



Inhaled Nitric Oxide (iNO) in the Air

Mr Mark Buick

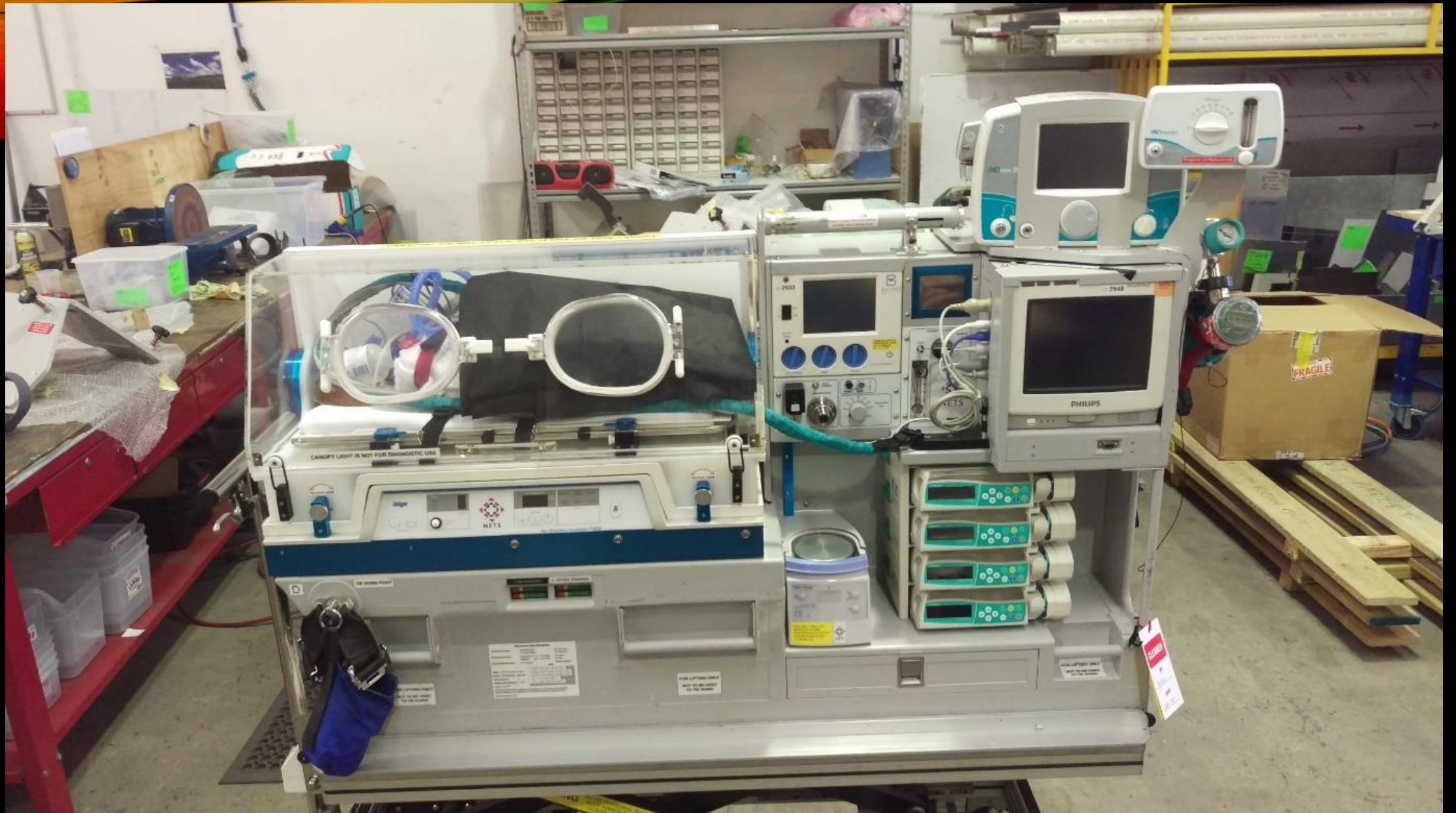
Disclosures: Designer and Manufacturer of an iNO delivery system

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'Standard' neonatal intensive care transport system





DEPARTMENT OF TRANSPORTATION
FEDERAL AVIATION ADMINISTRATION

	A24CE Revision 81 RAYTHEON
200 (A100-1 (U-21J))	
200C	
200CT	
200T	
A200 (C-12A) or (C-12C)	
A200C (UC-12B)	
A200CT (C-12D) or (FWC-12D) or (RC-12D) or (C-12F) or (RC-12G) or RC-12H) or (RC-12K) or (RC-12P)	
B200	
B200C (C-12F) or (UC-12F) or (UC-12M) or (C-12R)	
B200CT	
B200T	
300	
B300	
300LW	
B300C	
1900	
1900C (C-12J)	
1900D	
	March 4, 2002

TYPE CERTIFICATE DATA SHEET NO. A24CE

This data sheet which is part of Type Certificate No. A24CE prescribes conditions and limitations under which the product for which the type certificate was issued meets the airworthiness requirements of the Federal Aviation Regulations.

Type Certificate Holder: Raytheon Aircraft Company
9709 E. Central
Wichita, Kansas 67201

I - Model 200, Super King Air (Normal Category), Approved December 14, 1973 (See NOTES 10 and 11)
Model A200C (UC-12B), Super King Air (Normal Category), Approved February 21, 1979 (See NOTE 11)
Model 200C, Super King Air (Normal Category), Approved February 21, 1979
Model B200, Super King Air (Normal Category), Approved February 13, 1981
Model B200C (C-12F), (UC-12F), (UC-12M) and (C-12R), Super King Air (Normal Category), Approved
February 13, 1981, (See NOTES 10, 11, and 12)

For Notes, refer to Data Pertinent to All Model 200 Series

Engine	2 United Aircraft of Canada, Ltd., or Pratt & Whitney PT6A-41 (turboprop) per Beech Specification BS 22096 (200, 200C, A200C)
	2 United Aircraft of Canada, Ltd., or Pratt & Whitney PT6A-42 (turboprop) per Beech Specification BS 23319/1 (B200, B200C)
Fuel	JP-4, JP-5 (MIL-T-5624); JP-8 (MIL-T-83133); JET A, JET A-1, and JET B conforming to P&WC S.B. 1244 or ASTM SPEC. D1655. See NOTE 6 for emergency fuels
Oil (Engine & Gearbox)	UACL PT6 Engine Service Bulletin No. 3001 lists approved brand oils

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			effect.		
23.1309	<p>Equipment, systems, and installations.</p> <p>(a) Each item of equipment, when performing its intended function, may not adversely affect--</p> <p>(1) The response, operation, or accuracy of any equipment essential to safe operation; or</p> <p>(2) The response, operation, or accuracy of any other equipment unless there is a means to inform the pilot of the effect.</p> <p>(b) The equipment, systems, and installations of a multiengine airplane must be designed to prevent hazards to the airplane in the event of a probable malfunction or failure.</p> <p>(c) The equipment, systems, and installations of a single-engine airplane must be designed to minimize hazards to the airplane in the event of a probable malfunction or failure.</p>		<p>C</p> <p>Safe flight must also include the safety of all occupants including any patients. Equipment, systems and installations required by a patient are also considered under this section.</p> <p>The only potential hazard introduced as part of the Nitric Oxide integration that was not addressed in Aeromedical Fitout is the use of the nitric oxide itself and its effect on the medical and flight crew. When properly administered to newborn babies, it is beneficial in assisting in their</p>		

Ref	Requirement	Method	Compliance Statement	Report	Recommending and Finding Compliance
	<p>[(d) In addition, for commuter category airplanes, system and installations must be designed to safeguard against hazards to the airplanes in the event of their malfunction or failure. Where an installation requires a power supply and the function of that installation is necessary to show compliance with the applicable requirements, the installation must be considered an essential load on the power supply. The power sources and the distribution system must be capable of supplying the following power loads in probable operation combinations and for probable durations:</p> <p>(1) All essential loads after failure of any prime mover, power converter, or energy storage device;</p> <p>(2) All essential loads after failure of any one engine on two-engine airplanes; and</p> <p>(3) In determining the probable operating combinations and durations of essential loads for the power failure conditions described in paragraphs (d)(1) and (2) of this section, the assumption may be that the power loads are reduced in accordance with a monitoring procedure which is consistent with safety for the types of operations for which approval is requested.]</p>		<p>breathing and increases pulmonary blood flow. When not being medically administered (such as in the case of a leak), it may have a corrosive effect on eyes, the respiratory system, and the skin. Increasing concentrations result in more severe symptoms.</p> <p>TAS0510 Nitric Oxide Investigation Technote covers in great detail the benefits of the gas to infants and the negative implications if it is removed prematurely. It also outlines the risk of exposure to the other occupants if there is a failure to the system.</p> <p>In summary, operation with the Nitric Oxide system is considered safe for use in flight and compliant against this paragraph despite the risks due to several</p>		

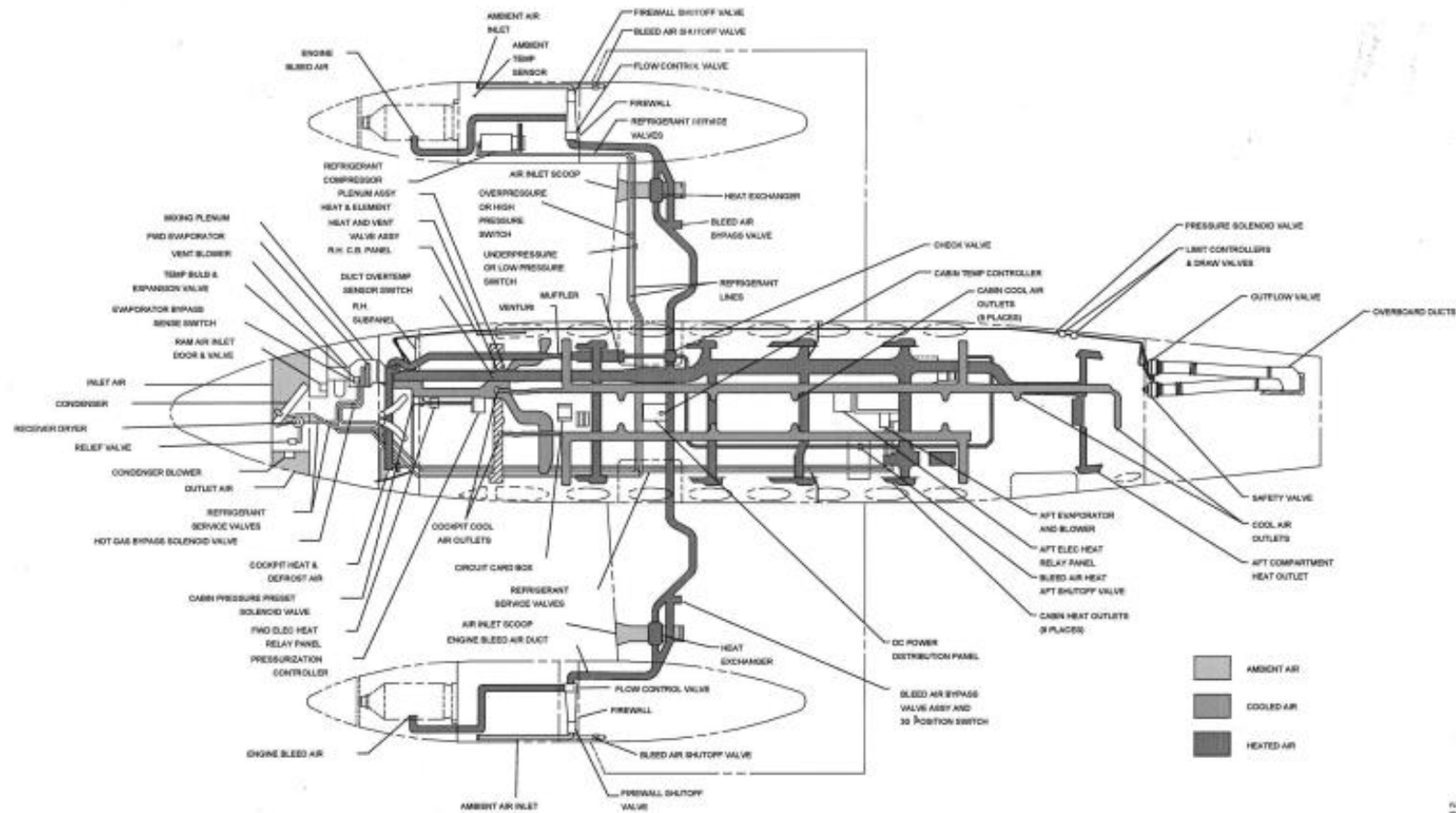
GAS TOXICITY SAFETY FACTORS

- 25ppm is broadly accepted as a maximum limit for continuous exposure to Nitric Oxide
- 100ppm is accepted as the transient limit
- The standard bottle mixture used for clinical purposes is 800ppm. (99.92% nitrogen) The mixture for treatment of an infant ranges from 10 to 30ppm.
- An American Academy of Pediatrics₁ report documents full-scale cabin tests on the Beech C90 King Air (similar to B200 geometry) where concentrations were measured below 1ppm with a leak of 20L/min at 40ppm.
- The calculated concentration in the cabin of a King Air following explosive failure is approx. 25ppm (consistent with the American Society of Paediatrics Report)
- Off-the-shelf monitors are able to detect concentrations of only 1ppm
- The cabin air in a pressurised B200 is turned over every 3-5 mins

GAS TOXICITY AND AIRWORTHINESS

- CASA Regulations do not differentiate between a healthy and sick occupant from a safety of flight perspective. The safety of the sick infant is in fact an airworthiness consideration
- The likelihood of an explosive NO failure is remote
- The consequences, by analysis and test are relatively benign
- The likely failure is a slow leak from the regulator
- The use of detectors adjacent the supply and in the cockpit provides the opportunity to apply proportional responses and procedures
- If practical, the environmental control system of the aircraft can be manipulated to mitigate effects of any leak eg: stopping scavenging air from the rear of the cabin

Super King Air B300/B300C Maintenance Manual
Environmental System - Description and Operation (FL-1 thru FL-492, FL-494 thru FL-499; FM-1 thru FM-13)



(FL-1 thru FL-492, FL-494 thru FL-499)



3 EMERGENCY PROCEDURES

3.1 AIRCRAFT AFM

There is no change to the aircraft Emergency Procedures.

3.2 EMERGENCY LANDING, DITCHING AND SEVERE TURBULENCE

1. For emergency landing and evacuation, the NO must be turned off at the cylinder.
2. All loose components including lines must be stowed and the stowage compartment closed.

3.3 NETS NEONATAL UNIT

1. Emergency procedures must be conducted with consultation between the pilot and NETS team, taking in to account patient safety and clinical concerns.
2. In the event of electrical malfunction or smoke within the Neonatal Unit, shut down the aircraft aeromedical bus power by turning the MED BUS switch to off.
3. Pull the three circuit breakers labelled "INTERNAL BATTERIES" on the Neonatal Unit Power Module. This will isolate equipment from the NETS Power Module. See Figure 2.
4. Completing the above steps results in only clinically critical components including the monitor, infusion pumps and ventilator operating off their own internal batteries. If necessary, turn these off using their individual control panel power (On/Off) switches.



3.4 INHALED NITRIC OXIDE (INO) MODULE

In the event of either the PIC's or iNO Module's environmental monitors alarming, or if there is any other evidence of a NO leakage, this may indicate an unsafe concentration of NO in the air. Carry out the following procedures:

NETS Team:

1. Notify pilot of increased NO concentration and note time and recorded concentration level. If use of NO not critical for patient well-being, turn off the cylinder at the regulator.
2. Check all lines and connections to ensure all are connected correctly and there are no obvious leaks. Rectify if possible.

Pilot:

3. Increase cockpit airflow to maximum and refer to personal monitor. According to Safework Australia 25ppm (TWA) is the 8 hour safe working limit for NO. The Environmental Monitor is set to alarm at 5ppm. For levels in excess of the safe working limit, descend and depressurise as appropriate.
4. If concentration less than safe working limit, consult with NETS Team at maximum of five minute intervals and monitor the concentration both for the pilot and the crew.
5. If NO has not dissipated after 10 minutes of monitoring, descend and depressurise as appropriate. Maintain maximum cockpit/cabin airflow.

NETS Team:

6. If concentration of NO increases over the safe 8 hour working limit, shut NO cylinder off.
7. When the aircraft has landed and is taxiing, the airflow through the cabin may reduce which may prevent the NO from dissipating. Continue monitoring levels until the aircraft has stopped and the doors are open.





THANK YOU

- References

1. "Use of Nitric Oxide during Inter Hospital Transport of Newborns with Hypoxemic Respiratory Failure" – American Academy of Paediatrics, 2011.