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Changing The Face Of Blood-Pressure Monitoring

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The word "tensymetry" has no definition in *Webster's Dictionary*, but it's well known in the medical world. Developed by Tensys Medical Systems, tensymetry is a technology that uses a proprietary combination of biomechanical, electrical, and software engineering. With that powerful trio, it can perform accurate, continuous, real-time, and non-invasive measurement of a patient's beat-to-beat blood pressure in an operating room.

The fruit borne from that technology has been the company's T-line Tensymeters. The most recent of this line, the TL-150, was introduced this March *(Fig. 1)*. Worn on a patient's cuff, the TL-150 vastly improves on its predecessors thanks to advances in motion tolerance. It measures blood pressure at the radial artery.

According to leading anesthesiologists, this development is nothing short of revolutionary. "The TL-150 will change the way we measure blood pressure in the future," says Dr. Peter Szmuk, associate professor of anesthesiology at the University of Texas Medical School, Houston. "Results show remarkable correlation between the T-Line and ALine (arterial line) reference during clinical situations in which a typical non-invasive blood-pressure (NIBP) cuff is known to be highly suspect and beat-to-beat vigilance is highly desirable."

The A-line reference is an FDA-approved standard (SP10:2002, accuracy specification 4.4.5.2.B) established by the Association for Advanced Medical Instrumentation (AAMI) for non-invasive blood-pressure monitors. It specifies a mean difference standard deviation within ±5 mm Hg (mercury), not to exceed 8 mm Hg, which the TL-150 meets. A case study confirms the T-Line's importance versus the use of infrequent non-invasive blood-pressure monitoring *(Fig. 2)*.

Blood-pressure monitoring is a routine part of every surgical case, and it's critical in determining the surgical patient's hemodynamic status. Rapid blood-pressure changes, which can occur within a few heartbeats, may signal potentially serious complications. The proprietary tensymetry technology, on which the TL-150 is based, enables blood-pressure monitoring from the radial artery without using any external calibration source.

HOW IT WORKS

The medical staff externally applies the single-use, disposable pressure sensor after confirming the presence of a palpable pulse. Then the sensor is mated to the instrument's proprietary bracelet. Other than entering the patient's height and weight into the system, no further intervention is necessary.

Once the "zero paddle" is removed from the sensor, the system automatically compensates for atmospheric pressure and initiates a scanning operation to define an optimum pressure-sensing position over the radial artery. Next, the system performs a dynamic application pressure search. This involves slightly compressing the radial artery to determine a patient's mean arterial pressure, which is then scaled.

Tensys' design uses an actuator to move a sensor over the patient's wrist. The sensor

has to float within a rigid frame attached to a serpentine arm designed to flex.

According to Stuart L. Gallant, chief technical officer for Tensys Medical, the TL-150 uses the patient's radial artery as the primary pressure source for the system. A proprietary algorithm determines diastolic and systolic pressures. A highfidelity beat-to-beat waveform is presented on either the TL-150's own display or an external display.

Proprietary servo-control algorithms enable the TL-150 to automatically and continuously respond to hemodynamic variations, as well as track significant blood-pressure changes without user intervention. The user is informed, via appropriate messaging and audible alerts, of any conditions that might affect patient safety, such as an abrupt loss of a signal.

"This device represents a significant improvement over the previously released TL-100. It is more userfriendly, requires fewer steps to gain an accurate waveform, and continues monitoring in more adverse conditions compared to its predecessor," says Dr. Gregory Janelle, assistant professor of anesthesiology at the University of Florida in Gainesville.

Anesthesiologists from the Emory University School of Medicine and the medical schools at the universities of Texas and Colorado also tested the TL-150 blood-pressure monitor and reported favorable results.

"With the TL-150, customers now have an accurate and non-invasive system that provides the superior control of beat-to-beat blood-pressure monitoring for cases where they currently use a traditional cuff," says Mike Martin, Tensys' chairman and CEO.

The TL-150 measures systolic blood pressure over a range of 30 to 245 mm Hg and diastolic blood pressure from 20 to 220 mm Hg. Its pulse-rate measurement capability is specified over a range of 30 to 250 beats per minute.

Other specifications include an operating temperature range of 15°C to 40°C and ac power input requirements of 120 V, 60 Hz, at 0.5 A maximum. (A B version is rated at 100 to 240 V ac, 50 to 60 Hz, at 0.8 A maximum.) The TL-150 measures 10 in. wide by 8.5 in. high by 9 in. deep (including a pole clamp) and weighs 5 lb.

PROTOTYPING DESIGN CHALLENGES

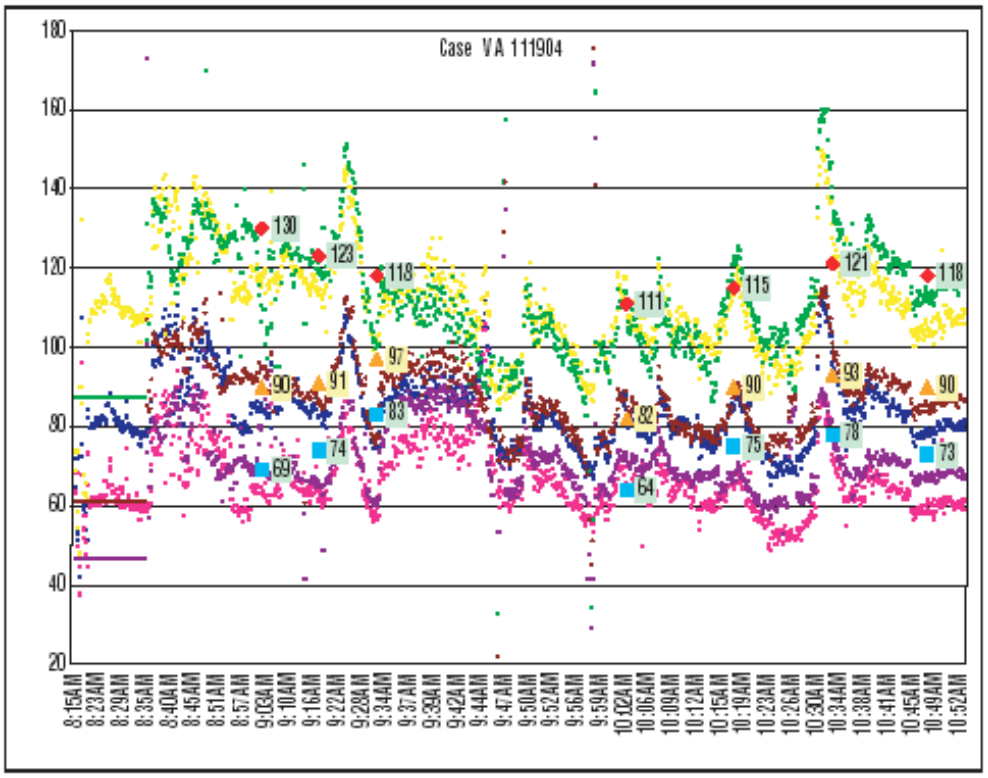
Earlier prototypes of the TL-150, which were developed using SLA castings, didn't permit verification testing. Also, the production-tool vendor could not construct the product properly. (SLA is a universal file format used in a rapid prototyping process. This file type contains raw geometric data).

Facing looming time-to-market deadlines, Tensys engineers took an unconventional step backward and explored rapid injection molding for prototyping and pilot production. Working with Protomold Co., the rapid injection molding process delivered the parts in a time frame that was 90% faster than that from other molding companies *(Fig. 3)*.

Figure 1

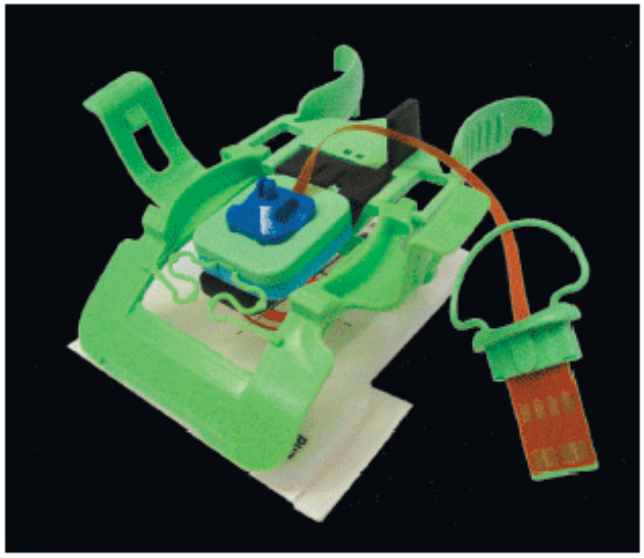
1. The TL-150 cuff-worn, non-invasive, continuous real-time blood-pressure monitor from Tensys Medical sets a new level of accuracy and ease of use for medical anesthesiologists when used for surgical procedures.

Figure 2



2. This chart shows the close correlation of blood-pressure measurements as a function of time for a 57-year old patient between A-line and T-line measurements. The numbered red squares are regular and infrequent A-line measurements corrected and picked up by the T-line.

Figure 3



3. A rapid injection molding process used by Protomold allowed designers of the Tensys Medical TL-150 blood-pressure monitor to deliver prototypes much faster than other molding methods. Shown above are molds of the T-line's bracelet and disposable sensor.

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