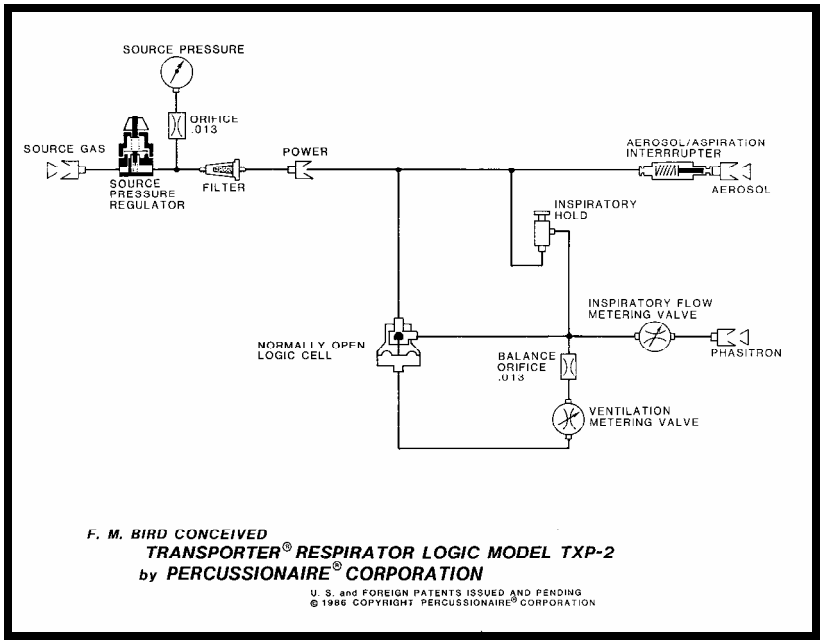
PART THREE

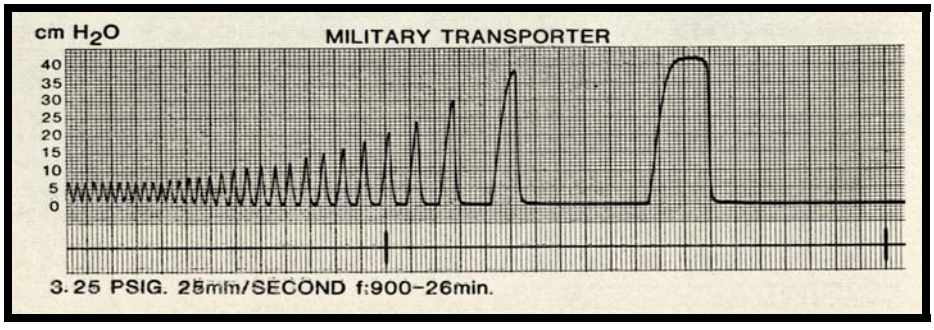
THE FAMILY OF TXP® MILITARY TRANSPORTERS®

The primary single flow/timing cartridge Military Transporter (TXP®-2) consists of a highly reliable acute care ventilator capable of effectively ventilating neonates through pediatrics to adults.

The TXP®-2 Transporter® ventilator for routine or CATASTROPHIC CARE ventilatory applications can be programmed to provide a wide range of percussive ventilatory programming with a single VENTILATORY PROGRAMMING control knob.

Flowrate metering at a selected operational pressure can be controlled by a pre-set regulator or a selectable INSPIRATORY FLOWRATE METERING VALVE.





<u>NOTE: As the single breathing rate control knob is rotated, the ALL IMPORTANT automatically balanced i/e and I/E ratios prevent uncontrolled breath stacking as rates are changed.</u>

THE TXP®-2 has an automatic i/e ratio control based upon the cycling rate selected. For example, at a rate of 10 breaths per minute the I/E ratio is about 1:4 with a decreasing i/e ratio of about 1:1 at cycling rates approaching 600 breaths per minute.

<u>THESE AUTOMATED FEATURES PROVIDE FOR AN IDEAL ACUTE CARE VENTILATOR WITH AN "UNLIMITED PATIENT SELECTION RANGE" IN THE HANDS OF LESSER SKILLED ATTENDING.</u>

ONE MINIATURIZED VENTILATOR WILL VENTILATE ANY HUMAN LUNG CAPABLE OF BEING VENTILATED BY MECHANICAL VENTILATION

LUNG COMPLIANCE PROVIDES FOR A VARIABLE AUTOMATIC FIO_2
<u>FOR THE MOST EFFICIENT OXYGEN UTILIZATION OF ANY VENTILATOR</u>

The mini TXP® housing is highly impact resistant. There is no manometer or any other accessory to break if dropped. Being totally fluidic and <u>without batteries</u> it will function in micro gravity, with all timing circuit gases being delivered to the patient to reduce gas consumption.

Patients with lung injuries could be expected to require an elevated FIO_2. Saturation is enhanced at any FIO_2 by intrapulmonary percussive gas mixing, enhancing gas exchange across the alveolar capillary complex.

Available portable, light weight, high impact (watermelon) compressed gas cylinders with unitized adjustable Pressure Reduction Regulators can provide oxygen for "hours of needed effective ventilation for any patient being capable of being mechanically ventilated".

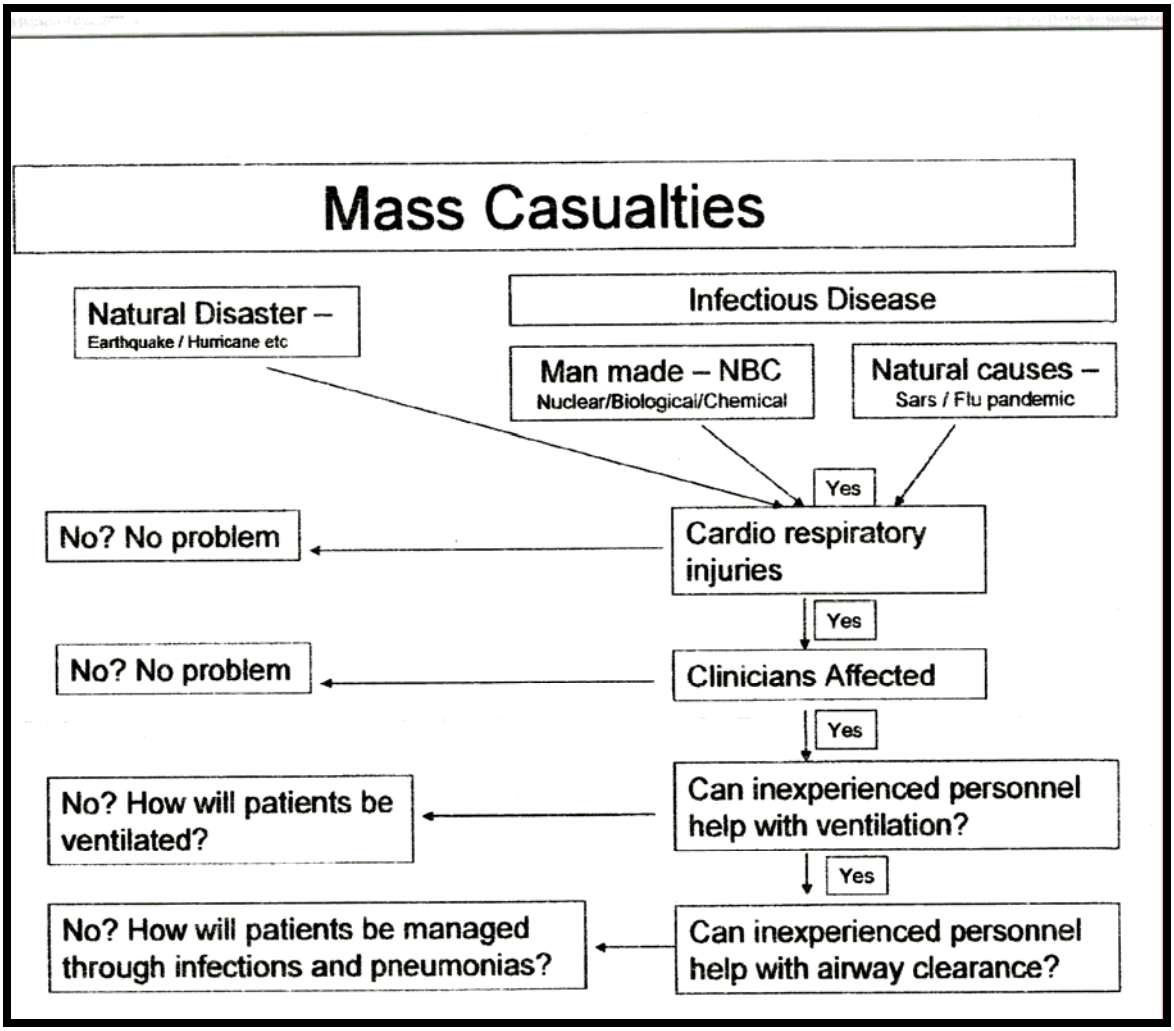
The fluidic time cycled TXP® is volume oriented, that is, it will employ the required reserve PIP (determined by operational gas pressure selection) to deliver the programmed (flow x time) volume under the peak pressure limit determined by the pre-selected operational pressure.

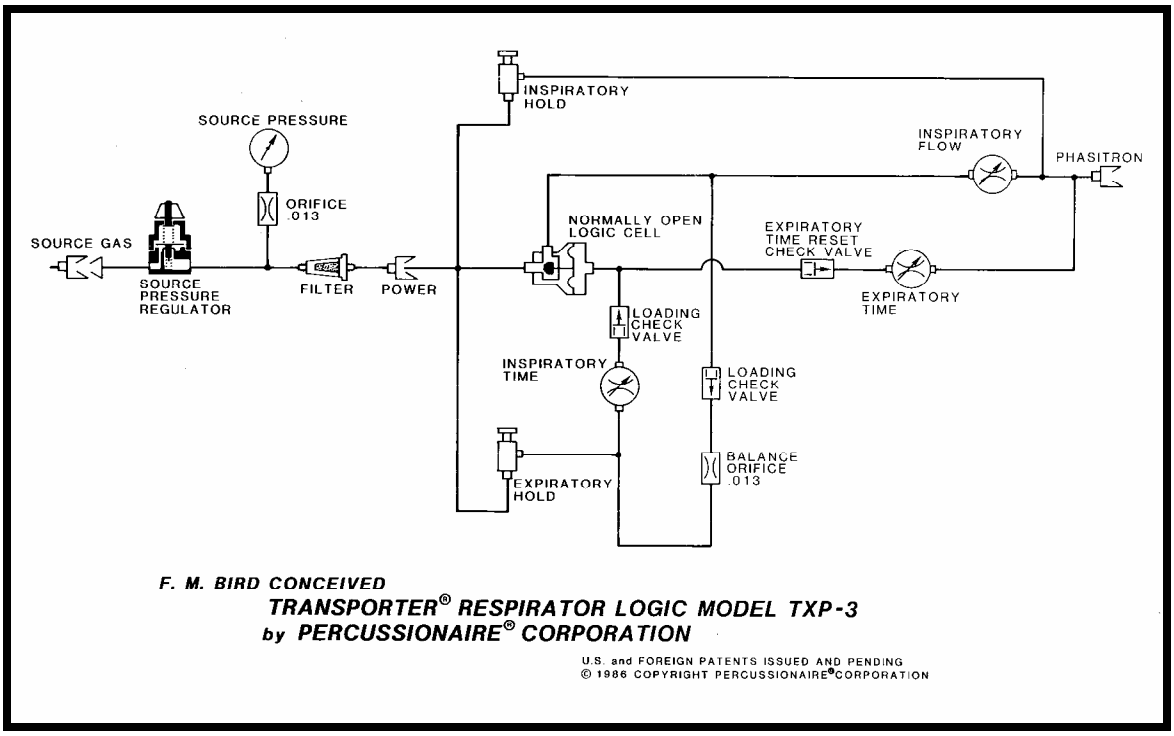
In most cases, the TXP® oxygen capacity should outlast a fully charged electronic respirator battery. Why have a ventilator with patient required oxygen, dependent upon both a battery and a mandated oxygen supply?

The Somalia military experience served to prove that the "state of the art" of emergency ventilator batteries is unknown and variable.

Of late, the New Orleans experience has confirmed the reliability of oxygen powered ventilators not dependent upon batteries or external electrical power supplies.

Most important, the user friendly Universal TXP® ventilator can remain connected to an oxygen supply with breathing circuit accessories in a common weather proof package, with a shelf life of over 10 years, and be ready for instant use by turning ON the oxygen tank valve. Additionally, the TXP Military Transporter® ventilators have been militarily battle hardened, functioning instantly in the coldest or hottest areas of the earth.





THE ABOVE TXP®-3 Military Transporter® ventilator version is designed to provide for a unique standard CMV ventilator with independent FLOWRATE as well as INSPIRATORY and EXPIRATORY TIME SELECTION. This provides for a standard time cycled (volume oriented) CMV ventilator with selectable I/E cycling rates of from 2 to 50 cycles per minute.

The TXP® MILITARY TRANSPORTER® ventilator is also packaged in a shock proof cylindrical housing.

I/E signifies an inspiratory/expiratory time ratio in SECONDS as used in low rate CMV.

i/e signifies an inspiratory/expiratory time ratio in MILLI-SECONDS as used in Higher Frequency ventilatory programming.

HUNDREDS OF THE MILITARY BATTLE HARDENED CYLINDRICAL HOUSED TXP® MILITARY TRANSPORTER RESPIRATOR WERE ORDERED FOR EXPECTED BATTLE CASUALTIES PRECEEDING THE 1991 DESERT STORM MILITARY OPERATIONS DIRECTED TOWARD CONTAINING IRAQ.

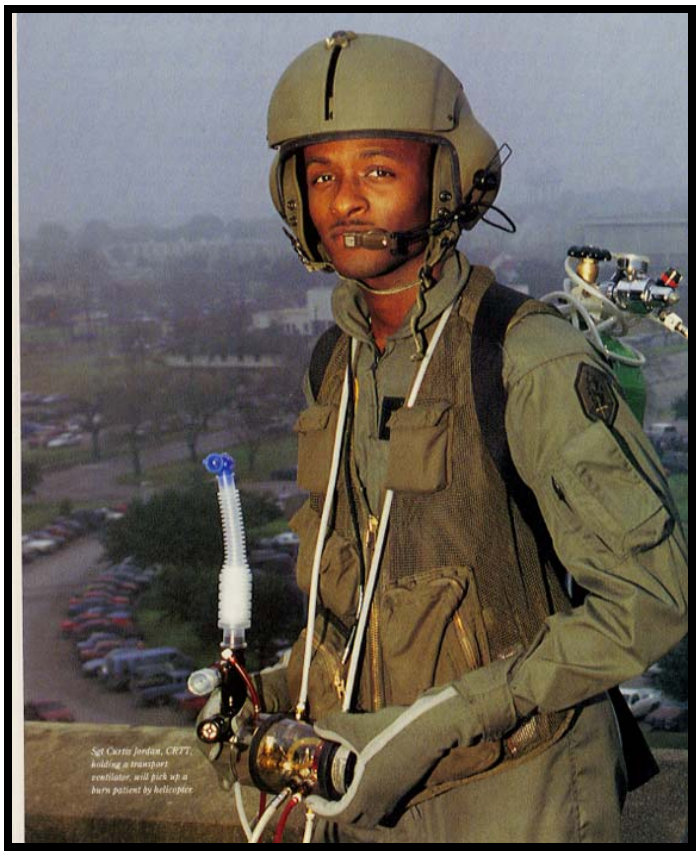
SINCE 1991, VERY LIGHT WEIGHT NEAR SHATTER PROOF HIGH PRESSURE GAS (watermelon shape) CYLINDER TECHNOLOGY HAS CONSIDERABLY ADVANCED, ALLOWING MANY HOURS OF OXYGEN TO BE CONTAINED IN AN OXYGEN BOTTLE ABOUT THE WEIGHT OF THE CLASSICAL MEDICAL E CYLINDER TYPE.

The cylindrical version of the TXP® ventilator provides a manometer for proximal airway pressure monitoring. However, is this accessory really necessary? What useful information under catastrophic resuscitative conditions is the manometer going to present to the Corpsman or EMT?

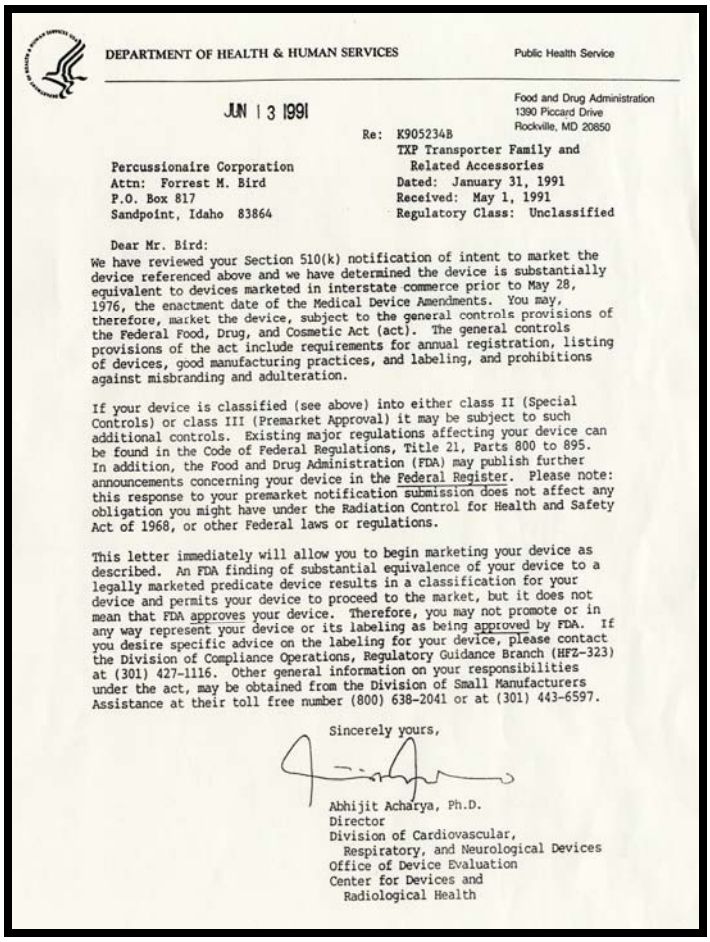
IN RETROSPECT, WAS THE CYLINDRICAL PACKAGED TXP® MILITARY TRANSPORTER THE IDEAL SELECTION, "FOR CATASTROPHIC INDIVIDUAL OR MASS CASUALTY RESUSCIATION" WHEN COMPARED TO THE mini TXP® MILITARY TRANSPORTER® VENTILATOR?

The mini TXP® Transporter® ventilator is only about half the size of the cylindrical housing, and performs the same functions without having to consider the breakage of a manometer "WHEN the ventilator is DROPPED", which it will be.

In reality, ventilation under catastrophic battle stressed environments allows the attending Corpsman or EMT little time for considerations. The light weight miniaturized ruggedized TXP® Military Transporter® ventilator is instantly ready to ventilate the smallest or the largest human lung.



Before and during the Desert Storm military operations, the cylindrical TXP® Military Transporter® was used as a logistical air/ground transport ventilator.



DEPARTMENT OF HEALTH & HUMAN SERVICES — Public Health Service

Food and Drug Administration
1390 Piccard Drive
Rockville, MD 20850

JUN 13 1991

Re: K905234B
TXP Transporter Family and
Related Accessories
Dated: January 31, 1991
Received: May 1, 1991
Regulatory Class: Unclassified

Percussionaire Corporation
Attn: Forrest M. Bird
P.O. Box 817
Sandpoint, Idaho 83864

Dear Mr. Bird:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments. You may, therefore, market the device, subject to the general controls provisions of the Federal Food, Drug, and Cosmetic Act (act). The general controls provisions of the act include requirements for annual registration, listing of devices, good manufacturing practices, and labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval) it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. In addition, the Food and Drug Administration (FDA) may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under the Radiation Control for Health and Safety Act of 1968, or other Federal laws or regulations.

This letter immediately will allow you to begin marketing your device as described. An FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and permits your device to proceed to the market, but it does not mean that FDA approves your device. Therefore, you may not promote or in any way represent your device or its labeling as being approved by FDA. If you desire specific advice on the labeling for your device, please contact the Division of Compliance Operations, Regulatory Guidance Branch (HFZ-323) at (301) 427-1116. Other general information on your responsibilities under the act, may be obtained from the Division of Small Manufacturers Assistance at their toll free number (800) 638-2041 or at (301) 443-6597.

Sincerely yours,

Abhijit Acharya, Ph.D.
Director
Division of Cardiovascular,
Respiratory, and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

THE US FDA TXP® RELATED ACCESSORY MARKETING CONFORMANCE ISSUED TO PERCUSSIONAIRE® CORPORATION, LICENSED TO USE PATENTS ISSUED TO DR. BIRD

IN SUMMARY

THE CURRENT BASIC CRITERIA FOR A VENTILATOR THAT WILL ACCOMMODATE "CATASTROPHIC CARE PATIENTS" MUST CONSIDER THE FOLLOWING:

It must be ruggedized with miniaturization (capable of nearly fitting in the palm of an adult hand), function in all positions (microgravity), withstand up to 10 g impacts if inadvertently dropped.

Be capable of immediately and continuously operating when cold or hot soaked under typical military field conditions.

Be powered by compressed oxygen or air with delivery pressures of from 25 to 75 psig. without any battery or electrical requirements.

Fluidically programmed, using the operational respiratory gas pressure drop for cycling, then delivering the timing gas to the patient for operational gas conservation.

Function while inadvertently immersed in water (while functioning or non functioning) without any potential for electrical malfunction. After water immersion, be capable of near instantaneous purging by simply activating the compressed gas power supply for immediate normal function.

Be internally automatically vented in the case of an explosive decompression during air evacuation. Be programmable while functioning under environmental ambient pressures from hypobaric conditions to over 51,000 feet, or down to three hyperbaric atmospheres.

Capable of effectively ventilating any neonatal, pediatric or large adult lung which is capable of being mechanically ventilated.

Provided with an automatic (spring loaded) clamping device to attach to a belt and or typical flat plate bracket.

Possess a proven mechanical reliability of continuous operations for periods of over ninety consecutive days as long as a source of operational source respiratory gas from 25 40 psig is supplied.

Be capable of entering into long term storage (in a dry weatherproof container) for periods of over 10 years, with immediate normal performance when supplied with a source gas. Accessorily, the ventilatory device should be stored attached to a high pressure vessel containing oxygen with at least a one hour peak operational oxygen supply, sealed by a positive shut OFF ON/OFF valve and a pressure reduction regulator.

Additionally, a complete multi purpose breathing circuit must be attached to the ventilatory device.

Ideally, sealed individual doses of vasoconstrictors and brochodilators (Epinephrine) can be ready for topical endobronchial nebulization, during initial resuscitation.

FUNCTIONALLY, AN INTUITIVE PROGRAMMING SCHEDULE MUST PROVIDE FOR A ONE TWO THREE TYPE SET UP, ENABLING IMMEDIATE PATIENT VENTILATION.

1. **ACTIVATE THE VENTILATOR BY TURNING THE GAS CYLINDER-ON.**

2. **OBTAIN A PATIENT TO VENTILATOR AIRWAY WITH A UNIVERSAL RELIABLE EFFECTIVE NEONATAL TO ADULT BREATHING CIRCUIT.**

3. **ROTATE A SINGLE CONTROL KNOB FROM A NEUTRAL MID RANGE POSITION, RIGHT FOR A SMALL LUNG AND LEFT FOR A LARGE LUNG, UNTIL THE DESIRED CHEST EXCURSIONS ARE OBSERVED.**

For acute airway obstruction, use a Therapy Nebulizer (specifically designed for a correct particulate spectrum to match the ventilator flow characteristics) to deliver endobronchial topical aerosolized vasoconstrictor bronchodilator solutions.

For long periods of continuous ventilation insert an Artificial Nose in the Breathing Circuit.

MOST IMPORTANT, IF YOU ARE THE KNOWLEDGEABLE CLINICAL EVALUATOR OF THE "CATASTROPHIC VENTILATORY DEVICE", VENTILATE YOURSELF ON THE DEVICE AND VERY CAREFULLY MAKE SURE THAT IF YOU WERE THE CATASTROPHIC PATIENT YOU COULD BE EFFECTIVELY VENTILATED IN COMPLIANCE WITH THE ABOVE CRITIQUES.