healthcare applications - Part 2: Connectors for breathing systems and driving gases
62D/2081A/RVC	Revised Result of Voting on 62D/2044/CDV - 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

TC 76 - Optical radiation safety and laser equipment	
Referência	Título
76/750/AC	Next meeting of TC 76 to be held in Kokura, Japan from 2024-08-25 to 2024-08-30
76/751/DA	Draft agenda for the meeting to be held in Kokura Japan from 2024-08-25 to 2024-08-30

TC 87 - Ultrasonics	
Referência	Título
87/850/INF	Review of Active Participation of P-members in the Work of TC 87
87/855/INF	Liaison Report of SC 62B to TC 87 for the plenary meeting to be held on 2024-04-26 in Offenbach Germany
87/854/INF	Report of WG 9 to TC 87 for the plenary meeting to be held on 2024-04-26 in Offenbach Germany
87/853/INF	Report of WG 8 to TC 87 for the plenary meeting to be held on 2024-04-26 in Offenbach Germany
87/852/RVC	Result of Voting on 87/840/CDV - IEC 62127-2 ED2: Ultrasonics - Hydrophones - Part 2: Calibration for ultrasonic fields
87/858/INF	Report of WG 6 to TC 87 for the plenary meeting to be held on 2024-04-26 in Offenbach Germany
87/857/INF	Report of WG 7 to TC 87 for the plenary meeting to be held on 2024-04-26 in Offenbach Germany
87/856/INF	Report of WG 14 to TC 87 for the plenary meeting to be held on 2024-04-26 in Offenbach Germany

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
	62/509/Q	Questionnaire on the establishment of a Preliminary Work Item (PWI): "Establishing the credibility of computational modelling in the field of medical devices through verification, validation, and uncertainty quantification"	2024-03-15	2024-04-26

TC 62A - Common aspects of electrical equipment used in medical practice				
GT/GTC	Referência	Título	Data de Circulação	Data de Encerramento
	62A/1581/Q	Nomination of a Co-convenor for SC62A/WG 46: Ionizing radiation hazards	2024-03-08	2024-04-05
	62A/1577/DC	Document for comment IEC 60447: Basic and safety principles for man-machine interface, marking and identification - Actuating principles	2024-03-01	2024-04-12
	62A/1559/CD	IEC TS 81001-2-2 ED1: Health software and health IT systems safety, effectiveness and security - Part 2-2:	2024-02-02	2024-04-26



		Guidance for the implementation, disclosure and communication of security needs, risks and controls		
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SC 62D - Particular medical equipment, software, and systems				
GT/GTC	Referência	Título	Data de Circulação	Data de Encerramento
	62D/2121/Q	Nomination of Convenor for IEC/SC 62D/MT16,Electro-optical equipment	2024-03-01	2024-04-12
	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	2024-03-01	2024-05-24
	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	2024-03-01	2024-05-24
	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	2024-03-08	2024-04-19
	62D/2124/CD	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	2024-03-08	2024-05-03
	62D/2123/CD	ISO 80601-2-67 ED3: Medical electrical equipment - Part 2-67: Particular requirements for basic safety and essential performance of oxygen-conserving equipment	2024-03-08	2024-05-03
	62D/2122/CD	ISO 80601-2-69 ED3: Medical electrical equipment - Part 2-69: Particular requirements for the basic safety and essential performance of oxygen concentrator equipment	2024-03-08	2024-05-03
	62D/2127/CD	ISO 80601-2-74 ED3: Medical electrical equipment - Part 2-74: Particular requirements for basic safety and essential performance of respiratory humidifying equipment	2024-03-15	2024-05-10
	62D/2126/CD	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	2024-03-15	2024-05-10

TC 87 - Ultrasonics				
GT/GTC	Referência	Título	Data de Circulação	Data de Encerramento
	87/851/FDIS	IEC 63412-1 ED1: Ultrasonics - Shear-wave elastography - Part 1: Specifications for the user interface	2024-03-08	2024-04-19

8. Deliberação dos Projetos de Normas:
 - a) Projeto ABNT IEC/TR 60878 - Símbolos gráficos para equipamentos elétricos na prática médica.
 - b) Projeto ABNT NBR ISO 80601-2-85 - Equipamento médico elétrico – Parte 2-85: Requisitos particulares para a segurança básica e desempenho essencial do equipamento de oxímetro de tecido cerebral.
9. Estruturação de GTs/GTCs da CE-026:020:001 e CE-026:020:002. Relatórios relativos aos GTs e GTCs;
10. Apresentação da situação atual das normas trabalhadas pelas CE-026:020:001 e CE-026:020:002;
11. Outros assuntos;
12. Planejamento dos próximos trabalhos;
13. Ações para a próxima reunião;
14. Próxima reunião:

Fevereiro	Março	Abri	Maio	Junho	Julho	Agosto	Setembro	Outubro	Novembro	Dezembro
02	01	05	03	07	05	02	06	04	01	06

15. Encerramento da reunião.



Convite

Os documentos das Comissões de Estudos CE-026:020.001 e CE-026:020.002, estão disponíveis no ABNT *Documents*, na seguinte pasta:

<https://sd.iso.org/documents/ui#!/browse/abnt/ct/abnt-cb-026/abnt-cb-026-ce-026-020-001>

<https://sd.iso.org/documents/ui#!/browse/abnt/ct/abnt-cb-026/abnt-cb-026-ce-026-020-002>

Para obter login e senha de acesso ao ABNT *Documents*, faça o cadastro no site <https://www.abntonline.com.br/normalizacao/> indicando que deseja participar da Comissão de Estudo e aceite o termo de confidencialidade.

Para indicar ou convidar potenciais interessados em participar dos trabalhos de normalização, estas pessoas precisam realizar o seu cadastro no link indicando a Comissão de Estudo de seu interesse.

Caso não tenha mais interesse em participar da Comissão de Estudo em questão, enviar e-mail para a Secretaria do Comitê Técnico (cb-026@abnt.org.br).

Solicitamos que a participação seja confirmada ou ausência justificada respondendo esta mensagem para a Secretaria do Comitê Técnico no e-mail cb-026@abnt.org.br.

Cordialmente,

Karla D. Martinez Fogaça

Chefe de Secretaria – ABNT/CB-026 Odonto-Médico-Hospitalar