

PART ONE CHAPTER TWO

HISTORICAL BRIEFS LEADING TO FOUR GENERATIONS OF AEROMEDICAL DEVICES CONCEIVED AND DEVELOPED BY

FORREST M. BIRD, M.D., PhD., ScD.

DR. BIRD'S CARDIOPULMONARY DEVICE CONCEPTIONS

FROM WW II to 2005

Anti g PRESSURE SUIT REGULATOR 1945

THE FIRST MANUAL IPPB VALVE 1947

THE BIRD® MARK 7® RESPIRATOR 1955

THE BIRD OXYGEN BLENDER 1963

THE BABYbird® 1969

**BIRD DEMAND CONTINUOUS POSITIVE PRESSURE BREATHING (D/CPAP)
1975**

**THE VENTILATORY CONCEPTS FOR INTRAPULMONARY PERCUSSIVE
VENTILATION (IPV®) 1980**

**THE TXP® MILITARY TRANSPORTER® FAMILY OF CATASTROPHIC
CARDIO-RESPIRATORY VENTILATORS 1987**

**THE EXPANDED PHYSICAL AND PHYSIOLOGICAL UNDERSTANDINGS OF
THE IPV® DYNAMICS 1990**

THE CLINICAL APPLICATIONS FOR (IPV®) & (VDR®) 2000

INTRAPULMONARY PERCUSSIVE VENTILATION (IPV®)

VOLUMETRIC DIFFUSIVE VENTILATION (VDR®)

HIGH FREQUENCY PERCUSSIVE VENTILATION (HFPV™)

HIGH FREQUENCY OSCILLATORY VENTILATION (HFOV)

Dr. Bird's conceptual aeromedical devices may have already impacted upon your personal life. Or they may provide you, the Clinician, an increased ability to mechanically support your patient's cardio-respiratory functions.

**EACH GENERATION OF AEROMEDICAL DEVICES CONCEIVED
BY
DR. BIRD HAS BEEN DEDICATED TOWARD**

**ENHANCING CLINICAL EFFICACY AND PATIENT SAFETY BY PROVIDING
AUTOMATED FAILSAFE FUNCTIONS BASED UPON ANALOG FLUID
DYNAMICS EMPLOYING BERNOULLIAN AND NEWTONIAN LOGIC.**

**MODULAR DESIGNS HAVE ENHANCED INHERANT FAILSAFE INTEGRITY
WHILE ALLOWING PROGRESSIVE LEVELS OF USER INTUITIVITY
WITHOUT SACRIFICING CLINICAL EFFICACY.**

**EACH SUCCESSIVE GENERATION HAS BEEN CONCEIVED AND
DESIGNED IN COMPLIANCE WITH EMERGING TECHNOLOGIES,
ADVANCING THE "STATE OF THE INVOLVED ARTS" FROM circa 1944 to
2005.**

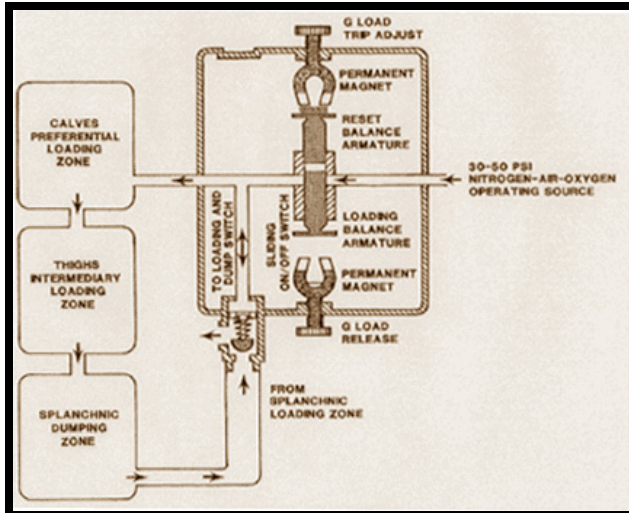
HISTORICAL SEQUENCE-

Dr. Bird (with a pre World War II aeronautical based education with both engineering and piloting abilities) commenced his activities relating to the mechanical ventilation of the lung as a U.S. Army Air Corps Pilot serving as a Technical Air Training Officer for the Air Transport Command (ATC) during WW II.

His first U.S. military Army Navy (AN) activities centered around a pressure breathing regulator enabling military pilots to fly over the then existing 28,000 foot altitude limitations due to failure to saturate the blood with sufficient oxygen. At that time, mechanical turbo-charging of aircraft engines was allowing Army Air Forces military fighters and bombers to exceed their pilot's physiological capacities.

At the cessation of WW II military operations, highly maneuverable military jet aircraft were entering into Air Force inventory. These aircraft created a physiological limitation to combat pilots associated with induced "pilot blackout" secondary to g loads imposed upon them during sustained combat flight operations. The blackouts were caused by blood leaving the cranial vault (brain) during high positive g forces created by abrupt maneuvers. This was becoming a major limitation during combat challenge, with the pilot who had the longest span of "useful consciousness" (other factors being equal) winning the battle, traditionally called a "dog fight."

Dr. Bird became involved in the development of an anti g aircraft regulator to peristaltically inflate an automatically functioning anti g suit. This employed fluid dynamics and a mechanical magnetic clutch logic using permanent magnets. This was an AN development as Dr. Bird remained on active military duty.



**THE ANTI g SUIT
REGULATOR CONCEIVED
BY DR. BIRD IN 1945
TO REDUCE BLACKOUT
POTENTIAL IN JET FIGHTER
PILOTS**

After WW II, Dr. Bird received an extensive medical education to provide him with biomedical qualifications. This allowed him to become more involved in human factors associated with military and civil aeromedical activities.



Shortly after WWII, Dr. Bird converted a Military Oxygen Breathing Regulator into the first manual Intermittent Positive Pressure Breathing device (IPPB). He used a Vaponefrin Nebulizer and an Aviation exhalation valve he re-designed to meet his design goals. This must have been the first IPPB used for COPD, circa 1947.

Beyond his continuing military commitments, Dr. Bird was enabled to commence parallel activities in clinical medicine

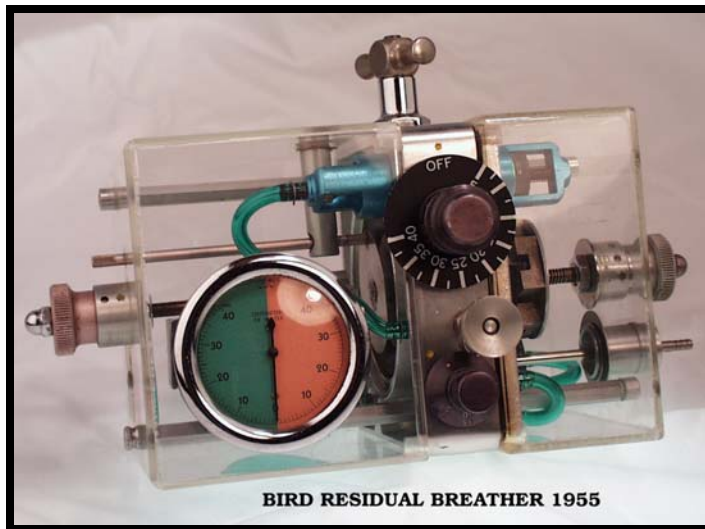
without his innovations becoming the property of the U.S. Air Force. By the late 1940's, Dr. Bird had developed the logic for an advanced medical respirator to breathe for the smallest baby or the largest adult patient and every patient in between, including other mammals from chipmunks to elephants. These innovations used the magnetic clutch logic employed in the anti g suit regulator.



Bird Respirator Prototype # 1

By the mid 1950's, Dr. Bird had perfected his "Bird Residual Breathing Respirator". By the seventh prototyping, toward the later mid 1950's, Dr. Bird had substantial animal and patient studies verifying his clinical concepts.

The on-patient clinical studies were first performed within the US Army's Walter Reed medical facilities and later within the U.S Air Force's Willford Hall hospital at Lackland Air Base in Texas. These initial studies were followed by civil medical studies at Columbia University's Bellview Hospital facilities in New York and Montreal Neurological Institute of McGill University in Montreal, as well as within international medical communities.



BIRD RESIDUAL BREATHING SYSTEM 1955

The Bird Residual Breathers were all hand made and were employed for patient studies. These prototypes served to prove the reliability of the design, and were actually the sixth generation of Prototypes.



BIRD MARK 7 RESPIRATOR 1957

By the end of the 1950's, Dr. Bird, upon completion of his seventh generation prototype, had called his new respirator the "Bird® Mark® 7 Respirator". With flexible military commitments, Dr. Bird had established Research, Development and Manufacturing facilities within the former military airbase located on the Palm Springs, California, Airport.

By the time the U.S had become deeply involved in the Vietnam War, Dr. Bird had expanded his novel technology to involve both heart and lung (cardiopulmonary) compromises in all patient populations. He had developed many dedicated models of his devices for the various clinical specialties. Additionally, he had standardized mechanical pulmonary ventilation in anesthesia with his Mark 4 Anesthesia Assistor Controller as well as Mark 14 and 17 Intensive Care ventilators.



Dr. Bird's Oxygen Air Blender reduced the risk of Oxygen toxicity (Retrolental Fibroplasia) in Neonates. The risk of oxygen toxicity during the mechanical ventilation of the lung in all patient populations was minimized. The U.S. Tri Services as well as military and civil medical facilities the world over were standardized on Bird Medical Respirators (which

at that time had expanded into some thirty patented devices and their accessories).

During the Vietnam War, Dr. Bird was able to honor both his military and civil commitments without conflict. During the Vietnam War, Dr. Bird introduced the logic and certain mechanical devices enabling critically injured or ill patients transported aboard helicopters and fixed wing aircraft to receive "INTENSIVE CARE TRANSPORT." This methodology consisted of clinically treating the patient's medical conditions en-route much like they would be within a hospital environment.

Mechanical ventilation of patients with cardiopulmonary trauma or disease played a major role in successful logistics. In other words, instead of the traditional ambulance "traveling beds," patients were starting to receive what today is advanced Emergency Medical Transport (EMT). This resulted in the savings of many soldiers with battlefield injuries.



In the late 1950s Dr. Bird highly modified a Navy PBY aircraft to transport as many as seven respirator dependent patients. This became the world's largest amphibious airplane, creating many standards for military and, later, civil air evacuation. His Air Evacuation devices continued to be evaluated within the USAF School of Aviation Medicine and Air Evac facilities.



The Bird Mark 10 became the standard Military Transport Respirator.

In 1969, Dr. Bird introduced his Babybird® Respirator, which again, as with all previous breathing device developments by Dr. Bird, were first evaluated within the U.S Air Force's Willford Hall medical center.

The Babybird Respirator was designed (around an aircraft pressurization outflow valve concept of Dr. Bird) to breath for premature babies with cardiopulmonary compromises, without mechanically damaging the lungs. The lung disease was often referred to (at the time) as a Respiratory Distress Syndrome.



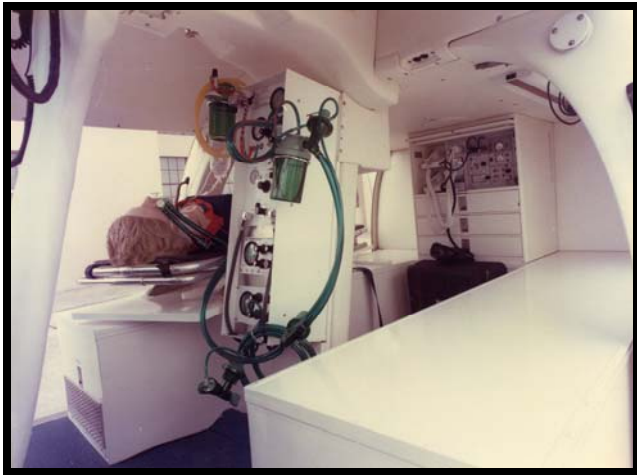
Within two years after the introduction of the Babybird (designed to care for very small babies with lung diseases), the Neonatal mortality was reduced from some 70% to less than 10%. This proved to be a major contribution.

In the early 1970's, Dr. Bird was devoting the majority of his available time to developing his third generation of cardiopulmonary devices. These were designed with fluidic time cycling concepts (pioneered in the Babybird®) in lieu of magnetic clutches predominantly employed in his first two generations. One of these was a very advanced critical care ventilator/respirator called an IMVbird® which advanced the concept of Intermittent Mandatory Ventilation (IMV), earlier pioneered in the Babybird® design.

From lessons learned during his Intensive Care transport activities in both fixed wing and helicopters during the Vietnam War, Dr. Bird started to pioneer civilian Intensive care transport.



Loma Linda University's first Intensive Care A Star Helicopter with a Bird Mark 14 Respirator powered by a Bird Air/Oxygen Blender for FIO2 selection as well as pneumatic power for airway aspiration.



The first multi patient helicopter outfitted with combination Bird ventilators and accessories to provide for intensive care transport in the Gulf of Mexico, used to transport injured oil workers from offshore oil platforms to land based hospital facilities.



Dr. Bird's early Model 23 Lear Jet was the first civil jet aircraft to be outfitted with Intensive Care Transport facilities. The Lear Jet could transport any patient anywhere at about 500 miles per hour.



Bird Institute of Biomedical Technology © 2006

Dr. Bird always claimed he could ventilate any mammalian lung from a Chipmunk to an Elephant. The “truth was”-- he could!



OFFICIAL US NAVY PHOTO JANUARY 1976 McMURDO Sound Antarctica, ventilating a SEAL with a BIRD Mark 9 Respirator. Sent to Dr. Bird by Bob Schneider, M. D. (Anesthesia MGH)

OVER THE YEARS THE BIRD MARK SERIES OF RESPIRATORS HAVE VENTILATED MAMMALIAN LUNGS OF ALL TYPES



THE SAN DIEGO ZOO EMPLOYES THE BIRD SUPER MARK 9 RESPIRATOR TO VENTILATE LARGE ANIMALS

Congress had voted for a Medical Device Act to be administered by the FDA to commence on May 28, 1976. After that time all new medical devices would be required to be introduced similar to new drugs. This would be a most expensive undertaking, ruling out the entrepreneurial introduction of new medical devices unless the devices were substantially the same as the “prior art existing on May 28, 1976”.

To this end Dr. Bird was determined to have his entire third generation of devices completed and in commercial production. This required considerable patent application. This proved to be a monumental task; however, his entire third generation of medical devices was finalized by April of 1976.

In the fall of 1976, Industrial Indemnity Corp., who had traditionally handled Dr. Bird’s Malpractice and General Insurance, advised him that they would no longer underwrite his Bird Corp. liability insurance at any premium. Bird Corporation had never settled or paid any monies to settle any litigation and there was no pending litigation.

Bird Corporation, wholly owned by Dr. Bird without debt, was unable to find another source of indemnification. Dr. Bird’s legal consultants advised him he must merge Bird Corporation into an organization which could accept the contingent and continuing liability through self-insurance. This action was based upon the vast number of Bird Respirators and their accessories in routine use (residual base of exposure) at that time of extensive medical legal interventions.

On January 11, 1978, Bird Corporation was merged into the 3M® Company. Dr. Bird retained all of his aircraft, research & development facilities as well as educational materials. Facilities at Palm Springs would be moved to his existing Idaho Bird Space Corporation complex, where most of his studies were (by then) on going. Thus, on January 11, 1978 Dr. Bird (with the exception of aircraft associated patents) had signed over all of his cardiopulmonary device related patents to the 3M Company.

After the 3M/Bird Corp. merger, Dr. Bird had a multi year transition of his aircraft facilities from his Palm Springs hangar to his Idaho facilities which had to be substantially expanded.

Dr. Bird as well as others within the Medical Device field (such as Dr. Emerson who had earlier invented a high frequency medical ventilator), had envisioned a means of breathing for a patient with a form of an effective high frequency vibratory intrapulmonary molecular agitation.

Dr. Bird had introduced intrapulmonary FLOWRATE on his Mark 7 Respirator in the 1950’s, which controlled the rate at which the induced respiratory gases would flow into the pulmonary airways to enhance alveolar distribution.

Dr. Bird well understood that if the inspiratory flow of gases into the lungs exceeded a certain velocity they would “trigger” a stretch reflex within the pulmonary airways called the Hering Breuer reflex. This reflex was fired by a rapid overstretching of the pulmonary airways which, if activated by an excessive triggering inspiratory flowrate, would cause the patient to forcefully exhale. In anesthesia this was called “bucking on the tube”.

With all of Dr. Bird’s commercial commitments other than limited consultation to 3M Bird satisfied, he planned to exploit a possible means of effectively ventilating the pulmonary structures “with rapidly injected percussive sub tidal gas volumes of respiratory gases”.

Following Dr. Bird’s departure from his Palm Springs Bird Corporation operations without Commercial deviations or monetary considerations, Dr. Bird was able to dedicate his total efforts toward the technological and clinical aspects of what he elected to call “High Frequency Percussive Ventilation”.

Dr. Bird’s fourth generation of novel Aeromedical devices were to introduce major clinical advances toward the mechanical management of Patients with Cardiopulmonary Compromises.

NOTES: