

Texas Health Resources

COVID-19 OPERATIONS GUIDANCE MANUAL V1.0 APRIL 16, 2020

For question and comments, please email coviDOps@TexasHealth.org

This document is intended to provide general operational guidance in the care of patients with known or suspected COVID-19 infection. Playbook content will be evaluated and updated continuously as new information becomes available and our understanding of this disease advances.



Table of Contents

THR Inpatient Surge: Unit/Room Preparation Checklist	2
Hospice Locations Identified by Entity	5
Hospice Beds Implementation Checklists	6
Hospice Beds Implementation Checklist (4 Bed Plan)	6
Hospice Beds Implementation Checklist (6 Bed Plan)	7
Hospice Beds Implementation Checklist (8 Bed Plan)	8
Hospice Beds Implementation Checklist (12 Bed Plan)	9
Incident Command Roles	10
COVID Email Address	11
Bed Activation Workflow	12
ED Surge Triage Plan Process Map	13
Ventilator Request Process:	14
Request Process for Transporting Medical Devices:	14
Anesthesia Machine to Ventilator Workflow	15
Facility Units Capable to Handle Anesthesia Power Requirements	16
Tips for Managing Anesthesia Devices	17
Anesthesia Machine to Ventilator SOPs	18
RESOURCE A: Draeger Customer Letter	20
RESOURCE B: Draeger Cleaning Agent Guide	31
RESOURCE C: Draeger SARS-CoV-2 and handling of Dräger Anesthesia Workstations	33
Anesthesia Machine to Ventilator SOPs	37
GE's APPENDIX A: COVID-19 - Requests for information regarding the off-label use of GE Healthcare and for ICU ventilation	
GE's APPENDIX 1: Intended Use/Indications for Use	50
GE's APPENDIX B: Setup and Monitoring Instructions – Anesthesia Machine as an ICU Ventilator	53
COVID-19 Showers & Changing Area Tip Sheet	
Shower & Changing Area Announcement Flyer	57
COVID-19 Greeter Guidelines for Patients and Visitors	58
Hotel rooms for caregivers	61
Clinical Guideline for Environmental Cleaning	72
End of Life In-person Visitation Guidelines	73
Scripting for In-Person End of Life Visitation	75



THR Inpatient Surge: Unit/Room Preparation Checklist

PATIENT UNIT / ROOM	UNIT PURPOSE	DATE

1	ENVIRONMENT OF CARE (EOC) AUDIT	RESPONSIBLE	IN PROGRESS	COMPLETE
EOC	Infection Prevention, Safety, Engineering, EVS, Employee Health, Quality/Risk, and department managers to assess readiness of the repurposed room(s)			
2	ITS	RESPONSIBLE	IN PROGRESS	COMPLETE
Equipment	Documentation stations			
Equipment	Printer & Paper Supply			
Equipment	TV or iPad			
ITS	Vocera Readiness (charging stations and badges, unit/rooms built in Vocera)			
ITS	Ensure nursing station phones are working & update directories			
ITS	Scanners for med/blood administration			
ITs	Nurse Call or other communication system (i.e. bell if necessary)			
ITS	Bed build in CC1 completed? - Must validate prior to placing patients			
Communication	Alert PBX of repurposed space			
3	ANCILLARY	RESPONSIBLE	IN PROGRESS	COMPLETE
Finance / HR / Supply Chain	Notify Finance, HR, & Supply Chain, of what beds / units are opening and ensure the following: ERP & Systems are Updated: Revenue cycle – charges and stat capture, CC1; Timekeeping/Payroll; HR; Oracle/Peoplesoft			
Pt. Logistics	Alert Patient Logistics Center of what beds / units are being activated			
Transport	Alert Transport Leadership of repurposed space for patient transport			
Respiratory	O2 Flow Meters & Suction (regulators, tubing suction tips, suction liners)			
Respiratory	O2 canisters available, labeled and secured			
Lab	Alert Lab of repurposed space for potential patient draws and point of care testing			
Pharmacy	Alert Pharmacy of repurposed space			
Pharmacy	Ensure PYXIS Active & Full			
Pharmacy	Coordinate Medication Refrigerators or alternative solution			
Pharmacy	Med. room supplies: Pill crushers/cutters, pill cups, patient bins, curos caps, TPN filters, blood admin sets, alcohol swabs			
Pharmacy	Ensure badge access to med room is programmed or door is locked			
Radiology	Alert Radiology of repurposed space			
Infection	Alert IP of repurposed space and ensure Isolation protocols are in			
Prevention	place			
4	NURSING / MATERIELS MANAGEMENT	RESPONSIBLE	IN PROGRESS	COMPLETE
PPE	Eye protection (visor & goggles)			
PPE	Face shield (provides eye, nose and mouth protection)			
PPE	Gloves			



4	NURSING / MATERIELS MANAGEMENT	RESPONSIBLE	IN PROGRESS	COMPLETE
PPE	Sterile Gloves			
PPE	Respirators (N95)			
PPE	Medical (surgical or procedure) masks			
PPE	Isolation Gowns			
Consumables	Disposable Stethoscopes			
Consumables	Mesh			
Consumables	Dressing/Bandages (2x2; 4x4; Non-Stick; and others)			
Consumables	Таре			
Consumables	Adhesive Remover			
Consumables	Wound Care Supplies (Silvadeen, Cleaning products, packing, dressing, long Q-Tips)			
Consumables	Specimen Cups			
Consumables	IV Tubing Sets (Primary, Secondary, Blood, Extension Sets, 2 Port)			
Consumables	IV Start Up Kits			
Consumables	Central Line Dressing Changes			
Consumables	Foley Catheter Kits			
Consumables	Condom Catheters			
Consumables	Feeding Tube Supplies			
Consumables	Needles (Different Sizes)			
Consumables	Syringes (1cc, 5cc, 10cc)			
Consumables	EKG Leads			
Consumables	TED hose			
Consumables	NG insertion kits			
Consumables	Blue Chux and/or Covidien Thick Bed Pad			
Consumables	Diapers			
Consumables	Swabs (Suction and Non-Suction			
Consumables	Patient Personal Items (Toothpaste, Toothbrush, Shampoo, Body Foam; warm wipes; Belongings Bag)			
Consumables	Brown Paper Bags			
Consumables	THR Pt Water jug			
Consumables	Pitchers			
Consumables	Urinals			
Consumables	Bed Pan(s)			
Consumables	Ice Packs			
Food Orders	Identify process for gathering patient menu orders (needs to be considered even if rm svc is avail in case no phones on unit)			
Food Orders	Identify process for gathering patient menu orders (needs to be considered even if rm svc is avail in case no phones on unit)			
Communication	Notify Hospitalists and Specialists if needed for staffing			
5	SUPPORT SERVICES (EVS/FNS/Facilities Management/Mission Control/Materials Mgmt)	RESPONSIBLE	IN PROGRESS	COMPLETE
Equipment	Ventilator			
Equipment	Monitors			
Equipment	Crash Cart			
Equipment	Alaris Pump(s)			
Equipment	Dynamap (vital signs)			



5	SUPPORT SERVICES (EVS/FNS/Facilities Management/Mission Control/Materials Mgmt)	RESPONSIBLE	IN PROGRESS	COMPLETE
Equipment	Bed s			
Equipment	Suction machine			
Equipment	EKG			
Equipment	Ultrasound (for IV's)			
Equipment	Ultrasound (Bladder retention)			
Equipment	Tube Feeding Pumps			
Equipment	Wipe Warmer			
Equipment	SCDs			
Equipment	IV Poles			
Equipment	Thermometers			
Equipment	Walker(s)			
Equipment	Ice Machine			
Floor Stock	Juices, Crackers, Coffee, Water, Jell-O, etc.			
Floor Stock	Plastic Ware (Sporks, Straws, Disposable Cups, etc.)			
Facilities	Fire extinguishers are charged, checked and up to date			
Facilities	AED Defibrillator			
Facilities	HVAC: Ensure system is functional & clean			
Facilities	Clocks are in place and are set			
Facilities	Water faucets and lights have been tested and are functional			
Facilities	Signage (if necessary), Room Numbers, & Wayfinding			
Facilities	"Call, Don't Fall" Ceiling Tiles (if available)			
Furniture	Portable Commode			
Furniture	Recliner, Chair, Couch or Cot, Overbed table, Nightstand, Phone			
Security	Alert Security of repurposed space and ensure all security cameras are active			
FNS / CBORD IT	Set up Room in CBORD			
EVS	Alcohol-based hand foam			
EVS	Purple-top Sani-Cloth Wipes			
EVS	Soap			
EVS	Paper Towels			
EVS	Toilet Paper & Kleenex			
EVS	Sharps containers			
EVS	Trash Cans			
EVS	Plastic bags			
EVS	Linen (bed linen, blankets, sheets, pillows & pillowcases, bath towels, wash clothes)			
EVS	Linen bags			
EVS	Biomedical Waste bag and Can			
Communication	Alert EVS Leaders of repurposed space to be added to the cleaning sched/staffing			
Communication	Alert FNS Leaders of repurposed space for food delivery			
Communication	Alert Clinical Nutrition Manager of repurposed space for potential nutritional consults			



Hospice Locations Identified by Entity

Entity	Number of Beds	Location within the Facility
THA	6 beds	Behavioral Health
THAL	4-6 beds	Outpatient Rehab
THAM	6 beds	Hospice Unit
THAZ	7 beds	Endoscopy Unit
THC		
THD	15 beds	Season's Hospice Unit
THDN	2 beds (non-Covid)	no defined location at this time but plans have been created
THF		
THFM		
THFW	16 beds	Harris 2
THHEB	19 beds	Oncology
THHV		
THK	2-3 beds	OB
THP		No space in hospital. Looking at THCDS.
THRW	5 beds	Special procedures prep and recovery
THS	5 beds	Med / Surg
THSH		
THSL		
THSW	8-11 beds	PACU



Hospice Beds Implementation Checklists

Hospice Beds Implementation Checklist (4 Bed Plan)

Staffing Durable Medical Equipment Medications: IV Push 3 regular Hospital beds and 1 bariatric hospital beds with 2 Providers per shift: 1 RN, 1 Linens and pillows (hospital laundry service and food service) LVN OR 2 RN Morphine 3.5 gm per week Dilaudid 125 mg per week IV Hep Lock Housekeeping staff - frequent Oxygen connections for nasal disinfecting protocol cannula or mask Ativan 335 mg per week PPE: Gloves, gowns, N95 masks, goggle/face shields, hair nets, shoe covers if required, surgical Haldol - 200 mg per week masks Hospital provided Attending Physician or physician group to make daily rounds OR hospital grants permission to hospice PCA Pumps if med shortage, IV physician who can act in push with syringes with lock; attending physician role Sharps containers in each room Versed - 335 mg per week **Foley Equipment** Robinul - 34 mg per week chucks, wipes, quilted Hospice to provide Social Work positioning pads for beds (if **Dulcolax Suppositories - 8 per** and Spiritual Care Coordinator available) week Barrier Cream (Lantiseptic, Zinc oxide, Medseptic, Desitin) IV Tylenol - 28 gm per week Hospice to provide Hospice Clinical Liaison for hospice oversight **Personal Care Supplies** IV Benadryl - 2.5 gm per week



Hospice Beds Implementation Checklist (6 Bed Plan)

Staffing Durable Medical Equipment Medications: IV Push 4 regular Hospital beds and 2 bariatric hospital beds with 2 Providers per shift: 1 RN, 1 Linens and pillows (hospital LVN OR 2 RN laundry service and food service) Morphine 5 gm per week IV Hep Lock Dilaudid 125 mg per week Housekeeping staff - frequent Oxygen connections for nasal disinfecting protocol cannula or mask Ativan 500 mg per week PPE: Gloves, gowns, N95 masks, goggle/face shields, hair nets, shoe covers if required, surgical masks Haldol - 300 mg per week Hospital provided Attending Physician or physician group to make daily rounds OR hospital grants permission to hospice PCA Pumps if med shortage, IV physician who can act in push with syringes with lock; attending physician role Sharps containers in each room Versed - 500 mg per week **Foley Equipment** Robinul - 50 mg per week chucks, wipes, quilted Hospice to provide Social Work positioning pads for beds (if Dulcolax Suppositories - 13 per and Spiritual Care Coordinator available) week Barrier Cream (Lantiseptic, Zinc oxide, Medseptic, Desitin) IV Tylenol - 42 gm per week Hospice to provide Hospice Clinical Liaison for hospice oversight **Personal Care Supplies** IV Benadryl - 4 gm per week



Hospice Beds Implementation Checklist (8 Bed Plan)

Staffing Durable Medical Equipment Medications: IV Push 6 regular Hospital beds and 2 bariatric hospital beds with 3 Providers per shift: 1 RN, 1 Linens and pillows (hospital LVN, 1 Tech OR 2 RN, 1 Tech laundry service and food service) Morphine 7 gm per week IV Hep Lock Dilaudid 125 mg per week Housekeeping staff - frequent Oxygen connections for nasal disinfecting protocol cannula or mask Ativan 750 mg per week PPE: Gloves, gowns, N95 masks, goggle/face shields, hair nets, shoe covers if required, surgical masks Haldol - 450 mg per week Hospital provided Attending Physician or physician group to make daily rounds OR hospital grants permission to hospice PCA Pumps if med shortage, IV physician who can act in push with syringes with lock; attending physician role Sharps containers in each room Versed - 700 mg per week **Foley Equipment** Robinul - 67 mg per week chucks, wipes, quilted positioning pads for beds (if Hospice to provide Social Work Dulcolax Suppositories - 17 per and Spiritual Care Coordinator available) week Barrier Cream (Lantiseptic, Zinc oxide, Medseptic, Desitin) IV Tylenol - 56 gm per week Hospice to provide Hospice Clinical Liaison for hospice oversight **Personal Care Supplies** IV Benadryl - 6 gm per week



Hospice Beds Implementation Checklist (12 Bed Plan)

Staffing Durable Medical Equipment Medications: IV Push 4-5 Providers per shift: 2 RN, 1 10 regular Hospital beds and 2 LVN, 2 Tech OR 2 RN, 3 Tech OR bariatric hospital beds with 3 RN, 1 Tech OR 3 RN, 1 LVN, 1 Linens and pillows (hospital laundry service and food service) Morphine 10 gm per week Tech Dilaudid 125 mg per week IV Hep Lock Housekeeping staff - frequent Oxygen connections for nasal disinfecting protocol cannula or mask Ativan 1 gm per week PPE: Gloves, gowns, N95 masks, goggle/face shields, hair nets, shoe covers if required, surgical masks Haldol - 600 mg per week Hospital provided Attending Physician or physician group to make daily rounds OR hospital grants permission to hospice PCA Pumps if med shortage, IV physician who can act in push with syringes with lock; Sharps containers in each room attending physician role Versed - 1 gm per week **Foley Equipment** Robinul - 100 mg per week chucks, wipes, quilted Hospice to provide Social Work positioning pads for beds (if Dulcolax Suppositories - 25 per and Spiritual Care Coordinator available) week Barrier Cream (Lantiseptic, Zinc oxide, Medseptic, Desitin) IV Tylenol - 84 gm per week Hospice to provide Hospice Clinical Liaison for hospice **Personal Care Supplies** oversight IV Benadryl - 8 gm per week



Incident Command Roles

INCIDENT COMMAND ROLE	ROLE DETAIL	NAME OF ASSIGNEE
Senior Official (President)	Incident Command Lead	
Operations Section Chief (CNO)	Nursing, PAS, Care Transitions, Pastoral Care	
Admin/Planning Section Chief (CMO)	Finance, ITS, FNS, Business Continuity	
Logistics Officer (PSO or Support Services Officer)	Materials Mgmt., Mission Control, Engineers, Employee Health, HR, Radio Communications, EVS	
Security (Security Officer or Director)	Access Control, Crowd Control, Traffic Control	
Public Affairs Officer		
Liaison Officer		
Cyber Officer		
COVID-19 Dashboard Owner		

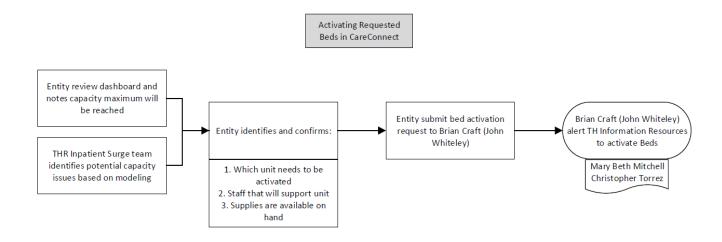


COVID Email Address

EMAIL BOX NAME	PRIMARY BOX OWNER	EMAIL ADDRESS
System Incident	Winjie Miao, SEVP Chief	COVIDCommand@tovashoalth.org
Command	Experience Officer	COVIDCommand@texashealth.org
Liaison Officer	David Tesmer, Chief	
Command	Community & Public Policy	COVIDLiaison@texashealth.org
Command	Officer	
Public Information	Mark Riordan, VP Stakeholder	COVIDPIO@texashealth.org
Command	Engagement	COVIDETO@texastleattil.org
Hospital Channel	Kirk King, COO Hospital	COVIDHOSP@texashealth.org
Operations	Channel	COVIDITOSP@texasileaitii.org
THPG Channel	Dr. Shawn Parsley, President &	COVIDTHPG@texashealth.org
Operations	COO, THPG	COVIDITIF G@ texasileaitii.org
Clinical Channel	Dr. Andy Masica, CMO Reliable	COVIDCLINICAL@texashealth.org
Operations	Health	COVIDCEINICAL@texasileaitii.org
Planning	John Mitchell, COO Amb/Post	COVIDBIanning@tovashoalth.org
Command	Acute/Channel Sup Services	COVIDPlanning@texashealth.org
Logistics (Supplies)	Shaun Clinton, SVP Supply	COVIDSupplies@toyachealth.org
Command	Chain Mgt	COVIDSupplies@texashealth.org
Finance Command	Rick McWhorter, EVP & Chief	COVIDE in an early as health arg
Finance Command	Financial Officer	COVIDFinance@texashealth.org
Human Resources	Carla Dawson, Chief People	COVIDHE@toxashoalth.org
Command	Officer	COVIDHR@texashealth.org
Logistics (ITS)	Joey Sudomir, SVP, Chief	COVIDITS@tovachoalth.org
Command	Information Officer	COVIDITS@texashealth.org

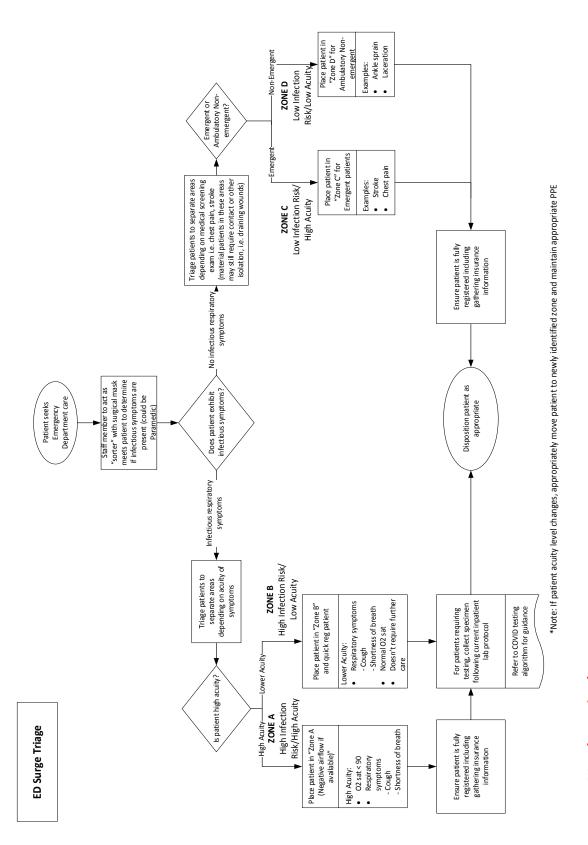


Bed Activation Workflow





ED Surge Triage Plan Process Map

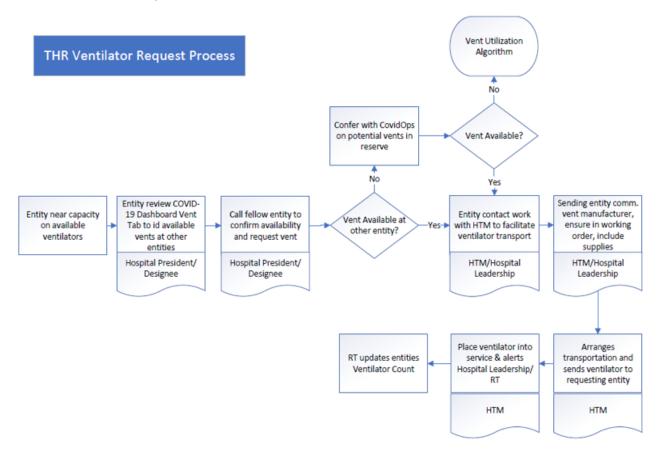


Updated 3.18.2020

May be revised to meet operational needs



Ventilator Request Process:



Request Process for Transporting Medical Devices:

To request transportation of THR assets, Biomed (HTM) On-Call Contacts:

Arlington/HEB/Southlake: (817)-239-7383

Alliance/Denton/Flower Mound: (940)-208-9347

Allen/Plano: (817)-239-6801

Azle/Fort Worth: (817)-247-4784

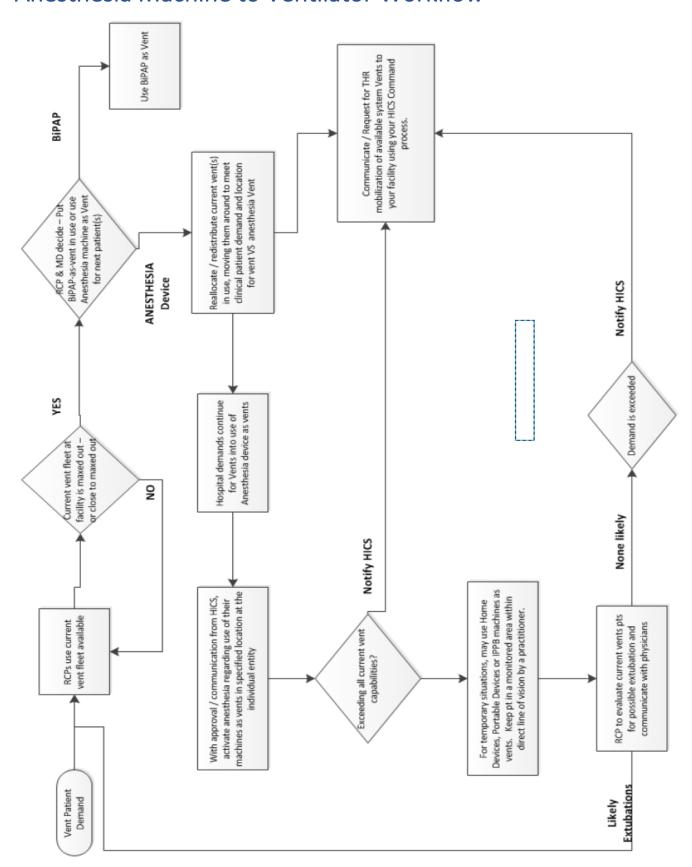
Cleburne/Southwest/Stephenville: (817)-822-5881

Dallas/Kaufman/Rockwall: (817)-239-6417

Please ensure as much advance notice as possible to expedite the request.



Anesthesia Machine to Ventilator Workflow





Facility Units Capable to Handle Anesthesia Power Requirements

Facility	ICU	PACU	M/S
Allen	Υ	Υ	N
Alliance	Υ	Υ	N
Arlington	Υ	Υ	N
Azle	Υ	Υ	N
Cleburne	Υ	Υ	N
Dallas	Υ	Υ	N
Denton	Υ	Υ	N
Fort Worth	Υ	Υ	N
HEB	Υ	Υ	N
Kaufman	Υ	Υ	N
Plano	Υ	Υ	N
Southwest	Υ	Υ	N
Stephenville	Υ	Υ	N



Tips for Managing Anesthesia Device

Tips for Managing Anesthesia Devices

Helpful tips for how to manage anesthesia devices have been created by entities across the system. Please reference the bullets below for additional information.

- **Air/Oxygen Mixing** A helpful tip for mixing the air and oxygen is to set the airflow to 10 L/min when operating an anesthesia device as a ventilator. From that point, the user can adjust the oxygen up or down on the device. This action will change the delivered FiO2.
- Operating Maintenance-Set running flows at 150% of minute ventilation will preserve the Soda-Lime, as well as keep the circuits dry.
- **Device Button Location** The anesthesia device buttons locations are different than a typical ventilator. The anesthesia provider can guide the RT team in locating the needed buttons on the machine.
- Managing Nitrous Gas Alarm- When placing an anesthesia device in ICU, the Nitrous gas source alert will sound and pop up on the screen to alert staff (due to the unavailability of gas in the ICU). Please note, the devices do not need Nitrous gas for ventilation. You can silence the audio alarm. The onscreen alert will remain lit.
- In Room Machine Accommodation- The anesthesia device has a large footprint. Consider removing additional furniture out of an ICU room before setting up the anesthesia device.
- **Re-check Reminder** Consider scheduling routine re-checks for the anesthesia devices every 72 hours to ensure all staff is present, as needed. Please note the machine will alarm if not checked.
- Managing EMR Documentation- If RT is managing the device, documentation will be consistent with the standard daily workflow. Some entities will use the anesthesia provider to manage the device. Their documentation will change from the normal daily workflow. Please review the Anesthesia Training Tip Sheets, located on the SharePoint site under "What's New".



Anesthesia Machine to Ventilator SOPs

Draeger Anesthesia Machine

12 amp pull

Procedure:

- Step 1: Reference the "COVID-19: Usage of Dräger anesthesia devices for long-term ventilation"
- Step 2: Remove all vaporizers and flush out any residual agents in the breathing system.
- Step 3: Disconnect any N20 gas tanks/lines from the system
- Step 4: Ensure the scavenging system is connected, if scavenging is unavailable disconnect the scavenging hose and scavenging bag
- Step 5: Perform the full start up procedure
- Step 6: Connect a 3L breathing bag for use
- Step 7: When starting a case ensure gases are flowing at least 150% of the minute volume of the patient is required
- Step 8: Have a trained clinician configure the device settings per the appropriate ventilation mode desired
- Step 9: Routinely check the CO2 absorber and replace as needed
- Step 10: Routinely check the breathing system and water trap for moisture and remove/clean as needed

Notes from Draeger:

Notice: Unit is not designed for long term standalone ventilation use so doing so is considered "off-label" use

IT IS HIGHLY RECOMMEND THAT THE ATTACHMENT "COVID-19: USAGE OF DRÄGER ANAESTHESIA DEVICES FOR LONG-TERM VENTILATION" BE READ BEFORE USAGE!

A MANUAL RESUSCITATOR MUST ALWAYS BE AVAILABLE AT THE DEVICE FOR EMERGENCY USE!

- ✓ **This is not designed like an ICU vent** medical personnel using the device must be well trained and familiar with the unique performance characteristics of the devices.
- ✓ Several modes may behave differently than in intensive care ventilators. (see pg. 11 for more details)
 - The user must understand the mode Man/Spon (Manual or Spontaneous Ventilation) which is a **unique** ventilation mode that is not available in most intensive care ventilators.



- The influence of the APL-valve must be understood as well. Users with no anesthesia background may expect that it also limits airway pressure during mechanical ventilation. The APL-valve has no influence in mechanical ventilation.
- ✓ The devices are designed to be tested each 24 hours to ensure readiness for operation. If the device test is not done, the readiness of operation is not tested, furthermore particularly the flow measurement may become inaccurate. Unlike many ICU ventilators, the flow measurement of the anesthesia device cannot be calibrated during operation.
- For performing the system test the <u>patient must be disconnected from the anesthesia device and for this time</u> <u>sufficient ventilation of the patient (e.g. via the resuscitator) has to be ensured.</u>
 - > The system test takes up to eight minutes and assistance of an experienced user is required for this step
 - If a system tests each 24 hours is not feasible due to clinical reasons, we recommend performing the test at least each 72 hours to reduce the likelihood of device malfunctions.
- ✓ To avoid that the rebreathing of the patient creates excessive additional humidity in the system, a **fresh gas** flow of at least 150% of the minute volume of the patient is required.
- ✓ The usage of a very large breathing bag (e.g. Dräger 3-liter breathing bag) is recommended to avoid that the spontaneous breath of the patient is limited by the size of the breathing bag.
- ✓ Only mechanical filters are suitable in long-term ventilation as with electrostatic filters the filtering performance is reduced when they become too humid. (See pg. 8 for solutions for use w/mechanical filters)
- ✓ To ensure system functionality the water trap has to be emptied or exchanged before it becomes full. The required frequency of doing this depends on the humidity of the sample gas.
- ✓ Ensure that no N2O hose and no N2O cylinder are connected to the anesthesia device.
- ✓ The user must be able to check the proper device status, ensure that all accessories are properly connected, and that the device is able to generate gas flow and pressure at the patient connector.
 - Accessories to check includes, but not limited to:
 - Ventilation hoses
 - Bacteria filter
 - Gas sampling line
 - Manual breathing bag
 - Water traps
- ✓ As the Dräger anesthesia devices are not designed for long time usage. The **overall status of the device and its** accessories has to be checked on regular base
 - At least each 12 hours (ideally more frequently) you must check:
 - Exhausted CO2-absorber



- Full water trap
- Standing water in breathing hoses
- Excessive condensation at filter
- ✓ The user interface of Dräger <u>anesthesia devices **CANNOT**</u> be protected <u>against non-authorized users</u>. Therefore, the operating organization must ensure that non-authorized users cannot approach the device to avoid that settings are changed, or therapy is stopped
- ✓ The alarm and safety concept of Dräger anesthesia is designed for a permanent presence of the user within a distance of up to four meters. Therefore, a remote supervision (e.g. via central station) is not sufficient.
 - In case of situations in which a user is not within direct proximity of the device it has to be ensured that the alarm volume is set to maximum (100%) to increase the probability that potentially live threatening situations are recognized in time.
- ✓ For enabling the device to generate the necessary alarms all alarm limits have to be set patient specific
- ✓ In general **leakages are not compensated** by Dräger anesthesia devices.
- ✓ The rebreathing of exhaled patient gases furthermore leads to another difference to ICU ventilators. The oxygen concentration of the inhaled gas (measured as "FiO2") may differ to the set oxygen concentration in the fresh gas as the result from mixing fresh gas with rebreathed gas of the patient. Therefore, **special attention** must be given to the FiO2 values and the FiO2 low alarm.
- ✓ In contrast to many ICU ventilators, the gas measurement of anesthesia devices is a side stream monitoring. Therefore, the gas measurement values and waveforms have a **delay of several seconds**.

Documentation	Printable Version
Draeger Customer Letter	Resource A
	Print pages 13 to 24
Draeger Cleaning Agent	Resource B
Guide	Print pages 25 to 26
Draeger SARS-CoV-2 and	Resource C
handling of Dräger	Print pages 27 to 32
Anesthesia Workstations	

RESOURCE A: Draeger Customer Letter

PLEASE SEE NEXT PAGE FOR RESOURCE CONTENT



Drägerwerk AG & Co. KGaA, 23542 Lübeck

To whom it may concern

Our reference

COVID-19 - PM Anesthesiology

+49 451 882-2665

+49 451 882-72665

Moritz.Rahlf-Luong@draeger.com

March 18th, 2020

COVID-19: Usage of Dräger anaesthesia devices for long-term ventilation

Dear customers, dear health care professionals,

The World Health Organization (WHO) declared COVID-19 a pandemic on March 11th, 2020 with over 118,000 cases of the coronavirus illness reported in over 110 countries worldwide. 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. In the last few days many customers and health care professionals approached us, to obtain information about possibly using Dräger anaesthesia 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, we believe it is our responsibility to provide some insights both (i) on the legal and regulatory perspective as well as (ii) on some known limitations of Dräger anaesthesia devices for long-term ventilation.



Page 3 / 11

II. Known Limitations of Dräger Anaesthesia Devices regarding Use in long-term Ventilation

WARNING: The following information list is based on our currently available knowledge as of the date of this letter. It does only apply to Dräger Anaesthesia Devices still being marketed. It is most likely not complete and exhaustive. If you detect important points which are missing, please let us know.

WARNING: Dräger as the manufacturer cannot and may not market or promote or sign-off such offlabel use of Dräger anaesthesia devices. The following information is therefore provided only to provide a better basis for the decision of the responsible health care professional. If a device is used off-label, the user does so in his own responsibility and at his own (liability) risk.

- Anaesthesia devices have a different working principle and different user interface (e.g. different
 operating modes) than intensive care ventilators. Therefore, <u>medical personnel using the
 device must be well trained and familiar with the unique performance characteristics of
 the devices.</u>
- Before connecting a patient, the user must be able to check the proper device status, ensure that all accessories (e.g. ventilation hoses, bacteria filter, gas sampling line, manual breathing bag, water traps) are properly connected and that the device is able to generate gas flow and pressure at the patient connector. With the exception of Australia and New Zealand the connectors for manual breathing bag and ventilation hoses have the same diameter. Therefore, the risk of incorrectly connected patient hoses is given. A false connection (e.g. bag hose connected to inspiratory port) would make the ventilation of the patient impossible. Therefore, particularly for connecting a patient properly to an anaesthesia device the user requires device knowledge and clinical experience with anaesthesia devices. Directly before connecting the patient the user has to check if the device is able to deliver pressure to the patient connector and that by unblocking the patient connector the pressure can be released and gas out (see e.g. website European Patient Safety Foundation: https://www.eupsf.org/safety-alert-wrong-tube-connections)
- The instructions for use state a manual <u>resuscitator must always be available at the device</u>
 which enables back-up ventilation of the patient in case of problems or malfunctions with the



Page 4 / 11

- device. Particularly for users with limited knowledge in anaesthesia devices, it is particularly important that <u>in case of irregularities</u> or unexpected system behaviour impairing patient therapy the patient has to be disconnected from the anaesthesia device and ventilated with an operator powered <u>resuscitator</u>.
- The user has to understand the mode Man/Spon (Manual or Spontaneous Ventilation) which is a unique ventilation mode that is not available in most intensive care ventilators. This mode might be live-saving in case of a failure of automatic ventilation and absence of the resuscitator. The influence of the APL-valve-has-to-be-understood-as-well. Users with no anaesthesia background may expect that it also limits airway pressure during mechanical ventilation. The APL-valve-has-no-influence-in-mechanical ventilation. It is only active in Man/Spon. In case of a ventilator failure Man/Spon becomes automatically active and the fresh gas flow will make the airway pressure rising up to the APL-setting. Therefore, also The patient. When setting the APL-valve to the desired PEEP level (or alternatively SPONT which equals zero) it is prevented that in case of a ventilator failure excessive airway pressures are generated to the patient. For the system test the APL-valve must be set to a relatively high value, therefore the user has to actively reduce this value also for mechanical ventilation.
- The user interface of Dräger anaesthesia devices cannot be protected against non-authorized users. Therefore, the <u>operating organisation must ensure that non-authorized users</u> <u>cannot approach the device</u> to avoid that settings are changed, or therapy is stopped (no alarm is generated when device is switched to standby).
- The alarm and safety concept of Dräger anaesthesia is designed for a permanent presence of the user within a distance of up to four meters. This facilitates fast recognition and response in the event of an alarm or in the event of any malfunction. Thus, the alarm volume has always to be set sufficiently loud, particularly in noisy environments. The alarm distribution via serial interface is not designed in a redundant (fail-safe) way. Therefore, a remote supervision (e.g. via central station) is not sufficient. In case of situations in which a user is not within direct proximity of the device it has to be ensured that the <u>alarm volume is set to maximum (100%)</u> to increase the probability that potentially live threatening situations are recognized in time.



Page 5 / 11

- For enabling the device to generate the necessary alarms <u>all alarm limits have to be set patient specific</u> and may have to be adapted over time to the changing clinical situations. Particularly important in these topics are the alarm limits for the minute volume (lower and upper limit) and the expiratory CO2 (lower and upper limit) to be able to generate alarms when hyporor hyperventilation occurs.
- Please be aware that in Dräger anaesthesia devices alarm notifications stop automatically when
 the alarm situation that caused the alarm is not valid any longer. In general, the alarm concept
 of ICU ventilators is completely different in this respect. Therefore, it is recommended to <u>check</u>
 <u>periodically the alarm history / alarm log of the anaesthesia device</u> to check if any alarms
 have been generated in absence of the user.
- The <u>devices are designed to be tested each 24 hours</u> to ensure readiness for operation. If the device test is not done, the readiness of operation is not tested, furthermore particularly the flow measurement may become inaccurate. Unlike many ICU ventilators, the flow measurement of the anaesthesia device cannot be calibrated during operation. The accuracy of gas measurement should not be affected as the gas measurement modules perform a zeroing independently of the system test. For performing the system test the patient must be disconnected from the anaesthesia device and for this time sufficient ventilation of the patient (e.g. via the resuscitator) has to be ensured. As the system test takes up to eight minutes (depending on device type), assistance of an experienced user is required for this step. If a system test each 24 hours is not feasible due to clinical reasons, we recommend to perform the test <u>at least each 72 hours</u> to reduce the likelihood of device malfunctions.
- As the Dräger anaesthesia devices are not designed for long time usage. The <u>overall status of</u> the <u>device and its accessories has to be checked on regular base</u> (at least each 12 hours, ideally more frequently). In particular the following situations have to be prevented: Exhausted CO2-absorber, full water trap, standing water in breathing hoses and excessive condensation at filter that may lead to increased resistance.
- One significant difference between intensive care ventilators anaesthesia devices is, that
 anaesthesia ventilators are based on a rebreathing system and adjustable fresh gas flows. This
 requires the use of a CO2 absorber to prevent high CO2 levels in the circuit. It is important to



Page 6 / 11

examine the CO2 absorber and change it when it is exhausted. An exhausted absorber can be detected by the measurement of increasing inspiratory CO2 or the changed colour of the Dräger CO2 absorber (see instructions for use of anaesthesia device and CO2-absorber for more information). The <u>activation of an inspiratory CO2-high alarm limit</u> helps to directly inform the user about an exhausted absorber.

- The breathing bag of most Dräger anaesthesia devices act as a reservoir during mechanical ventilation. The exhaled breathing gas is captured in the breathing bag. Therefore, the breathing bag moves during mechanical ventilation. The filling level of the breathing bag should be constantly sufficient.
- In general <u>leakages are not compensated</u> by Dräger anaesthesia devices. This has to be considered by the user, especially during all Volume Controlled ventilation modes. Depending on the device type the PEEP level might not be maintained. In fresh gas deficit situations (leakage higher than fresh gas flow) ventilation will be affected and immediate reaction of the operator is required (reduce leakage, increase FG-flow). As an alternative a disconnection of the manual breathing bag to use ambient air prevents a fresh gas low situation and increases the availability of ventilation. In this case the resulting inspiratory oxygen concentration will be in between the set fresh gas oxygen concentration and the 21% of the ambient air. If the fresh gas flow is high, less ambient air is entrained and the inspiratory oxygen concentration will increase.
- In order to prevent that anaesthetic agents are used in a situation in which it might harm the patient or the environment of the patient, it is recommended to <u>disconnect all vaporizers/agent dosing modules</u> from the anaesthesia device and to store them in the operation theatre. This is particularly important as already smallest concentrations of volatile agents may trigger malign hyperthermia (e.g. at the clinical personnel). If usage of anaesthetic agents is intended, please see the additional information about sedation with volatile agents in the Attachment 1.
- The rebreathing of exhaled patient gases furthermore leads to another difference to ICU ventilators. The oxygen concentration of the inhaled gas (measured as "FiO2") may differ to the set oxygen concentration in the fresh gas as the result from mixing fresh gas with rebreathed gas of the patient. Therefore, special attention must be given to the FiO2 values and the FiO2 low alarm. The difference in between fresh gas oxygen concentration and FiO2 values



Page 7 / 11

can be reduced to a minimum by increasing the fresh gas flow to at least 150% of the minute volume.

- In contrast to many ICU ventilators, the gas measurement of anaesthesia devices is a side stream monitoring. Therefore, the gas measurement values and waveforms have a delay of several seconds.
- To avoid that the rebreathing of the patient creates excessive additional humidity in the system, a <u>fresh gas flow of at least 150% of the minute volume of the patient is required.</u> A low fresh gas flow will increase the amount of rebreathed gas and therefore may lead to the following situations:
 - condensation in breathing system and hoses, which may accumulate to a point where it impairs the therapy
 - CO2-absorber has to be exchanged more frequently
 - high difference between the set fresh gas oxygen concentration and the measured inspiratory oxygen concentration
- In addition, a high fresh gas flow increases the robustness of the ventilation. When the fresh gas flow is too low the manual breathing bag (reservoir for the patient gas) may collapse in leakage situation and this would impair the ventilation. Particularly spontaneous breathing patients might require very high tidal volumes which they inhale from the manual breathing bag.

 The <u>usage of a very large breathing bag (e.g. Dräger 3 litre breathing bag) is recommended</u> to avoid that the spontaneous breath of the patient is limited by the size of the breathing bag.
- Regarding the infection prevention the hospital guidelines have to be followed. This includes the reprocessing of the device after the usage on infectious patients (particularly the device surfaces) but also the adequate usage of bacteria filters. Only mechanical filters are suitable in long-term ventilation as with electrostatic filters the filtering performance is reduced when they become too humid. More information regarding infection prevention in the context of COVID-19 are given in the Dräger 2019-nCoV infection prevention customer letters for anaesthesia and intensive care.



Page 8 / 11

- Two different solutions for the usage of mechanical filters can be recommended:
 - Solution 1 Passive humidification
 - Use of a combined element: Heat and Moisture Exchanger (HME) / mechanical breathing system filter (e.g. Dräger TwinStar HEPA)
 - Location: Only at the patient connector (Y-piece)
 - Solution 2 Active humidification
 - In combination with active humidification use two mechanical filters without HME (e.g. Dräger SafeStar filter series).
 - Location: At the inspiratory AND the expiratory port of the anaesthesia device
 - Please consider the following information in regard to active humidification in combination with anaesthesia devices.

If possible, from a clinical perspective HME / mechanical breathing system filters at the Y-piece (solution 1) should be used with Dräger anaesthesia devices.

The usage of <u>active humidification</u> is not approved with Dräger anaesthesia devices. Should nevertheless an active humidifier be used in this exceptional situation it has to be avoided that rebreathed humid gas creates excessive condensation in the breathing system of the anaesthesia device. Breathing circuits require <u>a water trap in the expiratory limb</u>. Dual heated breathing circuits must not be used with Dräger anaesthesia devices. Also, the usage of filters or even HME/filters at the Y-piece must be avoided to prevent excessive breathing resistance due to clogged filters resp. HME/filters during active humidification. When using a filter at the expiratory port the resistance can potentially exceed values demanded by the standard (ISO 80601-2-13:2011). Close monitoring of the respective ventilation, e.g. particularly narrow limits for the minute volume low alarm, and vital parameters are compulsory. Additionally, a filter must be used on the inspiratory port of the anaesthesia device. As mentioned before, only mechanic filters shall be used. A high fresh gas flow of at least 150% of the minute volume contributes to avoid excessive condensation in the breathing system as well as at the filter at the inspiratory port. Reprocessing of the anaesthesia device after each patient is



Page 9 / 11

essential and shall follow the recommendations for anaesthesia devices contaminated with SARS CoV-2.

- The water trap at the gas measurement module of Dräger anaesthesia devices protects the gas measurement module against humidity. To ensure system functionality the water trap has to be emptied or exchanged before it becomes full. The required frequency of doing this depends on the humidity of the sample gas. For usage of the Dräger anaesthesia device with high fresh gas flows and a combined HME-filter we expect that the filling level has to be checked each 12 hours.
- Modes that are not known by the user (e.g. Ext. Fresh Gas Outlet or Pause) shall not be used.
 Furthermore, <u>several modes may behave differently than in intensive care ventilators</u>.
 Details are listed in the Attachment 1.
- Modes, measurement values, settings, manoeuvres etc. that are possibly used with ICU ventilators might not be available in the anaesthesia devices.
- Nebulisation of drugs or aerosol therapy are not approved with Dräger anaesthesia devices. If aerosol or other drugs are given to the airways this may cause malfunctions (e.g. incorrect measurement of the gas analyser).

Content added due to market feedback after the initial publication of this letter on March 15th, 2020:

The fresh gas flow must only contain a mix of oxygen and medical air. The usage of nitrous-oxide (N2O) during long-term ventilation must be prevented as users with no anaesthesia experience are not familiar with the fact that a decrease of the oxygen concentration in the fresh gas flow would increase the N2O concentration in the inspiratory gas. Therefore, it has to be ensured that no N2O hose and no N2O cylinder are connected to the anaesthesia device. Furthermore, in Dräger anaesthesia devices with electronic gas mixer (Zeus (IE), Perseus A500 with electronic mixer, Primus and Primus IE) a usage without N2O has to be configured in the system configuration. [content added on March 18th, 2020]



Page 10 / 11

If you have any questions or remarks to this topic, please do not hesitate to contact your local Dräger representative. As mentioned, feedback is highly appreciated to enable us to share new information about this topic with medical caregivers worldwide.

Ray Husel M. Poly

With kind regards,

Ines Thams

Risk Manager

Ralf Heesch

System Engineer

Moritz Rahlf-Luong

Product Management Anaesthesiology

Attachements:

Attachement 1 - Comments to particular modes of operation



Page 11 / 11

Attachment 1- Comments to particular modes of operation:

- Volume Control and VC-Autoflow: In most ICU ventilators the upper airway pressure alarm limit "Paw-high" is not only used for generating the airway pressure high alarm but also used for limiting the maximum pressure generated by the therapy device. In Dräger anaesthesia devices the alarm limit is only used for generating the alarm but does not limit the pressure. For the pressure limitation the setting "Pmax" is used which also has to be set specific to the patient and the clinical situation.
- Pressure Support: When the patient triggers breaths with a lower frequency than the set minimum frequency (RRmin), the anaesthesia device remains in the mode Pressure Support and non-triggered breaths are given additionally to the spontaneous triggered breaths to achieve the set minimum frequency. In addition the alarm "Apnea Ventilation" is generated. In many of the Dräger anaesthesia devices the alarm can be configured to low or medium priority. As in long-term ventilation the user might not be directly in front of the device the medium alarm priority is recommended. Dräger anaesthesia devices have no dedicated apnea-time and apnea back-up ventilation mode like it is available in most ICU ventilators.
- Non Invasive Ventilation (NIV): Dräger anaesthesia devices do not offer a dedicated NIV-mode.
 Therefore the user has to pay particular attention to leakages when doing mask ventilation.
- Sedation with volatile agents: If the long-term ventilation is combined with a sedation of the patient with anaesthetic agents, the direct environment of the patient has to be protected against surplus of anaesthetic agent. Typically in the operating theatre an active scavenging takes care that the surplus of fresh gas is evacuated. In environments of use without an active scavenging an ejector may protect the direct environment of the patient against increased concentrations of anaesthetic agents (already smallest concentrations of anaesthetic agent may trigger malign hyperthermia). In the devices Fabius, Primus/Apollo and Zeus IE also the usage of activated char coal filters might be an alternative. Please check your respective regulations, e.g. employment protection requirements. The usage of low flow anaesthesia to reduce anaesthetic agent polluting the OR environment requires deep knowledge of the rebreathing function and will lead over time to difficulties with water condensation in the system. In this case a permanent supervision by an experienced anaesthesia user is mandatory.



RESOURCE B: Draeger Cleaning Agent Guide

PLEASE SEE NEXT PAGE FOR RESOURCE CONTENT



Cleaning Agent Guide Recommended Cleaning Solutions

Dräger knows the importance of hospital hygiene and infection control. We want to help keep your patients and workplace safe. Provided below, are cleaning agents that have been tested at our accredited Dräger Test Center and are compatible with all listed devices. There is no obligation to use these cleaning agents; however, Dräger strongly recommends the use of these approved cleaning agents on Dräger medical devices. Non-approved cleaning agents may cause harm and/or damage to the medical devices.

ANESTHESIA	Brulin® BruTab 65®	Clorox® Bleach Cleaner & Disinfactant Towels®	Ecolab® OxyCida™	Metrox® CaviWipes™
Apollo®	~	~	~	×
D-Vapor® 2000	~	~	~	×
D-Vapor® 3000	✓	~	~	×
Fabius® GS Premium	✓	~	~	×
Fabius® GS	✓	~	~	×
Fabius® MRI	~	~	~	×
Fabius® Tiro	~	~	~	×
Fabius® Tiro M	~	~	~	×
MDS7®	×	~	×	~
Perseus® A500	~	~	~	×
Scio®	/	~	~	×
Vamos®	/	~	~	×
Vapor® 2000	~	~	~	×

NEONATAL	Brulin® BruTab 6S®	Cleaner & Disinfectant Towels*	Ecolab® OxyCide™	Motrox [®] CaviWipes™
Babyleo® TN500	~	~	~	×
Babytherm® 8004/8010	×	×	~	×
BiliLux®	×	×	~	×
Caleo®	×	×	~	×
Globe-Trotter® GT5400	✓	×	~	×
Isolette® 8000	×	×	~	~
Isolette® 8000 plus	×	×	~	×
Isolette® TI500	×	×	~	~
Jaundice Meter JM-103	×	×	~	~
Jaundice Meter JM-105	×	×	~	×
NanoBlu® 500	×	×	~	×
Photo-Therapy 4000	×	×	~	×
Resuscitaire®	×	×	~	~
TI500 Globe-Trotter®	×	×	_	

Clorox® Bleach

PATIENT MONITORING	Brulin® BruTab 6S®	Clorox® Bleach Cleaner & Disinfectant Towe Is*	Ecolab® OxyCida™	Metrox [®] CaviWipes™
IACS® with C500	~	~	~	×
IACS® with C700	~	~	~	×
Infinity® CentralStation	~	~	~	×
Infinity® Delta/Delta XL	~	~	~	×
Infinity® Gamma/XL/XXL	~	~	~	×
Infinity® Kappa	~	~	~	×
Infinity® Kappa XLT	~	~	~	×
Infinity® M300	~	~	~	×
Infinity® M540	~	~	~	×
Infinity® MultiView Workstation	~	~	~	×
Infinity® Omega	~	~	~	×
Infinity® Omega S	~	~	~	×
Infinity® SC6002 XL	~	~	~	×
Infinity® SC7000	~	~	~	×
Infinity® SC8000	~	~	~	×
Infinity® SC9000 XL	~	_		×
Infinity® TruST Telemetry	~	~	~	×

Babylog® 8000 plus	~	~	~	×
Babylog® VN500	~	~	~	×
Carina®	~	✓	~	×
Evita® 2 dura	~	~	~	×
Evita® 4	~	~	~	×
Evita® Infinity® V500	~	~	~	×
Evita® XL	~	~	~	×
Oxylog® 1000/2000/3000 (plus) WORKPLACE INFRASTRUCTURE	~	~	~	×
	Brulin® BruTab 6S®	Clorax® Bleach Cleaner & Disinfectant Towels®	Ecolab® OxyCide™	Metrex ^e CaviWipes™
Agila®	~	~	~	×
Gemina® DUO	~	~	~	×
Movita®	~	~	~	×
Polaris® 50	~	~	~	×
Polaris® 100/200	~	~	~	×

RESPIRATORY

Ponta®

Consult Provisional Districting Seaton Casanit a Juspanit Proping Casanit a Juspanit Proping Casanit and Juspanit Proping Casanit Proping Casa

^{**}Clorox® Professional Disinfecting Bleach Cleaner & Dispatch® Hospital Cleaner Disinfectant Towels with Bleach



RESOURCE C: Draeger SARS-CoV-2 and handling of Dräger Anesthesia Workstations

PLEASE SEE NEXT PAGE FOR RESOURCE CONTENT



Drägerwerk AG & Co. KGaA, 23542 Lübeck

SARS-CoV-2 and handling of Dräger Anesthesia Workstations

February 20, 2020

Dear Sir or Madam.

The following information and recommendations are targeted for Anesthesia Workstations from Dräger that were used on patients infected or highly suspected to be infected with the novel coronavirus (SARS-CoV-2).

Background:

Coronaviruses (CoV) are a large family of enveloped viruses that cause illness ranging from the common cold to more severe diseases such as Middle East Respiratory Syndrome (MERS-CoV) and Severe Acute Respiratory Syndrome (SARS-CoV). The novel coronavirus (SARS-CoV-2) is a new strain that has not been previously identified in humans.

Coronaviruses are transmitted between animals and humans (zoonotic transmission). The possibility of transmission among humans especially of SARS-CoV-2 is now confirmed, but the extent of human-to-human transmission is still not clear-

The novel coronavirus (SARS-CoV-2) belongs to the category of enveloped viruses that in principle can be removed with disinfectants with limited virucidal effectiveness. However, for a higher safety level it is also possible to use locally registered hospital disinfectant with a label claim for a non-enveloped virus (e.g. norovirus, rotavirus, adenovirus, and poliovirus). Further information you can find on the following websites and further national organization websites:

- https://www.who.int/emergencies/diseases/novel-coronavirus-2019
- https://www.cdc.gov/coronavirus/2019-ncov/index.html
- https://www.ecdc.europa.eu/en/novel-coronavirus-china
- https://www.rki.de/covid-19



Page 2/5

System setup recommendations for confirmed or highly suspected SARS-CoV-2-patients:

A. Essential measures

A1 Anaesthesia device:

Use of a mechanical breathing system filter (BSF) such as MP01790 SafeStar 55
 (adults only) at patient side (between tracheal tube and y-piece of the breathing circuit (hoses). <u>Caution:</u> The gas sample line of the anesthesia device <u>must be connected on the device side of the BSF</u> in order to avoid contamination of the gas measurement unit and consequently the entire anesthesia device (see figure 1).

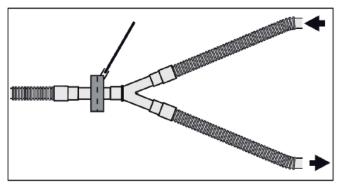


Figure 1

 Deploy disposable breathing circuit (hoses) only. For types and part numbers please see Dräger Accessory Catalogue.

A2 Endotracheal suctioning device:

- The VarioSafe® disposable filter system (MP00555) has to be used to reliably protect the suctioning device and the patient environment against contamination.
- We recommend to use Dräger Vacusmart Gel inserts for the suction canister.

A3 Monitoring accessories:

Disposable Monitoring accessories should be used and disposed after each patient.

- Disposable ECG leads
- Disposable SpO2 sensors
- Disposable NiBP cuffs
- Disposable temperature probes

For types and part numbers please see the Dräger Accessory Catalogue.



Page 4 / 5

Reprocessing recommendations:

Reprocessing of products, components and surfaces potentially contaminated can be achieved by following the standard procedures described in the Instruction for Use (IfU) and the usage of suitable disinfectants with at least limited virucidal effectiveness. The following recommendations for anesthesia devices contaminated with SARS-CoV-2 are based on general guidelines and practice for infectious diseases. For further details please refer to the newest 'list of surface disinfectants' in the Instructions for Use of your device and/or contact your local sales organization.

Due to

- the so far uncertain infection risk, and
- missing definitive data on its susceptibility to reprocessing measures,

we recommend for the time being the following enhanced procedure as an additional precaution:

C. Essential measures

- C1. Follow the occupational safety and reprocessing guidelines of the hospital and the local/ national health authorities.
- C2. Remove all disposable device components which are in contact with the patient's breathing gas:
 - the breathing circuit (hoses),
 - HME/ breathing system filters,
 - sample line and the water trap,
 - endotracheal suction accessories, tubes and filters
 - dispose off all of these safely
- C3 Regarding breathing system reprocessing (including valves & flow sensors), please proceed as described in the Instructions for Use.
- C4 Regarding suction system, please refer to the Instruction for use.
- C5 Clean and disinfect thoroughly with a suitable disinfectant (concentration and exposure time according to manufacturer's instructions) all accessible surfaces of the anaesthesia device, other devices and reusable components.
- C6 Allow to air dry



Page 5 / 5

- D. Optional measures following C, if devices were used without a Breathing System Filter (BSF). This part should be in line with the general hospital guideline for all medical devices in the patient vicinity. Prerequisite: All steps described in section C (essential measures) were performed.
- D7. Wrap the anaesthesia device, the other devices and reusable components completely with a plastic cover and store them safely for a specified time (e.g. 21 or 28 days) at room temperature or higher. Make sure all devices are switched off using the main switch to avoid deep discharge of batteries.
- D8. Remove plastic cover and dispose off safely
- D9. Clean and wipe disinfect thoroughly with a suitable disinfectant (concentration and exposure time according to manufacturer's instructions) all accessible surfaces of the anesthesia device, other devices and reusable components
- D9 Allow to air dry
- D10. Device can be released for reuse.

<u>General Remark:</u> Based on the individual situation, the hospital management responsible for infection control and epidemiology has the task to decide on the required measures. The measures described above are intended for devices used in the recommended manner. Devices used without a Breathing System Filter (BSF) have to be managed in each individual case in consultation with the competent authority. In justified cases of doubt we recommend the safe disposal of contaminated devices and reusable accessories.

If you have further questions, please do not hesitate to ask your local Dräger office for assistance.

Dräger can also provide personal protective equipment (PPE) for healthcare professionals.

With best regards,

Stefan Thal

System Product Manager
Infection Prevention & Control
Business Unit IT & Systeme
Medical Devision
Drägerwerk AG & Co. KGaA

Dr. Arne Martensen

Consultant for hygiene / environmental medicine Specialist for microbiology, virology and epidemiology of infectious diseases on behalf of Hygienisches Versorgungszentrum Hamburg (for specialist knowledge)



- Step 1: Reference Appendix A "GE Covid-19 off-label use of GE anesthesia devices" and Appendix B "Quick Reference Guide"
- Step 2: Remove all vaporizers and flush out any residual agents in the breathing system.
- Step 3: Disconnect any N20 gas tanks/lines from the system
- Step 4: Ensure the scavenging system is connected, if scavenging is unavailable disconnect the scavenging hose and scavenging bag
- Step 4.25: Ensure that there is an appropriate filter at the OTT and between the expiratory limb of the machine and the anesthesia machine.
- Step 4.5: Ensure the daily full power cycle and automated full machine check has been done in the last 24 hrs.
- Step 5: Perform the full circuit leak test; this should be completed before each case
- Step 5.25: Validate the gas connections are solid and tight and there are no leaks. A "Y" connector may need to be obtained.
- Step 5.5: Make sure ventilator fresh gas alarms are on and set a maximum volume.
- Step 6: When starting a case ensure gases are flowing and desired mix of O2 and Air to deliver desired FiO2.
- Step 7: Have a trained clinician configure the device settings per the appropriate ventilation mode desired
- Step 8: Routinely check the CO2 absorber and replace as needed
- Step 9: Routinely check the breathing system for moisture and remove/clean as needed
- Step 10: Ensure there are network ports for electronic documentation capture from anesthesia machine to RT vent flowsheet in CareConnectOne. If network ports are not available, documentation will need to occur manually. (Preferable to have electronic documentation and NOT downtime forms).
- Step 10.5: Required documentation will need to be completed every Q4 hours. (see tip sheet for vital signs documentation for nursing role and vent flowsheet documentation for vent management education)

Additional Notes:

- Reset the device every 24 hours and repeat step 5. If this cannot be done each day, perform this step between patients.



- Remove/disassemble the breathing system and clean any moisture that has accumulated within the system as needed. Do not reuse the breathing circuit.
- See below chart for reference

Desire	d FiO2 Oxyge	n to Air	Ratio	Oxygen flow for 5 L/min total	Air flow for 5 L/min total
21%	0 to 1 0.0	5.0			
25%	0.06 to 1	0.3	4.7		
30%	0.13 to 1	0.6	4.4		
35%	0.21 to 1	0.9	4.1		
40%	0.31 to 1	1.2	3.8		
50%	0.59 to 1	1.9	3.1		
60%	0.99 to 1	2.5	2.5		
80%	3 to 1 3.8	1.3			
100%	1 to 0 5.0	0.0			

- Anesthesia systems are designed to be fully attended/monitored at all times by a trained clinician
- o Recommend an anesthesia provider to vent ratio of maximum 8:1 to minimum 2:1, dependent on what role needed by provider, layout of cohorted location, and assistance from respiratory therapy. If utilizing provider in a nursing and respiratory capacity, consider use of minimum ratio.
- Have laminated Quick Reference Guide hanging on each anesthesia machine (Reference Appendix B)
- If spirometry is available, the baseline reference loops should be saved for later comparison

Documentation	Printable Version
GE's Off-Label Use	GE's Appendix A
Customer Letter	Print pages 36 to 45
GE's Appendix 1: Intended	GE's Appendix 1
Use/Indications for Use	Print pages 46 to 48
GE's Appendix B: Setup and	GE's Appendix B
Monitoring Instructions –	Print pages 49 to 52
Anesthesia Machine as an	
ICU Ventilator	



GE's APPENDIX A: COVID-19 - Requests for information regarding the off-label use of GE Healthcare anesthesia devices for ICU ventilation

PLEASE SEE NEXT PAGE FOR RESOURCE CONTENT



GE Healthcare

Life Care Solutions

23 March 2020

Topic: COVID-19 - Requests for information regarding the off-label use of GE Healthcare anesthesia devices for ICU ventilation

Dear valued customer,

The pandemic situation related to COVID-19 is leading to significant concern around the world regarding the availability of ICU ventilators to meet potential needs. We have generated this letter in response to numerous requests for information regarding whether existing anesthesia devices could temporarily be used to supplement ventilator capacity.

IMPORTANT: This document contains off-label information. This information is only being provided for consideration during the COVID-19 pandemic. Regulatory authorities (e.g. U.S. FDA, Health Canada, TGA, EU Competent Authorities) have not cleared or approved these anesthesia devices as safe and effective for use as ICU ventilators. The use of these devices as ICU ventilators has not been verified or validated.

However, recent U.S. FDA guidance¹ published 22 March 2020, states that during this COVID-19 health emergency, the U.S. FDA does not intend to object to the use of anesthesia gas machines for patients needing mechanical ventilation.

As U.S. FDA stated, "wherever possible, health care facilities should use cleared [or approved] conventional/standard full-featured ventilators when necessary to support patients with respiratory failure." The use of an anesthesia machine is considered off-label use (not formally cleared or approved by any regulators) and GE Healthcare does not in any way promote or recommend the use of anesthesia devices as ICU ventilators in any normal circumstances. However, we understand the extreme circumstances driving this request and the need to weigh the relative risks and benefits to support patients in these unprecedented times. 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 in order to minimize risks to patients. The information presented below is intended to describe the key differences between these anesthesia devices and ICU ventilators, and present important information related to the device functionality and patient safety.

IMPORTANT: The information presented is based on the current understanding of the potential risks and device functionality of the GE Healthcare Anesthesia devices mentioned below. This may not be comprehensive and may not cover all use scenarios and risks. As the COVID-19 situation and understanding evolves, we will do our best to continue to provide the most accurate information.

• We recommend regularly checking the GE Healthcare website (https://www.gehealthcare.com/covid19) for updates to this letter and additional information.

IMPORTANT: 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.

For the European Union and other countries, consult with your relevant Competent Authority or regulator regarding derogations for off-label device use/compassionate use during the COVID-19 pandemic.

1) US FDA - Enforcement Policy for Ventilators and Accessories and Other Respiratory Devices During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency Guidance for Industry and Food and Drug Administration Staff, March 2020

Refer to **Appendix 1** for the cleared indications for use/intended use for the GE Healthcare anesthesia devices.

IMPORTANT SAFETY INFORMATION

WARNING: 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 properly trained clinicians, continuously monitored, and used in accordance with the instructions for use.

Intended Use

- The cleared indications for use/intended use information is listed in Appendix 1. There are risks related to any use of those devices other than that for which they are indicated. Clinicians considering such use during the pandemic must weigh the risks and benefits and ensure proper training and safe handling of the devices.
- The risks of an anesthesia device used for ICU ventilation may be significantly greater for pediatric or neonatal patients. Such use is strongly discouraged.

Attended Devices

 Anesthesia devices are designed and intended to be <u>fully attended/monitored devices</u>, which requires a clinician to be in proximity of the device at all times. This is different from the potential use case in ICU ventilation. <u>It is critical to ensure the proper use and continuous monitoring of the anesthesia device</u> <u>function and ventilation is maintained</u>.

Training/Knowledge of the System

- Anesthesia devices are complex systems which rely on user knowledge and training for safe operation. The
 devices are intended to be used by clinicians who are trained in the administration of general anesthesia.
 There are unique characteristics that differentiate anesthesia devices from standard ICU ventilators. New
 or different personnel intended to handle the devices must be appropriately trained on the anesthesia
 device and complete instructions for use.
- All users should be familiar with the anesthesia system user interface, controls, functions, configurations, alarms, and theory of operation before using these devices.
- Ensure the device instructions for use are available for training and for reference during use.

Anesthetic Agent

- Anesthesia systems may contain residual amounts of anesthetic agents in the breathing system. Be sure to
 flush out any residual agent prior to use as an ICU ventilator to prevent the risk of medication interactions.
 There is a risk of malignant hyperthermia if the patient is susceptible to inhaled anesthetic agents. Even
 small amount of agent may trigger this risk.
- <u>It is highly recommended to remove/disconnect the vaporizers and any other unnecessary connections, such as N2O, before using the device.</u>

Circle Breathing Circuit, CO2, and Humidity/Moisture

- Circle breathing systems, such as those used in anesthesia devices, use unidirectional valves which may
 prevent the release of pressure from the patient connection; for example, if the expiratory breathing tube
 is occluded. <u>Users must be familiar with the theory of operation of circle breathing systems, including CO2</u>
 <u>absorption function, including how and when to change CO2 absorbent canisters, and flow and pressure</u>
 delivery functions prior to using the device.
- Use of circle systems for long-term ventilation may result in a buildup of excess moisture and condensation in the breathing system and device. Excess moisture can degrade the performance of the ventilator sensors and reduce ability to keep the system clean. Periodically monitor the device for indications of moisture buildup in the breathing tubes.
- If moisture or condensation occur, increasing the fresh gas flow may provide adequate gas flow to reduce excess buildup. It is recommended that the Fresh Gas Flow setting be set to at least 50% or more of the patient's minute volume to ensure adequate oxygenation and to reduce CO2 rebreathing. <u>Higher FGF closer to the minute volume will reduce rebreathing but may lead to drier inhaled gases.</u> Drain water as necessary if condensation in the breathing system occurs.
- Water condensation in the breathing circuit tubing may be lessened by using a Heat and Moisture Exchange Filter (HMEF) at the airway connection. Monitor and replace patient circuit filters as necessary. When using a GE Healthcare respiratory gas module, make sure to connect the sampling line to the sampling port on the device side of the HMEF, or to another sampling port (elbow connectors, T-pieces) proximal to the anesthesia device with respect to the HMEF, to protect the gas module from excess moisture and from contamination.
- <u>It is NOT recommended to use active humidification with these anesthesia systems.</u> Consider use of an HMEF for patients ventilated with anesthesia systems. If active humidification is required, consider transferring the patient to an ICU ventilator.
- Anesthesia devices are equipped with CO2 absorbers, which have a limited useful life. Failure to change the CO2 absorber when depleted, as described in the instructions for use, will result in

an increase in inspired CO2. Always use proximal / end-tidal CO2 and O2 monitoring.

- For devices which are compatible with the GE Healthcare respiratory gas module, the FiCO2 High alarm is disabled by factory default on many anesthesia systems. It is recommended to ensure this limit is set to an appropriate value to prevent CO2 rebreathing for an ICU patient.

Length of Use and Checkout

- Anesthesia devices are not intended for long term ventilation use and are designed to be <u>rebooted/restarted</u> <u>every day to ensure proper calibration, accuracy, and performance</u>. If an anesthesia device is used to provide mechanical ventilation in emergency/pandemic scenarios, it is recommended that patients requiring long term therapy are transferred to an ICU ventilator more suited for long term ventilation.
- GE Healthcare anesthesia devices are intended to be power cycled (turned on/off) and tested/checked out fully at least once a day. Complete circuit checks should be performed before each patient use and periodically for monitoring. Use of the device without appropriate periodic calibration per the instructions for use may result in the degradation of device delivery and monitoring performance, including pressure, flow and volumes, and spontaneous breath triggering. It is highly recommended that the checkout procedure is performed on these devices daily. To do this checkout during ventilation, you would need to disconnect the patient and manually ventilate. If this is not possible, devices must be power cycled and checked out between patients.
- The Aisys, Avance, Aespire and Aestiva family of anesthesia devices will shut down (stop ventilation) if they run for 49 days consecutively without a reboot. <u>Do not use anesthesia devices for extended time periods without rebooting.</u>
- <u>If a device has been used for more than 24 hours since the last checkout was completed, circuit compensation information will be cleared the next time the "Therapy" state is exited. This may affect the accuracy of delivered volumes. Checkout may need to be completed during the ventilation period for a single patient if the Therapy state is exited after 24 hours since the last checkout.</u>

Ventilation Modes/Alarms/Settings

- Anesthesia devices and ventilators frequently use similar names / nomenclature to refer to ventilation modes, settings, and procedures which may be slightly different. Ensure device

users are familiar with the performance requirements and limitations of the system.

- Anesthesia systems are designed for use in an attended environment. Device audio alert levels (volume) may not be adequate for the ICU use environment. Ensure the device audio level is adequate for the ICU or provide alternative methods of continual status monitoring. The anesthesia machines do not have the ability to generate alerts via the hospital nurse call alarm systems.
- <u>It is vital to ensure alarm limits are configured appropriately to provide warning of patient or device issues during mechanical ventilation. It is recommended that all alarms are enabled at all times.</u>
- Anesthesia devices do not provide automatic leak compensation found in many ventilators, and while higher fresh gas flow may compensate small leaks, they are not designed to be used with large leaks in the breathing circuit, such as non-invasive ventilation. If non-invasive (masked) ventilation must be used, use a spontaneous, pressure-target mode such as CPAP + PSV. Increasing fresh gas flows may provide additional compensation, if the leaks from the mask are small. The device may alarm if leaks exceed the configured alarm limits. Bellows provide a visual indication of leaks: if the bellows does not reach the top of the housing at the end of expiratory cycle, check for leaks. Ventilation delivery accuracy cannot be guaranteed with large leaks and the patient may not have sufficient oxygenation or CO2 clearance. Always ensure alternative methods of ventilation and monitoring are available.

- Anesthesia devices may be optionally equipped with non-ventilation modes such as Monitoring Only mode, and Cardiac Bypass. These modes are designed for little to no ventilatory support or monitoring and should not be used for ventilation purposes.
- Anesthesia devices may have different performance specifications from ventilators, such as inspiratory
 flow capability, pressure limitations and other ventilation performance needs. Anesthesia devices may
 have increased inspiratory and expiratory resistance compared to traditional ICU ventilators. Ensure
 patients are suitable for ventilation based on the specifications of the anesthesia devices before beginning
 therapy.
- Anesthesia devices (other than those with "PSV Pro" mode) are not equipped with "Backup Mode"
 functionality, which is provided with many ventilators. <u>Devices will not provide baseline mechanical</u>
 ventilator support unless initiated and configured, and will not switch to mechanical modes in the event of
 an apneic event. Always ensure the ventilation mode is adequate to ventilate the patient. Always provide
 continuous monitoring of patients.
- The CPAP + PSV mode may be configured with a minimum rate setting.
- The PSV Pro mode is an optional vent mode on some anesthesia systems, and this mode does utilize backup ventilation functions. Ensure the user is familiar with configuration of the mode and backup ventilation settings prior to using these advanced modes.
- Pmax Anesthesia devices and ICU ventilators are both equipped with automatic response to high pressure scenarios, by cycling to exhalation (ending an inspiratory period early) if a Pmax alarm limit violation occurs. Anesthesia devices are not equipped with the ability to open the patient circuit to atmosphere under sustained pressure or occlusion scenarios, unless the working pressure exceeds 110 cmH2O. The devices will cut off inspiratory flow if prolonged pressure scenarios occur, but do not have the ability to immediately relieve pressure in case of an obstruction.
- There should always be an alternative oxygen source such as an oxygen cylinder and a self-inflating bag available and tested. If there is any problem with the ventilation, the first action is to connect the self-inflating bag directly to the patient airway, without any filters or adapters, to ensure ventilation and oxygenation of the patient.

Gas Monitoring (O2 and CO2)

- Always use proximal / end-tidal CO2 and O2 monitoring. Ensure the actual delivered O2 levels are appropriate for the patient. Remember, when fresh gas flows are lower than minute volume, the O2 concentration in the fresh gas will be diluted, so the set O2 level will be different from what the patient actually receives.
- Elevated FiCO2 values are an indication that the CO2 absorber canister requires replacement / refill. The
 CO2 absorber is used to remove excess CO2 from the circle system; failure to change the absorber may
 result in rebreathing, excess CO2, or insufficient oxygenation. Consult the device instructions for use on how
 to exchange the CO2 canister during a case.

Use Environment/Transport/Drive Gas

- The anesthesia devices are not intended or designed to function while moving and are not for use during transport within a facility or between facilities.
- The anesthesia devices should not be used for agent delivery outside of an Operating Room (OR) environment and without users trained on the proper setup of the system.
- If the device is moved to use environments outside of its normal location in the OR, the device must be reinstalled/configured by professionals trained in the proper setup of facility connections such as scavenging and gas inputs.
- The anesthesia devices are not intended or designed to function without adequate scavenger extract flow. Without adequate scavenger extract flow, unintended Positive-End Expiratory Pressure (PEEP) may occur. The anesthesia gas scavenging system (AGSS) must be opened to atmosphere by removing the hose connected to the AGSS and removing the visual indicator bag (if equipped).
- To conserve supplies of O2, the drive gas may be changed from O2 to medical air in accordance with the service instructions (Technical Reference Manuals). This must be performed by trained and authorized service personnel and they must complete the appropriate testing outlined in the Technical Reference Manual.

Reprocessing and Cross-contamination

- Facilities should follow local procedures and guidelines and the device instructions for use regarding device reprocessing. You may also refer to the GE Healthcare Anesthesia and Respiratory Cleaning Guidance Letter for COVID-19. It is strongly recommended that viral/bacterial filters be used to protect the patient connection ports (inspiratory and expiratory).
- If an HMEF is used at the patient Y-piece, additional filtration is not required at the inspiratory port. If an HME is used at the patient Y-piece, ensure filtering is present at the inspiratory port. Use an expiratory viral/bacterial filter at all times. Follow filter guidelines on replacement timelines/frequency.
- Devices equipped with airway module sample gas configured to the breathing system should disable Sample Gas Return, including disconnecting the tube connecting the gas monitor to the device. Contact GE Healthcare Service representatives for support.
- If the device uses the "Circuit O2 Cell" for oxygen monitoring (e.g. Aestiva and Aespire families), ensure precautions are taken to replace or protect the O2 cell from contamination. The O2 cell cannot be reprocessed.

Case Setup

Anesthesia devices are designed and intended to be used by trained clinicians who have detailed knowledge of
the equipment. The devices are also designed to be attended/monitored at all times. The device instructions
for use should be consulted for configuration, setup,navigation and utilization, and troubleshooting. <u>It is
recommended that users with extensive experience with the device perform any necessary configurations
and installations</u>, and execute the system checks.

- The devices are intended to be power-cycled and to complete checkout daily. If the device cannot be cycled and checked daily, it must be power cycled and checked between patients. Always complete checkout with the circuit used for the patient to be ventilated, including any filters or circuit accessories. This is important to ensure the circuit compliance and other parameters that impact ventilation delivery are accurate.
- If checkout is not completed every 24 hours, the device may indicate a "Please Do Checkout" general message. If this message is displayed, the device will clear the internally stored circuit compensation data upon ending a case. Do not select End Case until Therapy is completed for the current patient.
- Anesthesia devices equipped with the "ACGO" circuit option have similar looking patient connection ports.
 The ACGO configuration is intended for single limb flow and not for mechanical ventilation. Ensure the patient circuit is connected to the circle system ports; consult the device operating instructions for proper circuit setup. Always confirm adequacy of ventilation before leaving any device and always maintain monitoring.

Start a case

- When starting a case, always ensure gases are flowing. Always ensure the ventilation mode and settings are appropriate for the patient prior to beginning mechanical ventilation. Mechanical ventilation begins as soon as the "Bag to Vent" switch is placed in "Vent" mode, after a case is started.
- Anesthesia devices are designed for use in an attended environment. <u>It is vital to ensure alarm limits are configured appropriately to provide warning of patient or device issues during mechanical ventilation. It is recommended that all alarms are enabled at all times.</u>
- Always use a respiratory gas monitor for CO2 and O2. If the respiratory gas monitor is not directly connected to the anesthesia device, external monitoring solutions are required.

Alternate O2

- Alternate O2 is a mechanism to provide an alternative source of fresh gas flow to the patient, in the event of a gas mixer failure (only on applicable anesthesia devices). In some device malfunction conditions, ventilation may continue using Alternate O2 (100% O2) instead of the set Fresh Gas flow and concentration. Ensure the Alternate O2 flow setting is high enough to provide adequate oxygenation to the patient in the event of a gas mixer failure.
- There should always be an alternative oxygen source such as an oxygen cylinder and a self-inflating bag available and tested. If there is any problem with the ventilation, the first action is to connect the self-inflating bag directly to the patient airway, without any filters or adapters, to ensure ventilation and oxygenation of the patient.

Settings

- Anesthesia "Gas Settings" are used to configure the oxygen concentration to be delivered to the patient. <u>In a circle system, delivered gas may be partially diluted if the fresh gas flow is set too low. It is recommended that the Gas Flow level is set to at least 50% or more of the patient minute volume.</u>

 Anesthesia "ventilation settings" are used to determine the volume or pressure delivered to the patient, and the type of control mode used. Names of settings and modes may not directly match that of ICU ventilators. Ensure ventilation modes and settings are selected with an understanding of the anesthesia device theory of operation.

Bag to Vent (BTV)

- Anesthesia devices are not automatically configured to begin mechanical ventilation when a case is started. The devices are configured for both manual ventilation (often referred to as "Bag Mode") and mechanical ventilation. When the device is in "Bag Mode", that is when the "Bag to Vent" switch is in the Bag position, the device is not providing any ventilation support to the patient. There is gas flowing, however the clinician must manually provide ventilation using the equipped bag.
- When the device is in manual ventilation, maximum pressure is managed by the adjustable pressure limit (APL) knob. If ventilating the patient manually, ensure the APL pressure limit is appropriate for the patient. Too low of an APL setting may result in no flow actually delivered to the patient. Too high of an APL setting may result in barotrauma.
- Mechanical ventilation begins by moving the "Bag to Vent" switch to the Vent position. Ventilation will begin at the previously configured / default settings. Always ensure the ventilation settings are appropriate for the patient prior to starting mechanical ventilation. Automatic pressure protection using the Pmax setting is enabled while in mechanical ventilation.
- Consider placing the device in manual ventilation mode ("Bag Mode"), if a closed suction routine is required. Closed suction while in mechanical ventilation may temporarily cause system alarms. As discussed above, confirm the APL valve setting is appropriate for the patient to avoid barotrauma.

Nebulization

 Anesthesia devices are not equipped with compensations for external flows added, such as with pneumatic nebulizers. It is not recommended to use nebulized drugs added to the ventilation with these devices.

Troubleshooting

- Because anesthesia devices are designed as attended devices, most anesthesia devices do not continue ventilation therapy in the event of a critical device malfunction. Ensure the device troubleshooting information (located in the instructions for use) is available at all times. In the event of a system error, the device may transition to error states (and may not provide ventilation). Ensure constant monitoring of the device and patient status.
- The device bellows provides a visual indicator of ventilation status. If the bellows is not rising and falling, there is no ventilation being provided.

- Anesthesia devices equipped with an electronic gas mixture may provide 100% oxygen flow (Alternate O2, "Alt O2") in the event of a mixer failure. Ensure the Alt O2 flow setting is adequate to provide oxygenated gas to the patient prior to starting mechanical ventilation.
- Anesthesia devices can utilize manual ventilation mode, with either "Alt O2" or flow knobs, to manually deliver oxygenated flow to the patient in the event of an emergency.
- Please follow the normal practices for reporting of any adverse events to GE Healthcare and local regulatory authorities.

If you have any additional questions, please reach out to your local GE Healthcare representative.

Sincerely,

Matti E. Lehtonen

General Manager, Anesthesia and Respiratory Care

GE Healthcare



GE's APPENDIX 1: Intended Use/Indications for Use

PLEASE SEE NEXT PAGE FOR RESOURCE CONTENT

Appendix 1: Intended Use/Indications for Use

Note: Products may not be available in all markets.

Device: Aisys CS2

The GE Datex-Ohmeda Aisys CS2 Anesthesia System is intended to provide general inhalation anesthesia and ventilatory support to a wide range of patients (neonatal, pediatric, adult). The device is intended for volume or pressure control ventilation.

Device: Avance CS2

The GE Datex-Ohmeda Avance CS2 is intended to provide general inhalation anesthesia and ventilatory support to a wide range of patients (neonatal, pediatric, adult). The device is intended for volume or pressure control ventilation.

Device: Carestation 620/650/650c

The Carestation 620/650/650c anesthesia systems are intended to provide general inhalation anesthesia and ventilatory support to a wide range of patients (neonatal, pediatric, adult). The anesthesia systems are suitable for use in a patient environment, such as hospitals, surgical centers, or clinics. The systems are intended to be operated by a clinician qualified in the administration of general anesthesia.

Device: Aisys

The GE Datex-Ohmeda Aisys Anesthesia System is intended to provide general inhalation anesthesia and ventilatory support to a wide range of patients (neonatal, pediatric, adult). The device is intended for volume or pressure control ventilation. The Aisys is not suitable for use in a MRI environment.

Device: Avance

The GE Datex-Ohmeda Avance Anesthesia System is intended to provide general inhalation anesthesia and ventilatory support to a wide range of patients (neonatal, pediatric, adult). The device is intended for volume or pressure control ventilation.

Device: Aespire View

The Aespire View anesthesia system is intended to provide general inhalation anesthesia and ventilatory support to a wide range of patients. The device is intended for volume or pressure control ventilation.

Device: Aespire 7900

The family of GE Datex-Ohmeda Aespire anesthesia systems with 7900 ventilator (Aespire 7900 and Aespire View) is intended to provide general inhalation anesthesia and ventilatory support to a wide range of patients. The devices are intended for volume or pressure control ventilation.

Device: Aestiva MRI

The Aestiva/5 MRI Anesthesia System provides the functional feature set offered by the conventional Aestiva/5 to the clinician with the added ability to be used in the MR environment. Among those standard Aestiva/5 features is the Datex-Ohmeda user interface, all the ventilation parameters of the SmartVent along with Aestiva breathing circuit. The Aestiva/5 MRI Anesthesia System performed to specifications when tested directly next to 1.5 and 3.0 Tesla shielded MRI devices in a field strength that did not exceed 300 gauss.

Device: Aestiva 7900

This version of the Datex-Ohmeda 7900 Ventilator is used in Datex-Ohmeda Aestiva Anesthesia Systems. It is a microprocessor based, electronically controlled, pneumatically driven ventilator that provides patient ventilation during surgical procedures. The 7900 ventilator is equipped with a built-in monitoring system for inspired oxygen, airway pressure and exhaled volume. Sensors in the breathing circuit are used to control and monitor patient ventilation as well measure inspired oxygen concentration. This allows for the compensation of compression losses, fresh gas contribution and small leakage in the breathing absorber, bellows and system. User setting and microprocessor calculations control breathing patterns. User interface keeps settings in memory. The user may change settings with a simple and secure setting sequence. A bellows contains breathing gasses to be delivered to the patient. Positive End Expiratory Pressure

(PEEP) is regulated electronically. Positive pressure is maintained in the breathing system so that any leakage that occurs is outward. An RS-232 serial digital communications port connects to and communicates with external devices. Ventilatory modes for the device, include Volume Mode, Pressure Control Mode, Synchronous Intermittent Mandatory Ventilation (optional), Pressure Support with Apnea Backup Ventilation. (optional).

This device is to be used only by trained and qualified medical professionals.

Device: 9100c NXT**

**Not cleared or approved in the US or Canada.

The 9100c NXT anesthesia systems are intended to provide general inhalation anesthesia and ventilator support to a wide range of patients (neonate, pediatric and adult). The anesthesia systems are suitable for use in a patient environment, such as hospitals, surgical centers, or clinics. The systems are intended to be operated by a clinician qualified in the administration of general anesthesia.

Device: 9100c**

**Not cleared or approved in the US or Canada.

The 9100c anesthesia machine is a compact, integrated, and intuitive anesthesia delivery system. The 9100c anesthesia machine provides general inhalation anesthesia and ventilatory support for patients during surgery as well as monitoring and displaying various patient parameters. This anesthesia system is designed for mixing and delivering inhalation anesthetics, Air, O2 and N2O. This anesthesia system is not suitable for use in an MRI environment. This system must only be operated by medical personnel

authorized and trained to use this product. It must be operated according to the instructions in this User's Reference Manual

GE's APPENDIX B: Setup and Monitoring Instructions – Anesthesia Machine as an ICU Ventilator

Appendix B

Setup and Monitoring Instructions - Anesthesia Machines as an ICU Ventilator

SETUP

- Insure manual ventilation device readily available
 - Connect/Check Central Gas Supplies
 - o Check Line pressure 45 psi or better
 - o Full E-cylinders of oxygen and air as backup
 - Remove nitrous oxide hoses and cylinders
 - Bellows ventilators configured for compressed air supply Biomed can do with manufacturer guidelines
 - Scavenger
 - Connect to suction or allow to enter patient room
 - Vaporizers
 - o Remove or drain
 - Configure machine with disposables
 - o Breathing Circuit
 - Filters
 - HMEF on airway, gas sampling on machine side
 - Second filter on the expiratory limb if possible (required if no filter on airway)
 - ?? Active humidifiers NOT recommended but may be needed if no HME. Will require special monitoring if placed.
 - o Large (3 Liter) Reservoir Bag
 - Gas analyzer for oxygen and carbon dioxide
 - Perform Self-Test
 - o Compliance measurement essential do not change disposables after this
 - Confirm no errors
 - Check alarms, set limits, set to max volume NOTE: Defaults may not apply to ICU patients
 - Inspired CO2 alarm at 5 mmHg
 - o Expired CO2 alarm for permissive hypercapnia
 - o Pressure alarms High and low if apnea pressure alarm
 - Volume/Minute Ventilation
 - Set APL valve to 0 cmH20

INITIATE THERAPY

- Fresh Gas Flow Options
 - Option 1: Low fresh gas flow to conserve oxygen
 - Preserves humidity
 - CO2 Absorbent must be available and maintained
 - Inspired CO2 Alarm must be set to 5 mmHg
 - Option 2: Fresh gas flow => minute ventilation
 - No CO2 Absorbent needed (increase FGF if Inspired CO2 present)
 - Humidification is essential consider active humidifier

Setting Oxygen Concentration

- o Electronic Flowmeters Set delivered concentration and monitor inspired oxygen that results
- Mechanical Flowmeters
- o Air/oxygen mix needed for delivered O2 concentration (see table)
- o Inspired oxygen concentration will need to be monitored especially during low flows it will be less than the set concentration

Set Ventilator (See CCM guidance)

- Ventilation Mode
- Settings
- o Rate
- o Volume
- o I:E Ratio
- o PEEP

Start Ventilator

- SET SPIROMETRY LOOP REFERENCE IF AVAILABLE WHEN VENTILATION STARTED
- O NOTE PRESSURE AND FLOW WAVEFORMS CONSIDER PHOTO OF BASELINE SCREEN
- Record monitored values
- Pressure Volume relationships
- Gas concentrations as expect



Setup and Monitoring Instructions – Anesthesia Machine as an ICU Ventilator

MONITORING SCHEDULE (Record manually time and value if EMR not connected to machine)

Task	Continuous	Hourly	q 4 hours	q 24 hours
Alarms	X			
CO2 Absorbent		X		
 Monitored Parameters Insp Oxygen Insp and Exp CO2 Insp Pressure Tidal Volume Spirometry Agent concentration 		X		
Inspect for humidity and secretions • Filters • Water trap		Х		
Check Vap Fill if Sedating				
Change Filter/HME			Х	X (check with RT)
Increase FGF to MV or above for 15 minutes			X	
Perform Self-Test*				X

^{*}Anesthesia machine WILL NOT provide ventilation during the self-test. An alternate ventilation strategy that can be maintained for several minutes is required. Consider transport ventilator if manual ventilation bag not likely to be successful. Power to the machine should be cycled between every patient and at least every 25 days.



COVID-19 Showers & Changing Area Tip Sheet

Overview

As the number of COVID-19 patients increases at Texas Health hospitals, we should have plans in place to provide staff a place to shower and change after their shift is over prior to going home so that they can decrease the risk of potentially bringing COVID-19 back to their families and people they live with.

Process

- a. If your facility has a fitness center, consider utilizing this space
- b. If your facility does not have a fitness center or if the fitness center is not centrally located within the hospital, consider utilizing:
 - i. Closed floors, rooms on low volume floors
 - ii. Physical Therapy or Cardiac Rehab
 - iii. OR and/or L&D locker rooms
 - iv. If none of the above are viable options, please reach out to <u>HannahTupper@texashealth.org</u> for assistance with potential alternatives
- 2. Create a shower schedule
 - a. Suggested shower times: 6:00 A.M. 8:00 A.M and 2:00 P.M. 8:00 P.M.
 - b. Methods for scheduling for all the options below there will need to be a point person/team to manage requests and track volume of staff utilizing showers
 - i. Set up entity call number for scheduling
 - ii. Set up entity SharePoint webform to use for scheduling
 - iii. Assign staff (ex: fitness center staff) to man check-in for showers
- 3. Grant all staff access to showers and changing areas
- 4. Provide plastic bags for used clothing/dirty scrubs for staff to safely transport clothing home
- 5. Work with EVS to set cleaning schedule for showers increase frequency of cleanings if possible
- 6. Communicate availability of showers and changing areas to staff via e-mail
 - a. Utilize the Shower & Changing Area Announcement Flyer (Attached Below on page 49)

Showers & Changing Areas Now Available

Hours of Operation:

6 - 8 a.m. and 2 - 8 p.m.

7 days a week

Add information on how to access showers/changing areas

Add information on how to schedule a shower

Please bring the following:

- Texas Health ID Badge
- Towel
- Shower Shoes
- Toiletries
- Change of clothes

A bag will be provided for used clothing/scrubs





COVID-19 Greeter Guidelines for Patients and Visitors

Updated Monday, April 6, 2020 9:00 am | Includes Texas Travel History Screening

A staff member will greet every <u>patient and potential visitor</u> entering a Texas Health facility. Staff will determine <u>if the patient requires a face mask</u> to protect against COVID-19, flu, or other contagious illness. Staff will also determine <u>if a visitor is allowed to enter</u> a Texas Health facility. NOTE: These guidelines are only for patients and visitors.

What to do:

Greet patients with good morning, afternoon or evening.

To help protect our patients, caregivers and community we are asking all <u>patients</u> several questions.

- 1. Are you short of breath? [Direct to ED or call internal code if emergent or in distress]
- 2. Have you been around someone with COVID-19, or who is waiting on test results?
- 3. Do you have a cough?
- 4. Do you have a fever now or have you had a fever recently?
- 5. In the last 14 days have you traveled to Texas and:
 - a. went through an airport in the states of New York, New Jersey, Connecticut, or the city of New Orleans?
 - b. are returning from Louisiana by road or air travel?
 - c. are returning by air from:
 - i. State of California
 - ii. State of Washington
 - iii. City of Atlanta, Georgia
 - iv. City of Chicago, Illinois
 - v. City of Detroit, Michigan
 - vi. City of Miami. Florida

If a patient answers "YES" to one or more of the questions:

Ask them to put on a face mask and explain that they need to keep the mask on while in the facility.

If you see visitors accompanying the patients, inform the patient that there are no visitors allowed at this time except for special circumstances.

"For your safety, we are not allowing visitors unless you have a special circumstance. I need to find out more about why you're here to determine if you can have a visitor."

EMERGENCY DEPARTMENT CARE OR HOSPITAL OUTPATIENT CARE

If patient is receiving care in the Emergency Department or Hospital Outpatient Services, do they have <u>an</u> <u>impairment or mobility need</u>?

- NO: To help protect our patients, caregivers and community we have implemented a new no visitor policy. I'm sorry, we're not allowing visitors.
- YES: To help protect our patients, caregivers and community we have implemented a new visitor policy. I'll need to tell you more about it before we proceed.



- Patients with impairments or mobility needs can have only one visitor in our waiting area but will be escorted to the treatment area by staff alone.
- We will need to ask you a few questions before coming into the hospital.
 - Do you have a fever of 100.0 F or higher?
 - Are 16 years old or younger?
 - Have shortness of breath, cough or fever?
 - Have you been around someone with COVID-19, or who is waiting on test results?
 - In the last 14 days have you traveled to Texas and:
 - went through an airport in the states of New York, New Jersey, Connecticut, or the city of New Orleans?
 - are returning from Louisiana by road or air travel?
 - are returning by air from:
 - State of California
 - State of Washington
 - o City of Atlanta, Georgia
 - o City of Chicago, Illinois
 - o City of Detroit, Michigan
 - o City of Miami, Florida

If a visitor answers "NO" to all the following questions, they may enter the facility. Please advise them:

Please remember that for the safety of our patient and staff, you'll not be allowed back into the treatment area and it's important to:

- Keep a social distance of at least 6 feet from others
- Practice good hand washing
- Follow all hospital staff instructions

If a visitor answers "YES" to one or more of the following questions, do not let them into the facility. I'm sorry we're not able to allow you to enter today with a symptom that could indicate a contagious illness.

ALL OTHER CARE SETTINGS

If patient is receiving care in:

- Hospital Inpatient, no visitors allowed. Exceptions may be made for critically ill patients who may be at end of life. Elevate to shift leader to determine if appropriate. All visitors will be screened as above, given a mask and wristband.
- Labor and Delivery/Postpartum, one visitor only (subject to health screening). No doulas for Persons Under Investigation (PUI).
- Neonatal ICU (NICU), two parents/guardians only (subject to health screening).

If patient attempts to bring a visitor that does not meet the criteria above for exceptions:



You will not be able to have a visitor accompany you. We know that support is important. But we have changed our policy to help slow the spread of COVID-19 in our community.

If patient has a visitor that does meet the criteria for exceptions:

To help protect our patients, caregivers and community we have implemented a new visitor policy. I'll need to tell you more about it before we proceed.

- We will need to ask you a few questions before coming into the hospital, and we'll also need to take your temperature.
 - Anyone who have a temperature over 100.0°F will not be allowed to enter today, as that symptom could indicate illness. If visitor refuses temperature, inform them that if we're unable to screen them, they are not able to enter today.
- o If the forehead temperature is below 100.0 F, tell the visitor their temperature, and proceed:
 - Now, I have to ask you a few questions:
 - Are 16 years old or younger?
 - Have shortness of breath, cough or fever?
 - Have you been around someone with COVID-19, or who is waiting on test results?
 - In the last 14 days have you traveled to Texas and:
 - o went through an airport in the states of New York, New Jersey, Connecticut, or the city of New Orleans?
 - o are returning from Louisiana by road or air travel?
 - o are returning by air from:
 - State of California
 - State of Washington
 - City of Atlanta, Georgia
 - City of Chicago, Illinois
 - City of Detroit, Michigan
 - City of Miami, Florida

If a visitor answers "NO" to all the following questions, they may enter the facility. Please advise them:

Please remember that for the safety of our patient and staff, you'll not be allowed back into the treatment area and it's important to:

- Keep a social distance of at least 6 feet from others
- Practice good hand washing
- Follow all hospital staff instructions

If a visitor answers "YES" to one or more of the following questions, do not let them into the facility. I'm sorry we're not able to allow you to enter today with a symptom that could indicate a contagious illness.



Hotel rooms for caregivers

FRONT-LINE WORKERS

Hilton/American Express Frontline Medical Professionals Room Program

Situation

Texas Health employees who wish to stay in a hotel while treating COVID patients have the opportunity to access free rooms across North Texas.

Background

Hilton and American express are donating one million hotel room nights across the US for frontline medical professionals through May 31, 2020. Rooms are first come, first served and may be reserved for 7 nights at a time, subject to availability.

Analysis

Hilton properties participating in the program are designated with a green box in this deck. Other Hilton properties participating in the program may be found by clinking on the Frontline Medical Professional Discount link and searching by location and date.

Recommendation

Texas Health employees who wish to access the program need to do two things:

- 1. Follow the embedded Frontline Medical Professional Discount link to reserve a room at their preferred participating Hilton hotel; **AND**
- 2. Email Ann Marie Bell at the American Hospital Association (abell2@aha.org) and let her know 1) You are employed by Texas Health and have a Texas Health ID and 2) the city destination where you want to stay

Please do not share the booking link for this program outside of Texas Health

Best available (non-negotiated) rates as of 4/6

	ТНА	ТНАГ	ТНАМ	ТНАΖ	ТНС	THD	THDN	THFW	王	ТННЕВ	Ŧ	王	THS	THSW
Bw western.				\$60							\$60			
Hilton	\$71	\$79	\$50		\$68	\$79	\$0	\$90	\$83	\$71		\$59	\$70	\$87
Marriott. HOTELS- RESORTS- SUITES	\$79	\$7 1	\$69		\$59	\$25	\$69	\$59	\$77	\$71		\$76		\$84
WYNDHAM HOTELS & RESORTS	\$59		\$50	\$69	\$43	\$50	\$55		\$59	\$43		\$59	\$45	\$50

National Rate, book online; actual pricing depends on specific check in/out dates and length of stay



Caregiver discounts: Allen

Hilton/AmEx Program



Homewood Suites

455 N Central Expy Allen, TX 75013 (214) 383-6673

Estimated price with discount:

\$0/night

How to access:

Email Ann Marie Bell at AHA (pg. 54) and follow link below to reserve

https://www.100millionmasks.org/hilton-honorsand-american-express-hotel-rooms-offer



Residence Inn Dallas Allen/ Fairview

295 Murray Farm Road Fairview, Texas 75069 (972) 548-480

Estimated price with discount:

\$79/night

How to access:

Go to Marriott.com Enter destination city; under Special Rates, click Corporate / Promo / SET# and enter code: **QWO**

WYNDHAM HOTELS & RESORTS

LaQuinta Inn & Suites at The Village

1220 N Central Expy Allen, TX 75013 (214) 667-6772

Estimated price with discount:

\$59/night

How to access:

Call hotel directly and identify as a Texas Health employee

Caregiver discounts: Alliance

Hilton/AmEx Program



Hilton Garden Inn Fort Worth Alliance Airport

2600 WestPort Parkway Fort Worth, TX 76177 (817) 562-3047

Estimated price with discount:

\$0/night

How to access:

Email Ann Marie Bell at AHA (pg. 54) and follow link below to reserve

https://www.100millionmasks.org/hilton-honorsand-american-express-hotel-rooms-offer Marriott.

Residence Inn Fort Worth Fossil Creek

3751 NE Loop 820 Fort Worth, Texas 76137 817-847-0044

Estimated price with discount:

\$71/night

How to access:

Go to Marriott.com Enter destination city; under Special Rates, click Corporate / Promo / SET# and enter code: **QWO**



Caregiver discounts: Arlington

Hilton/AmEx Program



Hilton Garden Inn Arlington South

521 E Interstate 20 Arlington, TX (817) 557-8233

Estimated price with discount:

\$0/night

How to access:

Email Ann Marie Bell at AHA (pg. 54) and follow link below to reserve

https://www.100millionmasks.org/hilton-honors-and-american-express-hotel-rooms-offer

Hilton

Hilton Arlington

2401 E Lamar Blvd Arlington, TX 76006 (817) 640-3322

Estimated price with discount:

\$59/night

How to access:

Call hotel directly, identify as a Texas Health employee, and request the essential personnel rate offered through the Arlington Convention Bureau



Sheraton of Arlington

1500 Convention Center Dr Arlington, TX 76011 (817) 261-8200

Estimated price with discount:

\$69/night

How to access:

Go to Marriott.com Enter destination city; under Special Rates, click Corporate / Promo / SET# and enter code: **QWO**



Spring Hill Suites

1975 E Lamar Blvd Arlington, TX 76006 (817) 860-2737

Estimated price with discount:

\$79/night

How to access:

Call hotel directly, identify as a Texas Health employee, and request the rate offered through the Arlington Convention Bureau



LaQuinta Inn & Suites Arlington North

825 N Watson Rd Arlington, TX 76011 (817) 640-4142

Estimated price with discount:

\$50/night

How to access:

Call hotel directly and identify as a Texas Health employee



Caregiver discounts: Azle



Hilton Garden Inn Fort Worth Alliance Airport

2600 WestPort Parkway Fort Worth, TX 76177 (817) 562-3047

Estimated price with discount:

\$0/night

How to access:

Email Ann Marie Bell at AHA (pg. 54) and follow link below to reserve

https://www.100millionmasks.org/hilton-honorsand-american-express-hotel-rooms-offer



Best Western Plus Lake Worth Inn & Suites

3920 Boat Club Rd Lake Worth, TX 76135 (817) 238-1199

Estimated price with discount:

\$60/night

How to access: Call hotel directly, ask for Nilesh

WYNDHAM HOTELS & RESORTS

LaQuinta Inn & Suites Fort Worth

5800 Quebec St Fort Worth, TX 76135 (817) 900-3814

Estimated price with discount:

\$69/night

How to access:

Call hotel directly and identify as a Texas Health employee

Caregiver discounts: Cleburne

Hilton/AmEx Program

Hilton

Hampton Inn & Suites

1996 W Henderson St Cleburne, TX 76033 (817) 641-7770

Estimated price with discount:

\$0/night

How to access:

Email Ann Marie Bell at AHA (pg. 54) and follow link below to reserve

https://www.100millionmasks.org/hilton-honors-andamerican-express-hotel-rooms-offer Hilton/AmEx Program

Hilton

Hampton Inn & Suites Fort Worth South/Burleson

13251 Jake Ct Cross Timber, TX 76028 (817) 295-2727

Estimated price with discount:

\$0/night

How to access:

Email Ann Marie Bell at AHA (pg. 54) and follow link below to reserve

 $\frac{https://www.100millionmasks.org/hilton-honors-and-american-express-hotel-rooms-offer}{}$

WYNDHAM HOTELS & RESORTS

Super 8

1707 W Henderson St Cleburne, TX 76033 (817) 556-3330

Estimated price with discount:

\$43/night

How to access:

Call hotel directly and identify as Texas
Health employee or <u>Direct Booking Link</u>
(ctrl+click to follow)



Caregiver discounts: Dallas

Hilton/AmEx Program
Hilton

Hilton Anatole

2201 North Stemmons Freeway Dallas, TX 75207 (214) 748-1200

Estimated price with discount:

\$0/night

How to access:

Email Ann Marie Bell at AHA (pg. 54) and follow link below to reserve

 $\frac{https://www.100millionmasks.org/hilton-honors-and-american-express-hotel-rooms-offer}{}$

Hilton

Home2Suites Dallas North Park

8180 Midtown Blvd Dallas, TX 75231 (469) 232-9351

Estimated price with discount:

\$83/night

How to access:

Go to <u>Heart of Hilton</u> (ctrl+click to follow), enter city and dates; promo code is automatically applied



Courtyard Dallas Richardson Spring Valley

1000 S Sherman St Richardson, TX 75081 (972) 235-5000

Estimated price with discount:

\$25/night

How to access:

Go to Marriott.com Enter destination city; under Special Rates, click Corporate / Promo / SET# and enter code: QWO



Courtyard Dallas Central Expressway

10325 N Central Expy Dallas, TX 75231 (214) 739-2500

Estimated price with discount:

\$25/night

How to access:

Go to Marriott.com Enter destination city; under Special Rates, click Corporate / Promo / SET# and enter code: **QWO**



Garden Dallas North

2645 Lyndon B Johnson Fwy Dallas, TX 75234 (972) 243-3363

Estimated price with discount:

Free

How to access:

Call hotel directly and identify as a Texas Health employee

WYNDHAM HOTELS & RESORTS

LaQuinta Inn & Suites Dallas North Central

10001 N Central Expy Dallas, TX 75231 (214) 361-8200

Estimated price with discount:

\$50/night

How to access:

<u>Direct booking link</u> (ctrl+click to follow), enter city and dates; promo code is automatically applied



Caregiver discounts: Denton

Hilton

Embassy Suites Denton Convention Center

3100 Town Center Tr Denton, TX 76201 (940) 243-3799

Estimated price with discount:

\$79/night

How to access:

Go to <u>Heart of Hilton</u> (ctrl+click to follow), enter city and dates; promo code is automatically applied Hilton/AmEx Program

Hilton

Hampton Inn & Suites

1513 Centre Place Drive Denton, TX 76205 940-891-4900

Estimated price with discount:

\$0/night

How to access:

Email Ann Marie Bell at AHA (pg. 54) and follow link below to reserve

 $\frac{https://www.100million masks.org/hilton-honors-and-american-express-hotel-rooms-offer}{}$

Hilton/AmEx Program

Hilton

Hilton Garden Inn

3110 Colorado Blvd Denton, TX 76210 940-891-4700

Estimated price with discount:

\$0/night

How to access:

Email Ann Marie Bell at AHA (pg. 54) and follow link below to reserve

https://www.100millionmasks.org/hilton-honors-and-american-express-hotel-rooms-offer



Spring Hill Suites

1434 Centre Place Drive Denton, TX 76205 940-383-4100

Estimated price with discount:

\$69/night

How to access:

<u>Direct booking link</u> (ctrl+click to follow), enter city and dates; promo code is automatically applied



LaQuinta Inn & Suites

4465 I 35 Frontage Rd Denton, TX 76207 (940) 808-0444

Estimated price with discount:

\$55/night

How to access:

Call hotel directly and identify as a Texas Health employee



Caregiver discounts: Fort Worth



Hilton Garden Inn Fort Worth Medical Center

912 Northton St Fort Worth, TX 76104 (817) 921-0788

Estimated price with discount:

\$90/night

(30% discount off regular rates)

How to access:

Go to <u>Heart of Hilton</u> (ctrl+click to follow), enter city and dates; promo code is automatically applied



Home2 Suites Fort Worth Southwest Cityview

5401 SW Loop 820 Fort Worth, TX (817) 349-3782

Estimated price with discount:

\$0/night

How to access:

Email Ann Marie Bell at AHA (pg. 54) and follow link below to reserve

 $\frac{https://www.100 million masks.org/hilton-honors-and-american-express-hotel-rooms-offer}{}$



Spring Hill Suites Fort Worth Stockyards

2315 N Main St Fort Worth, TX 76164 (682) 255-5100

Estimated price with discount:

\$59/night

How to access:

Go to Marriott.com Enter destination city; under Special Rates, click Corporate / Promo / SET# and enter code: **QWO**



Courtyard Fort Worth Downtown/Blackstone

601 Main Street Fort Worth, TX 76102 (817) 885-8700

Estimated price with discount:

\$79/night

How to access:

Go to Marriott.com Enter destination city; under Special Rates, click Corporate / Promo / SET# and enter code: **QWO**



Caregiver discounts: Frisco



Hampton Inn & Suites Dallas/Frisco North

6070 Sports Village Road Frisco, TX 75033 (972) 668-4200

Estimated price with discount:

\$0/night

How to access:

Email Ann Marie Bell at AHA (pg. 54) and follow link below to receive

https://www.100millionmasks.org/hilton-honors-and-american-express-hotel-rooms-offer



TownePlace Suites Dallas Plano/Legacy

5005 Whitestone Lane Plano, TX 75024 (469) 969-0953

Estimated price with discount:

\$77/night

How to access:

Go to Marriott.com Enter destination city; under Special Rates, click Corporate / Promo / SET# and enter code: **QWO**



LaQuinta Inn & Suites Dallas/Plano

6624 Communications Pkwy Plano, TX 75024 (214) 265-8900

Estimated price with discount:

\$59/night

How to access:

Call the hotel directly and identify as a Texas Health employee



Wingate by Wyndham Frisco

14700 State Highway 121 Frisco, TX 75035 (214) 504-3974

Estimated price with discount:

\$64/night

How to access:

Go to link <u>Wyndham Hotels and</u> <u>Resorts COVID Emergency Rate</u> Enter Frisco as the destination. Rate will automatically populate.



Caregiver discounts: HEB



Homewood Suites Fort Worth - Bedford

2401 Airport Fwv Bedford, TX 76021 (817) 283-5006

Estimated price with discount:

\$0/night

How to access:

Email Ann Marie Bell at AHA (pg. 54) and follow link below to reserve

https://www.100millionmasks.org/hilton-honors-and-american-express-hotel-rooms-offer



SpringHill Suites Dallas/Arlington North

1975 E. Lamar Blvd Arlington, TX 76006 (817) 860-2737

Estimated price with discount:

\$71/night

How to access:

Go to Marriott.com Enter destination city; under Special Rates, click Corporate / Promo / SET# and enter code: **QWO**

WYNDHAM

Super 8 Bedford DFW Airport West

1800 Airport Ewy Bedford, TX 76022 (817) 803-4055

Estimated price with discount:

\$43/night

How to access:

Call hotel directly and identify as a Texas Health employee or <u>Direct booking link</u> (ctrl+click to follow)

Caregiver discounts: Kaufman



Tru by Hilton Terrell

200 Olivia Drive Terrell, TX 75160 (469) 837-7200

Estimated price with discount:

\$0/night

How to access:

Email Ann Marie Bell at AHA (pg. 54) and follow link below to reserve

https://www.100millionmasks.org/hilton-honors-andamerican-express-hotel-rooms-offer Best Western

Best Western LaHacienda Inn

200 E US-175 Frontage Rd Kaufman, TX 75142 (972) 962-6272

Estimated price with discount

\$60/night

How to access:

Call hotel directly and identify as a Texas Health employee



Caregiver discounts: Plano



Homewood Suites North Dallas - Plano

4705 Old Shepard Pl Plano, TX 75093 (972) 758-8800

Estimated price with discount:

\$59/night

How to access:

Call hotel directly and identify as a Texas Health employee



Hampton Inn & Suites

Dallas - The Colony

3650 Plano Parkway The Colony, TX 75056 (469) 362-1111

Estimated price with discount:

\$0/night

How to access:

Email Ann Marie Bell at AHA (pg. 54) and follow link below to reserve

https://www.100millionmasks.org/hilton-honors-and-american-express-hotel-rooms-offer



Courtyard Dallas Plano/ Legacy Park

6840 North Dallas Parkway Plano, Texas 75024 (972) 403-0802

Estimated price with discount:

\$79/night

How to access:

Go to Marriott.com Enter destination city; under Special Rates, click Corporate / Promo / SET# and enter code: **QWO**



Residence Inn Dallas Plano/Legacy

5001 Whitestone Lane Plano, Texas 75024 (972) 473-6761

Estimated price with discount:

\$76/night

How to access:

Go to Marriott.com Enter destination city; under Special Rates, click Corporate / Promo / SET# and enter code: **QWO**



LaQuinta Inn & Suites Dallas/Plano

6624 Communications Pkwy Plano, TX 75024 (214) 265-8900

Estimated price with discount:

\$59/night

How to access:

Call hotel directly and identify as a Texas Health employee



Caregiver discounts: Stephenville



Hampton Inn & Suites

910 South Harbin Drive Stephenville, TX 76401 (254) 918-5400

Estimated price with discount:

\$0/night

How to access:

Email Ann Marie Bell at AHA (pg. 54) and follow link below to reserve

https://www.100millionmasks.org/hilton-honors-andamerican-express-hotel-rooms-offer

WYNDHAM HOTELS & RESORTS

Super 8 Stephenville

921 S Second Street Stephenville, TX 75401 (254) 965-0888

Estimated price with discount:

\$45/night

How to access:

Call hotel directly and identify as a Texas Health employee or <u>Direct Booking Link</u> (ctrl+click to follow)

Caregiver discounts: Southwest



Homewood Suites Fort Worth CityView

6350 Overton Ridge Blvd Fort Worth, TX 76132 (817) 585-1160

Estimated price with discount:

\$0/night

How to access:

Email Ann Marie Bell at AHA (pg. 54) and follow link below to reserve

 $\frac{https://www.100millionmasks.org/hilton-honors-and-american-express-hotel-rooms-offer}{}$



Fairfield Inn & Suites Fort Worth SW at CityView

4880 Citylake Blvd E Fort Worth, TX 76132 (682) 250-7500

Estimated price with discount:

\$84/night

How to access:

Go to Marriott.com Enter destination city; under Special Rates, click Corporate / Promo / SET# and enter code: **QWO**

WYNDHAM HOTELS & RESORTS

LaQuinta Inn & Suites Fort Worth CityView

4900 Bryant Irvin Rd Fort Worth, TX 76132 (817) 370-2700

Estimated price with discount:

\$50/night

How to access:

<u>Direct booking link (ctrl+click to follow)</u>, enter city and dates; promo code is automatically applied



Clinical Guideline for Environmental Cleaning

Room Type	Type Pressure Relationship		Minutes between Patient Occupancy				
Patient Room	N/A	6	46				
Operating Room	+	20	21				
C Section Suite	+	20	21				
ED Triage	-	12	35				
Radiology Areas	N/A	6	46				
Bronchoscopy	-	12	35				
Isolation Rooms	-	12	35				
Cath Lab	+	15	28				
Trauma Rooms	+	15	28				

Texas Health Resources Guideline for Environmental Cleaning

Legend

- (+) = Positive Pressure Relationship/Out
- (-) = Negative Pressure Relationship/In
- (N/A) = Not Applicable Air Pressure Relationship
- Once a patient has been discharged or transferred, Healthcare Personnel (including environmental services) may clean the room before the air exchanges have occurred if they are wearing the appropriate PPE for the disease (e.g., gown, gloves, facemask, and face shield for COVID-19).
- Gown and gloves should always be worn during cleaning, even after air exchanges have occurred.
- Routine cleaning and disinfection procedures (e.g., using cleaners and water to pre-clean surfaces prior to applying an EPA-registered, hospital-grade disinfectant to frequently touched surfaces or objects for appropriate contact times as indicated on the product's label) are appropriate for SARS-CoV-2 in healthcare settings, including those patient-care areas in which aerosol-generating procedures are performed.
- If the patient wore a surgical mask during the entirety of their stay, the air exchange requirement is NOT required before cleaning the room or placing another patient in the room.

(Reference Table is based on Texas Administrative Code 25)

References:

https://www.cdc.gov/coronavirus/2019-ncov/infection-control/control-recommendations.html https://www.cdc.gov/infectioncontrol/guidelines/environmental/appendix/air.html#tableb1 https://www.epa.gov/pesticide-registration/list-n-disinfectants-use-against-sars-cov-2



End of Life In-person Visitation Guidelines

In an effort to support our patients who are at the end of their life and provide their families and loved ones the opportunity to have a last visitation, the following guidelines were created. Out of respect for the care teams (the physicians and nurses) caring for these patients and their relationships with the families, we leave the number of visitors to their discretion if they receive a request to include more than 1-2 visitors. However, it is highly recommended to keep the number below five and to as few as possible.

A. Identifying, screening of grieving visitors:

- a. For patients who are imminently dying, 1-2 visitors may be allowed at the bedside for a one-time 15-30 minute visit with the following exclusions:
 - i. Those individuals who are symptomatic or who are COVID +
 - ii. Children younger than 16 years of age
- b. Potential visitors should be screened by a member of the primary care team or nursing staff by phone 1-2 hours prior to arrival with the following questions (Does not apply to ED patients):
 - i. "Have you had a fever of greater than 100°, cough, shortness of breath, or other symptoms recently?"
 - ii. "Have you tested positive for COVID?"

Answers to the questions above should be documented in Care Connect. If the answer to the questions above is "yes", the family member should be informed that they will not be able to visit in person. (See Virtual options for end of life visitation)

Additionally, visitors should be advised that they will be required to don personal protective equipment (PPE) including gloves, gown, face mask and face shield. Visitors who refuse this or have health conditions that hinder their ability to wear this equipment will not be allowed to visit in person. (See Virtual options for end of life visitation)

c. Once visitors are identified by the family and have passed screening for increased infectious risk, nursing staff should enter the visitors' names in the Visitor info section of the Demographics for the patient

B. Procedure for visit:

- a. Visitors can enter through the approved hospital entrance where they will be met by a hospital representative, their temperatures will be checked (must be less than 100°), and they will again be screened for infectious symptoms prior to visitation. Visitors will be masked and escorted to the unit where the patient is located.
- b. Visitors escorted to the hospital unit should wait in the nursing unit family waiting room. The nurse should provide the following guidance to the visitors:
 - i. There should be no touching of the patient above the neck which includes kissing of the face.
 - ii. We strongly advise against hugging the patient.
 - iii. The nurse should clean the patient's hand so the visitors can hold their hand as it is the contact that provides the least risk to the visitor.
 - iv. The visit should be for the shortest time possible and should last no more than 15-30 minutes (any addendum to the timeframe is left to the patient's care teams discretion).



- v. At minimum visitors should wear disposable gloves, gown, face mask, and face shield A nurse or physician should review the procedure for donning/doffing PPE with visitors before they enter the room and should then assist family members in donning PPE.
- vi. Nursing staff should place a clean sheet over the patient's body prior to any contact with the visitor.
- vii. After a maximum of 15-30 minutes the visitors will be asked to exit the room and a nurse or physician will assist with the doffing of PPE. Hand hygiene should be performed after the removal of each article of PPE. After removal of gloves, hand hygiene should be performed. The visitor should be given a clean mask after doffing their PPE and before their walk back to the hospital exit.
- viii. Once PPE has been removed, the visitor cannot reenter the room.
- c. Pastoral Care should be notified by the nursing unit of family's arrival to hospital. A chaplain may deliver pastoral care to grieving visitors outside patient room, maintaining a distance of at least 6 feet to assure safety. The chaplain may deliver grief materials to the unit in person or electronically per the visitor's preference.
- d. Visitors will be escorted to the hospital exit.

C. Additional considerations

- a. Non-COVID patients
 - i. The restrictions around physical contact with the patient for these visitors is at the discretion of the nursing staff.
 - ii. The care team caring for our Non-COVID patients know these patients and can apply their discretion to the PPE requirements around the visitors in order to reduce the usage of PPE. The visitors must remain masked however as they travel to the patient's room and to the hospital exit.

b. Patient belongings

- i. Patient's belongings should be documented in Care Connect, should be placed in a bag and given to the spouse or family member of the patient at the end of the visit. The family should be instructed to handle the patient's belongings with the utmost care using appropriate hand hygiene after handling, or to leave them inside the bag for a few days before handling them.
- ii. The nurse should document in Care Connect the name of the individual that received the patient's belongings.

NOTE: Hospital volume and PPE availability are being closely tracked and are informing the guidelines above. As the situation evolves, the number of visitors may be further restricted, or visitation may be eliminated altogether.



Scripting for In-Person End of Life Visitation

- Family members are met at the ED entrance screened and masked and escort takes them to the family waiting area on the nursing unit they will be visiting.
- The nursing staff will have the preliminary conversation with the visitors.

"Thank you for coming. Hi my name is ______. I am a nurse and I am here to help guide you through this today. I can imagine that this is a very difficult time, but we are honored for you to have this time to say your final words to your loved one. We believe (patient's name) may be able to hear you, so take comfort in knowing that your presence and love will be felt.

So, we encourage you to visit and say whatever you feel is needs to be said. If you are more comfortable sitting in silence that is alright as well.

Please remember that (patient's name) would never want to cause you harm and if you do not feel comfortable or safe going in the room, we want you to know that is fine, too.

However, in this situation, it is very important that we keep you safe and you understand the risk involved. I know there is a lot of information out there on COVID-19, but I would like to moment to explain how it is spread. The COVID-19 virus is spread through droplet germs that are pushed out through breathing and coughing. These droplet germs can land on the (patient's name), on any surfaces, or on you. If you touch (patient's name) and then touch your face, you can also get sick.

With that in mind, here's what we ask you to do in order to keep you and others safe:

Since your visit is limited to 15-30 minutes, think of some things that you would like to say to (patient name) before we go in. 15-30 minutes may seem like a long time, but it can also seem very quick. Also, keep in mind that once your visit is over, you will not be able to go back into (patient's name)'s room for safety purposes. assisting you with putting on a gown, gloves, mask, and goggles before you enter the room.

Once in the room we will ask you to sit in the chair at the bedside. You can hold (patient's name) hand.

For your safety and others, we ask that you do not touch (patient's name) anywhere above their chest. Its preferable that you limit touching to holding (patient name)'s hand. However, if you would like to touch (patients name)'s arm or chest, please do so on top of the sheet. Please keep it mind that is not safe to reach under the sheet to touch or to lay your head on (patient name).

Since this is an emotional time it is common for people to cry. Many people want to wipe their tears, nose, or face when they cry. For your safety, we ask that you while you're in the room that you allow your tears to roll down your face and to not use your hands to wipe them way or wipe your nose. This is important for keeping you and others safe. We will provide you with tissues outside of the room so you can wipe your eyes and nose.

At the end of your visit we will help talk you through hand washing as you remove your protective equipment.

Before we go in, what questions or concerns do you have?