

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 10ª Reunião Conjunta 2018 da ABNT/CE-026.020.001 e ABNT/CE-026.020.002, a ser realizada conforme a programação a seguir:

Data: 09.11.2018

Horário: 09h00 às 17h00

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

Acesso Remoto:

<https://abimo.webex.com/abimo-pt>

Número da reunião: 739 693 883

Senha da reunião: PmMcpdGa

Pauta:

1. Abertura;
2. Apresentação dos membros presentes;
3. Análise, correção e aprovação da Minuta de Ata da Reunião anterior;
4. Definição da pauta, com aceitação da pauta proposta anteriormente ou modificação da mesma;
5. Análise de Votos dos seguintes documentos internacionais existentes no Livelink, nas pastas:
 - 5.1. Comissão CE 26.020.01 > Library > Projetos > Documentos para Voto Recebidos ISO/IEC SC 62A > 2018 > Reunião 201811;
 - 5.2. Comissão CE 26.020.02 > Library > Projetos > Documentos para Voto Recebidos ISO/IEC SC 62D, TC 76 e TC 87 > 2018 > Reunião 201811:

Comitê	Referência	Descrição	Data de Circulação	Data de Encerramento
SC 62A	62A/1288/CD V	IEC 62366-1/AMD1 ED1: Medical devices - Part 1: Application of usability engineering to medical devices	12/10/2018	04/01/2019
SC 62D	62D/1627/CD	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	31/08/2018	23/11/2018
SC 62D	62D/1628/CD	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	31/08/2018	23/11/2018

SC 62D	62D/1630/CD	ISO 80601-2-13 ED2: Medical electrical equipment - Part 2-13: Particular requirements for basic safety and essential performance of an anaesthetic workstation	14/09/2018	07/12/2018
SC 62D	62D/1633/CD	ISO 80601-2-85 ED1: Medical electrical equipment - Part 2-85: Particular requirements for the basic safety and essential performance of cerebral tissue oximeter equipment (t-NIRS)	12/10/2018	07/12/2018
SC 62D	62D/1635/NP	PNW 62D-1635: Medical electrical equipment - Part 2-xx: Particular requirements for the basic safety and essential performance of medical beds for children	19/10/2018	11/01/2019
TC 87	87/699/CDV	IEC 61828 ED2: Ultrasonics - Focusing transducers - Definitions and measurement methods for the transmitted fields	14/09/2018	07/12/2018
TC 87	87/699(F)/CD V	IEC 61828 ED2: Ultrasonics - Focusing transducers - Definitions and measurement methods for the transmitted fields	05/10/2018	07/12/2018
TC 87	87/701/CD	IEC TS 63081 ED1: Ultrasonics - Methods for the characterisation of the ultrasonic properties of materials.	14/09/2018	07/12/2018
TC 87	87/703/CD	IEC 63045 ED1: Ultrasonics - Non-focusing pressure pulse sources - Characteristics of fields	21/09/2018	14/12/2018
TC 87	87/704/CD	IEC TS 61390 ED2: Ultrasonics - Real-time pulse-echo systems - Test procedures to determine performance specifications	21/09/2018	14/12/2018

6. Documentos recebidos da IEC e ISO existentes no Livelink, nas pastas das Comissões:

6.1. CE 26.020.01 > Library > Projetos > Documentos para Conhecimento Recebidos ISO/IEC SC 62A > 2018 > Reunião_201810);

6.1.1. 62/327/RQ - Result on 62/326/Q: Questionnaire on a Liaison A to be established with the International Medical Device Regulators Forum (IMDRF)

6.1.2. 62A/1166C/INF - Design Specification for Amendment 1 to IEC 60601-1-2:2014 Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral Standard: Electromagnetic disturbances – Requirements and tests (Revision 1)

6.1.3. 62A/1275A/CC - Compilation of Comments on 62A/1256/CD - 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.

6.1.4. 62A/1291/RQ - Result of Questionnaire on 62A/1286/Q: Questionnaire on a Liaison A to be established with the International Medical Device Regulators Forum (IMDRF)

6.1.5. 62A/1292/CC - Compilation of Comments on 62A/1283/CD - ISO 81001-1 ED1: Health software and health IT systems safety, effectiveness and security - Foundational principles, concepts and terms

6.1.6. 62A/1293/INF - Follow-up information regarding the revision of IEC 62304, Health software – Software life cycle processes - PowerPoint presentations from 2 and 4 October 2018 – share the status of document with National Committees

- 6.1.7. 62A/1294/INF - Results of the National Committee Enquiry on Proposal from the German National Committee for a new Technical Report in the IEC 60601 series - Medical Electrical Equipment – Part 4-5: Guidance and interpretation – Safety related technical security specifications for medical devices
- 6.1.8. 62A/1295/AC - Call for experts - PT 60601-4-5, Medical electrical equipment – Part 4-5 Guidance and interpretation – Safety related technical security specifications for medical devices
- 6.1.9. 62A/1296/RVC - Result of Voting on 62A/1282/CDV - ISO 14971 ED3: Medical devices - Application of risk management to medical devices
- 6.1.10. 62A/1297/CC - Compilation of Comments on 62A/1284/CD - ISO TR 24971 ED2: Medical devices -- Guidance on the application of ISO 14971
- 6.2. CE 26.020.02 > Library > Projetos > Documentos para Conhecimento Recebidos ISO/IEC SC 62D, TC 76 e TC 87 > 2018 > Reunião_201810);
 - 6.2.1. 62D/1435A/RVN - Result of Voting on 62D/1417/NP - Medical electrical equipment - Part 2-xx: Particular requirements for the basic safety and essential performance of cerebral tissue oximeter equipment (t-NIRS)
 - 6.2.2. 62D/1580A/RVC - Result of Voting on 62D/1532/CDV - IEC 80601-2-77 ED1: Medical Electrical Equipment - Part 2-77: Particular requirements for the basic safety and essential performance of robotically assisted surgical equipment
 - 6.2.3. 62D/1581A/RVC - Result of Voting on 62D/1531/CDV - IEC 80601-2-78 ED1: Medical Electrical Equipment - Part 2-78: Particular requirements for the basic safety and essential performance of medical robots for rehabilitation, assessment, compensation or alleviation
 - 6.2.4. 62D/1623A/CC - Compilation of Comments on 62D/1565/CD - IEC TR 61289 ED2: High frequency surgical equipment and high frequency surgical accessories - Operation and maintenance
 - 6.2.5. 62D/1631/RQ - Result of Questionnaire on 62D/1616/Q: Questionnaire on a Liaison A to be established with the International Medical Device Regulators Forum (IMDRF)
 - 6.2.6. 62D/1632/RVD - Result of Voting on 62D/1618/FDIS - ISO 80369-1 ED2: Small-bore connectors for liquids and gases in healthcare applications - Part 1: General requirements
 - 6.2.7. 62D/1634/RR - Review report of IEC 60601-2-19:2009 ED2: Medical electrical equipment - Part 2-19: Particular requirements for the basic safety and essential performance of infant incubators
 - 6.2.8. 62D/1636/RR - Review Report of IEC 60601-2-20 ED2: Medical electrical equipment - Part 2-20: Particular requirements for the basic safety and essential performance of infant transport incubators
 - 6.2.9. 62D/1637/RR - Review report of IEC 60601-2-21 ED2: Medical electrical equipment - Part 2-21: Particular requirements for the basic safety and essential performance of infant radiant warmers
 - 6.2.10. 62D/1638/RR - Review report of IEC 60601-2-50 ED2: Medical electrical equipment - Part 2-50: Particular requirements for the basic safety and essential performance of infant phototherapy equipment
 - 6.2.11. 62D/1639/RR - Review report of IEC 80601-2-35 ED2: Medical electrical equipment - Part 2-35: Particular requirements for the basic safety and essential performance of heating devices using blankets, pads and mattresses and intended for heating in medical use
 - 6.2.12. 62D/1640/RVD - Result of Voting on 62D/1619/FDIS - ISO 81060-2 ED3: Non-invasive sphygmomanometers: Part 2: Clinical investigation of intermittent automated measurement type
 - 6.2.13. 76/613/DL - List of decisions taken at the meeting of TC 76, held in Kista, Sweden from 2018-09-17 to 2018-09-21

- 6.2.14. 76/614/RM - Unconfirmed minutes of the meeting held in Kista, Sweden from 2018-09-17 (starting time: 09-00h) to 2018-09-21 (ending time: 11-15h)
 - 6.2.15. 76/615/MTG - Meeting Documents from Plenary in Kista 2018-10
 - 6.2.16. 87/693A/RVDTS - Result of Voting on 87/681/DTS - IEC TS 63001 ED1: Measurement of cavitation noise in devices used for ultrasonic cleaning
 - 6.2.17. 87/669B/CC - Compilation of Comments on 87/662/CD - IEC 60050-801/AMD1 ED2: Amendment 1 - International Electrotechnical Vocabulary- Chapter 801: Acoustics and electroacoustics, Section 32 - Underwater acoustics
 - 6.2.18. 87/688A/RVDTS - Result of Voting on 87/677/DTS - IEC TS 63070 ED1: Ultrasonics - Field characterisation - Infra-red imaging techniques for determining temperature elevation in tissue-mimicking material and at the radiation surface of a transducer in still air
 - 6.2.19. 87/691A/CC - Compilation of Comments on 87/679/CD - IEC 63009 ED1: Ultrasonics - Physiotherapy systems - Field specifications and methods of measurement in the frequency range 20 kHz to 0.5 MHz
7. Envio de projeto de norma para consulta nacional:
- 7.1. Projeto de norma ABNT NBR IEC 60601-2-40 - Parte 2-40: Requisitos particulares para a segurança básica e o desempenho essencial de eletromiógrafos e equipamentos de potencial evocado
8. Estruturação dos GTs/GTCs das CE 26:020.01 e CE 26:020.02;
- 8.1. Situação das normas
 - 8.2. Relatórios apresentados pelos Relatores dos GTs e GTCs;
 - 8.2.1. Próximas reuniões internacionais
 - 8.2.2. Informações dos Relatores
 - 8.3. Atualização da lista de participantes cadastrados no Livelink;
9. Comunicados do Coordenador e Secretário da CE
- 9.1. Informações Regulatórias
 - 9.1.1. Atualizações do FDA
 - 9.1.2. Atualizações da ANVISA
 - 9.1.3. Atualizações da Europa
 - 9.1.4. Atualizações de outros mercados
 - 9.2. Projeto MS-OPAS/ABIMO para Internalização de Normas Técnicas Internacionais;
10. Próxima reunião: 07/Dezembro/2018;
- 10.1. Planejamento das reuniões da CE 26:020.01 e CE 26:020.02 ao longo do ano de 2018:

Mês	FEV	MAR	ABR	MAI	JUN	JUL	AGO	SET	OUT	NOV	DEZ
Dia	2	2	6	4	8	13	3	14	5	9	7

11. Ações para a próxima reunião;

12. Encerramento da reunião.

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

Cordialmente,
Karla D. Martinez
Chefe de Secretaria – ABNT/CB-026