BZAEK Questionnaire on Wipe Disinfection to CED Members

Total number of replies: 20

Countries: Ireland (IE), Slovakia (SK), Czech Republic (CZ), Croatia (HR), Spain (ES), Portugal (PT), Germany (DE), United Kingdom (UK), Denmark (DK), Iceland (IS), Netherlands (NL), Lithuania (LT), Hungary (HU), Estonia (EE), Cyprus (CY), Latvia (LV), Poland (PL), Norway (NO), Greece (GR), Slovenia (SL)

Q: **Is the definitive disinfection of medical devices like polymerisation lamps or X-ray sensors by wipes permitted in your country?**

	IE	SK	CZ	HR	ES	PT	DE	UK	DK	IS	NL	LT	HU	EE	CY	LV	PL	NO	GR	SL
Yes																				
No																				

If yes, which requirements must be fulfilled?

IE: While wipes are currently permitted, barrier methods are recommended and more commonly used.

PT: no requirements. Disinfection of medical devices by wipes should be done in each dental consultation after treatments

DE: The definitive disinfection by wipes is not forbidden yet, but the authorities wrote an "information letter" to the medical/dental institutions. In this letter they announced that there is no possibility to validate the "pressure on the wipes" during wipe disinfection. In German law it is obligatory to use "validated procedures" in processing medical products, so the authorities announced, that they will not accept unvalidated processes anymore.

UK: When cleaning is necessary it should be in accordance with the manufacturer's instructions.

DK: Using products recommended in the National Infection control Guideline

IS: When cleaning instruments (washing/disinfection and sterilization), approved methods must be used and in accordance with the manufacturer's instructions. Requirements for validation and general monitoring of medical device sterilization are based on ISO standard 11137. For more details, see "Requirements for Disinfection and Sterilization of Instruments Used in Healthcare Services" from the Directorate of Health. https://assets.ctfassets.net/8k0h54kbe6bj/eBfEnwj4KIKsgAw3Y8pfv/cd4452c55b545d847cd33187f034c194/S_tthreinsun_og_dau_hreinsun___skur_stofum__23.11.2020___endurn_jun_2024.pdf

NL: Disinfection is necessary in situations where sterility is not required and where cleaning alone does not sufficiently reduce the level of contamination. For disinfecting surfaces, equipment, and materials in dental practices, a selection of chemical disinfectants can be used. Each disinfectant has a specific spectrum of activity for inactivating microorganisms, a recommended concentration, and a specific contact time.

LT: There are no specific requirements for wipes, but the general requirements for infection control for the management and disinfection of medical devices (HN 47-1:2020 (version 2022)) apply. It should be noted that in Lithuania, the general infection control requirements stipulates that.

HU: In Hungary, the requirements for the disinfection of medical devices such as polymerisation lamps or X-ray detectors depend on the type of device and the manufacturer's instructions. Manufacturers usually provide detailed cleaning and disinfection instructions for their products, which must be strictly followed to ensure proper disinfection and to preserve the lifetime of the devices. The use of disinfectant wipes may be appropriate for certain instruments, especially if recommended by the manufacturer. BRADOLIFE disinfectant wipes, for example, are suitable for disinfecting hands and surfaces of various objects by wiping them clean, providing protection against bacteria, viruses and fungi. However, many medical instruments, especially surgical instruments, require specific disinfection procedures. For example, Descoton 2% GDA, marketed by Dr. Schumacher, is a formaldehyde-free formulation that can be used to disinfect all types of medical instruments, including flexible and rigid endoscopes. Therefore, it is essential that when disinfecting any medical device, you follow the cleaning and disinfection instructions provided by the manufacturer and use appropriate disinfectants. If disinfection with wipes is not recommended by the manufacturer, other recommended methods should be used to ensure disinfection.

EE: CE marking disinfection wipes and disinfection guidelines must be fulfilled

CY: Use approved disinfection way.

LV: yes, but some medical devices has a note (not to use ethanol). then we have to use process according the Instruction on use.

PL: regular procedure, according to the manufacturer's recommendations; additionally disposable overlays are used

NO: Definitive disinfection of medical devices by chemical disinfectant wipes is permitted in Norway. It is recommended that the wipes are approved by the authorities as set out in national regulations on chemical disinfectants for use in the health sector. Furthermore, it is recommended that the

disinfectant is accompanied by an instruction manual in Norwegian. If the wipes are not approved by such regulations, one may also use wipes with CE-approval, defined as medical equipment.

GR: For LED composite resins' polymerization lamps it is absolutely permitted but a relevant suggestion exists for wrapping both the handle and the tip with cellulose wrap or prefabricated single use nylon sleeves. After the removal of the sleeve, ethyl alcohol or isopropyl alcohol saturated wipes are used for additional protection. For the x Rays sensors is absolutely mandatory to use single use prefabricated single use polymeric sleeves and no wiping.

SL: Two step technique (one time wipe, let dry and wipe again)

Q: **Is proof of the effectiveness of the procedure required?**

	IE	SK	CZ	HR	ES	PT	DE	UK	DK	IS	NL	LT	HU	EE	CY	LV	PL	NO	GR	SL
Yes																				
No																				

If yes: What kind of proof is necessary? Which tests must be conducted?

PT: No requirements but should be included in an internal manual on disinfection practices for dental cabinets

DE: It is not clear yet which tests are required (e.g. protein tests), the authorities would like to install a system of "validators" who come to the clinics and practices and control (how?) the pressure on the wipe during the process. That seems to be not only ridiculous but more than this expensive and means much more bureaucracy for the dental team.

HU: Yes, in Hungary the effectiveness of disinfection procedures for medical devices must be demonstrated, especially for devices that come into direct contact with the patient. There are several reasons for this: Legal requirements: - Medical device disinfection procedures must comply with the EU Medical Device Regulation (MDR - 2017/745). - The hygiene and disinfection requirements set by the National Centre for Public Health and Pharmacy (NCHR) must also be met. Authorisation of disinfectants: - Products for the disinfection of medical devices must be authorised under the European Biocidal Products Regulation (528/2012/EU). - Disinfectants must have certificates of efficacy, as required by EN 14885. Manufacturer's specifications: - Manufacturers of medical devices shall provide detailed cleaning and disinfection protocols. These must be validated and institutions must document the effectiveness of disinfection. Healthcare institution requirements: - Hospitals, clinics and practices must ensure that the disinfection methods used are effective in removing potential pathogens. - Periodic microbiological tests should be carried out to monitor disinfection processes.

PL: internal control report

NO: It is the responsibility of the authorities to make sure that there is sufficient proof of the effectiveness of the procedure required. Approval should only be given if concentration acquirement, application time and durability is tested. Disinfectants should have a broad spectrum against possible microbes.

Q: **Is a validation of the procedure required by the authorities?**

	IE	SK	CZ	HR	ES	PT	DE	UK	DK	IS	NL	LT	HU	EE	CY	LV	PL	NO	GR	SL
Yes																				
No																				

If yes: At what intervals must validation be conducted and what are the average costs?

IE: A dental practice is expected to do a risk assessment of all their infection control protocols and keep a record.

PT: The validation is not required and there are no costs.

DE: It is not clear yet, how high the costs are and what is the frequency.

HU: Yes, in Hungary, the official validation of medical device disinfection procedures is required in certain cases. The purpose of validation is to ensure that the disinfection method used complies with the legal requirements, ensuring the hygienic safety of the devices and the prevention of infections. When is regulatory validation required? - If the disinfection method is new or deviates from commonly used protocols If a healthcare facility or practice wishes to use a specific disinfection method (e.g. wipe disinfection), validation of the procedure may be required. - If the authorisation of the disinfectant for medical devices is not clear The disinfectant used must be approved under the National Centre for Public Health and Pharmacy (NCHMP) or the European Union Regulation (EU) No 528/2012 on biocidal products. - For surgical and critical devices The efficacy of disinfection of high-risk devices (e.g. surgical instruments, invasive diagnostic devices) should be validated by laboratory tests. - Quality assurance and audits in healthcare institutions - Hospitals and clinics must demonstrate that the disinfection process complies with EN 14885 and the requirements of the health authorities. - The National Public Health and Veterinary Service (PHS) and other authorities may carry out audits of disinfection procedures. How is the official validation done? ?Documentation and licensing: proof of the effectiveness of the disinfectant and method. ? Microbiological testing: validation of the method by laboratory tests. ? Official control: the Public Health Authority may carry out an on-site audit or inspection. ? Compliance with ISO and EN standards: The procedure must follow ISO 17664 and EN 14885.

NO: No validation of the procedure is needed for wipes.