Effective Communication by Saudi Food and Drug Authority with Healthcare Professionals and Public during (COVID-19)

Table of Contents:

Health Care Professionals:

Safety Communication is a communication provides an important information and recommendations about safety of medical devices, issued by Medical Devices Sector within SFDA and addressed to public, healthcare providers and/or health professionals, such as:

1. Best Practices When Using Masks and Gowns during the COVID-19 Outbreak:

According to the current Corona (COVID-19) outbreak, which requires intensive coordination and management from the concerned parties (healthcare providers, users, and medical suppliers) to maintain a proper utilization of high-consumed medical products during the corona outbreak.

From that perspective, medical Gowns and Masks are personal protective products designed to protect the wearer from injury or the spread of infection or illness. Hereafter are some recommendations to ensure best practices when using masks and gowns during the (COVID-19) outbreak:

1. Use only SFDA-authorized surgical masks and gowns.
2. Use surgical masks and/or gowns that meet national and international standards / recommendation for fluid resistance and bacterial filtration efficiency
3. Implement the use of reusable gowns instead of disposable single-use gowns to reduce consumption of this product
4. Use the Gowns sterile non-surgical isolation gowns) for surgery/invasive procedures with a low risk of contamination.
5. Use sterile surgical isolation gowns for surgery/invasive procedures with a medium to high risk of contamination
6. Use non-surgical isolation gowns for routine care of patients that are suspected to be infected with COVID-19.
7. Perform hand hygiene between treating patients with the same infectious disease diagnosis or exposure who are maintained in a confined area. If the mask, gloves, or gowns become contaminated, replace them.

8. Be aware that surgical masks do not provide a reliable level of protection from inhaling infectious aerosols.
9. Re-use surgical masks during care for multiple patients, only when this does not create a risk to the healthcare provider or patient. If the mask becomes contaminated, replace it.
10. When there is a severe shortage, Extend the use of single use gowns for healthcare providers. If the gown becomes contaminated, replace it.

2. Teleworking in Health Sector during COVID-19 Emergency:

Teleworking in health sector during COVID-19 emergency Regarding to health care services and medical applications provided via teleworking strategy, include exchange and transfer health data, which may increase during a wide-scale public emergency such as that caused by the (COVID-19) virus. Through exchange information between SFDA & international health organizations in the field of medical device safety.

SFDA recommend healthcare facilities to adopt the recommendations in the below link as a reference to consider important factors in teleworking strategy that minimize downtime and latency while supporting patient care, operational and IT security, and supply chain resilience, during a wide-scale public emergency such as that caused by the (COVID-19) virus, to ensure the efficiency and continuity of medical services provided to the community. (https://healthsectorcouncil.org/covid-checklist/)

3. Ventilator Supply Mitigation Strategies during the Outbreak of (COVID-19):

Patients suffering from respiratory complications as a result of COVID-19 may require ventilatory support. These patients may require assistance via mechanical ventilation through the controlled delivery of gases, including the delivery of oxygen during inhalation and/or the removal carbon dioxide during exhalation.

The need for ventilators, ventilator accessories, and other respiratory devices may outpace the supply available to health care facilities during the outbreak of (COVID-19), wherever possible:

- If the number of ventilators in your facility is running low, consider alternative devices capable of delivering breaths or pressure support to satisfy medically necessary treatment practices for patients requiring such ventilatory support.
- Take appropriate precautions with environmental control (for example, negative pressure) or additional filtration where feasible
- Conserve the use of accessories used with ventilators

4. Issues to be Encountered through Reusable and Single-use of Medical Devices:

a) **Reusable Medical Devices:**

- Maintain a clear policy and procedures for reprocessing reusable medical devices, highlighting the importance to follow the manufacturer recommendations when reprocessing these devices, with respect to the suitability process, conditions, and frequencies, considering the device expected lifespan.
- Supply central sterile services departments (CSSD) with resources and time that enable a proper reprocessing of reusable medical devices.
- Investigate reusable medical devices, before reprocessing, against any damages, to prevent the potential growth of pathogens in cracks that cannot be reached with sterilization methods.
- Provide healthcare personnel with refresher training to reinforce the site procedures and manufacturers guidelines to minimize COVID-19 transmission.

b) **Single-use medical devices:**

- Maintain a clear policy and procedures for single-use medical devices, highlighting the importance of preventing reusing single use devices, under all conditions.
- Provide healthcare personnel with a clear distinction between single use medical device and single patient use medical devices, where the latter is to be reprocessed in accordance to the manufacturer recommendations.

- Provide healthcare personnel with refresher training on using protective personal equipment (PPE) appropriately, which involves selecting the proper PPE and being trained in how to put on, remove and dispose of it.
- Assess better optimization of PPE, as revealed by the WHO published guideline, entitled "Rational use of personal protective equipment for coronavirus disease 2019 (COVID-19)", which define the rational and appropriate use of PPE in healthcare settings, beside the effective management of supply chains.
- Conduct online webinar titled (New regulatory changes implemented by SFDA-Medical Devices sector as result of the COVID-19 outbreak including the emergency authorization for Personal Protective Equipment (PPE) and overview of the available medical diagnostic options of the disease).

5. Recommendations of Non-contact Infrared Thermometers during COVID-19 Pandemic:

During the current crisis (Corona pandemic) and within the diagnostic medical procedures, , **non-contact infrared thermometers** are used in a large extent in medical screening procedures within health care facilities and in other locations. Therefore, we would like to share some tips and recommendations regarding the accuracy of this type of device:

- Non-contact thermometers are widely used in medical scanning as a preliminary examination of body temperature. Moreover, it is always recommended to observe other vital indicators during the screening to ensure accuracy and to avoid any unreliable results.
- One of the advantages of this type of device is that it shortens the time for examination, which gives an opportunity to measure the largest possible number of patients; in addition to that, it is the least methods of transferring the infection due to the absence of any direct contact.
- There are several factors that affect the accuracy of non-contact infrared thermometers such as (the distance between the device and the patient, the room temperature, the humidity, the position and angle of the device with respect to the patient, hand stability during the measurement).

- To ensure effective use, users must be well trained in the use of the device, and always follow the instructions of use and precautions that provided with the device.
- Ensure that the used device is authorized by SFDA.
- Paying attention to the technical features of the device, which have a significant impact on the accuracy of its results such as (sensor quality, insulation, and other variables) . When measuring results are suspected, it is recommended to use other alternative devices and methods that is available in health care facilities.

6. Warning of IVDs Unauthorized Test Kits for Diagnose (COVID-19):

Saudi Food and Drug Authority (SFDA) warns all health care providers from purchasing unauthorized medical devices by SFDA claiming to be home self-tests for COVID-19, either online or through unauthorized distributors.

All COVID-19 tests products that have been authorized by SFDA are designed to be used under the direction of a health professional or through a medical laboratory.

Advices on IVDs kits for COVID-19:

1. Purchase products from a reliable source such as the legal manufacturer, or authorized distributor by SFDA.
2. Check the device's marketing authorization that is issued by SFDA.
3. Ask for copy of the SFDA license certificate of the distribution company in the Saudi Market.
4. Avoid purchasing Medical Devices and from unknown source or online channels.
5. Read the instructions for use carefully to understand the intended use of the product.
6. Monitor the quality of the medical devices to ensure safety and efficacy.
7. Report any problems and/or incidents to both SFDA and the manufacturer or authorized representative in Saudi.

7. (COVID-19) Requests for information regarding the off-label use of GE Healthcare anesthesia devices for ICU ventilation:

Responding to numerous requests for information regarding whether existing anesthesia devices could temporarily be used to supplement ventilator capacity. However, the use of these devices as ICU ventilators has not been verified or validated. And regulatory authorities (e.g., FDA, Health Canada, TGA, EU competent authorities) have not cleared or approved these anesthesia devices as safe and effective for use as ICU ventilators.
GE states that the use of an anesthesia machine as an ICU ventilator is considered off-label use (not formally cleared or approved by any regulators), and GE does not promote or recommend the use of anesthesia devices as ICU ventilators in any normal circumstances. GE states that it understands the extreme circumstances driving this request and the need to weigh the relative risks and benefits to support patients during the pandemic. While an anesthesia device has a ventilator within it, the overall device is not the same as an ICU ventilator, and it is critical to understand the differences to minimize risks to patients.

IMPORTANT SAFETY INFORMATION:

- Use of the device in an off-label manner is the sole responsibility of the device owner and is done at his/her own (liability) risk.
- GE Healthcare anesthesia machines are life supporting/life sustaining devices. There is a risk of serious injury or death if the devices are not used by professionally trained clinicians, continuously monitored, and used in accordance with the instructions for use.
- For more information, Please check the letter for GE's full analysis (click here).

8. Usage of Draeger Anesthesia Devices for Long-term Ventilation:

The pandemic has created a high demand for mechanical ventilation that may exceed the number of available ICU ventilators in hospitals treating patients with the disease. Draeger states that it has received requests for information regarding use of Draeger anesthesia devices for long-term ventilation as an alternative ventilator when existing devices are fully utilized and there is no other ventilator option.

Against these special circumstances, Draeger believes it is their responsibility to provide some insights both (1) on the legal and regulatory perspective as well as (2) on some known limitations of Draeger anesthesia devices for long-term ventilation.

Any use of the device outside of the intended use specified in the instructions for use (e.g. long-term ventilation) constitutes off-label use.

If a device is used off-label, the user recognizes that it is not the intended use of the device and does so in his own responsibility and at his own (liability) risk. However, in a situation in which a patient requires long-term mechanical ventilation but cannot be ventilated due to a lack of intensive care ventilators, the benefit of being able to ventilate such a patient with a Dräger anesthesia devices has to be weighed against the risk of the off-label usage of a Dräger anesthesia device. This risk benefit assessment and the resulting decision has to be made by the responsible health care professional based on the circumstances of the particular case.

9. Ventilating ICU Patients Using Flow-i, Flow-c and Flow-e Anesthesia Machines:

In view of the situation with the coronavirus, Novel Coronavirus (2019-nCoV), and the possibility to repurpose Flow-i, Flow-c and Flow-e anesthesia machines for use in the ICU as a ventilator only, the manufacturer would like to draw your attention to important information in the following three sections:

1. General information and warnings.
2. Preparations for use.
3. Key system differences (between Flow anesthesia machines and ICU ventilators):
    - Rebreathing
    - Manual and automatic ventilation (MAN/AUTO) and APL
    - O2 flush
    - AGSS (Anesthesia Gas Scavenging System)
    - Emergency ventilation
    - Alarms, monitoring, and System checkout.

IMPORTANT SAFETY INFORMATION:

- Use of the device in an off-label manner is the sole responsibility of the device owner and is done at his/her own (liability) risk.
- Anesthesia machines are life supporting/life sustaining devices. There is a risk of serious injury or death if the devices are not used by properly trained clinicians, continuously monitored, and used in accordance with the instructions for use.
- Check the letter from the manufacturer for more information (here).

Manufacturers and Companies:

- Answering all received inquiries from local / international manufacturers and authorized representatives relating to surgical masks, ventilators, Infrared thermometers and IVDD kits for COVID-19
- Communicate with Ventilators' manufacturers and their authorized representatives to ensure safety, efficacy, and performance of the devices, perform maintenance if needed.

Internal Communication-SFDA:

Conduct online webinar addressing the SFDA-MDS efforts to manage the outbreak of COVID-19

External- Media:

Publish awareness material about the Infrared thermography imaging systems.