Transonic Systems, Inc.

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Project Title: Transonic HD01 Hemodialysis Flow Monitor

Technology Developed

The success: SBIR Phase-I and -II funding allowed Transonic Systems, Inc. to develop and validate a device that will measurably improve the health of 210,000 American kidney failure patients receiving hemodialysis, and may potentially save Medicare and other insurers an estimated $0.9 billion dollars/year.

The health problem: SBIR funding allowed Transonic Systems, Inc. - a business dedicated to engineering, manufacturing, and marketing innovative clinical and research blood flow measurement devices - to develop, validate and gain clinical acceptance of a pioneering new method and device that diagnoses the health of the dialysis "shunt" (a surgically-created connection between an artery and a vein) in kidney failure patients undergoing hemodialysis. Patients suffering from kidney failure – formally known as End-Stage Renal Disease (ESRD) - typically receive three hemodialysis treatments of their blood each week. These treatments remove toxins and liquids normally removed by the kidneys. The patient is dialyzed by connecting the patient's cardiovascular circuit to the dialysis machine via needles inserted into the patient's shunt, thus making the shunt the critical connection for removing blood and returning filtered blood to the patient's cardiovascular system. This shunt is the patient's link to life: without a well-functioning shunt a patient cannot receive adequate dialysis. Unfortunately, shunts tend to develop a progressive disease called stenosis, meaning that the shunt gradually blocks up. When the stenosis progresses to the point where the shunt flow is less than the flow drawn by the dialysis machine, then patient will become under-dialyzed and become sick, since the dialyzer will recirculate freshly dialyzed blood rather than process the patient's entire blood supply. If stenosis is allowed to progress even further, full thrombosis (blockage) of the shunt occurs, which then requires traumatic and expensive surgery to clear the blockage or surgically replace the graft. However, if the access stenosis is detected early enough, then the disease can be reversed by a minimally invasive procedure such as angioplasty.

The Transonic Systems approach to measuring access flow: Clinical studies done in the early 1990s indicated that a drop in shunt flow is a reliable warning of the onset of access stenosis; if caught in time this disease can be reversed by minimally-invasive procedures such as angioplasty. At that time the only available testing method was Color Doppler Ultrasound; this method was costly (because it is an expensive device, and its measurements requires a medical specialist and a separate office visit) and inaccurate (because of turbulent flow conditions normally seen in the shunt.)

Supported by NIH SBIR funding, Transonic pioneered a new method for measuring shunt flow called ultrasound indicator dilution. This method uses special clip-on ultrasonic sensors attached to arterial and venous dialysis tubing lines. These sensors measure both volume blood flow in the dialysis circuit, as well as indicator dilution changes in blood ultrasonic velocity caused by small saline injections. Under Transonic's novel shunt flow measurement protocol, the patient's dialysis blood lines are temporarily reversed so the dialyzer pump returns the patient blood into the shunt, upstream from its intake line. A bolus of saline is then introduced in the upstream dialysis line; the sensor on that blood line registers the initial saline concentration. After mixing in the shunt, the downstream intake line samples the saline concentration, and the ultrasonic sensor placed on the downstream dialysis line registers the indicator dilution curve resulting from the saline injections. The shunt flow is then calculated by processing and analyzing the upstream and downstream indicator dilution curves.

In developing this technology, the Transonic SBIR project team worked closely with prominent Nephrology researchers to validate the clinical significance in their research. This collaboration also

helped Transonic develop software that made the technique and the Transonic device (the "HD01 Hemodialysis Monitor") robust and simple to use. The result was an FDA-cleared, compact, and inexpensive device and measurement protocol that will work with any manufacturer's hemodialysis machine and indeed can be performed by a technician after only one day of in-service training. Once trained, the technician can perform a full patient diagnostic test in 15 - 20 minutes.

Uses of Technology:

Because of the HD01 Hemodialysis Monitor's simplicity, practicality and effectiveness, it has been estimated that the average hemodialysis patient may spend 10 fewer/days/year in the hospital due to hemodialysis-related complications. The cost of access morbidity was approximately $7,871/year/patient in 1994 (Hakim *et al.,* 1998), and for 1999 it is estimated to be $8,800/year/patient. It is estimated that HD01 monitoring can reduce these costs by approximately 50%. With more than 210,000 hemodialysis patients in the U.S. alone, Medicare and other insurance providers can save $0.92 billion/year. Since Medicare pays for the care of over 90% of U.S. hemodialysis patients, U.S. taxpayers will therefore benefit from most of these savings. Recognizing the benefits to patient health and the cost savings to Medicare & other insurers, the CPT Editorial Panel of the American Medical Association has approved a new Medicare reimbursement code for monitoring the blood flow in grafts during hemodialysis. This code will become effective on Jan. 1, 2001.

Global Acceptance of SBIR/STTR-developed technology

The clinical studies spearheaded under this SBIR project (and continued by the Nephrology community) have fueled a world-wide change in hemodialysis patient monitoring procedures. At this writing researchers have published 95 papers and abstracts on this new technology, and the Transonic HD01 method is now listed as a preferred measurement approach in the National Kidney Foundation's 1997 "Dialysis Outcome Quality Initiative". The HD01 Hemodialysis Monitor is now being used in approximately 7% of the USA clinics (with further sales strongly depending on new Medicare reimbursement policy). Device acceptance in countries with socialized medicine has been even more dramatic: 25% of the dialysis clinics in Canada, 35% of the clinics in France, and 70% of the clinics in Holland use the Transonic HD01 in their scheduled patient care. And a final note: US News & World Reports (July 17, 2000) published a list of 50 Best Hospitals for Kidney Disease in the USA. Half of these hospitals use the Transonic HD01!

For More Information on the Transonic Systems HD01 & Flow Quality Control:

Pictures of the HD01 Hemodialysis Monitor	http://www.transonic.com/hd01_monitor.html
Transonic Web Page on Hemodialysis Quality Control	http://www.transonic.com/hemodialysis.html
Caring for a patient's hemodialysis shunt (access)	http://www.springnet.com/ce/p003b.htm

For Touching & Compelling Descriptions of Life on Dialysis

A woman's experience with hemodialysis	http://www.geocities.com/HotSprings/Falls/7375/index.html
A man's experience with hemodialysis	http://www.cc.utah.edu/~cla6202/DrF.htm
A child's experience with hemodialysis	http://members.tripod.lycos.co.kr/jaihyuk/index1.html

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