A Novel Neonatal Telemetry System for Sleep Monitoring

Mark Johnson[1], Joseph Giuffrida[3], Mohammad Modarreszadeh[3], Hani Kayyali[3], and Mark Scher[1,2]

3. Department of Pediatrics, Rainbow Babies and Children's Hospital - University Hospitals of Cleveland, OH

4. School of Medicine, Case Western Reserve University, Cleveland OH

3. Cleveland Medical Devices Inc., Cleveland, OH

Objective

The project objective was to illustrate that a novel, practical, and inexpensive means of monitoring the physiological and behavioral state of neonates during sleep provided the same information as a traditional cart-mounted monitoring unit.

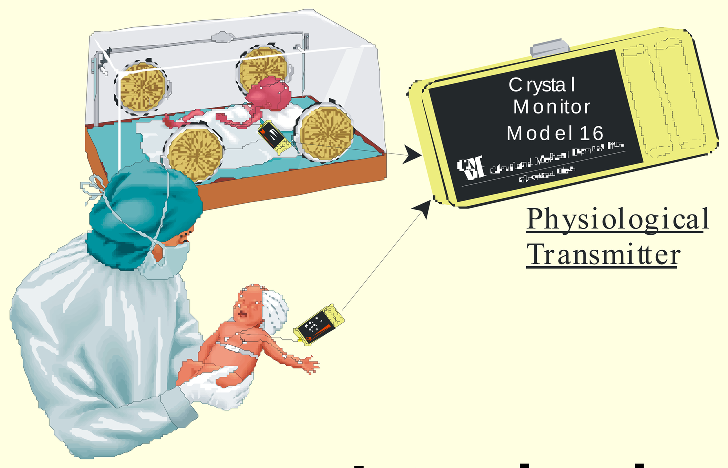

Figure 1. Polysomnography studies on neonates typically involve multiple leads that tether patients to a cart mounted monitoring system.

Introduction

Traditional, cart-mounted bedside units, at present are large and cumbersome, which impede nursing care and inhibit the clinical traffic around the infant in an isolette in a busy neonatal intensive care unit. Innovative methods for assessing brain function, therefore, are needed that can take advantage of technological advances to accommodate the unique needs of the high-risk neonatal patient in a neonatal intensive care setting.

Normal Neonate Sleep Cycles

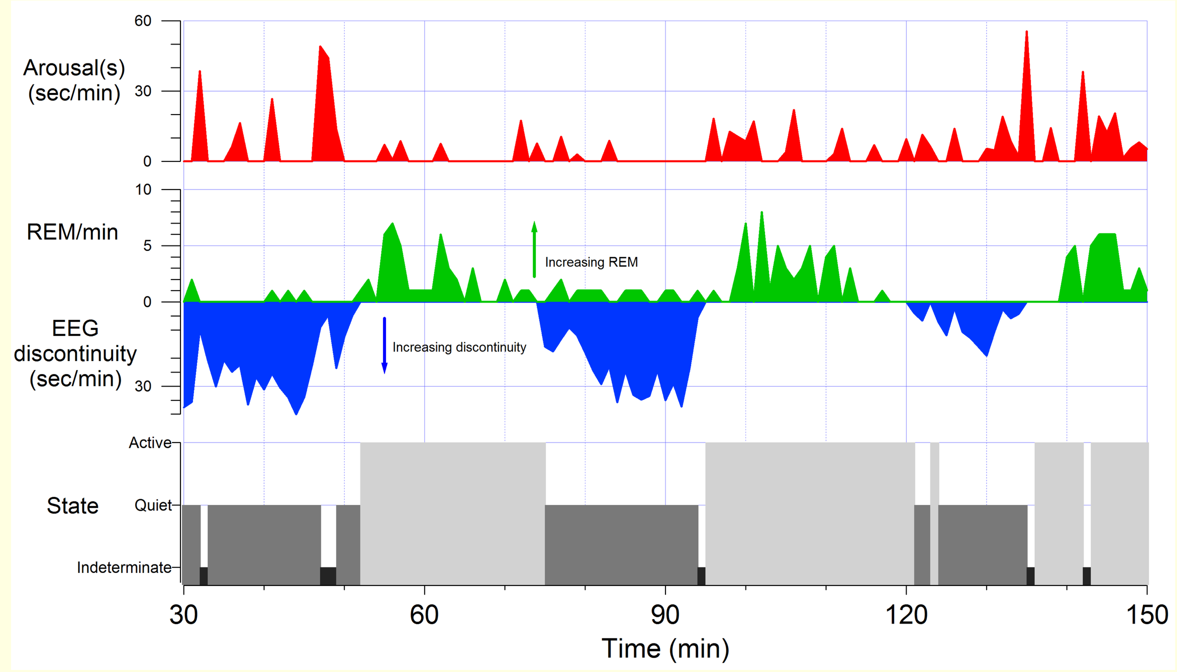

Figure 2. Normal neonatal sleep cycles between Trace Discontinue (quiet sleep) and REM (active sleep) with short periods of arousal throughout.

Primary Neonatal Sleep States

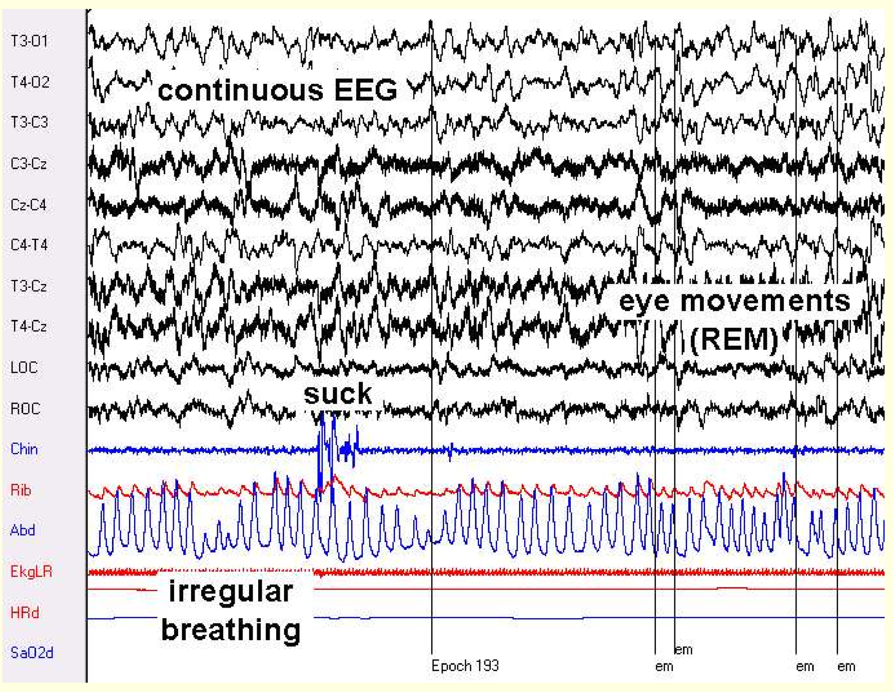

Figure 3. Active Sleep State

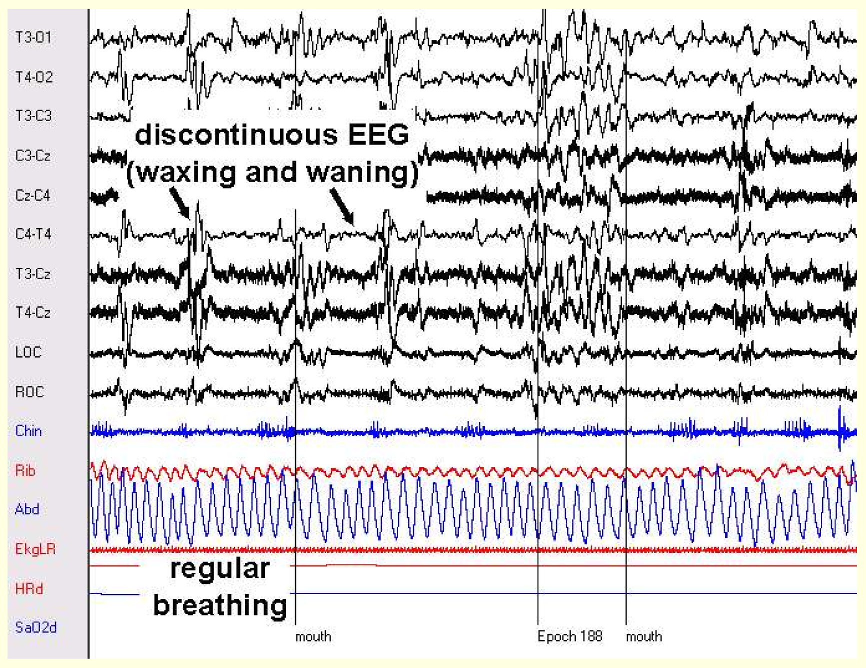

Figure 4. Quiet Sleep State

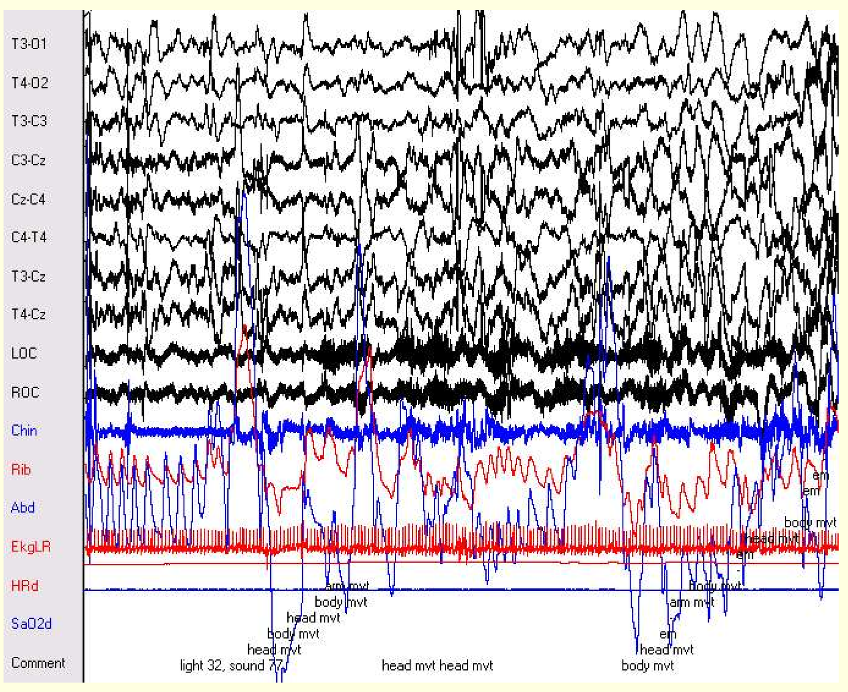

Figure 5. Arousal-Indeterminate

Methods

A novel, untethered system for monitoring sleep, the Crystal Monitor® Model 16, was developed to record and transmit physiological data to a laptop computer located up to 200 feet away. This small (4.0" x 2.2" x 0.7"), lightweight (3.8 oz) system was evaluated in a side-by-side comparison to a traditional cart mounted, Nihon Kohden system. Physiological data was recorded from seventy neonatal subjects in the neonatal intensive care unit of University Hospitals of Cleveland. All neonates were between 31 and 33 weeks post conceptional age. Using the same recording electrodes, data was simultaneously recorded with both the novel and traditional systems. Six channels of electroencephalography (EEG) and two channels of electro-oculography (EOG) were collected for each neonatal subject. Each sleep study lasted approximately three hours. EEG recording sites included T3, C3, T4, C4, Cz, O1, and O2. Collected data from each system was scored by the same clinician for EEG sleep state. Presence of trace discontinu indicates quiet sleep state in neonatal subjects whereas continuous EEG indicates active sleep. The clinician was blinded to the system and patient during scoring of EEG sleep state. The inter-system reliability between the traditional and novel system was computed by calculating Cohen's Kappa scores.

Crystal Monitor Model 16 Unit

Figure 6. Crystal Monitor Model 16 eight channel wireless physiological monitor patient unit.

Results

To this point, scoring has been completed on fourteen of the seventy collected data files. The inter-system reliability Kappa score for EEG sleep state was 82.1%. These results indicate that the correlation between the scores produced by the Crystal Monitor 16 and the traditional systems were similar. In addition to the quantitative scores, the novel untethered system provided less obtrusive monitoring than the traditional cart mounted system. The miniature system required substantially less space in the neonatal intensive care unit than the cart mounted system.

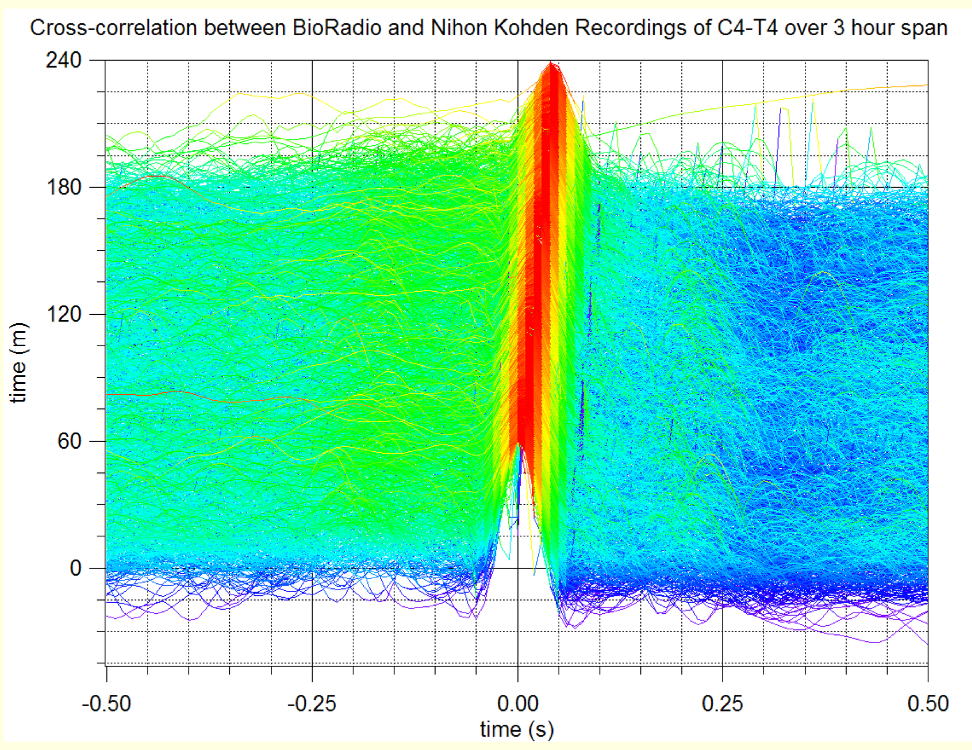

Figure 8. The cross-correlation between Crystal Monitor 16 and the Nihon Kohden system of C4-T4 EEG signal over a 3 hour span.

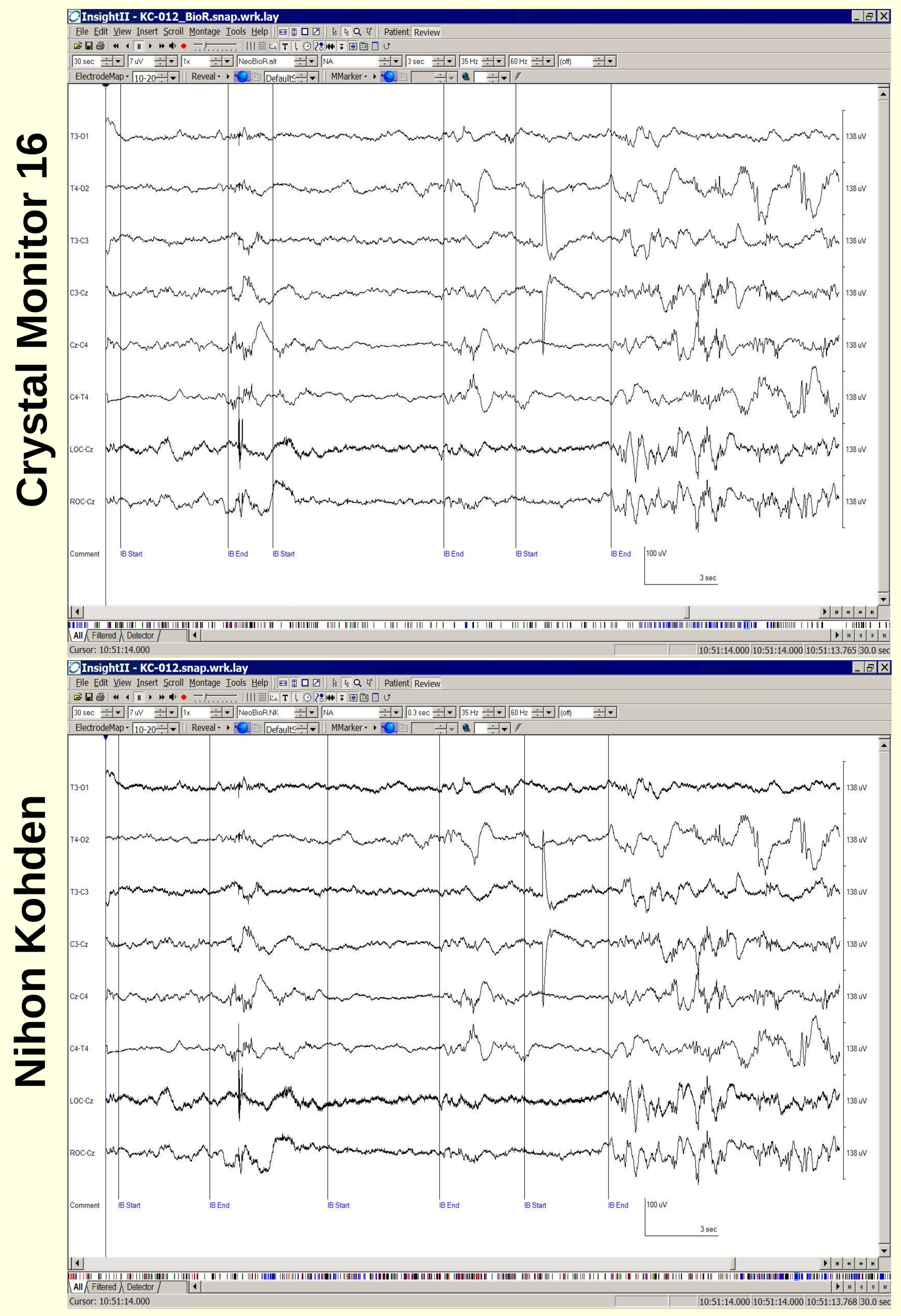

Figure 7. A side-by-side comparison of the temporal polysomnographic signal characteristics from the same subject at the same time with the Crystal Monitor 16 (top) and Nihon Kohden (bottom). Note the annotations by the neurologist designating start and end of the trace discontinu interbursting pattern.

Conclusions

The wireless Crystal Monitor Model 16 monitoring system provided EEG state scores comparable to the traditional cart mounted system. This miniaturized bedside EEG and sleep monitor may greatly enhance clinicians' abilities to diagnose and treat neonatal brain disorders.

Acknowledgments

This work was supported by NIH Phase II SBIR grant: 5R44NS041118-03

For further information

More information on this and related research projects can be obtained at *www.clevemed.com*.