WHITE PAPER

FloTrak Elite – A flexible platform for the future

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ABSTRACT

The FloTrak Elite Module , the next generation respiratory monitoring solution from Respironics, in combination with its mainstream and sidestream gas monitoring solutions, is poised to enable a host of clinically valuable monitoring solutions. This module integrates the latest in technology to provide a robust on-airway solution in the most challenging of clinical environments (1) and is equipped with the processing capability to power the next generation of value-added applications.

INTRODUCTION

The measurement of proximal flow in the critical care environment can often be challenging, particularly given the high humidity and secretions present and the length of mechanical ventilation that can last from days to weeks (2).

Due to their robustness, differential pressure based flow sensors are often used in clinical environments (3). To maintain performance and function in this environment over time, differential pressure based respiratory measurement systems generally include zeroing and purging functions. Periodic zeroing, performed by exposing the two sides of the differential pressure sensors to the same pressure for a short period of time, is required because pressure sensors drift due to both intrinsic and extrinsic factors including changes in temperature. High humidity in the breathing circuit often leads to condensation of moisture in the pressure transmission tubing eventually resulting in a damped and distorted pressure signal (e.g. reduced accuracy) if not cleared. Therefore, pressure transmission tubes are periodically purged with a source of gas (either air or inspiratory gas) to reduce the adverse effects of condensate on pressure and flow measurements.

The complexity associated with the valves and interconnections required for zeroing and purging functions has resulted in conventional respiratory measurement systems with "bulky", multi-piece designs, which are difficult to assemble due to many individual pneumatic connections. Additionally, the number of connections between different components results in a greater potential for leaks at these interfaces and increased variability between the two pneumatic pathways thus affecting the reliability of the measurement.

FLOTRAK ELITE MODULE – OVERVIEW

The FloTrak Elite module (Figure 1) provides a cost-effective respiratory measurement solution that (a) eliminates the pneumatic connections that must be made manually, (b) improves long term reliability, (c) improves performance and (d) improves inter-unit repeatability by reducing the variability between pressure transmission tubing pathways. The FloTrak Elite module consists of an electronic circuit board with valves and pressure sensors assembled with a manifold and pump. The manifold has two connectors to which tubing from the flow sensor receptacle is attached.

The FloTrak Elite module manifold is of unitary construction and incorporates all the functionality of existing flow/pressure measurement systems that use either multi-piece manifolds or individual pieces of tubing with fittings. The manifold is formed to include channels for transmitting pressure, a cavity to serve as a pressure reservoir, openings and channels to pneumatically interface the sensors and valves with each other, and the measurement ports. The size and complexity of the flow measurement system has been significantly reduced by integrating all of the pneumatic tubing and the reservoirs into a single piece manifold and at the same time eliminating the need for individual unit balancing, creating a more reliable and manufacturable product.

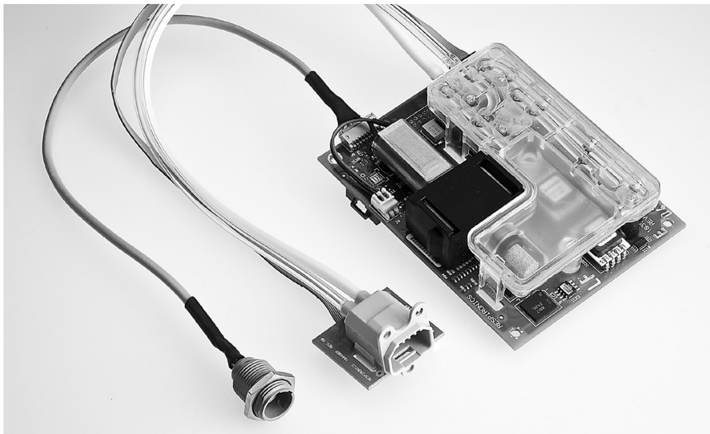

Figure 1 - Photograph of FloTrak Elite Module with receptacle for flow sensor and connector for Capnostat or LoFlo sensor shown.

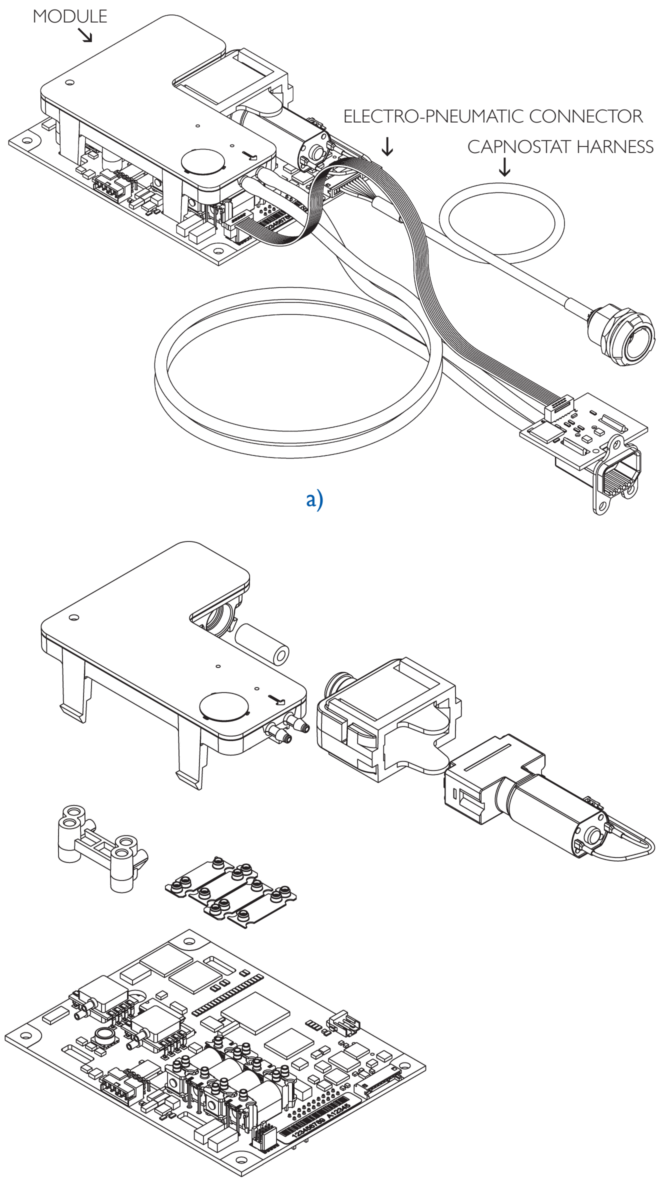

Figure 2 – FloTrak Elite module (a) assembled and (b) exploded views.

FLOTRAK ELITE MODULE – FEATURES

The FloTrak Elite module is 510(k) cleared and is intended for: "spirometric, and carbon dioxide monitoring in neonatal, pediatric and adult patients during general anesthesia and in the intensive care unit (ICU) and the emergency department (ED). Separate combination CO_2/flow sensors are provided for adult, pediatric and neonatal use."

The FloTrak Elite module, shown in block diagram form (Figure 4), is a microprocessor based data acquisition system consisting of differential, absolute and gauge pressure transducers, CO_2 measurement (when the Capnostat CO_2 sensor or LoFlo module is connected) and control circuitry, valving, purge and valve actuation pumps, manifold and a high speed serial interface.
The module's firmware resides in a Flash ROM. The module uses SRAM for data storage and an EEPROM to store system parameters.

The operations performed by the module include data acquisition, zeroing, purging, parameter calculation including cardiac output (using the optional cardiac output re-breathing control board), and corrections to the flow signal for gas composition, airway pressure and barometric pressure.

FLOW/PRESSURE MEASUREMENT – Flow is measured with sensors that are fixed orifice, target pneumo-tachometers, and as such the pressure drop is proportional to the square of the flow. Combination CO_2/flow sensors are available in three flow ranges that are tailored for neonates, pediatric patients and adults. Flow only sensors are available in two flow ranges that are tailored for infant/neonate and pediatric/adult patients. Airway pressure is measured with a gauge pressure transducer. Barometric pressure is measured with an absolute pressure transducer with built-in temperature compensation. Because of the need for a high resolution system with a fixed orifice sensor, the signal is low pass filtered and digitized by a 24-bit analog to digital converter (ADC) to obtain the needed high dynamic range for flows (e.g. 2 to 180 L/min for the adult sensor) passing through the fixed orifice sensor.

PARAMETER CALCULATION – The software processes the acquired waveforms of flow, pressure, and CO_2 (if available). It calculates parameters on a breath-by-breath basis and at predetermined or user configurable averaging intervals. These include simple flow based measures such as breath rate and expired volume, and more sophisticated measures such as resistance, compliance, carbon dioxide production, and airway deadspace. CO_2 based measures such as $PETCO_2$ and inspired CO_2 are calculated by the CO_2 sensor and transmitted to the FloTrak Elite module for transmission to the host system. More detail on these parameter calculations is available. See reference (4).

ZEROING – Because of baseline drift, the FloTrak Elite module periodically actuates the zeroing valves, which in turn open the gauge pressure transducer to the atmosphere and connect the ports across the differential pressure transducer. This latter step simulates a zero-flow signal which is measured and subtracted from the measured differential pressure transducer output to compensate for baseline drift.

PRESSURE TRANSMISSION LINE PURGE – In addition, the FloTrak Elite module includes an intermittent purge which keeps the pressure sense lines free from water condensate, medications and patient secretions. The purge and control valves are sequentially opened to allow each pressure sensing line to be cleared with the pump. The pump provides a flow rate < 2 LPM during the short purge operation.

GAS COMPENSATION – Most flowmeter systems ignore the effects of various gas compositions found in critical care and in anesthesia. The FloTrak Elite module allows the host system to select between several predefined gas compositions. Additionally, using specialized software, the constituent gas concentrations can be entered via the communications port for better performance.

SYSTEM OUTPUTS AND INTERFACING – The FloTrak Elite module communicates with a host monitoring system using a proprietary protocol via bi-directional serial communications with signal levels conforming to the RS-232 standard. Essentially, the serial port communicates parameters, real-time waveforms of flow, pressure and CO_2 (if available) and error message strings comprised of a mix of ASCII characters and scaled binary digits. Connectors (see Figure 3) are provided for external interfaces. Connection to a host system requires single voltage (+5V), ground and serial TxD and RxD lines. Four mounting holes (one in each corner) provide for easy mounting within a host system.

AUTOMATIC IDENTIFICATION OF FLOW SENSOR TYPE – Given a specific CO_2/flow or flow sensor type, the physical characteristics of each sensor type will be consistent from one sensor to another. However, due to the differences in the physical size and geometry of the various sensor types (i.e., Adult CO_2/Flow, Pediatric CO_2/Flow or Neonatal CO_2/Flow, Adult/Pediatric Flow or Infant/Neonatal Flow) it is required to use different coefficients in the calculation of flow. Each flow sensor has a unique code that identifies its type. This pattern is encoded onto the connector and is read optically by the system without user intervention.

CARDIAC OUTPUT – With the addition of the cardiac output board to the FloTrak Elite module and use of the NICO sensor (a combined CO_2/flow sensor with a rebreathing valve and loop), noninvasive pulmonary capillary blood flow and cardiac output are easily determined using partial rebreathing (5). The cardiac output board features a solenoid valve and pump, along with associated sensors and electronic circuitry, including a gauge pressure sensor and a 12 bit A/D convertor, to pneumatically control the rebreathing valve. This board is interfaced to the FloTrak Elite module using the I^2C interface which controls the various functions of this board.

SELECTED TESTING

The use of proximal volume measurement in the pediatric and neonatal populations has increased due to the recognition of clinically relevant circuit compliance volume loss and to help assure the adequacy of delivered ventilation. Small differences in the dynamic response between the + and - sides of the pneumatic pathway may result in transient differential pressure signals (falsely interpreted as flow) during rapid and large changes in breathing circuit pressure. This can appear as artifactually high or low tidal volumes. Therefore, some manufacturers tune each flow measurement system to compensate for this effect.
As noted earlier, the FloTrak Elite has sought to minimize this effect by using a highly integrated single piece molded manifold. The performance of the FloTrak Elite module as implemented in the NM3 monitor (Respironics, Wallingford, CT) was evaluated by simulating an intubated neonate with very low compliance lungs (6). Inter-unit variability was assessed in 10 monitors by pumping a 10 ml calibration syringe (at 50 breaths/min) into a neonatal CO_2/Flow sensor connected to atmosphere (i.e. unloaded) and to a very low compliance isothermal neonatal fixed compliance test lung (C=0.28ml/cm H_2O) (loaded). The resulting inspiratory and expiratory tidal volumes (VTI and VTE) for each condition were recorded. The bias and precision for the unloaded VTI and VTE are -0.13±0.11 ml and -0.27±0.15 ml, respectively. The bias and precision for the loaded VTI and VTE (compensating for compression loss) are -0.14±0.14 ml and -0.12±0.19 ml, respectively. The respective coefficient of variation for the unloaded VTI and VTE are 1.0%, 1.5%, and for loaded 1.4% and 2.1%, respectively. These test results have shown comparable accuracy and inter-unit variation under both unloaded and extreme loaded conditions thereby suggesting that the FloTrak Elite module accuracy can be maintained at the lower lung compliance values observed in the neonatal and pediatric populations.

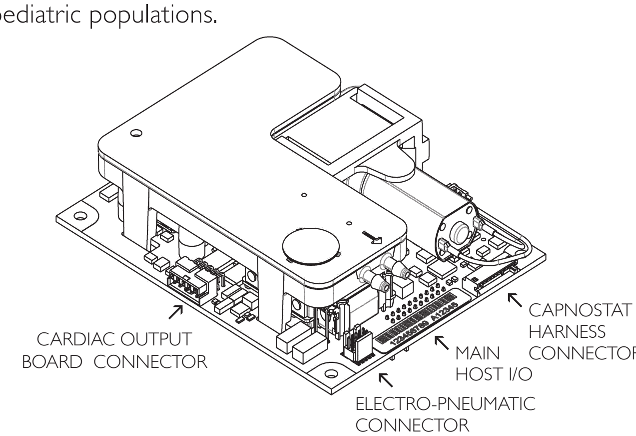

Figure 3 – FloTrak Elite module with external interfaces provided for the CO_2 sensor (Capnostat Harness connector), host (Main Host I/O), cardiac output board and electro-pneumatic connector.

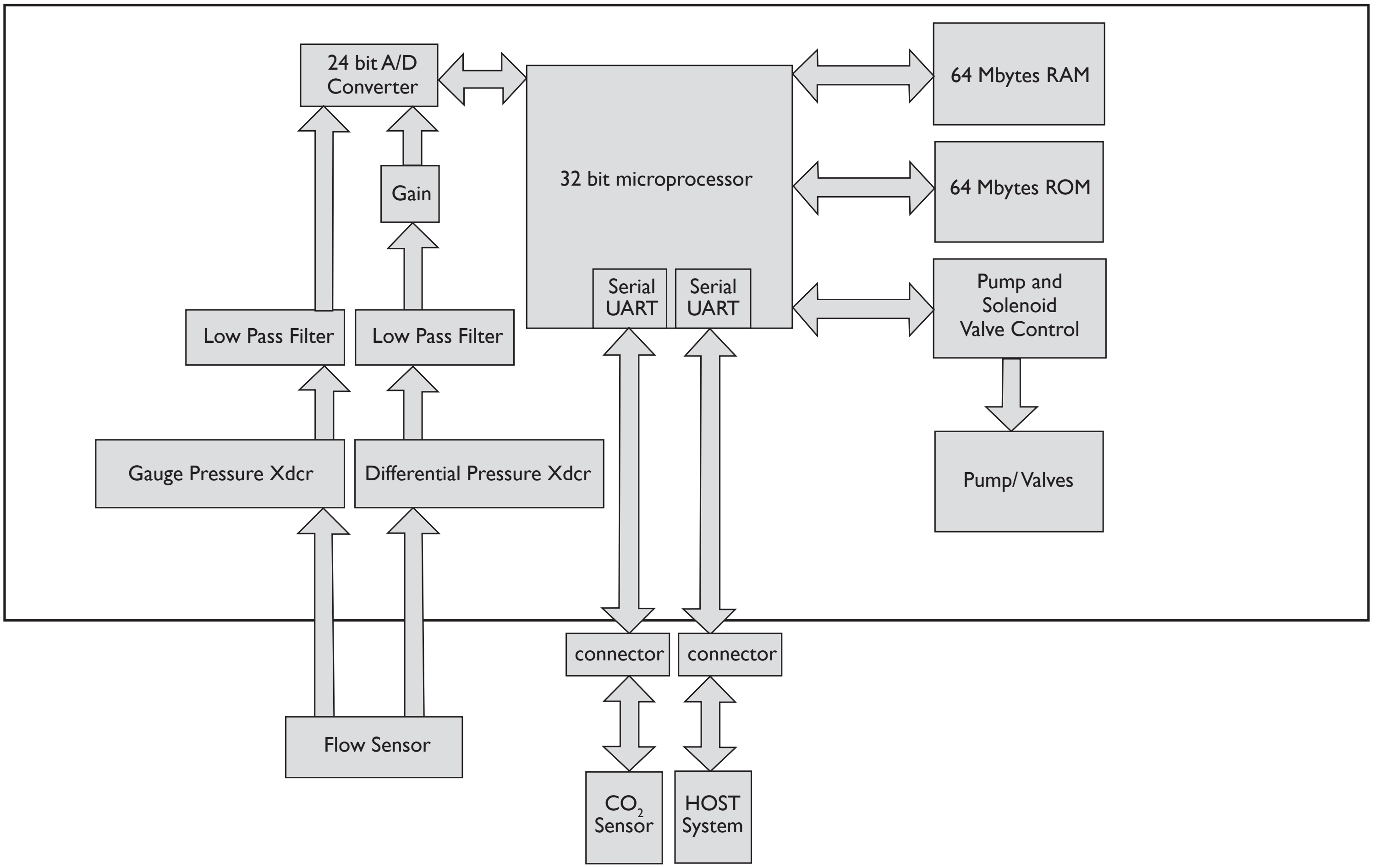

Figure 4 - Block Diagram of FloTrak Elite Module

In addition to the current measurement portfolio, the FloTrak Elite module was designed to serve as the platform for even more advanced capabilities.

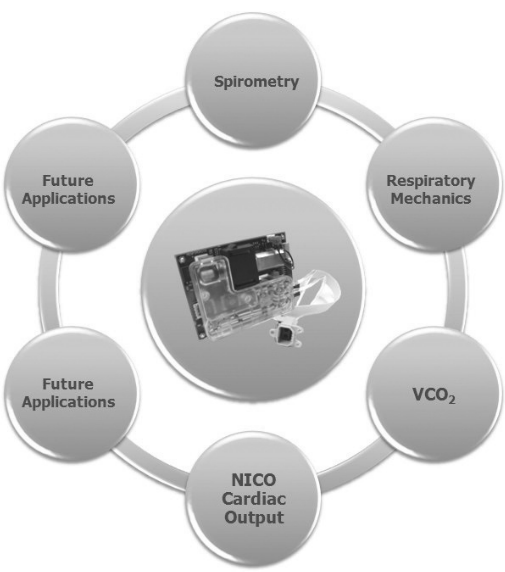

Figure 5 - FloTrak Elite "engine" - Applications enabled

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