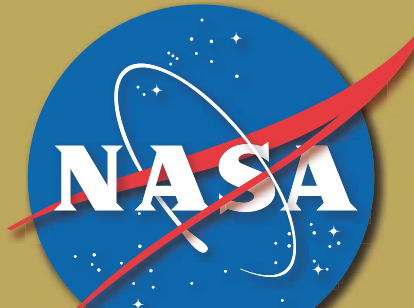


Lightweight Trauma Module - LTM

by **IMPACT**[®]

in partnership with



Overview:

Current patient movement items (PMI) supporting the military's Critical Care Air Transport Team (CCATT) mission as well as the Crew Health Care System for space (CHeCS) have significant limitations: size, weight, battery duration, and dated clinical technology. The LTM is a small, ~20 lb., system integrating diagnostic and therapeutic clinical capabilities along with onboard data management, communication services and automated care algorithms to meet new Aeromedical Evacuation requirements. The Lightweight Trauma Module is an Impact Instrumentation, Inc. project with strong Industry, DoD, NASA, and Academia partnerships aimed at developing the next generation of smart and rugged critical care tools for hazardous environments ranging from the battlefield to space exploration. The LTM is a combination ventilator/critical care monitor/therapeutic system with integrated automatic control systems. Additional capabilities are provided with small external modules (see right).

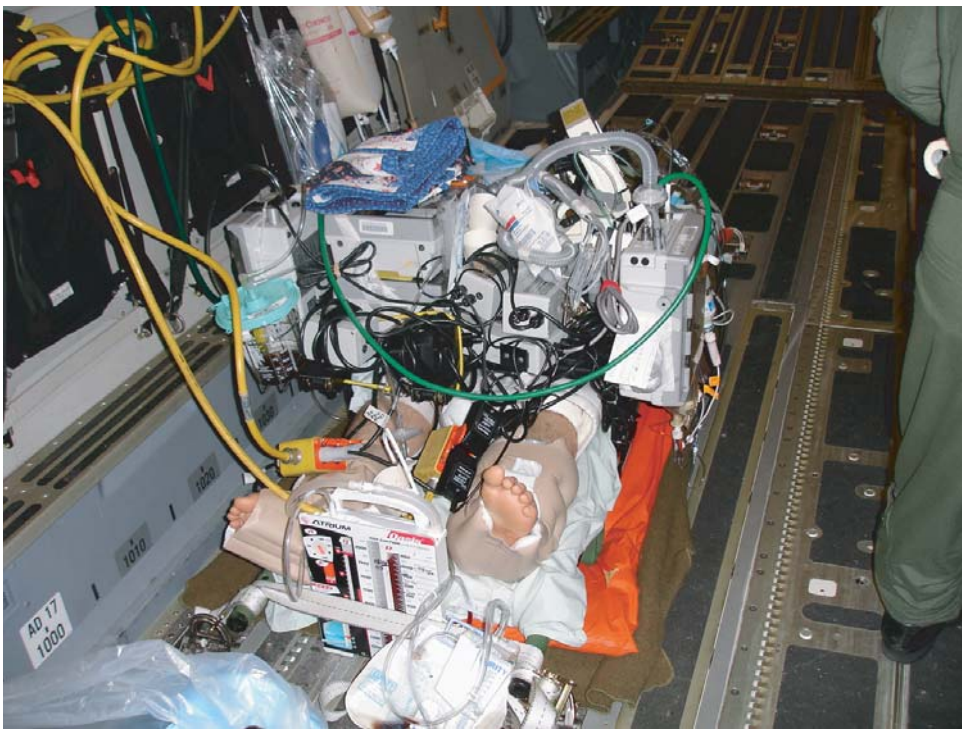
What's so special about the LTM?

The LTM represents a leap forward in capabilities as a result of the key design strategy of a modular, open source architecture. Internal and external devices all interface to the core processor via USB. If one system or sensor fails, the remainder of the systems will continue to function. If an improved device or algorithm is available years after initial deployment of the LTM, a quick software upgrade (and user training) is all that is required to take advantage of the new capability.

As a result of this modular approach, the system becomes scalable and upgradeable. In addition to this benefit, redundant capabilities (along with the wasted mass, power, and volume) disappear. In the past, there were multiple devices at the bedside, each with its own battery, screen, enclosure, etc. With the LTM, all user interfaces take place on one screen. Additional features are provided by external modules to the LTM, but they are still accessed and controlled by the LTM display.

This leads to an improvement in reliability for space and military applications as well. For space, if the core processor of an LTM fails, the working modules can be accessed via the same software on a laptop. For the military, another LTM could be used to control the functional components.

In addition to these improvements, an integrated electronic medical record system both improves individual patient care as well as providing a new, valuable source of data to fuel research for improving medical care in the field.



The complexity and weight of current PMI is an obstacle to care during transport.

Summary of Improvements:

The LTM improves upon current systems with several advantages:

- 60% weight/volume reduction
- Improved standard of care – reduced morbidity/mortality
- Integrated electronic medical record
- Faster patient handoffs between echelons of care
- Faster integration of new techniques/technology by exploiting an open architecture
- Forward maintenance through a deployable remote calibration module.



Integral Systems:

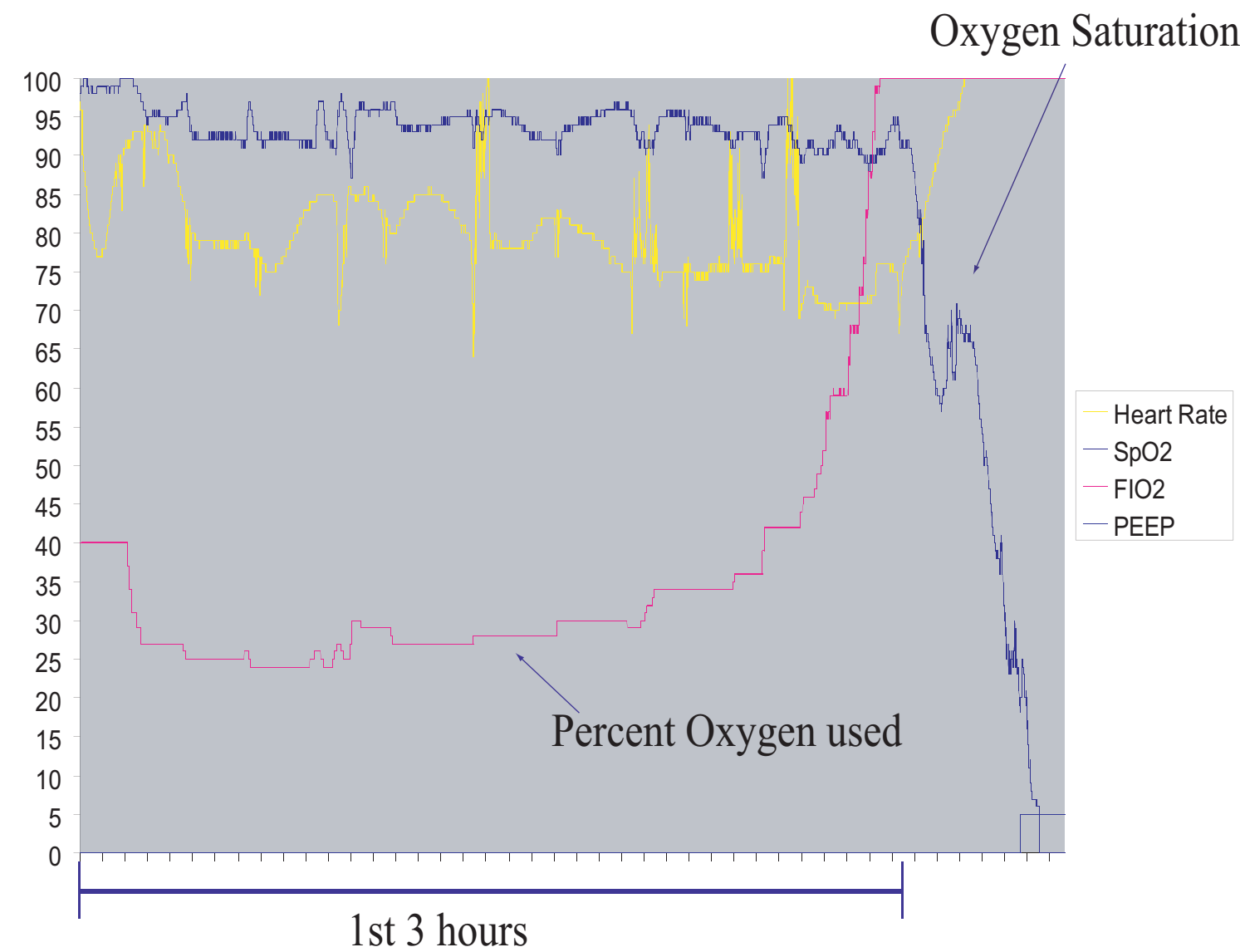
- Ventilator
- 12 / 5-lead ECG
- Pulse-Ox
- Non-Invasive Blood Pressure
- End-Tidal CO₂
- Temperature
- Invasive pressure
- Remote monitoring / control
- Smart, context sensitive help
- Automatic control software
- Data logging
- Electronic medical record



Research:

A significant portion of the funding for LTM goes to clinical research towards automated algorithms for treatment. A primary example of this is closed loop ventilation. Hardware and software jointly developed by Impact and Wyle/NASA is currently undergoing human clinical trials at the University of Cincinnati (Johannigman et al.) The trials are investigating an algorithm that automatically controls the amount of oxygen delivered to a patient based upon the measured saturation of oxygen in the blood (SpO₂). This algorithm, if approved by the FDA, would allow the device to make intelligent decisions about how to manage the ventilatory parameters of a patient when in the absence of a skilled care provider. The algorithm does not replace a clinician, but rather supplements the care. This has beneficial applications for natural disasters and managing mass casualty events, as well as managing care during patient transport or at remote locations, i.e. the International Space Station.

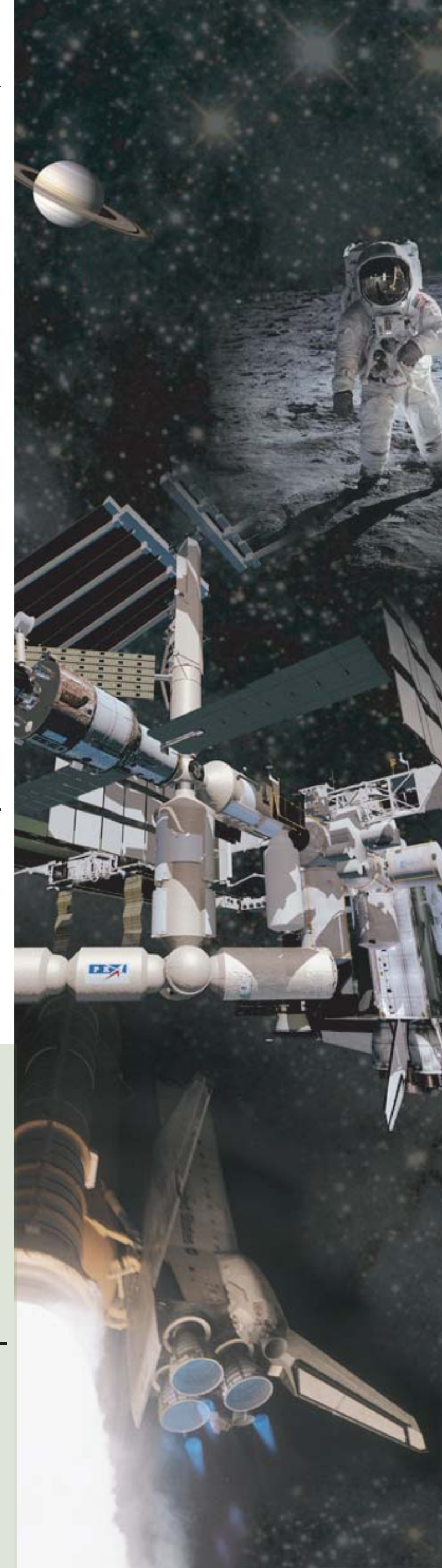
A patient is managed under closed loop control via laptop based algorithms during clinical trials at the University of Cincinnati.



The graph above illustrates the effectiveness of the closed-loop-control algorithm in managing the oxygen saturation (SpO₂ blue line) of a pig experiencing blunt chest trauma (analogous to trauma caused by large caliber fire to body armor.) The algorithm kept the saturation within the target window (above 94%) for the first 3 hours of the injury while requiring less than 40% oxygen. Traditional treatment would likely have used 100% O₂ for most of this duration. The picture at left illustrates a test patient under closed-loop-control from the laptop-based algorithm.

Partnership Model:

All of the contributors to the development of the LTM have been part of a makeshift consortium representing industry, government, and academia. This 'NASCAR' approach, as the members have come to refer to it, allows for multiple parties to contribute their expertise while sharing access to the work of other team members. This teaming arrangement allows for the exchange of hardware designs and technical information, software code and algorithms, clinical processes and protocols, as well as physical hardware. In kind support towards mutual goals is commonplace.

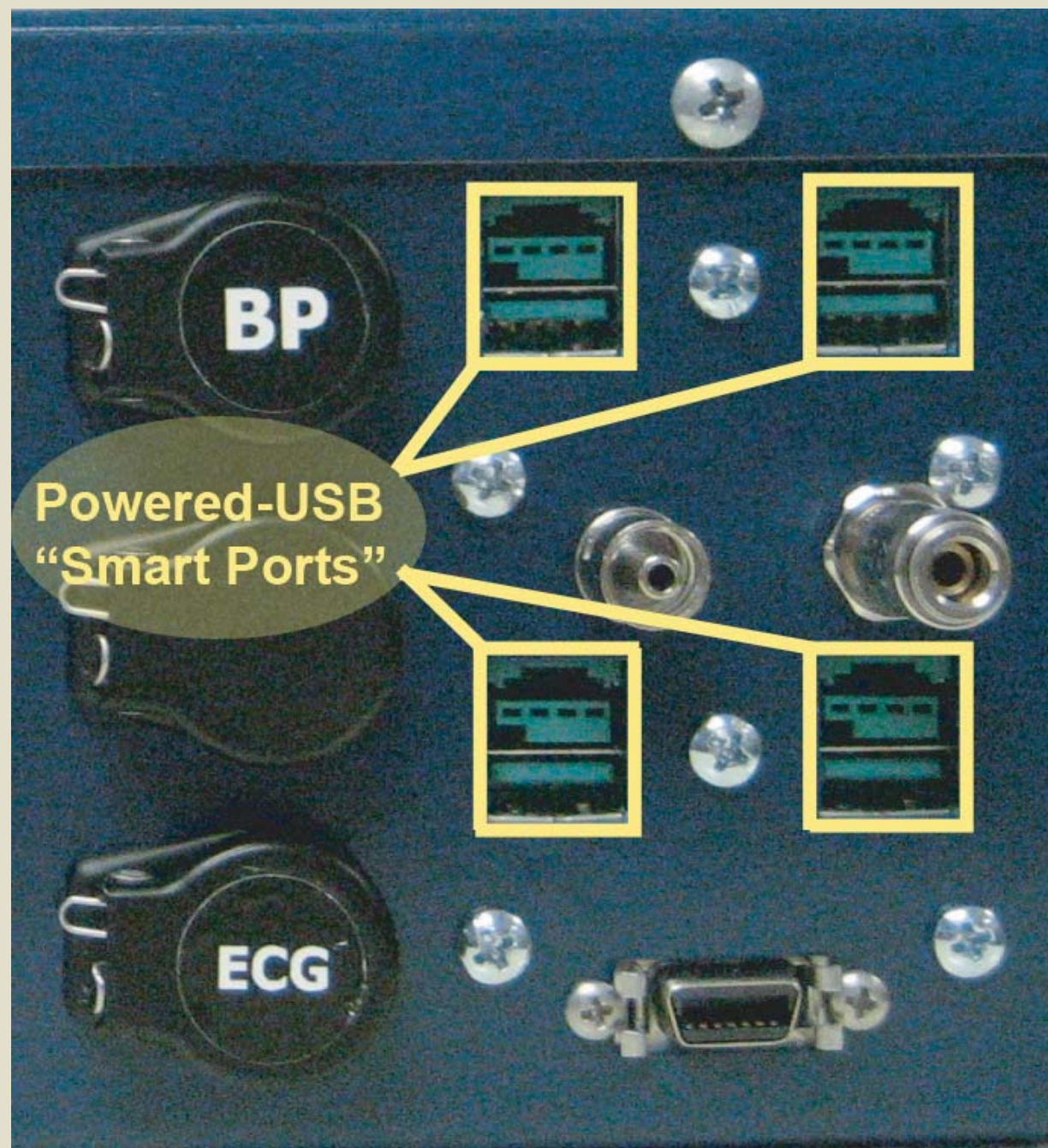


Current Status:

Two functional version 3.1 pre-production prototypes were completed and demonstrated to the military and NASA partners at the 2007 Advanced Technology for Combat Casualty Care (ATACCC) conference. This unit possessed functional implementations of all integral systems. The prototype (shown right) weighs less than 20 pounds, and fits within a form factor of 12" x 6" x 13".



After military briefings and the 2007 Advanced Technology Applications for Combat Casualty Care (ATACCC) military medical conference, it appears that LTM has wide support among the services. It is anticipated there will be efforts to complete the FDA product development process for LTM and field units in the next 18 months with Congressional funding from FY08 budget. The LTM team is currently working on a v4.0 design to support Human Clinical Trials under Investigational Device Exemption (IDE) in the spring of 2008 and a v5.0 version to support an initial FDA 510k submission in 2009. Current efforts have been directed towards preparing the designs for scaled manufacturing and completing the software for managing the patient medical records. Multiple interim devices are being constructed to support user field testing and continued research. Partnerships with researchers are yielding algorithms that will be incorporated into the LTM design to better meet patient and user needs for the device. The LTM prototypes currently in construction through funding from the Office of Naval Research will support research at the Army Institute for Surgical Research, University of Texas Medical Branch, University of Cincinnati, and Massachusetts General Hospital.



Smart Port Concept:

The LTM also supports external IV pumps connected via Powered-USB "Smart-Ports." Although the software has not been integrated, the ultrasound capability has been demonstrated with LTM v3.1.

Potential external modules include:

- Patient controlled analgesia
- Aspirator
- Spirometer
- O₂ concentrator
- Patient warming
- Stress test
- Anesthesia module
- Visualization
- Oto/ophthalmoscope
- Macro lens camera



Operational Challenges:

The operational challenges faced by the military and NASA include distributed and remote operations, long transport distances, low light, high noise, limited space, and consumables (power, O₂, fluids, etc.) and varying skill sets for medical providers. The Lightweight Trauma Module (LTM) is an integrated suite of physiological monitoring, therapeutic hardware and software. The LTM is being developed to be smaller, lighter and more energy efficient than current Patient Movement Items (PMI) for the military and for potential use on the International Space Station (ISS) and for exploration. The LTM software provides an infrastructure for patient-side and remote care with integrated data storage, autonomous care, and remote monitoring and control. The system is able to support ongoing closed-loop ventilation and IV fluids administration research for the reduction of consumables, reduced care-provider/crew training, and reduced mission risk by reducing the requirements for constant patient-side attention by Crew Medical Officer. The issues driving the continued development of the LTM are relevant to the spaceflight environment, military combat casualty care and transport and mass casualty/pandemic events.

Military & NASA Challenges:

- Distributed operations
- Remote operations
- Greater transport distances
- Limited number of care providers
- Limited Space
- Limited consumables (i.e. Power, O₂, Fluids, etc.)
- Low light, high noise environment



NASA Contribution:

The NASA Medical Informatics and Health Care System (MIHCS) branch at the Johnson Space Center in Houston has been working with Impact Instrumentation under a Space Act Agreement for several years to develop the LTM. NASA is providing personnel to support the ongoing LTM hardware and software development. Military funding via Space Act Agreement partner Impact Instrumentation is supporting additional labor and all of the expenses relating to the procurement and development of custom and Original Equipment Manufacturer (OEM) subcomponents of the LTM. Although the military is currently the major driver for the project, spaceflight requirements are being included in the original design: ruggedness and redundancy, power use, materials, support for patient from injury to definitive care facility aboard various transport vehicles, and remote calibration and maintenance.



LTM v2.0

LTM v3.0

LTM v3.1