



Prezados(as) Senhores(as),

A ABNT, como único Foro Nacional de Normalização, mediante a demanda de normalização no campo Odonto-Médico-Hospitalar, criou a Comissão de Estudo de Aspectos Comuns de Segurança para Equipamentos Eletromédicos (ABNT/CE-026.020.001), para discutir e estabelecer, por consenso, regras, diretrizes ou características para o referido assunto.

Desta forma, convidamos V.Sa. a participar da 2ª Reunião de 2020 da ABNT/CE-026.020.001, a ser realizada conforme a programação a seguir:

Data: 06.03.2020

Horário: 09h00 às 12h00

Local: Av. Paulista, 1313, 8º Andar, Conj. 806, São Paulo/SP

Acesso Remoto Individual:

<https://abimo.webex.com/abimo-pt/j.php?MTID=mbe1dbd937e5acf0799f26349c3d44505>

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 da mesma);
5. Comunicados do Coordenador da CE;
6. Documentos recebidos da IEC e ISO;

Referência	Título
62/342A/INF	Revised Results of 62/333/DC: Document for comments on architecture aspects of safety standards for medical electrical equipment, medical electrical systems, and software used in healthcare
62A/1350A/RVC	Revised Result of Voting on 62A/1320/CDV - IEC 60601-1/AMD2 ED3: Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
62A/1351A/RVC	Revised Result of Voting on 62A/1321/CDV - IEC 60601-1-2/AMD1 ED4: Amendment 1 – Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral Standard: Electromagnetic disturbances – Requirements and tests.
62A/1353A/RVC	Revised Result of Voting on 62A/1324/CDV - IEC 60601-1-6/AMD2 ED3: Amendment 2 – Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance – Collateral standard: Usability
62A/1354A/RVC	Revised Result of Voting on 62A/1325/CDV - IEC 60601-1-8/AMD2 ED2: Amendment 2 – Medical electrical equipment – Part 1-8: General requirements for basic safety and essential performance – Collateral Standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems
62A/1355A/RVC	Revised Result of Voting on 62A/1326/CDV - IEC 60601-1-9/AMD2 ED1: Medical electrical equipment – Part 1-9: General requirements for basic safety and essential performance – Collateral Standard: Requirements for environmentally conscious design
62A/1356A/RVC	Revised Result of Voting on 62A/1327/CDV - IEC 60601-1-10/AMD2 ED1: Amendment 2 – Medical electrical equipment – Part 1-10: General requirements for basic safety and essential performance – Collateral Standard: Requirements for the development of physiologic closed-loop controllers
62A/1357A/RVC	Revised Result of Voting on 62A/1328/CDV - IEC 60601-1-11/AMD1 ED2: Amendment 1 – Medical electrical equipment – Part 1-11: General requirements for basic safety and essential performance – Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment
62A/1358A/RVC	Revised Result of Voting on 62A/1329/CDV - IEC 60601-1-12/AMD1 ED1: Medical electrical equipment – Part 1-12: General requirements for basic safety and essential performance – Collateral Standard: Requirements for medical electrical equipment and medical electrical systems intended for use in the emergency medical services environment



62A/1375A/CC	Revised Compilation of Comments on 62A/1360/CD - IEC 80001-5-1 ED1: Safety, security and effectiveness in the implementation and use of connected medical devices or connected health software - Part 5-1: Security - Activities in the product lifecycle
62A/1383/RVC	Result of Voting on 62A/1349/CDV - IEC 62304 Ed. 2: Health software - Software life cycle processes

7. Análise de Votos dos seguintes documentos Internacionais (No Livelink, na pasta da Comissão CE 26.020.01 > Library > Documentos de Apoio > Documentos da Secretaria > Documentos para Votos > 2020 – 03)

GT/GTC	Referência	Descrição	Data de Circulação	Data de Encerramento
	62/348/Q	Questionnaire on the approval of Architecture aspects of safety standards for medical electrical equipment, medical electrical systems, and software used in healthcare	2020-01-24	2020-04-17
	62A/1380/CD	IEC TR 60601-4-5 ED1 - Medical electrical equipment ; Part 4-5 Guidance and interpretation; Safety related technical security specifications for medical devices	2019-12-13	2020-03-06
GT20	62A/1379/CDV	IEC 63120 ED1: Refurbishment of medical electrical equipment, medical electrical systems and sub-assemblies and reuse of components as part of the extended life-cycle	2020-01-31	2020-04-24
GTC7	62A/1384/CD	IEC 80001-5-1 ED1: Safety, security and effectiveness in the implementation and use of connected medical devices or connected health software - Part 5-1: Security - Activities in the product lifecycle	2020-01-31	2020-04-24

8. Estruturação de GTs/GTCs da CE 26:020.01 . Relatórios relativos aos GTs e GTCs;
9. Apresentação da situação atual das normas trabalhadas pela CE 26:020.01;
10. Planejamento dos próximos trabalhos;
11. Próxima reunião:

Fevereiro	Março	Abril	Maio	Junho	Julho	Agosto	Setembro	Outubro	Novembro	Dezembro
07	06	03	08	05	03	07	04	02	06	04

12. Ações para a próxima reunião;
13. Outros assuntos;
 13.1 – Consulta CT08/DICLA/CGCRE sobre classificação IP da norma geral
14. Encerramento da reunião.

SOLICITAMOS QUE CONFIRME SUA PRESENÇA OU JUSTIFIQUE AUSÊNCIA RESPONDENDO ESTA MENSAGEM PARA O E-MAIL cb-026@abnt.org.br.

Cordialmente,

Secretaria – ABNT/CB-026