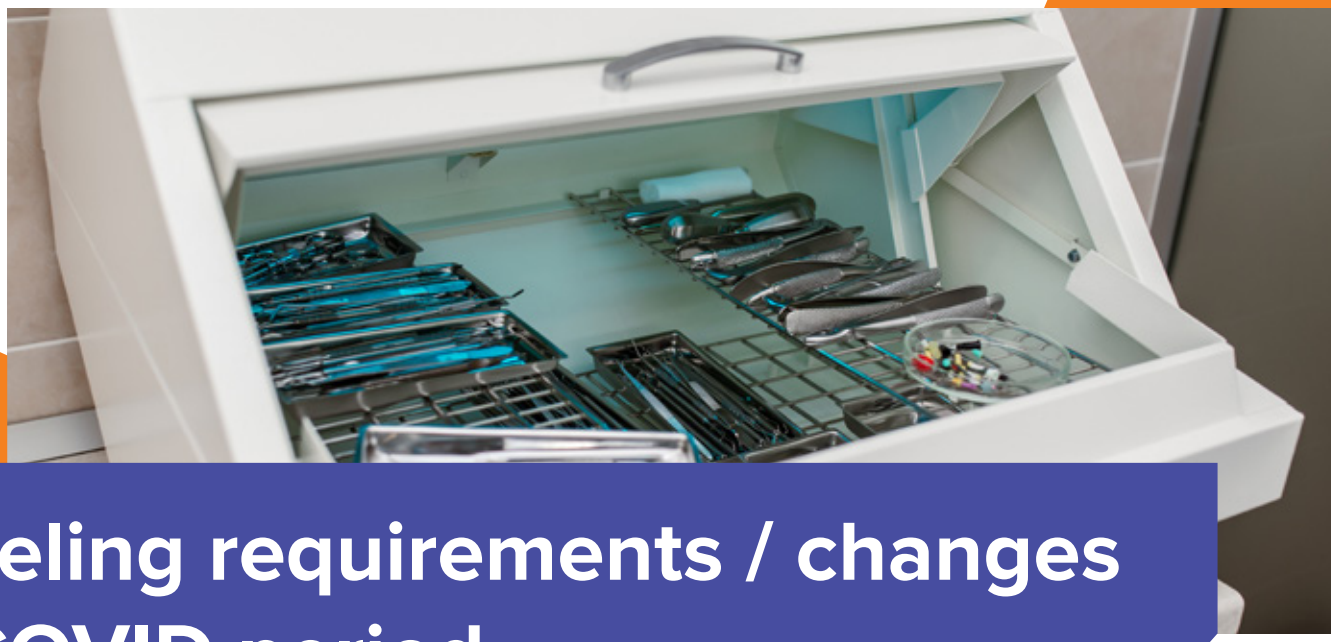

Labeling requirements / changes in COVID period

FDA is committed to providing timely guidance to support response efforts to this pandemic situation of COVID-19. In this regard FDA has implemented few guidance documents immediately without prior public comment, because this is not feasible or appropriate at this pandemic time, but it remains subject to comment in accordance with the Agency's good guidance practices. As recommended by FDA the devices submission would be required as per Quality System Regulation requirements (21 CFR Part 820 {21 CFR Subpart K - § 820.120 Device labeling&§ 820.130 Device packaging Control}), Reports of Corrections and Removals requirements (21 CFR Part 806 {reporting information}), and Label to bear a unique device identifier (21 CFR Part 830 and 21 CFR 801.20) regulations as necessary.

The recommended guidance documents contains proposed changes in both the device technical function and labeling context (including methods, standards, etc).Below are some of the medical devices types as per new recommendations.

- A Remote Ophthalmic Assessment and Monitoring Devices
- B Sterilizers, Disinfectant Devices, and Air Purifiers
- C Infusion Pumps and Accessories
- D Face Masks and Respirators
- E EUAs for Face Masks and Respirators

A. Modifications for Remote Ophthalmic Assessment and Monitoring

FDA expanding the capability of remote ophthalmic assessment and monitoring devices and Tonometers may help facilitate patient care while reducing patient and healthcare provider contact and risk of exposure to SARS-CoV-2.Recommended modification for device function/indications provided in Table 1 and labeling modification are in Table 2.

TABLE 1: Modifications on the Indications and Functionality

Device Type	Product Code	Device Classification	Modification to Devices on Indication, functionality and software/Hardware
1. Visual Acuity Charts, Visual Field Devices, and General-Use Ophthalmic Cameras			
Camera, Ophthalmic, General-use	PJZ	II (exempt)	1. Indications and functionality designed to permit the use of the device for • monitoring and/or assessment of the ophthalmic parameters (not indicated/designed) • Home use and/or by consumers rather than eye care providers • Telemedicine consultation, allowing the eye care provider to assess specific ophthalmic parameters remotely. 2. Devices containing software and/or hardware intended to • Implement intended device functionality for use directly by consumers at home (e.g., visual acuity assessment, visual field assessment, image capture). • Facilitate remote access (e.g., addition of wireless or Bluetooth capability).
Visual Acuity Chart	HOX	I (exempt)	
Amsler Grid	HOQ	I (exempt)	
Perimeter, AC-powered	HOO	I (exempt)	
2. Tonometers			
Tonometer, AC-powered	HKX	II	1. The device is intended to • determine when patients need immediate clinical intervention to assure patient safety • be solely or primarily relied upon by the eye care provider or patient to make a clinical diagnosis or treatment decision; 2. The modifications add the functionality to • acquire, process, or analyze a pattern or signal from a signal acquisition system that was not present in the FDA-cleared device; or Modifications are made to device components that have direct contact with the eye.
Tonometer, Manual	HKY	II	

Table 2: Labeling Modifications for Remote Ophthalmic Assessment and Monitoring Devices and Tonometers:

Device Type	LABELING IMPACT (Yes/No)	
	IFU	Artwork
1) A clear description of the available data on the device's new indications, and/or functions including information regarding: a. Device performance; b. Method of determining any diagnostic or treatment recommendations; and c. Potential risks.	**Yes**	**Yes** (indication statement)
2) Adequate instructions for use for the intended user and indicated environment(s) of use. The labeling should highlight the differences in design compared to the unmodified version of the device, along with instructions for mitigating any known risks associated with these differences.	**Yes**	**Yes** (indication statement)
3) Information so that the eye care provider and/or patient can independently review the basis for any diagnostic or treatment recommendations	**Yes**	**No**
4) For devices previously cleared for use only in a hospital or other health care facility and for which the environment of use has been expanded to include in-home use, adequate instructions for use in the home setting with appropriatelay terminology	**Yes**	**Yes**

5) For FDA-cleared devices, clear distinction delineating FDA-cleared indications from those that are not FDA-cleared. In addition, FDA recommends the labeling include a general statement about changes that have not been cleared by FDA. For exempt devices listed in Table 1, FDA recommends that the labeling include a statement about indications outside the limitations of exemption in 21 CFR 886.9 for that device type.	**Yes**	**Yes**
6) A prominent notice to both the patient and eye care provider that recommendations provided by the device are adjunctive (supporting) and should not be solely or primarily relied upon to prevent, diagnose, or treat ocular conditions	**Yes**	**Yes**

B. Modifications for Sterilizers, Disinfectant Devices, and Air Purifiers:

FDA has recommended standards (TABLE 3) and labeling modifications (Table 4) on sterilized or disinfected conditions to patients and healthcare providers for usage of sterilizers, disinfectant devices, and air purifiers during this public health emergency.

TABLE 3: Modifications/applied standards for Sterilizers, Disinfectant devices, and Air purifiers

Device Type	Product Code	Device Classification	FDA-Recommended standards for Sterilized or Disinfected Devices on Indication or functionality
I. Sterilizers			
Endodontic dry heat sterilizer	KOK	III	» **Steam Sterilizers** • ANSI/AAMI ST8:2013 Hospital Steam Sterilizers • ANSI/AAMI ST55:2016 Table-Top Steam Sterilizers • ANSI/AAMI ST79:2019 Comprehensive Guide to Steam Sterilization and Sterility Assurance in Health Care Facilities. » **Dry Heat Sterilizers** • AAMI ST50:2004 (R2018) Dry Heat (Heated Air) Sterilizers • ANSI/AAMI ST40:2004m (R2018) Table-Top Dry Heat (Heated Air) Sterilization and Sterility Assurance in Health Care Facilities » **Ethylene Oxide Sterilizers** • ANSI/AAMI ST24:1999 (R2018) Automatic, General Purpose Ethylene Oxide Sterilizers and Ethylene Oxide Sterilant Sources Intended for Use in Health Care Facilities, 3ed. • ANSI/AAMI ST41:2008 (R2018) Ethylene Oxide Sterilization in Health Care Facilities: Safety and Effectiveness » **Other Sterilizers** • ANSI/AAMI/ISO 14937 Sterilization of Health Care Products — General Requirements for Characterization of a Sterilizing Agent and the Development, Validation and Routine Control of a Sterilization Process for Medical Devices » **Chemical Indicators** • ANSI/AAMI/ISO 11140 – 1 Sterilization of Health Care Products—Chemical Indicators—Part 1: General Requirements » **Sterile Packaging** • ANSI/AAMI/ISO 11607-1 Packaging for Terminally Sterilized Medical Devices – Part 1: Requirements for Materials, Sterile Barrier Systems and Packaging Systems • ANSI/AAMI/ISO 11607-2 Packaging for Terminally Sterilized Medical Devices » **Rigid Sterilization Containers** • ANSI/AAMI/ISO ST77:2013 Containment Devices for Reusable Medical Device Sterilization » **Biological Indicators** • ANSI/AAMI/ISO 11138 Sterilization of Health Care Products—Biological Indicators Series • ANSI/AAMI/ISO 14161 Sterilization of Health Care Products — Biological Indicators — Guidance for the Selection, Use and Interpretation of Results
Glass bead sterilizer	ECC	III	
Ethylene-oxide (EO) gas aerator cabinet	FLI	II	
Chemical Sterilizer	MLR	II	
EO gas sterilizer	PJJ	II	
Dry heat sterilizer	FLF	II	
Steam sterilizer	FLE	II	
Sterilizer automated loading system	PEC	II	

ii. Disinfectant Devices			
1. Chemical/Physical Disinfectant Devices			
Cleaning accessories for endoscope	FEB	II	» **Steam Sterilizers** » **AAMI ST58:2013 (R2018) Chemical Sterilization and High-Level Disinfection in Health Care Facilities** » **Association of Official Analytical Chemists (AOAC) 6.3.05:2013 Official Method 966.04 Sporicidal Activity of Disinfectants** » **AOAC 6.3.06:2012 Official Method 965.12 Tuberculocidal Activity of Disinfectants** » **AOAC 6.3.02:2006 Official Method 955.17 Fungicidal activity of Disinfectants Using Trichophyton Mentagrophytes** » **AOAC 6.2.01:2013 Official Method 955.14, Testing Disinfectants Against Salmonella Choleraesuis, Use-Dilution Method** » **AOAC 6.2.04:2013 Official Method 955.15, Testing Disinfectants Against Staphylococcus Aureus, Use-Dilution Method** » **AOAC 6.2.06:2013 Official Method 964.02, Testing Disinfectants Against Pseudomonas Aeruginosa, Use-Dilution Method**
Medical devices sterilant	MED	II	
Medical devices disinfectors	MEC	II (exempt from premarket review unless indicated for high level disinfection or for use on endoscopes and accessories)	
Medical devices cleaners	MDZ	II	
High level disinfection reprocessing instrument for ultrasonic transducers, mist	OUJ	II	
High level disinfection reprocessing instrument for ultrasonic transducers, liquid	PSW	II	
2. Ultraviolet (UV) Disinfecting Devices			
UV radiation chamber disinfection devices	OSZ	II	
III. Air Purifiers			For the purposes of this guidance, FDA recommends that manufacturers of air purifiers evaluate or perform the following:
Medical recirculation air cleaner	FRF	II	1. Demonstration of a 4 log reduction (through a combination of capture or destruction) of claimed particulates. 2. If intended for use against bacteria, effectiveness against representative gram positive and gram negative species. 3. If intended for use related to SARS-CoV-2, effectiveness against a representative virus 4. If the device generates ozone, the maximum acceptable level of ozone per 21 CFR 801.415. If intended for use in areas that have a sterile field or controlled air flow, a risk assessment to address turbulent air flow and/or potential site contamination.
Medical UV air purifier	FRA	II	

Table 4: Labeling Modifications for Sterilizers, Disinfectant Devices, and Air Purifiers:

FDA RECOMMENDED LABELING MODIFICATIONS	LABELING IMPACT (Yes/No)	
	IFU	Artwork
1. A clear description of the available data on the device's new indications or functions related to SARS-CoV-2 or co-existing conditions, such as: a) Device performance; and b) Potential risks (e.g., risk of UV exposure)	**Yes**	**Yes** (indication statement)
2. A clear distinction delineating FDA-cleared or FDA-approved indications from those that are not FDA-cleared or FDA-approved. In addition, FDA recommends the labeling include a general statement about changes that have not been cleared by FDA.	**Yes**	**Yes**

3. For all disinfectant devices, a clear statement of the level of disinfection.	**Yes**	**Yes**
4. For UV disinfecting devices:	**Yes**	**Yes**
a) A caution that UV disinfection will reduce the number of pathogens on the device, but it will not eliminate them completely.	**Yes**	**No**
b) A statement that the device is an adjunct to currently existing reprocessing practices and not a replacement or modification to such practices.	**Yes**	**No**
c) A statement regarding the time, distance, and maximum area over which the device has been evaluated for effectiveness.	**Yes**	**No**
d) An appropriate UV hazard warning label.	**Yes**	**No**
e) Identification of the expected UV lamp operational life and instructions for procedures on replacement of the UV lamp when needed.	**Yes**	**No**
f) Procedures to follow if the UV lamp malfunctions or fails.	**Yes**	**No**
g) Description of the preparation of equipment or the room for disinfection	**Yes**	**No**
h) A statement that the equipment intended to be disinfected is UV compatible.	**Yes**	**No**
i) Identification of the UV dose.	**Yes**	**No**

▶ Modifications for Other category of devices that are not having significant impact

The below are not having significant impact for emerging regulations (general use of masks and other PPE items)

DEVICE TYPE/CATEGORY	DESCRIPTION	PROPOSED LABELING RECOMMENDATIONS/ CHANGES	IMPACT	
			IFU	LABEL
3. Enforcement Policy for Infusion Pumps and Accessories (Emergency Use Authorization)				
• Labeling of Modified Devices	This enforcement policy described and applies to the following infusion pumps & their accessories used to treat patients who require continuous infusion therapy during the COVID-19 emergency. E.g., Class II devices of; » Infusion Pumps, » Patient- controlled analgesia (PCA) Infusion Pump, » Infusion Pump Accessories, » Infusion Safety Management Software, » Other Class II infusion sets/ devices.	» Clear description of new indications/functions/information on the performance & potential risks/Clear distinction on FDA cleared & not cleared indications. » Adequate instructions on indicated environment(s) changes (label should highlight the changes from previous version. Ex. Design changes may impact on MR safe/unsafe/conditional.	**Yes**	**Yes**
		Products currently not marketed in the US, FDA recommends providing the following information. » Contact information, name and place of business, email address, contact information for U.S agent, including proprietary/ brand name, model number, and marketing authorization in the country/region. » A copy of the product labeling; containing information. • Device's current marketing authorization in another regulatory jurisdiction. Ex. EU CE Mark, TGA, Health Canada, Japan along with copy of marketing authorization letter/certificate/relevant corresponding information. » Device is designed with a power supply that is compatible with United States stands & necessary information for healthcare professionals, other individuals, and emergency contact details.	**Yes**	**Yes**

4. Enforcement Policy for Face Masks and Respirators				
• Face Masks Intended for a Medical Purpose that are NOT Intended to Provide Liquid Barrier Protection	Face masks & respirators meet device definition (for medical purpose use by health care professionals) under section 201(h) of the Federal regulations. No federal regulations applied for non-medical purpose items.	Product labeling includes accurate description and list of body contacting materials (which do not include any drugs or biologics & reduced risk of use) & UDI requirements.	**Yes**	**Yes**
• Face Shields Intended for a Medical Purpose	Devices are complying with standards of Occupational Safety and Health Administration (OSHA) and also follow QSR & UDI requirements of FDA.	Product labeling includes accurate description and list of body contacting materials (items don't causes flammability, or product meets Class I or Class II flammability requirements) & undue risk statement to public health emergency.	**Yes**	**Yes**
5. FDA's Intended Approach for EUAs for Face Masks and Respirators (Emergency Use Authorization)				
• EUAs for Face Masks Intended for a Medical Purpose, • Surgical Face Masks and • N95 Respirators	These EUAs are intended to help increase availability of these devices to front-line personnel during the public health emergency used by healthcare professionals	» Face mask & respirator currently not marketed in the US, FDA recommends below information: • Contact information, name and place of business, email address, contact information for U.S. agent, including proprietary/ brand name, model number, and marketing authorization in the country/region. » A copy of the product labeling including device marketing authorization status in another regulatory jurisdiction (including certification number, if available).		
EMA recommendation of use of OFF-LABEL drugs				
Off-label medicines of anesthetics, antibiotics, muscle relaxants, and medicines used in the COVID therapy.		Due to shortage of certain **medicines in member states being used to treat COVID-19 patients,** EMA given relaxation to market those products with closely monitoring. **"Off-label" means the medication is being used in a manner not specified in the FDA's approved packaging label, or insert.**	**NA**	**NA**

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