WHITE PAPER

CAPNOSTAT 5 CO_2 Sensor – A Robust and Reliable Sensor

RESPIRONICS
Envisioning tomorrow. Improving today.

ABSTRACT

The CAPNOSTAT 3 sensor, the most widely used mainstream CO_2 sensor in use today, owes much of its success to its robust and extremely rugged solid state design. The CAPNOSTAT 5 CO_2 sensor's increased complexity necessitates even greater attention to robustness and reliability. To assure the high level of reliability that customers have come to expect from Respironics, new test methods — in addition to the standard existing test methods of shock, drop and vibration — are required. This document describes the extreme-severity drop testing and highly accelerated life testing (HALT) of the CAPNOSTAT 5 CO_2 sensor. This drop testing and HALT has confirmed the ruggedness and durability of the CAPNOSTAT 5 CO_2 sensor (Figure 1).

INTRODUCTION

The CAPNOSTAT 3 CO_2 sensor, introduced in 1995, has been known for its reliability and ruggedness. The introduction of the fully integrated CAPNOSTAT 5 CO2 sensor — with its greatly increased density of electronics and component count — necessitates even more careful attention to the robustness of the device in the clinical setting. The stress that a complicated electro-optical device undergoes when subjected to high G forces associated with drops onto hard surfaces is complicated and difficult to model due to the complex geometries and the many contact conditions.[1] These external forces can induce stresses and strains in the circuit boards, which result in forces experienced by integrated circuit packages and their interconnections. It is therefore, essential for such devices to be sufficiently robust to withstand the occasional severe impact.[2] Standard drop testing of complete devices consists of either single or repeated free fall testing.[3] Repeated free fall testing is intended for testing cable-connected devices where the device may be dropped frequently onto hard surfaces. Each specimen of the device is tested individually to a prescribed number of falls from a specified height onto a hard surface. The test notes that the number of falls shall be related to the intended usage of the item. The height of fall shall be 0.5 meter (approximately 20 inches). Handheld electronic products have been expected to survive 20 – 30 drops from 5 feet.[4] Given that the CAPNOSTAT 5 CO_2 sensor is used in clinical environments, ranging from less abusive environments such as operating rooms and intensive care units to more abusive environments such as emergency departments or pre-hospital situations, the need to drop the sensor from a greater height and a significant number of times is apparent.

METHODS

The drop testing described consists of repeated 6-foot drops varying the orientation (Figure 2) onto a rigid non-dampened surface of 3/4" aluminum. To perform this testing, the CAPNOSTAT 5 CO_2 sensor is placed into the housing holder of the pole-mounted drop test fixture (Figure 3). The placement of the CAPNOSTAT 5 CO_2 sensor in the holder will alternate among the orientations shown in Figure 2. Since the sensor is secured only by the cable in the drop fixture, the actual impact on a given surface is somewhat variable such that edges and corners adjacent to the target surface also randomly receive impacts.

Figure 1 - CAPNOSTAT 5 CO_2 sensor with airway adapter

All possible orientations are used with the exception of the face opposite face E because the cable and strain relief prevents the CAPNOSTAT 5 CO_2 sensor from falling on that face. The CAPNOSTAT 5 CO_2 sensor is dropped ten (10) times on each side, for a minimum of fifty (50) drops. The CAPNOSTAT 5 CO_2 sensor is visually examined after five (5) drops. After ten (10) drops, function checks are performed and the CO_2 reading is recorded. If a CAPNOSTAT 5 CO_2 sensor should fail to operate properly or sustain catastrophic visible damage before fifty (50) drops, the cause and nature of the failure are determined, and the device will be considered to have failed the test. If the failure does not compromise the utility of the test, testing continues to expose the next weakest mechanical component. The drop test will continue (10 drops per side) until a failure occurs. The number of drops and all observations are recorded.

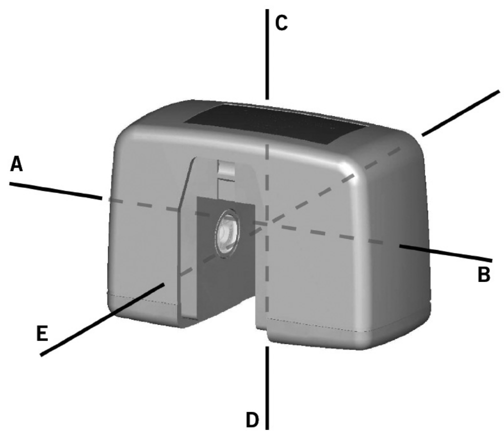

Figure 2 - CAPNOSTAT 5 CO_2 Sensor Drop Orientations:
A – Source Side; B – Detector Side; C – Closed U Side;
D – Open U Side; E – Face

RUGGEDIZATION

To achieve the robustness and reliability, attention must be paid to the details of construction and assembly. This includes, but is not limited to, how the device is assembled, the means of fastening and bonding, and clearances of all components. The "rigid" base structure to which the components are assembled adds to the robustness.

A film with novel electrical, thermal, chemical and mechanical properties is applied to prevent components from direct contact with the outside walls, case sealing adhesives, and other nearby components. Strain reliefs are used to prevent interconnecting wires from undue mechanical stress.

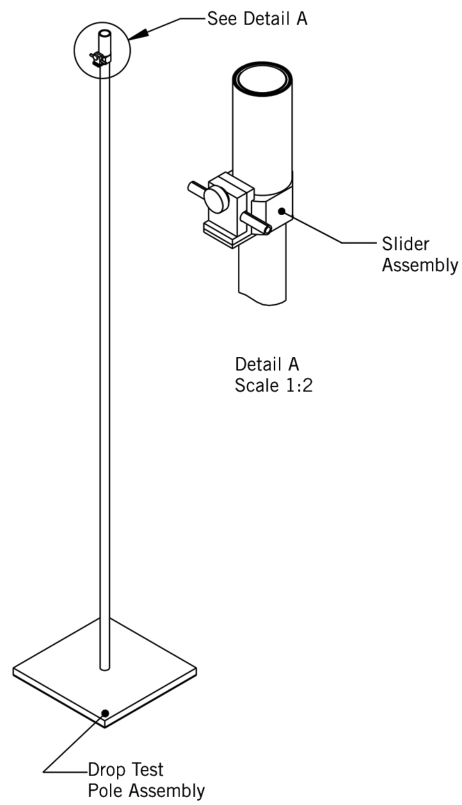

Figure 3 - Drop test pole and slider; pole 72 inches long; aluminum plate 12" x 12" x 3/4"

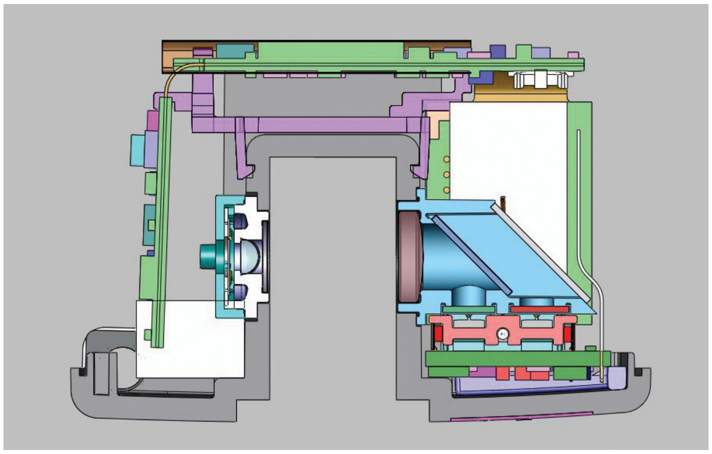

Figure 4 - Cross-section of the CAPNOSTAT 5 assembly.

RESULTS – DROP TESTING

Seventy-seven production CAPNOSTAT 5 CO_2 sensors were dropped to the point of failure per the protocol. At no time during this testing did the external housing fail such that any internal components or wires were exposed, nor did any hazardous conditions arise. The mean number of drops of all tested sensors was determined to be 297, which is substantially above the design target of 100. Figure 7 shows the inverted cumulative distribution function of the fraction of CAPNOSTAT 5 CO_2 sensors surviving as a function of the number of drops.

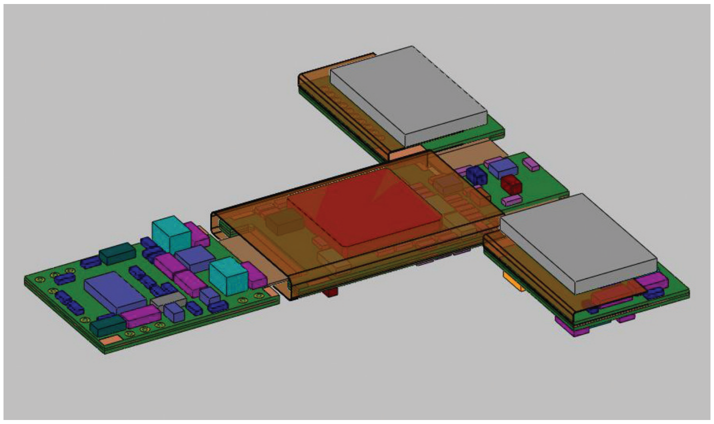

Figure 5 - Cross-section of the CAPNOSTAT 5 assembly.

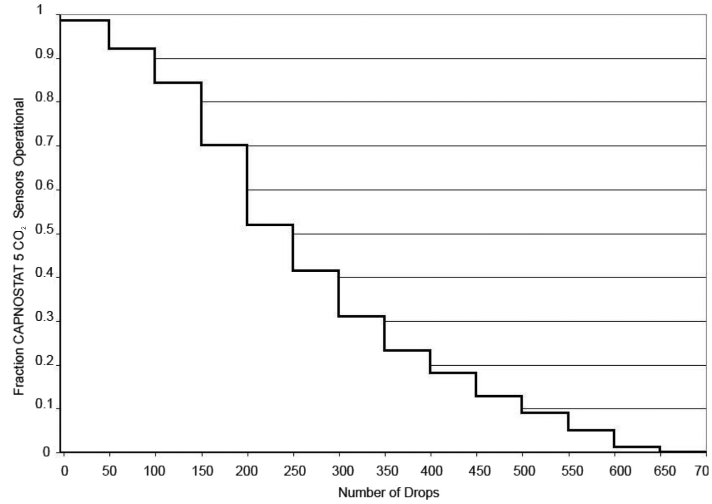

Figure 7 - Fraction of CAPNOSTAT 5 CO_2 sensors remaining operational vs. number of drops (bin size = 50)

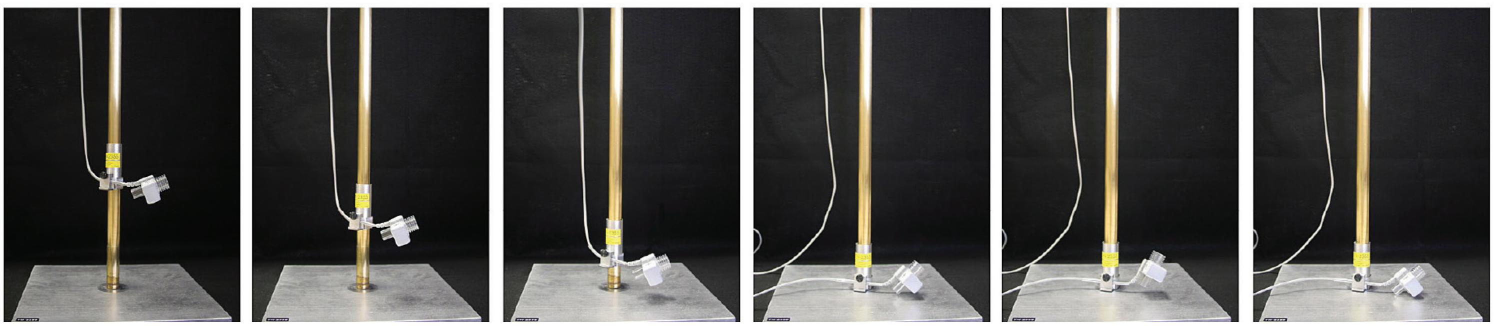

Figure 6 - Drop Test - Sequential Images

OTHER TESTING

Highly Accelerated Life Testing (HALT)

Product ruggedization through stress application, often called HALT, is used to improve a product so that failures due to workmanship, marginal design, or faulty components are minimized. The application of rapid rate thermal stress and vibration to a product can expose design problems as well as assembly process problems. HALT has been a standard testing methodology used in military applications and is now being applied in other industries including the medical device industry. HALT exposes the product to a step-by-step cycling in environmental variables such as temperature, shock and vibration. HALT involves vibration testing in all three axes using a random mode of frequencies. Finally, HALT can include the simultaneous cycling of multiple environmental variables. For example, temperature cycling plus vibration testing for a closer approximation of real-world operating environments. A rapid rate thermal chamber with a 6-axis random vibration table is used to apply HALT on the devices under test (DUT). Unlike conventional testing, the goal of HALT is to break the product. After a product has failed during HALT, the weak component(s) are typically upgraded or reinforced. The revised product is then subjected to another round of HALT, often with the range of temperature, vibration, or shock further increased. HALT should also be performed on actual production units, to ensure that the transition from engineering design to production has not resulted in a loss of product quality or robustness. This testing is intended to take the product to the point of failure. Table 1 summarizes the HALT performed on 12 production CAPNOSTAT 5 CO_2 sensors (3 per test). All of the DUTs were powered during testing and all but one remained functional upon completion of the testing. Figure 8 illustrates the cycling of temperature and steps for vibration for rapid thermal with vibration test.

ADDITIONAL TESTING

The CAPNOSTAT 5 CO_2 sensor is also tested to the following standards:

- EN60068-2-6 Sinusoidal Vibration
- EN60068-2-27 Shock
- EN60068-2-64 Random Vibration

In addition, the mechanical strength and flexibility of the CAPNOSTAT 5 CO_2 sensor cable was also addressed during the design and tested. The cable strain (bend) relief system for the sensor enclosure is required to withstand a pull of 30 pounds without failure to either the cable or the enclosure. The connector strain relief system is required to withstand an excess of 10,000 bend-cycles. The average retention force of the standard connector when pulling on the cable is 90 Newtons (20 pounds).

Table 1 - Summary of testing performed in HALT chamber

Test Summary	
Vibration	5-65 Grms added in 5-Grms steps, 10 minutes at each step
Low Temperature	20, 0, -10, -20, -30 degrees C, steps of 10-degree C, 15 minutes at each temperature
High Temperature	20, 40-90 degrees C, steps of 10-degree C, 15 minutes at each temperature
Rapid Thermal Test	-20 to -80 degrees C, 10 minutes at each (2.5 min between), repeated N times
Rapid Thermal w/ Vibration Test	Same as rapid thermal test with 6-72 Grms added in 6-Grms steps

Note: Grms - root mean square value of the acceleration (measured in Gs)

CONCLUSION

The mechanical reliability and resistance to physical abuse of the CAPNOSTAT 5 CO_2 sensor exceeds the design requirements by a considerable margin. The CAPNOSTAT 5 CO_2 sensor can confidently be expected to maintain the reputation for ruggedness and reliability in clinical use previously established by the CAPNOSTAT 3 sensor.

REFERENCE

(1) Wong EH, Mai YW, Seah SKW, Rajoo R, Lim TB, Lim CT, Field J. Drop Impact Reliability – A Comprehensive Summary. 2005 Conference on High Density Microsystem Design and Packaging and Component Failure Analysis. 2005; June:1-11.

(2) Lim CT, Ang CW, Tan, LB, Seah SKW, Wong EHl. Drop impact survey of portable electronic products. Proceedings. 53rd Electronic Components and Technology Conference. 2003; May 27-30:113 – 117.

(3) IEC 60068-2-32:1975, Environmental testing, part 2-32: Tests —Test Ed. Free fall. Amendment 1:1982. Amendment 2:1990.

(4) Goyal S, Upasani S, Patel DM. The role of case-rigidity in drop tolerance of portable products. Int J Microcircuits and Electron Packag. 1999;22(2):175-184.

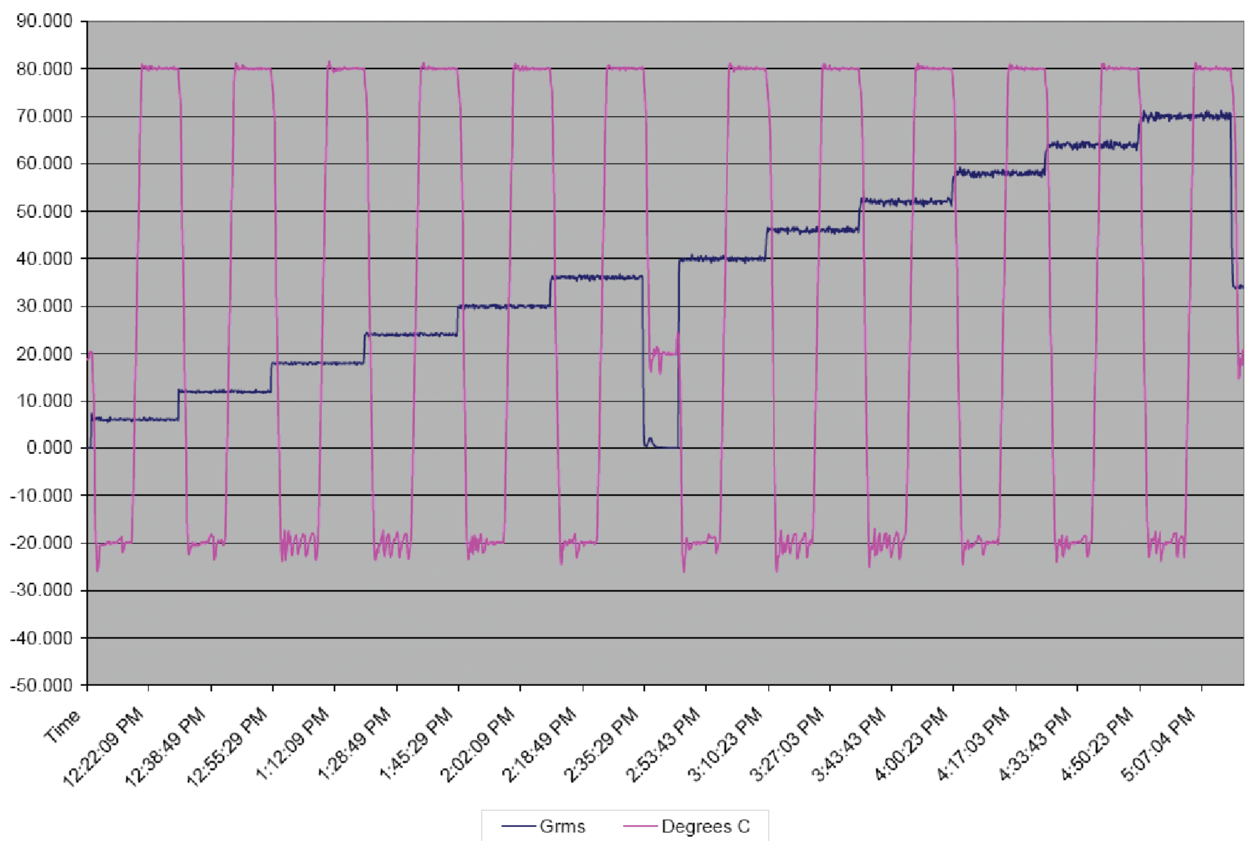

Figure 8 - HALT cycling for Rapid Thermal w/Vibration Test