

Cleveland Medical Devices Inc.

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Technology Developed under NINDS funding: BioRadio™¹, Crystal-EEG™, and Crystal-Sleep™

Total sales for the company:

1996: \$381K
1997: \$801K
1998: \$1,344K
1999: \$2,016K

All of the above sales may be attributed to the technologies developed under the SBIR program. This has allowed Cleveland Medical Devices to grow to over 20 employees.

Uses of technology: The BioRadio is a wireless physiological monitor that can be used for medical research. Crystal-EEG and Crystal-Sleep are currently in the FDA review and approval cycle and will provide untethered EEG and sleep monitoring for patients.

The Role of the SBIR Program in the Commercial Success: The BioRadio, Crystal EEG, and Crystal-Sleep all utilize the MicroRadio™, RadioWear™ and programmable data acquisition technologies that were developed in part under **16 different SBIR programs** from the NIH (NINDS, NIMH, NHLBI, NIDCD, NIA), US Air Force, US Army, NSF, and DoEd. **The National Institute of Neurological Disorders and Stroke (NINDS) has been the primary funding Institute, providing over half the funds.**

Cleveland Medical Devices Inc. of Cleveland, OH is an example of a success story in process. The SBIR program has allowed the company to achieve its rapid growth, averaging a compound annual growth rate of 46% per year (1994-1998). This growth rate allowed us to be **named by Inc. Magazine (May 2000) as the 34th fastest growing company in an Inner City in the United States.** In 1999, this five year average grew to a **73.8% compounded annual growth rate.**

The SBIR program also allowed Cleveland Medical Devices to develop the platform technologies of MicroRadio, RadioWear and programmable data acquisition. The company used the research from 16 SBIRs over the last 7 years to develop the BioRadio product (a wireless physiological monitor) which is currently used by researchers; and the Crystal-EEG and Crystal-Sleep, which are anticipated to be introduced in the year 2000, after receiving FDA approval.

The BioRadio comes in two versions: the BioRadio 100 for untethered EEG and Auditory Evoked Response testing; and the BioRadio 110, which is a programmable data acquisition system used by researchers such as those at Lawrence Livermore National Laboratory for obtaining heart information using a radar chip from untethered subjects. Other examples of users of the BioRadio include the Catholic University and the Northeast Center for Telecommunications Technologies for obtaining real-time physiological data from patients/subjects free to roam about for telemedicine experiments. The BioRadio is also being developed into a low cost tool to teach physiological monitoring at a biomedical engineering program at another university.

The BioRadio provides two major advances to the state-of-the-art. First, it is the first wireless EEG to efficiently transmit brain wave data using unlicensed radio bands from patients free to move about a ward or their home while being continuously monitored, wearing only a "deck of cards" size device weighing only 3.8 oz. It's light weight allows the device to be head mounted, eliminating wires across the neck, significantly reducing motion artifacts. Second, because the filters and gains in the device are programmable, the same piece of equipment can be used for EEG, EKG, EMG, EOG, and PSG testing. This allows a single piece of equipment selling for under \$8,000 to replace over \$100,000 worth of single-use devices.

¹ BioRadio, Crystal EEG, Crystal ECG, Crystal EMG, Crystal Sleep, Crystal Patient Monitor, Crystal Neonatal Monitor, Crystal Home Monitor, MicroRadio and RadioWear are all trademarks of Cleveland Medical Devices Inc. of Cleveland, OH.

Although the BioRadio is in its own right a success, the real potential of the platform technologies that the SBIRs helped to develop will be shown over the next decade. Two new corporations have been formed to commercialize the technologies. Clevemed.com was recently formed to commercialize the Crystal line of medical patient monitors (Crystal-EEG™, Crystal-Sleep™, Crystal-EMG™, Crystal-ECG™, Crystal Patient Monitor™, Crystal Neonatal Monitor™, and Crystal Home Monitor™). It will use the internet both as a low cost sales media, and as tool to move patient data from the patient to the physician. RadioStorm Inc. is commercializing the “Cyclone” wireless data acquisition system (based on the BioRadio) for industrial applications.