VII. POLYSOMNOGRAPHY PROTOCOL

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A. Environment and Equipment Requirements

1. Equipment

A *Healthdyne ALICE 3* system (currently version 1.17) will be used for the laboratory polysomnographic recordings. The basic reference is the *ALICE 3* System Software User's Manual (Adult/Infant Acquisitions) 1994 edition. This system which consists of a 486/33 IBM computer and 20" monitor also includes (a) a HP LaserJet IIIP Printer, (b) an 800 mB optical disk drive and one or more disk drives (such as a 3.5" high density floppy disk drive). *ALICE 3* requires interfacing with an amplifier/signal processor unit (CALVIN) and special input device. It includes infant software to analyze cardiorespiratory, EEG, and sleep state data.

In order to raise sampling rates and allow for adequate storage, an additional 486 computer (Gateway 2000), referred to as the Data Analysis System (DAS) will be interfaced with *ALICE 3*. The DAS will use 12 bit storage rather than the 8 bits used by *ALICE 3*. See Appendix A.

2. Recording Methods

The montage to be used for the CHIME study is listed in **Table 1**.

Since this is a research protocol and the data are to be analyzed by computer, the montage as specified must be used under all circumstances. Changes should only be made under exceptional circumstances and should be noted on the chart/log and in the *ALICE 3* initial screen or subsequent comment section.

To complete the monitoring montage, the *ALICE 3* system will be interfaced with the CHIME Monitor and a monitor that produces an end-tidal PCO_2 output. Audio/video monitoring equipment also must be used during the sleep study.

3. Environment

The laboratory should consist of two adjacent rooms, one for the sleeping infant and one for the equipment. The parent or caregiver will be instructed not to interfere with the infant during the study, but may sleep in a nearby bed. During sleep a 40W light should be on in the infant sleeping room to permit continuous surveillance through a TV monitor/VCR system. Sophisticated split-screen monitors are optimal but not required. See item list in **Table 2.**

Access from the equipment room to the infant sleeping room should be easy in case of emergency. The infant sleeping room should have resuscitation equipment and tray in case this is needed as well as a system for alerting support personnel. A sink, a scale and other routinely used equipment should be handy. Carpeting is desirable so that arousals are minimized, but anti-static treatment should be considered. Overhead fluorescent lights may introduce artifacts and should not be used during monitoring. Room temperature control is desirable but not always available.

The sleeping room is used for infant preparation. Infants must sleep in a crib with sides that can be lowered easily.

TABLE 1: PSG MONTAGE

Channels			
1	R EOG	12	Impedance
2	L EOG	13	Rib Cage
3	C_4 - M_1	14	Abdomen
4	C_3 - M_2	15	Sum
5	O_2 - M_1	16	CO_2
6	O_1 - M_2	17	CO_2 Number
7	Chin	18	Thermistor
8	Position	19	Oximeter Pulse Waveform
9	Temp	20	O_2 Saturation
10	ECG	21	Actimeter (*ALICE 3*)
11	Cardiotachometer		

*If not used, blank out the channel by inserting jumper cables in the appropriate inputs of the *ALICE 3* input device. **DO NOT** change/rearrange the number order/position of the channels.

B. Parental Education

As part of the PSG consent process, study personnel will visit with the parent(s)/caregiver(s) of the study infant to discuss the purpose of the PSG and what can be expected in the laboratory. A photograph album is typically used to illustrate procedures; questions are encouraged. Easy to read handouts in the appropriate language should be made available for parents and caregivers. These handouts should contain information about where the PSG is to be conducted, what the parents need to bring and when they need to bring the baby. See Appendix B for an instruction sheet example.

TABLE 2

INFANT SLEEP LAB

LIGHTING

1. Preparation Stage - Standard Overhead Lighting
2. Monitoring Stage - 40 W Adjustable Lamp

TEMPERATURE

1. Ambient 23^{O}C

BED

1. Infant Crib

INFANT SUPPLIES

1. Diapers
2. Shirts
3. Blankets
4. Pacifiers
5. Suction Bulb
6. Formula/Breast Milk
7. 1 Piece Sleeper

ASSOCIATED EQUIPMENT

1. Sink
2. Scale
3. O_2
4. Suction

INFANT SLEEP ROOM

1. Video Camera
2. CO_2 Monitor
3. CHIME Monitor
4. Carpeting

EQUIPMENT MONITORING ROOM

1. *ALICE 3* Monitoring System
2. Video Monitor Recorder
3. Telephone

CHIME BACKUP MONITOR

EMERGENCY CART/TRAY

C. Scheduling

1. Healthy Term Infants

When a Healthy Term infant is enrolled, the DCAC will inform the site at what age to perform a PSG.

2. Apnea of Infancy Infants

Apnea of Infancy subjects should be scheduled within two weeks of study intake.

3. Preterm Infants

Preterm infants should be scheduled to have a PSG within two weeks of study intake.

4. Siblings of SIDS Infants

Subsequent siblings should be scheduled to have a PSG at 1 month of age. Surviving twins of SIDS victims receive a PSG which should be scheduled as soon as possible after the death of their twin.

D. General PSG Procedures

1. Preparation of the Laboratory

It is critical that the laboratory is surveyed at the completion of a recording and prepared for the next recording. The polysomnographic equipment should be left in good operating condition. Monitoring personnel should maintain an equipment log (See example in Appendix B) so that engineers can identify problems encountered during the night when they are not typically available. Several hours prior to the next monitoring session the laboratory should again be checked, preferably by technical personnel and all equipment prepared, tested and settings verified.

For sites where PSG staff initializes CHIME Monitor cartridges, see CHIME Monitor PSG cartridge parameters in Appendix B. At other sites CHIME staff will provide prepared PSG and new home cartridges for each PSG.

2. Duration of Monitoring

Physiological monitoring should begin prior to 9pm when all infant preparation and calibrations have been completed. One and a half hours for these preparatory tasks is realistic. Recordings should be terminated after no less than 8 hours of recording, followed by calibration and preparation of infants for departure.

3. Staffing

Infants should be under **continuous** observation of trained personnel in sufficient numbers to observe the baby and properly annotate the study. When considering staff requirements, one should take into account the need to continue annotation while the infant is awake and cared for as well as staff fatigue. Funds for two staff were budgeted.

4. Procedures Prior to Polysomnography

It is important that arrival time in the hospital is selected so that parents/caregivers are in a position to bring the infant (e.g. after working hours) and that the trip is safe (in some settings, parking and hospital ground escorts may have to be considered).

Each laboratory should have a log book in which details about the infant and the polysomnographic session can be entered. A loose leaf folder can be designated for each infant in which all relevant information is contained. The infant's **Study ID#** is critical because all information will be filed under this number.

It is important to review procedures with the parents and to offer explanations. Parents can be invited to watch or hold the child as needed. Much of the skin preparation and attachment of electrodes can be done while the baby is bottle fed. In some laboratories the mother/caregiver will be permitted to stay throughout the night but few elect to do so (exceptions are those who prefer to breast feed the baby). In some laboratories one parent or caregiver is required to stay with the baby to help with caregiving. A maternal sleeping room should be made available so that unnecessary awakenings are prevented.

Prior to preparing the study infant for monitoring, the **Post-Enrollment Medical Follow-up Form** (**Form D**) should be completed if one has not been completed in the past 2 weeks. If the infant has been home on a study monitor, technicians should collect the **Alarm Log** (**Form H5**) from caregivers.

A CHIME POLYSOMNOGRAPHY CHECKLIST (Form F1: See Appendix B) should be initiated at this time and items completed as the calibrations and sleep study progress. Refer to Table 3, PSG Preparation and Acquisition Checklist, as a reminder of steps to be followed.

a. CHIME PSG Thermometer preparation. See Appendix A.

TABLE 3

PSG PREPARATION AND ACQUISITION CHECKLIST

1. The Begin Study data calibration must begin no later than 2100 hours, therefore, preparation should commence by 1900-1930 hours. Have baby brought to lab at 1830-1900 hours.

2. Prior to infant arrival do the following:

☐ a. Lay out all electrodes, supplies, equipment, including extra baby diapers, etc.
☐ b. Have backup CHIME Monitor and CHIME supplies ready.
☐ c. Get out all forms - this checklist, H2-Visit, H5, F1, Channel Checklist, Optical Disk-Log and Cry Log.
☐ d. Set up Nellcor or CO_2 monitor as needed.
☐ e. Have CHIME PSG and home cartridge, as well as the optical disk ready for use.
☐ f. Connect all components to *ALICE 3*. Turn *ALICE3* on and check CO_2 range values.
☐ g. Check audio-video equipment, emergency box and notification routine.
☐ h. Prepare other site-specific forms/logs as needed.
☐ I. Synchronize time clocks as needed.

3. Infant arrival:

☐ a. Collect H-5 from caregiver; do Form D if necessary.
☐ b. Check CHIME Monitor and condition of electrodes.
☐ c. Remove home cartridge out of the CHIME Monitor and replace it with the PSG cartridge. Do not turn monitor on until baby is quiet and you are ready to check waveforms (5 minutes of quiet recording is required to set monitor baselines).
☐ d. Enter patient information on *ALICE3* and estimate begin and end acquisition times.
☐ e. View waveforms and go to calibration to set filters and check impedances. Use jumper cables to eliminate ECG artifacts if necessary.
☐ f. Adjust and reapply sensors as needed to get impedances < 10K ohms and clean waveforms. Type final impedances on *ALICE3* screen at study initiation.
☐ g. Set end acquisition to allow 8 hours post 2100 plus enough time for post calibration, time check and Cry if ordered. Remember *ALICE3* cannot do more than 10 hours <u>total</u>.
☐ h. It should be no later than 2030 at this point. If all is well, start oximeter time check process, calibrations and then begin study. Type **Begin Study** on *ALICE3* directly after end of Calibrations.
☐ I. Enter interventions, feeding, diaper changes, temperature and humidity on **Form F1**.
☐ j. During PSG recording, annotate all behaviors of the infant and staff which may impact on the PSG recording. See Section 16, Chart Annotation. Do not forget to comment at least every 5 minutes, especially during sleep; note eyes closed (EC). <u>DO NOT USE ANY UNDEFINED ABBREVIATIONS PLEASE.</u>

END OF STUDY CHECKLIST

☐ 1. If you set the stop acquisition time for, say, 0530 then you must be prepared to do the oximeter time routine, 1 minute of calibrations and up to 5 minutes (?) for the Cry **before** 0530.

☐ 2. If **Begin Study** occurred prior to 2100 hours and you want to end after 8 hours but before the stop time you entered, you can, but remember to do time check, calibrations, Cry if needed, and recheck impedances first!

☐ 3. After *ALICE 3* is stopped, the file will automatically transfer the data to the optical disk. Note end temperature and humidity and any observation of infant condition on Form F1.

☐ 4. Turn CHIME Monitor power off and remove PSG-cartridge. Put new home cartridge in monitor.

☐ 5. Remove electrodes, replacing CHIME Monitor sensors if necessary. Prepare baby for return to nursery or home. Chart or log baby out of Sleep lab.

☐ 6. Put together all forms and cartridges needed for CHIME analysis.

☐ 7. Clean all sensors, equipment as needed.

☐ 8. Back-up optical file as soon as possible, complete back-up optical log and Form F1.

1. Verify that the RJ45 cable is connected between the PC and the Calvin amplifier box. The Calvin box should be plugged into the socket marked "**PHONE**" on the computer. **NEVER PLUG IN PHONE JACK OR UNPLUG IT IF *ALICE 3* POWER IS ON.**

2. Make sure your computer power is on, and the *ALICE 3* System Main Menu is displayed.

3. Select the first option on the Main Menu, Acquisition and Analysis, by pressing the letter "**A**" or by clicking on the option with the left mouse button. A list of montages will be displayed.

4. Select the CHIME montage that you will be using for the CHIME study. The screen will display the message, "Please wait for CALVIN self-check..." The Patient information Screen will be displayed after the self-check process is complete.

5. Enter the patient's Event Record Label in last name field, first name, date of birth, sex and gestational age. Press **<ENTER>** to move from one field to the next (see box below).

6. In comment section enter infant's assigned group, i.e., comparison, SIDS SIB, ALTE, and impedances.

Event Record Label :	21 CHARACTERS MAX	
First name :	21 CHARACTERS MAX	
Date of birth :	12 12 92	Sex : F
Gestational age :	40	
Comments :	21 CHARACTERS MAX	
	21 CHARACTERS MAX	
Acquisition start time :	00 00	
Acquisition stop time :	06 00	

NOTE: If you make an error, continue to enter information until you have completed all fields. You will

have an opportunity to correct any mistakes before leaving this screen.

6. Polygraphic recording preparation
   The polygraphic recording should contain the information requested on the ALICE 3 screen as illustrated in 5a.

[ALICE 3 screen at study initiation will

be added here when software is

available on ALICE 3]

7. Application of Electrodes

Directions are presented in the optimal order of application. **Table 4** summarizes the necessary array of electrodes by placement site. Extra sensors must be available in case last minute replacements are required. This is particularly important for specialized sensors such as the Healthdyne thermistor and actimeter. See Appendix D for a listing of approved sensors.

TABLE 4

ELECTRODES AND SUPPLIES REQUIRED

BODY

1. ECG (5)
2. Respiratory Bands
3. Oximeter Probe
4. Position Sensor from CHIME Monitor (back of diaper)
5. *ALICE 3* Actimeter

HEAD

1. EEG (7)
2. EMG (3)
3. Kerlix Wrap

FACE

1. CO_2 Cannula
2. Healthdyne Neonate/Infant Nasal/Oral Thermistor
3. EOG (2)

a. ECG: Ensure that the baby's skin is dry and free of powder, oil or perspiration to provide for good contact between the sensors and the skin. A total of five ECG electrodes will be applied: two Jenson hydrogel squares* to interface with the CHIME monitor and three IttyBitty Contour hydrogels for the *ALICE 3* connections. Be sure to snap the lead wire snaps to the electrodes **BEFORE** placing the electrodes on the baby. Peel the electrode off the plastic strip and place as follows: the sites are illustrated in Figure 1.

ELECTRODE PLACEMENT RESPIBAND PLACEMENT

CHIME Monitor: B=Black Snap, W=White Snap. During the PSG the red ground electrode of the CHIME monitor is not used.

ALICE 3: [O] *ALICE3*; 2 ECG leads; 1 ground (G)

Figure 1

Connecting Respiband to Patient Cable

Respiband placements (RC and AB). Fasten securely but not too tight. Loose ends where connector snaps should be arranged to come out of the front of the sleeper if it snaps at the midline. REMEMBER no gaps in the tails.

Figure 2

CHIME Monitor Leads: RA (Right Arm) white snap on the right chest at the nipple level. LA (Left Arm) black snap on the left chest at the nipple level.

***ALICE 3*:** Left and right leads should be placed adjacent to the CHIME monitor leads (at the side of, slightly above, but not touching). The *ALICE 3* ground snap electrode will be placed on the left abdomen, just above the level of the AB respiband.

*If the baby comes from home with Jenson electrodes already in place and they look clean and intact, they can be left on and used for the PSG. If there is any question of their adequacy, replace them.

b. Respiration Effort: Always use new respibands even if the baby has new ones on when he/she arrives for the PSG. Use 15" or 24" bands as appropriate for the size of the baby. Place the top respiband around the ribcage (**RC**) at the level of the nipples (slightly above so as not to irritate the nipple) and the bottom band around the abdomen (**AB**) at the level of the umbilicus, see **Figure 1** for starting positions. Fold the loose ends of the bands over the baby to meet at the midline. Press the bands firmly together so they are snug but do not impede breathing. Snap the CHIME monitor RC cable connectors to the end of the top ribcage band and the AB cable connectors to the bottom band, **Figure 2**. Be sure there are no gaps between baby and the velcro/snap end. In order to prevent sliding on the skin, the bands can be secured with a band-aid.

c. Temperature: See Appendix A. Sites will be notified when and how to use this equipment when it is made available to the sites.

d. EEG: Seven Grass gold cup electrodes (C3, C4, O1, O2, M1, M2, Ground) will be placed on the scalp (**Figure 3**) and held in place with electrode cream (such as Elefix or Ten-20) covered with gauze squares or cotton balls. Using the International 10-20 system, measure the head to locate the site and mark each site with a water soluble, non-toxic soft marker. Directions for measuring the head are outlined below.

1. Refer to Figure 3 for the location of the sites. Even numbers refer to the right side of the head; odd numbers to the left and Z to midline.

2. Use a flexible, disposable/washable centimeter tape and,

3. Place the 0 cm end of the tape on the nasion (depression between the nose and forehead) and direct the tape to the back of the head. Read off the cm at the inion (the protuberance at the back of the head.)

4. With the tape still held in place, locate the halfway point of your nasion-inion distance. For example: if the nasion-inion distance is 25cm, 12.5 is the midpoint. Mark this point (CZ.)

5. Leaving the tape in place, measure up 10% from the nasion (2.5cm in our example.) This is the FPZ site on the forehead. (Locate the ground electrode about 30% of the distance from the nasion to the hair line.)

6. Repeat this process from the inion: 10% up on the midline is OZ.

7. Remove the tape and place one end on the preauricular point (the depression in front of the ear) and direct the tape across the head through the CZ mark to the other preauricular point. Note the distance in cm.

8. With the tape in place find the point that is half the "ear to ear" distance and mark the intersection with your nasion-inion CZ mark.

9. With the tape still in place, measure up 10% from the preauricular point on each side of the head (T3 and T4 in Figure 3) then measure 20% up from T3 and mark C3; measure 20% up from T4 to mark C4.

10. Measure the circumference of the head by placing the tape along the 10% markings all the way around. Note half the distance and then calculate 10% of this distance.

11. Mark 10% to the left and right of FPZ; these points are FP1 and FP2. Direct the tape through FP1 back to the 10% marks on the left side of the inion at the circumference line. Mark the intersection. This intersection is 01. Repeat this process on right side from FP2 to locate 02.

12. M1 and M2 are the left and right mastoid, respectively. Palpate the bone behind the ear and avoid any blood vessels to reduce ECG artifact.

Abrade sites with Omniprep or similar substance on cotton tip applicator. Fill the gold cup with paste and press firmly to prepared site. Hold in place 10-20 seconds; cover with gauze or cotton ball. Be sure cable-lead wire is directed away from face toward back. Repeat for each site. When all are placed, check impedances on *ALICE 3* impedance screen. All values should be less than 10K ohms (green or yellow lines). Lead wires should be secured in a "pony tail" with all the other face and head wires.

Standard International 10-20 placement sites for scalp electrodes. CHIME designations are shown as solid circles. Due to the way *ALICE3* references are hardwired, the ipsilateral scheme must be overridden by manually reversing the lead pins placed into M1 and M2. That is, plug the scalp M1 lead into the *ALICE3* input for A2 and lead for M2 into input for A1. The EEG ground will be centered on the forehead midline approximately 20-30% up from the nasion.

FIGURE 3

e. Submental EMG:

1. Preparing the skin site.

    a. Clean (3) skin sites on the chin where the electrodes will be applied: See Figure 4.
        1. Tip of the chin.
        2. Right digastric muscle (as far back on lower jaw).
        3. Left digastric muscle (as far back on lower jaw).

    b. The priority in selecting the combination of sites to measure chin EMGs are:
        1. The tip of the chin and the right digastric muscle.
        2. The tip of the chin and the left digastric muscle.
        3. The left and right digastric muscle.

2. Preparing the electrodes.

    a. The surface and cavity of the electrode should be clean and dry to attach the adhesive washer (double-sided adhesive discs) and to fill the cavity with electrode gel.
    b. Remove the adhesive washer from its backing strip using the blue tab, and apply the adhesive washer to center the hole over the electrode cavity. Press adhesive washer down to seal the surface of electrode.
    c. Squeeze Signa Gel electrode gel to just fill the cavity. Check that NO BUBBLES are introduced in to the cavity.
    d. Remove the round backing paper for the adhesive washer and place the electrode on the prepared skin surface.
    e. Press the electrode down firmly to attach and seal the electrode to the skin.

3. Cleaning the electrodes after each use.

    a. Remove the main bulk of the gel with a cotton swab.
    b. Use distilled or deionized water to wash out remaining gel inside the cavity. NEVER USE TAP WATER.
    c. Soak electrode in a container with mild saline solution until the next application.
    d. Do not allow the “old” gel to dry or harden in the cavity.

Please annotate on Alice (you may type in “G-electrodes”) when you use the GEREONICS EMG electrodes. Doing so will allow the PSG reviewer to know when these electrodes are being used.

After application of EEG and EMG electrodes, check impedances with the *ALICE3* and, if available, the Cleveland impedance meter, and note them down on Form F1. Be prepared to enter these values later onto the *ALICE3* screen at study initiation.
To check impedance and get a better idea of how good your connections are, press <F10>. The screen will provide a color-coded, graphic representation of the top of the patient's head with the selected montage indicated:

COLOR	COMMENT	IMPEDANCE
green	good signal	<5K ohms
yellow	warning (watch the electrode, there may be a problem)	5-10K ohms
red	bad signal (poor connection, recheck the electrode)	>10K ohms

If impedances on EEG and EMG are less than 10K ohms, the head can be wrapped with Kerlix to secure chin and head electrodes. See Figure 5 for head wrap pictures.

Filter settings must be adjusted at the time you check impedances. The following settings must be adopted by each site:

EEG:	40 Hz	1.0 Hz
EMG:	45 Hz(default)	5.0 Hz
Notch Filter:	ON	

Filter settings are toggles and directions appear on the bottom of the *ALICE 3* monitor. A checklist of tasks that need to be carefully performed is provided in The CHIME POLYSOMNOGRAPHY CHECKLIST (Form F1, Appendix B).

EOG AND EMG ELECTRODE PLACEMENT
FIGURE 4

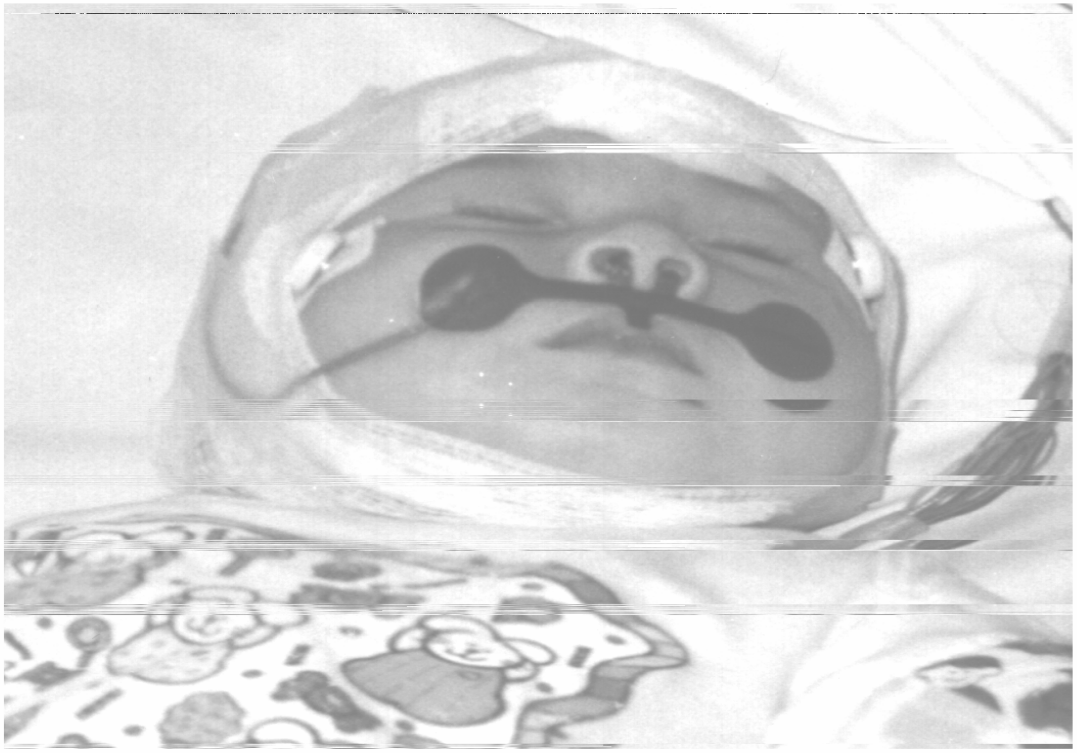


FIGURE 5

f. **Pulse Oximeter (SaO_2):** Place the probe light source on the top of the baby's left foot. Wrap the stretch tape around the foot so that the detector is on bottom of the foot **opposite** the light source, **Figure 6**. Direct the lead wire up the body or out the bottom of the sleeper. A Posey may be used to further secure the probe on the foot.

g. **Position Sensor:** Tape to the back of the baby's diaper with the blue DOT away from the body.

h. **$P_{ET}Co_2$:** A nasal cannula to sample air for continuous PCO_2 determination is secured in front of the nares. (Refer to capnograph directions at each site.)

i. **Thermistor:** Prior to placement on infant check operation by blowing on sensors and observing waveforms on ALICE3. If no waveforms replace! Clean sensor. Affix the double-sided tape on the back of the Healthdyne nasal/oral thermistor. Press the sticky side under the nose so that the tips are in front of but not touching the nares and mouth. It may be necessary to carefully bend the tips slightly away from the brown strip. See Figure 7.

j. **Actimeter:** With actimeter connected to CALVIN shake it gently to establish that it is operational. Black boxes/rectangles should appear on the ALICE3 screen during acquisition mode if it is working. If not, use alternate. Repeat process. Place the Healthdyne actimeter on the bottom of the right foot and secure with tape.

k. **LEOG/REOG:** Prepare the sites with alcohol or Omniprep. Use Contour IB snap or gold cup electrodes and place LEOG 0.5 cm above and 0.5 cm away from the outer canthus of the left eye; REOG is placed 0.5 cm down and 0.5 cm away from the outer canthus of the right eye. Direct lead wires away from the face and into the "pony tail." See Figure 4.

Probe is placed on left foot with red light source on top of foot. Tape to foot so that the detector is on the bottom of the foot opposite the light source.

PULSE OXIMETER PLACEMENT
FIGURE 6

The illustration below shows a top view of the cover plate.

The red LED light provides various indications:

- a continuous, steady light indicates that the unit is powered on and is ready for signal acquisition;

- a slow, flashing light indicates data is being transferred; and

- a fast, flashing light indicates an error condition

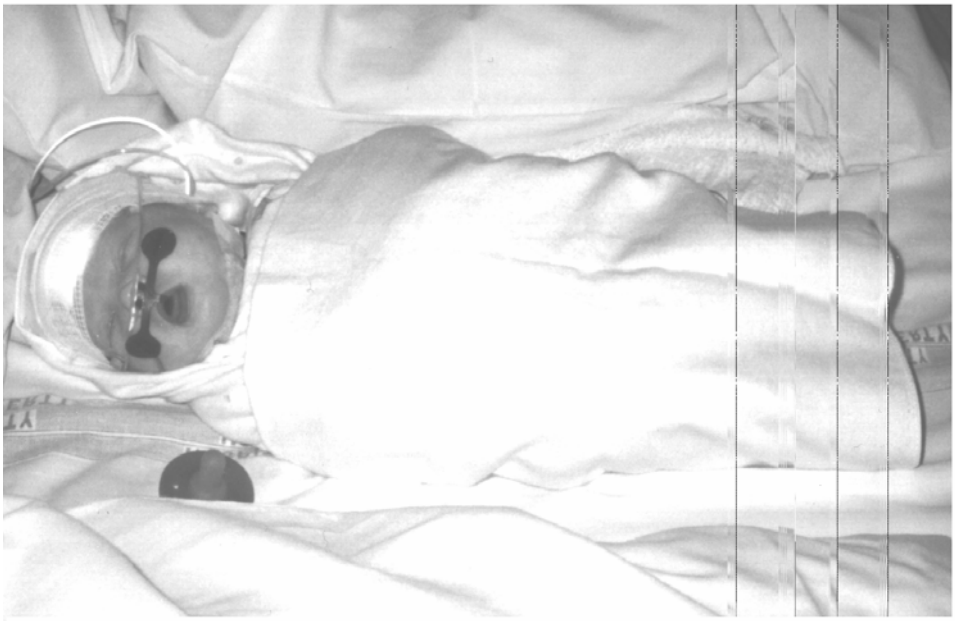
The cable from the patient box plugs directly into the 50-pin **INPUT DEVICE** connector.

Figure 8

WARNINGS AND CAUTIONS

These Warnings and Cautions apply specifically to the CALVIN amplifier unit.

- ☞ Never pick up the unit by the cover plate. Always use two hands to handle the unit by its base.
- ☞ Always place the unit on a sturdy, level surface.
- ☞ Do not set the unit on a polygraph or on top of a computer monitor.
- ☞ Do not expose the unit to heat or direct sunlight.
- ☞ Do not attempt to autoclave, EtO, gas or pressure sterilize the unit.
- ☞ Do not place the unit within three feet of oxygen tanks or oxygen tents.
- ☞ Do not drape the cable to the computer over a polygraph, light fixtures, or medical devices.
- ☞ Do not use the cable if it appears to be damaged, broken, or frayed.
- ☞ Do not attempt to service the unit if it does not appear to be working properly.



8. CHIME Monitor Signal Evaluation

Each infant enrolled in the CHIME protocol will bring her (his) CHIME Monitor to the sleep laboratory. If the parents do not bring their monitor, use the backup monitor assigned to the Sleep Lab. Plug in the monitor. The cartridge from the CHIME Monitor should be replaced with a newly initialized cartridge for use during the overnight polysomnogram. Consult PSG cartridge parameters in Appendix B. When the baby is quiet, the CHIME monitor, positioned in the sleep room, can be started. This event recording system will be used at its preset record settings for the duration of the polysomnographic recording.

9. <u>Connecting the Infant to Infant Patient Box/Calvin</u>
(From: *Healthdyne ALICE 3, User Manual 1994*).
Understanding the Patient Connector Box

The illustration and call-outs below describe the appropriate CHIME inputs for the Infant Patient Box.

Figure 9

WARNINGS AND CAUTIONS

These Warnings and Cautions apply specifically to the Patient Box.

☞ Never place the unit on top of a <u>polygraph</u> or other medical devices.

☞ Use only the connectors that have been supplied with the *Alice 3* System.

☞ Use only the accessories that have been recommended by HealthDyne.

Connecting the EEG Electrodes

1. Plug the right mastoid electrode into the left reference inputs of the Patient Box, and the left mastoid electrode into the right reference input.

2. Insert all of the leads that you have attached on the patient into the appropriate connectors on the Patient Box.

3. Insert the lead pin from the Ground EEG electrode into the ISOGROUND receptacle on the Patient Box.

Completing the Connection

Insert the connector end of the Patient Box into the 50 pin cable connector on the top side of Calvin, Figure 8.

Connect CHIME Monitor to CALVIN with Computer Interface Cable

The CHIME Monitor leads are already connected to the CHIME monitor. Check all connections and make sure the PSG cartridge is in the CHIME Monitor. Turn the CHIME Monitor on to check the quality of the CHIME monitor cardiorespiratory signals and pulse oximetry. REMEMBER the ECG you see on the screen is from *ALICE 3* not CHIME Monitor.

Never plug in or unplug PC Calvin phone jack if *ALICE* is on.

10. Positioning Infant

The electrode array does not permit monitoring in the prone position. Babies should be laid supine, or their backs may be propped slightly with a clean, rolled up blanket or towel. Infants under one month of age should be swaddled, while mittens or arm restraints may be used in older infants. You are now ready to begin the acquisition. Never plug in or unplug PC Calvin phone jack if *ALICE* is on.

11. Environmental Conditions

Covering of the infant depends on room temperatures. Efforts should be made to maintain room temperatures between 22 and 24 degrees centigrade; when a thermostat is available, choose the 23 degree setting. Ambient light should be comparable among centers but control of ambient noise can probably not be assured. Unexpected noises such as sirens must be annotated on the chart. A nightlight not exceeding 40 watts should remain on in the infant room. Infants will be dressed in a dry disposable diaper (2 tog units), one piece sleeper (2 tog units), and covered with 2 flannel blankets (3-4 tog units).

12. Assessing Signal Quality

The signals should be stored on ALICE while you are performing these tasks. The light should be dimmed and, when personnel and parents/caregivers have left the infant room, the recording can begin. Allow a half hour to an hour for channel and baby adjustments. If the quality of one of the signals is poor, limited re-application can be contemplated at this time. The art and skill of overnight polysomnography in infants pivots on the adequacy of the initial application. This should be done thoroughly, quietly and without unduly upsetting the baby. Rushing through it is not advisable even with a late start because a shortened recording of high quality is more valuable than a long one with deteriorating signals.

Although the infant cannot be asked to perform the maneuvers requested of older children and adults, the signal quality can be assessed by observing spontaneously occurring behaviors. When the child is awake, there should be a good quality EOG signal with the left and right EOG of opposite polarity. If the eye movements are recorded but are of the same polarity, check the position of the electrodes.

Be sure there is a good quality chin EMG signal that increases during crying or sucking. Adjust the gain, check electrode position and/or plug in a different pair of EMG electrode leads until a good quality signal is reached. If ECG artifact is present in the EMG channel, choose a different pair of electrodes to select the signal. If active REM's observed prior to the begin calibration, that is during AS, adjust the gain on the chin EMG so minimal tonic muscle activity is recorded (the signal should not be totally removed since some muscle activity will then be lost). The near isoelectric EMG tracing can then be used to make amplitude comparisons between states. During the recording, periodic checks should be made to ensure that no change to artifact amplitude has occurred.

Observe the baby's breathing and be sure that synchronous breathing is reflected in synchronous chest wall and abdominal signals. If the chest wall and abdomen appear to be out of phase on ALICE 3, be sure that the child's breathing is out of phase on inspection. Move the baby's foot that is connected to the actimeter to be sure that motion can be detected. Since there is no gain adjustment on this channel, if the signal is unsatisfactory, the actimeter must be reapplied.

13. Test Signal Transfer to DAS. See Appendix A.

14. Synchronization of time clocks between *ALICE 3* computer and CHIME monitor.

By synchronizing the *ALICE 3* computer, and the CHIME monitor, events recognized by one system can be compared with events recognized by the other system.

Both systems record events based on the time of day they occur. This time is derived from each of the computer system's clock. However, the CHIME monitor clock may not be set at the TRUE time of day. This is mainly due to the fact that all CHIME monitor clocks are set to local standard time and are not updated when Daylight Savings goes into effect. *ALICE 3* computer clocks should always by checked prior to the PSG to insure that they reflect the TRUE time of day.

For technical reasons, no attempt will be made to synchronize the two computer system clocks. Instead, a calibration signal common to both systems will be simulated at the beginning of the PSG and at the conclusion of the PSG. This simulated signal will then be used to calculate the offset in time between the two systems so that events can be compared.

The simulated calibration signal will be created on the *ALICE 3* Oximeter PULSE channel by disconnecting the Oximeter Cable from the CHIME monitor in the following manner (Note: the oximeter sensor should already be attached to the infant's foot):

* Just prior to the one minute of calibration markers, with CHIME monitor on for at least 5 minutes.

1. Disconnect the Oximeter cable from the CHIME monitor by depressing the spring lock on the connector and removing the cable from the monitor.
2. Count to 10 (one-one thousand, two-one thousand, etc.).
3. Reconnect to Oximeter cable to the CHIME monitor.
4. Count to 10 (one-one thousand, two-one thousand, etc.).
5. Disconnect to Oximeter cable from the CHIME monitor.
6. Count to 10 (one-one thousand, two-one thousand, etc.).
7. Reconnect to Oximeter cable to the CHIME monitor.

* After **END** study calibration markers and before the cry recording (while data is still being saved to the optical disk):

1. Disconnect the Oximeter cable from the CHIME monitor.
2. Count to 10 (one-one thousand, two-one thousand, etc.).
3. Reconnect to Oximeter cable to the CHIME monitor.
4. Count to 10 (one-one thousand, two-one thousand, etc.).
5. Disconnect to Oximeter cable from the CHIME monitor.
6. Count to 10 (one-one thousand, two-one thousand, etc.).
7. Reconnect to Oximeter cable to the CHIME monitor.

The technician will verify that each step of the synchronization procedure is completed on the CHIME POLYSOMNOGRAPHY CHECKLIST (F1).

15. Calibration

When you are satisfied with the quality of the signals, calibrate for 1 full minute, beginning on the minute. **The onset of calibration marks the onset of computer analysis for the CHIME protocol. From this time onward, the computer can not be turned off** until the completion of the end calibration. Please note the warning above. EEG and EMG signals should not be reapplied and calibration should not be undertaken in the middle of recording.

A calibration signal of 100 microvolts can be displayed for the EOG, EEG, EMG, and ECG channels. Press **<F9>** at the Raw Data screen and you will be transferred to the Calibration Signals screen to see this signal. Since you must know the amplitude of the EEG signals, this screen will indicate whether the internal amplifiers are working correctly and responding equally to the 100 microvolt signal. Check all EEG channels to make sure they are identical in appearance. You should access the Calibration Signals screen at the beginning and at the end of the study to visually check that the amplifiers have worked correctly during the study. If after looking at the Calibration Signals screen the EEG signals look differently or are not responding correctly, contact Healthdyne.

The official start time when the rules of intervention become active is after the calibration period. Some laboratories call this "lights out", although the lights may have been out for a long time already. For this protocol, designate this as "begin study".

16. Chart Annotation

During the PSG recording, complete annotation is important for interpretation of physiological data, identification of artifact and sleep state coding. The behaviors and activities to be charted are outlined in **Table 5A**, ITEMS TO BE ENTERED INTO ALICE 3 AND ON THE PSG CHECKLIST (F1 FORM).

The CHIME STUDY: PSG ANNOTATION CODING SHEET (Table 5B) minimizes the number of codes that are used during annotation of the PSG. This CODING SHEET should be posted next to ALICE so that it can be used during the PSG.

a. Technicians should code all infant movements and behaviors using the codes defined on the CHIME STUDY: PSG ANNOTATION CODING SHEET.

1. Caregiving: Feedings, diaper changes, comforting of the infant are examples of caregiving. These periods will be designated as Awake. Annotate the beginning of caregiving period by typing **BEGIN**. Use TABLE 5A: ITEMS TO BE ENTERED ON ALICE to assist with the type of information that should be recorded during caregiving periods. Annotate the end of the caregiving by typing **END**.

2. Interventions: Technical adjustments to sensors or interventions other than for caregiving. These periods may still be designated to an infant sleep state. It is essential that these periods be clearly and accurately described. Annotate the beginning of the intervention by typing **IN**. Describe the intervention. Use TABLE 5A: ITEMS TO BE ENTERED ON ALICE to assist with the type of information that should be recorded

during an intervention. Annotate the end of the intervention by typing **OUT**.

b. Especially note that when feeding, the baby may drop off to sleep. The person with the baby must notify the annotator. If the mother is present, she needs to be instructed not to intervene unless, e.g., for feeding. Note: a pacifier is allowed during monitoring, but the room should not be constantly entered to insert a pacifier which has fallen out.

   1. Technicians must clearly annotate Awake and Asleep periods. Use the EC and EO comments to denote these periods.

   2. If during quiet sleep no special events happen, make a notation anyway every 5 minutes. Consider putting the annotation chart in plastic and keep it handy. It is very important to comment EC or EO.

c. Infant movements or behaviors that cannot be placed in one of the listed categories on the CODING SHEET should be annotated by typing in a description of the movement or behavior.

   In summary:

   1. Annotate caregiving periods by typing **BEGIN**, followed by a description of the caregiving activity, and when the caregiving is completed, type **END**. These periods will be designated as Awake.

   2. Annotate Interventions by typing **IN**, followed by a description of the intervention, and when the intervention is completed, type **OUT**. These periods may still be assigned an infant sleep state.

   3. If you are unsure whether an activity is an Intervention or a Caregiving period, use the codes for Interventions and then describe the intervention.

17. Guidelines for Re-application of Electrodes During PSG Recording

Electrodes may get dislodged. Since sleep and wakefulness are target variables, awakenings for electrode re-application should be the exception. For the purpose of this study, an infant should only be awakened if the $EtCO_2$, the ECG or SaO_2 tracings have been lost. No effort should be made to re-apply the EEG and EMG electrodes since such re-application will almost certainly arouse the infant and preclude undisturbed sleep. During spontaneous awakenings for feeding, the eye movement sensor, the nasal/oral thermistor, or other sensors can be readjusted, if necessary. After diaper changes, remember to retape the position sensor to the back of the diaper.

TABLE 5A
ITEMS TO BE ENTERED ON ALICE3 AND ON THE PSG CHECKLIST (F1 FORM)

PLEASE ENTER INFORMATION ASSOCIATED WITH THE TOPICS LISTED BELOW INTO ALICE AND ON THE PSG CHECKLIST (F1 FORM).

TECHNICAL DATA: Enter BEGIN when the caregiving starts, describe the caregiving, then enter END when it is completed. Caregiving procedures are those that generally involve the infant being in an awake state. Examples include:

- EEG and EMG impedances values.
- Changes in gain to any of the channels.
- Any problems associated with the operation of ALICE.

Caregiving: Enter BEGIN when the caregiving starts, describe the caregiving, then enter END when it is completed. Caregiving procedures are those that generally involve the infant being in an awake state. Examples include:

- Infant feedings: what, how long, amount, burping periods, etc.
- Diaper changes.
- Comforting, patting rocking.

INTERVENTIONS: Enter IN when the person enters the infant's room, describe the caregiving, then enter OUT. These are interventions that do not necessarily awaken the infant. Examples include:

- Nurse/Parent/Technician entering the infant's room.
- Nurse/Parent/Technician touching the infant.
- Removal or addition of blankets.
- Re-application of sensors, i.e. EtCO2, ECG, SaO2.
- Responses to alarms.
- Emergency procedures.

ENVIRONMENTAL CONDITIONS; Enter this information directly into ALICE at the time it is obtained. These are changes in the environment that could affect the infant's sleeping. Examples include:

- Bi-hourly temperature and humidity.
- Sirens or exceptional noises.
- Lights out and lights on period (dimlight should remain on).
- Conditions such as lightning and searchlights that affect sleep.

TABLE 5B
CHIME STUDY: PSG ANNOTATION CODING SHEET

BEHAVIOR CODING: PLEASE USE THE CODES LISTED BELOW AND ENTER THE CODES AS SOON AS POSSIBLE AFTER THE BEHAVIORS ARE OBSERVED.

Codes	Definition and Description of Coding Item	
	AWAKE vs. ASLEEP Periods:	
EO	Eyes Open	Indicates that the infant is awake.
EC	Eyes Closed	Indicate that the infant is asleep.
	* If infant is asleep and no behaviors are noted for 5 minutes, enter EC.	
	INTERVENTIONS;	Enter IN, then describe the intervention, then enter OUT.
IN	Person IN infant's room.	
OUT	Person OUT of infant's room	
	Caregiving;	Enter BEGIN, describe the caregiving, then enter END.
BEGIN	Beginning of caregiving period	
END	End of caregiving period.	
BM	Body Movements:	Use BM to describe any of the body movements listed below.
	Stretching	Slow, extending movement of trunk or hand or extremities.
	Rolling over	Change in position between lateral, supine, or prone.
	Jerky movement	Accelerated, quick movement involving one or more extremities.
	Twitching	repetitive, sudden, quick jerky motion.
	Writhing	Twisting or turning movements, squirming, contorting.
	Limb movements	Movement of one or more extremities.
STR	Startle:	Sudden unexpected movement, usually involving all extremities.
FM	Facial Movements:	Use FM to describe movements involving the face and mouth
	Smiling	Joyful facial expression.
	Grimacing	Discontented facial expression.
	Yawning	Wide, open mouth, with prolonged inhalation.
MO	Mouthing:	Repetitive, open and closing of the mouth.
SUCK	Sucking:	Periodic sucking movement of mouth and lips.
SIGH	Sigh:	Long, deep, audible exhalation.
	PACIFIER USE	
BPAC	Begin Pacifier	The infant has begun using a pacifier.
EPAC	End Pacifier	The infant has ended the use of a pacifier.
	VOCALIZATIONS	
BCRY	Begin Cry	Beginning of a crying period.
ECRY	End Cry	End of a crying period.
VOC	Other vocalizations	Sounds produced by the infant, including those listed below:
	Whimpers	Low, whining, broken cry sounds.
	Babbling	Incoherent vocal sounds.
	Grunting	Short, deep, hoarse sounds.

Hiccough	Sharp quick sound caused in involuntary contraction of diaphragm.

ANNOTATE ALL OTHER BEHAVIORS BY TYPING IN A DESCRIPTION OF THE BEHAVIOR.

REFER TO TABLE 5A FOR ADDITIONAL INFORMATION CONCERNING TECHNICAL DATA AND ENVIRONMENTAL CONDITIONS THAT SHOULD ALSO BE ANNOTATED.

18. Nurse/Technical/Caregiver Interventions

Routine infant care will be continued during the PSG. Nurses/technicians can help mothers breast feed their infants at the crib/bedside without substantially affecting the quality of the recording. Infants should always be burped well prior to resumption of sleep. Other interventions should be restricted to those predicated on the severity of physiological patterns, i.e. only for resuscitation. See **E. Protocol for Emergency Intervention during PSG** and **CHIME POLYSOMNOGRAPHY CHECKLIST** (Form F1).

19. Adjustment of Waveforms During PSG Recordings

During the PSG recordings waveforms should be continuously scanned to see whether adjustments are necessary. All channels except the following may be changed during the overnight recordings: EEG (1-4), position (7), temp (8), cardiotachometer (10), and endtidal CO_2 (15). Expect seconds delay before *ALICE* implements the direction to change sensitivity.

Adjusting the Gain

(From: *Healthdyne ALICE 3, User Manual 1994*).

NOTE: Only the channels with numbers displayed below the channel label abbreviation on the screen can be adjusted, namely, ECG, chin EMG, respiratory effort, and airflow.

1. To make adjustments to a channel, press **<ESC>**. The channel label that you can change will be highlighted in red.

2. To move to another channel, press the **<TAB>** key.

3. When you have highlighted the channel you want to adjust, press the "+" and "-" keys to adjust the gain up or down.

The signals and activity shown on the screen must be checked on a regular basis to determine if gain adjustments are necessary. It is recommended that you wait for more than a minute to check the change on the screen after you have made any type adjustment.

20. Termination of Monitoring

Monitoring should be terminated after no less than 8 hours of recording, that is, 8 hours between calibrations. After the end calibration, the synchronization signal should be simulated on the oximeter pulse channel, then the cry analysis protocol must be performed, (See Step 23, Cry Recording), followed by the identical calibration sequence as at the onset of recording.

To stop data acquisition, follow these steps.

How to exit the system
(From: *Healthdyne ALICE 3, User Manual 1994)*.

In a normal acquisition, the recording of information will stop at the time you selected on the Patient Information screen. However, if you want to stop the study before this time, you have two options:

- Press **<ALT> + S** to stop the study and abort the program immediately.

- Press **<CTRL> + <END>** to discontinue the study within a three-minute window. When you initiate this command, the system will continue to record (from 0 - 3 minutes) until it reaches the end of the current three-minute time frame. You will receive the message, "**Scanning, please wait.**" At this time, the software will close all of the collected files, the recording will then stop, and you will be returned to the Main Menu. All information recorded up to this point will be saved as if the system recorded until the original study end time.

After completion of this sequence *ALICE 3* can be turned off and the infant room can be entered. Prior to removal of any electrodes, check and note the end impedances of the EEG and EMG electrodes. Upon removal of electrodes check their condition carefully. Remove the paste remnants with some lukewarm water and prepare the infant for return to the nursery or departure with the parents. Apprise parents of any redness or rashes that have been observed and how to take care of these. On the **Form F1** note any special circumstances, especially adverse reactions to paste, tape or heat on the infant's skin. Study personnel should also complete an **H2-Visit** form to document how the CHIME monitor functioned throughout the PSG. On **Form H2-Visit**, under "**Type of Contact**", check **PSG Comparison**.

Before the CHIME monitor is returned to the caregivers for home use, replace the PSG cartridge with a newly initialized cartridge in the event mode and give caregivers a new Alarm Log (**Form H5**) to take home. Enter both cartridge serial numbers on the **H2-Visit** form. If the monitor was found to malfunction during the PSG, a replacement should go home with caregivers.

21. Site Assessment of PSG Quality

The designated CHIME Study PSG Reviewer is responsible for maintaining the quality of the PSGs from that site. As soon as possible this person should review each PSG recording and should complete page 5 of the CHIME POLYSOMNOGRAPHY CHECKLIST (Form F1). The primary aim is to identify and immediately resolve problems to insure improved subsequent recordings. Any information should be reviewed with the PSG technicians who performed the recording so that appropriate changes and modifications will be made.

The completed page 5 should be forwarded to DCAC for inclusion with the rest of the PSG documentation.

22. DCAC Assessment of PSG Quality

The DCAC has implemented a standard review process for all PSGs. The results of the review are summarized on DCAC: PSG QUALITY REVIEW FORM. See Appendix B. A copy of this review is included with each disk that is returned from the DCAC to the CHIME site. The purpose of this form is to document the PSG quality and to provide feedback to each site concerning the quality of the PSG as compared to PSGs collected from all other sites. PSG personnel at the site should review this form If there are any questions or comments concerning the results of this review, these should be discussed first with the local CHIME PSG REVIEWER and, if necessary then contact the DCAC for further clarification

DCAC PSG QUALITY REVIEW FORM: A summary of the qualities of the PSG signals, in respect to any problems that may have occurred during the PSG recording session will be documented on the DCAC PSG QUALITY REVIEW FORM.

The header region of the form summarizes information relating to the site, Study ID, PSG date, optical transmittal disk, and who completed the PSG review.

Subsequent sections:
1-22. Signal quality: summarized each channel of data. A subjective determination is made as to whether the signals are of sufficient quality to be used for scoring purposes. In general, the quality of the signal must be adequate for at least 2/3 (66%) of the night. Channels that are highlighted are those that are most important to sleep state and respiratory scoring. If a signal is deemed unscorable for the majority of the night, a comment is made as to the reason for the signal being unscorable.

23-24. Annotations: Awake periods must be clearly marked. Likewise, movements should also be clearly annotated.

25. Filter Settings: These are determined from the data in the user event table and should be the same as those already listed.

26. Calibrations: EEG and EMG calibrations are the ALICE calibrations that designate the beginning and end calibration times for the PSG. The NIMS calibration are the times that the CHIME monitor was synchronized with ALICE.

27-20. Indicate whether PSG documentation material was received at the time the PSG was reviewed.

30-31. Indicate whether all the data from the PSG was retrievable from the optical disk. If a problem with restoring the data occurs, a description of the problem and a request for additional information or for the site to resubmit the data may be made.

32. Overall comments: These are general comments concerning the DCAC review of the PSG.

23. Cry Recording

All study infants will have a cry session at the conclusion of the PSG with the sensors still on the infant and the *ALICE 3* still "on". Refer to Manual of Operations, section VIII, Cry Protocol.

EMERGENCY PROCEDURE DURING POLYSOMNOGRAPHY

There will be very few instances during the carefully monitored and supervised overnight polysomnographic recordings when clinical interventions will be indicated.

The baby will be on the CHIME Monitor in the continuous mode.

If an apnea greater than 20 seconds in duration occurs, it is advisable to look at the SaO_2 and heart rate. If a downward trend is evident, go look at the baby, refraining from stimulating her (him) until:

a. SaO_2 desaturation <85% for >30 seconds, or

b. Heart rate <60 bpm for at least 10 seconds.

EMERGENCY INTERVENTION

1. If baby is having a significant clinical event as described above, stimulate the baby by flicking the heels.

2. If the significant clinical event continues, make sure airway is patent, reposition and suction if needed, and bag baby with a few puffs of O_2.

3. If the perfusion and SaO_2 do not return to previous levels, continue to bag baby and call appropriate code for physician.

4. If seizure activity is noted (rather than tremors), verify the EEG. Check for cyanosis and airway patency. Provide supplemental O_2 to maintain saturation at pre-seizure level. Page the appropriate physician.

F. PSG SCORING

1. Introduction to Scoring

Scoring protocols are designed to describe:

1. Sleep and waking states

2. Several aspects related to event occurrences, including:

   a. characteristics of events that occurred during the overnight PSG study

   b. *ALICE* PSG event scoring as compared to CHIME Monitor scoring
      - the accuracy of event detection
      - the significance of small chest or abdominal deflections

3. EEG, respiratory and cardiac summary variables for the entire study

To achieve these goals the protocols described below are to be followed. Except for Step 2, scoring will be the responsibility of DCAC.

2. Procedures for Scoring

AT *ALICE*

STEP 1: QUALITY CONTROL

Load the appropriate optical disk and check whether the **Infant ID #** is correct and identifying information complete. If not, remedy.

- To begin scoring, turn *ALICE* system on. When menu appears, select *ALICE 3* option. (Please refer to Healthdyne *ALICE 3* Manual as needed.)

- On Main Menu, select **View Patient** by pressing **<ENTER>** or CLICK on **L** mouse button when arrow is on View Patient (or press "**V**" on keyboard).

- From list of saved acquisitions, select study to be scored, press **<ENTER>** or click **L** mouse as usual.

- Check box at upper right of screen to be sure you have the study you want. If not, click **R** mouse and return to Main Menu and try again.

STEP 2: INITIAL SURVEY AND DCAC COMMUNICATION

Step 2 should be performed within three working days of the recording so that subject and personnel can benefit.

1. Review the data for **clinical events** that require immediate attention and/or notification of a physician. During the night the technician will have flagged these on the comment sheet. Each laboratory has its own directives for this category.

2. Principal Investigator or designated individual scans the *ALICE* tracings and comments in order to provide feedback to PSG personnel and CHIME. Fill out the **Feedback to PSG Personnel** on Page 5 of **Form F1** and post a copy in the laboratory if you wish.

3. Consult **CHIME PSG Form F1** and mail to DCAC in the weekly Transmittal Log.

4. Consult **CHIME Communication Log** for inquiries from PSG personnel.

Material to be sent to DCAC:

1. DCAC Transmittal and Disk Log sheet, Optical disk with *ALICE 3* patient data (disk will be returned promptly)

2. Patient identification sheet

3. CHIME PSG Checklist (Form F1, pages 1-5)

STEP 3: INITIAL *ALICE* REPORT

Obtain a **printout** of *ALICE 3* automatic output and file away for future reference.

From **Healthdyne *ALICE 3*, User Manual 1994 Chapter VI: Reports**

NOTE: The "**Print Analysis Report**" allows you to generate reports summarizing the acquisition. After selecting this option, a list of all saved acquisitions will be shown. Studies highlighted in green have not been saved to the optical drive and are still in the work directory. The study number, acquisition date, patient's name, and montage name is shown for each study. After selecting a study, the reports selected under the "**Printer settings**" option on the **Configuration Modification** menu will be printed. Although you may not choose to print them all, there are 11 available reports for adults and **10 available reports for infants** (some reports have multiple pages). Each report type is listed below. Select the starred reports and file.

* Recording Identification/Information
* Technical settings
* Signal Quality Analysis
* Sleep Data (adult studies - 3 pages/infant studies - 1 page)
* Respiratory Events (adult and infant studies - 3 pages)
* Heart Rate Summary
  pH Summary (infant studies only)
* Oxymetry Summary (adults and infant studies - 2 pages)
  CPAP Report (adult studies only)
  Miscellaneous results - Snoring and Myoclonus Summaries (adult studies only)
* Allnight Screen
* Event List

STEP 4. SLEEP/WAKE STATE (STAGE) SCORING

Note: Study sites will not be responsible for completing Steps 5-9. They are included for documentation purposes only.

DEFINITIONS:

Sleep state/wake coding will follow the guidelines of Anders, Emde, Parmelee (1971). This method will be applied to infants through one month of age as well as older infants. Some centers will also follow the sleep stage scoring guidelines of Rechtschaffen and Kales (1968) in infants ≥ 3 months of age (PCA).

PROCEDURES:

1. Select scoring Alternate Montage 1 (must include EEG (C_3-M_2; C_4-M_1; O_1-M_2; O_2-M_1; LEOG/REOG and/or EM; EMG; ECG; abdominal respiration; airflow; CO_2 waveform; SaO_2 waveform and actimeter).

   NOTE: Look at ECG to screen for arrhythmias and to be able to correlate the R waves with artifacts in other channels.

   Comments will automatically be reprinted on the raw data screen. Refer to data acquisition section for abbreviations, Table 5B.

2. Retrieve the event log (from Step 1) for this infant. To get a general impression of the recording and to identify periods of wakefulness/feeding, scan this log. When you get to these epochs, determine whether you agree with *ALICE 3* decisions. If baby is awake you can assign a "**W**".

   Also on the report print out, note the gestational and post-conceptional age, so that you know whether to expect certain patterns such as trace-alterant or sleep spindles.

3. Go to the All Night Screen (**F3**) and select samples of AS, QS, and Awake (that is A, Q, W per *ALICE* scoring). Determine whether the EMG varies in level according to sleep states. If it does not, look further into the record to see if tonic variations are present. If there is no variability, eliminate this channel from scoring.

4. Go to the raw data screen (**F4**) and verify that you are at the first full epoch <u>after</u> the onset calibration. Start scoring at the first full minute epoch after calibration. 17:00 not 16:59:30.

5. Individual parameter codes will be assigned to each epoch between onset and offset calibrations. See Appendix B.

   When is a signal good enough to serve as one of the five parameters? This must be established by gaining an overview of the recording during the night, in particular during A, Q and W. Fill in "**X**", if data is unavailable. Irregular respiration in preterms will make many epochs "**I**" for irregular and hence Indeterminate Sleep (**IS**). Keep that information rather than force the epoch into quiet sleep. Parameter codes are in Table 6 and in parameter scoring section that follows.

   <u>Parameter scoring</u>

   a. **EM:** Determine if one or more REMs occur in the epoch. If a REM is present, code as +; - otherwise.

   b. **EEG:** Check the frequency of the EEG by clicking mouse and manually counting the number of cycles and reading the Hz/cycles per second. Always look at C_4/A_1 unless it is obscured or not otherwise available. Identify EEG pattern that occupies > ½ the epoch and select the EEG code for that pattern. Use CHIME single letter codes, not those in Anders et al. Use the 50% rule: If an

epoch has ≥ 50% of a pattern, the epoch is assigned that pattern. Patterns have been defined as: H ≥50 microvolts; and F as <35 microvolts, and M(mixed) is a combination of H and F. Differentiate between eye movements in the EEG and true HVS activity.

c. **EMG:** Determine EMG tonic level, plus or minus. If level does not vary, do not include EMG in the scoring, and score based on four (or three parameters). Use the 50% rule. If an epoch has ≥ 50% of a pattern, the epoch is assigned that pattern.

d. **RESPIRATION:** Measure airflow regularity using method in **Figure 10**. Respiratory disturbances (pauses, periodic breathing pauses, scorable apnea/hypopnea) are discounted when considering whether respirations are regular or irregular. Respiratory pauses >3 seconds are ignored (considered an apnea) for determination of I and R.

e. **MOVEMENTS:** Note presence and type of movement and enter movement code (**+,—**). Refer to night log for clarification as needed. Phasic activity such as twitching is a body movement. Arousal or questionable movement can be accepted as a movement if a time-locked artifact (flat or irregular erratic waveforms) is seen in SaO_2 pulse wave form channel. See **Alternate Montage 2**. Quiet sleep: allow for mouthing, startles and sucking; that is, they are coded as - in quiet sleep. See **Table 6**.

f. There may be a random artifactual signal on EOG, perhaps a "bleed in" from the EEG. When this occurs, extra care is necessary to be certain eye movements are present. If unsure, do not use this channel in scoring and apply the ¾, or $^3/_3$ rule. **See Table 6.**

g. Refer to Appendix B for summary of coding parameters and examples.

6. Regularity or irregularity or respiration is the characteristic most useful for sleep stage scoring. The EEG signal is also fairly robust. A patient who is not moving, with regular respirations, and an EEG pattern showing high voltage slow waves or trace-alterant is likely to be in quiet sleep, and the scorer should be absolutely certain of the quality of the EMG and eye movement signals before assigning such a patient to indeterminate sleep. Similarly, a patient with low voltage irregular or mixed EEG, irregular respirations and body movements is likely to be in active sleep or awake. A brief period of another state (often indeterminant) interrupting an ongoing period of a given sleep state by 30 seconds (one epoch) should be scored the same as the surrounding epochs.

1 2

Put cursor on peak of shortest cycle (**1**) and click **L** button; holding down button, drag mouse/cursor to next peak. Read CPM value in box at upper left screen. Repeat for longest cycle. If the cpm values differ by 20 then code as **I** and if less and 20 code as **R**.

25.8 42.9

(25.3 cpm)) (42.9 cpm)

RESPIRATION RATE IN *ALICE 3*
FIGURE 10

ARTIFACTS:

a. Disruptions or artifactual signals of 15 seconds or less duration may be present within an epoch. Ignore them and code the clean part of the tracing. Movement artifact (X) > ½ an epoch but < 2 epochs can be "smoothed over" if previous and subsequent states are the same. Continue the surrounding state through the ones with artifact. For example: WXW must be changed to WWW. If the states are different, code the variables for that portion of the following state that is readable. If artifacts last more than 2 epochs, score all epochs as awake. If movement results in a state transition, code the part of the movement that can be read.

b. Examples of specific artifacts are in Appendix B.

TABLE 6

Codes to States

States	Individual Parameters
Q (QS)	EEG H, T, M EOG - EMG + Resp R BM -, Mouthing, Sucking
A (AS)	EEG F, M EOG + EMG - Resp I BM +, mouthing sucking
IS	3 Q + 2 A codes or 2 Q + 3 A codes e.g. H + - R - = IS F - + I - = IS
W (AW)	Awake = eyes open, alert or crying Feeding

Awake is scored **W** regardless of individual parameter codes. To determine **Q**, **A** or **IS**, you determine the combination of codes for each epoch and if 4 of 5 (or 5 of 5) are **Q** parameters, then the state assigned is **Q**. If 4 of 5 are **A** codes, then **A** is assigned. Any other combination is **IS**. However, if one or more variables cannot be used for state determination (eg. EMG and/or eye movements) the rules change to ¾ or ³/₃. Some parameters are consistent with both A and Q. It is possible to have ¾Q codes and ¾A codes for the same epoch. Score these epochs as IS. Code **X** for movement can be used during hand scoring, it is not an option on *ALICE 3*.

8. If the state selected differs from that displayed on *ALICE 3*, use the modification mode and enter your code. Remember, the smoothing option in 7a applies to *ALICE* scoring entries.

9. As coding proceeds, identify and score EEG arousals. See **Step 5 Arousal Scoring Procedures** for specific directions.

10. After all epochs are coded, return to the main menu.

Adding Comments After the Acquisition

(From: *Healthdyne ALICE 3, User Manual 1994*).

You may add comments after the acquisition and before the reports are printed. In addition, you can also supply a new start and end time for the study to be included in the printed results. If you want to change a note or a comment in the Event Table, you may edit it by following the instructions below:

1. If you want to change the start and/or end times of the study, position the cursor at that time on the All-night or One-hour screen.

2. Press **<ALT>** + "**O**".

The Observations screen will be displayed.

3. You can enter comments (up to 40 characters per line) in the 15 observation fields provided. Use the **<ENTER>** key or the **<TAB>** key to move from line to line.

4. If you want to change the start time, move the cursor to the "**Lights Off**" field. If you have positioned the cursor on the new time, press **<Insert>**. The new time will automatically be entered into the field. You may also manually enter the new time.

5. If you want to change the end time, move the cursor to the "**Lights On**" field. Enter the new end time, or if you have placed the cursor on the desired new end time press **<Insert>** and the new time will automatically be entered.

6. Press **<F10>** to exit the screen.

STEP 5. TRANSIENT AROUSAL SCORING RULES AND PROCEDURE

DEFINITIONS:

An EEG arousal is an abrupt shift in EEG frequency which may include theta, alpha, or other frequencies greater than 16 Hz (not including spindles). In infants, alpha frequencies generally will not be present. The following Rules and Procedures are based on the Atlas Task Force, EEG Arousals: Scoring Rules and Examples, Sleep, 1992; 15: 174-184. A copy of this reference is included in the Appendix C.

PROCEDURE:

1. In the state scoring montage (EEG and EMG displayed), examine the EEG for evidence of transient arousals only during quite sleep and indeterminate sleep.

2. If the rules are met, place the cursor at the beginning of the arousal and drag the mouse to the end of the arousal. When you release the mouse, a menu screen will be displayed and you may click on appropriate arousal type.

3. Each arousal will be classified as a spontaneous arousal (**SA**), evoked arousal (**EA**), apnea termination (**AA**), or clinically significant event technician related arousal (**TA**). To determine the type of arousal first switch to Alternate Montage 2 displaying the cardiorespiratory signals for the presence of precipitating respiratory events and then examine the technician notations to determine if there was a precipitating environmental stimulus for the arousal.

    a. **EA** - An evoked arousal is preceded by a change in the environment or is induced by the caretaker or technician.

    b. **AA** - An apnea termination arousal begins during or immediately after an apnea or hypopnea ≥ 4 seconds in duration.

    c. **SA** - A spontaneous arousal has no discernable precipitating stimulus.

    d. **TA** - Arousals induced by caretaker or technician stimulation required for the resolution of a clinically significant, prolonged cardiorespiratory event.

4. Scored arousals will appear on the final *ALICE* event log.

5. Arousal examples are in Appendix B.

RULES:

In order to be considered an arousal, the following criteria must be met:

1. A 10 second period of sleep must precede an arousal. Disregard the arousals that do not meet the duration criteria of > 3 seconds (you can round up from $\geq$ 2.5 seconds).

2. The minimum duration of time between arousals should be 10 seconds. These examples below clarify the use of this criterion:

   a.
      1. 4 second arousal - 12 seconds quiet - 4 seconds arousal = 2 arousals.
      2. 4 second arousal - 3 seconds quiet - 4 seconds arousal = 1 arousal
      3. 4 second arousal - 1 second quiet - 4 seconds arousal = 1 arousal

   b.
      1. 2 second arousal - 12 seconds quiet - 4 second arousal = 1 arousal
      2. 2 second arousal - 4 seconds quiet - 4 second arousal = 1 arousal
         (Note: This assumed 4 seconds of quiet EEG preceding the 2 second arousal)
      3. 2 second arousal - 1 second quiet - 4 second arousal = 1 arousal
         (Note: This assumed 4 seconds of quiet EEG preceding the 2 second arousal)

3. During quiet sleep (**Q**) or **IS** an arousal may occur in the absence of an increase in EMG amplitude.

4. If movement artifact, delta waves or signal blocking occur within an arousal these are included in meeting the duration criteria. Blocking must be clearly accompanied by a preceding increase in EMG amplitude.

5. Isolated sleep state or stage transitions are not scored as arousals.

6. Although transient arousals have an end-point by definition, there is no specific termination criterion and duration of arousals is not scored. If the arousal proceeds to an awake state, the arousal ends at the point the infant is no longer asleep.

STEP 6. SCORE APNEA EVENTS ≥ 10 SECONDS

NOTE: *ALICE 3* provides a tally of central, mixed and obstructive apnea, which require verification and possibly additions and deletions.

DEFINITIONS:

Central apnea: Absence of airflow in the CO_2 and thermistor channels lasting ≥ 10 seconds and accompanied by an absence of chest and abdominal respiratory efforts.

Obstructive apnea: Absence of airflow in the CO_2 and thermistor channels lasting ≥ 10 seconds with continued ribcage and abdominal respiratory efforts.

Mixed apnea: Absence of airflow in the CO_2 and thermistor channels lasting ≥ 10 seconds with both central and obstructive components manifest in the ribcage and abdominal channels. The central and obstructive components must each last at least 3 seconds.

PROCEDURES:

1. Retrieve the *ALICE 3* event report and identify all events ≥10 seconds.

   An event that occurs during sleep, even if the epoch is scored as wakefulness, should be considered as an event.

2. Using Alternate Montage 2 follow *ALICE 3* procedures to view each 30 second epoch for your selected infant, beginning after the onset-calibration at the first full minute, on the minute and concluding with the last full 30 second before the end-calibration. Since there will be a minimum of 8 hours of recording, you will be scanning at least 960 epochs. Your objective is to evaluate the apnea flagged by *ALICE 3* and identify any missed ones. You may wish to do these two tasks separately or simultaneously.

   Alternate Montage 2 consists of ECG, cardiotachometer, ribcage, abdomen, sum (VT), CO_2, THERM (nasal/oral airflow), pulse waveform, O_2 saturation, and actimeter.

3. If an apnea ≥ 10 seconds (central, mixed or obstructive apnea) is present in a certain 30 second epoch, you first measure the duration. If you consider the duration incorrect, modify the *ALICE 3* record by inserting the correct duration.

   Rules for these and other decisions are outlined in **Rules** (Page VII-58). If you do not agree about the presence of an apnea, you remove the flagged apnea from the *ALICE 3* event table. If you remove an event because one or more of the respiratory traces are obscured by movement or artifact, add the notation "uninterpretable" (**U**) to the comments.

4. You then proceed to get additional information about the accepted apnea which is to be entered in DCAC data matrix.

   _ Is it central, obstructive or mixed?

   _ The time the event began (time of peak measurement began).

   _ What was the sleep state when the apnea occurred (A, Q, IS, W)?

   _ Duration to whole second of entire apnea and duration of central portion if a mixed apnea.

   _ If the apnea precipitated (see Rules) a significant desaturation (SaO_2 < 90%), identify the lowest desaturation value on **Form F2** in low SaO_2 field.

   _ Verify that event precipitated arousals (**AA** or **TA**) were identified. Rules about arousals can be found in **Step 5, PSG AROUSAL SCORING**.

   _ Is the apnea preceded by a sigh? Enter sigh (Y/N).

(From: ***Healthdyne ALICE 3, User Manual 1994*****).**

ALICE **procedures for viewing the display and editing the event table**

EVENTS TABLE (Figure 11)

On the Events Table, the information you entered on the Patient Information screen will be shown in a box in the upper right corner of the screen. The table shows: the event type, sleep state, duration of respiratory events (as shown on the flow and effort channels), heart rate, saturation data as it relates to each given event, and the values of the heart and oxygen saturation rates. You can use the following keys on the main keyboard to navigate through the entire table and review the events you have marked.

<UP> and **<DOWN>** arrow keys	Highlights an event
<Page Up> and **<Page Down>** arrow keys	Moves through each screen of the table
<ENTER> key	Selects an event to view on the Raw Data Screen
- key	When placed in the validation column (**Val**), the minus sign signifies that you want a specific event excluded from the final summary report. The event will not be "highlighted" in the Raw Data.
+ key (**<Shift>** and +)	When placed in the validation column (**Val**), the plus sign signifies that you want a specific event included in the final summary report.

NOTE: Do not use the keys on the keypad, unless the **<Num Lock>** key is activated.

Continue to page through the screens of the Events Table until you have analyzed all events to your satisfaction.

EVENTS TABLE

FIGURE 11

OPERATING INSTRUCTIONS

(From: *Healthdyne ALICE 3, User Manual 1994*).

RAW DATA SCREEN

The Raw Data screen allows you to view more detail and access the waveforms associated with a specified event. This screen shows the original physiological data recorded on each channel.

1. Move through the screens by pressing the **<PgUp>** and **<PgDn>** keys on the main keyboard (not on the keypad, unless the **<Num Lock>** key is activated). Using the left or right arrow keys will cause the program to continuously scroll through the entire study.

2. To stop scrolling through the study, press the **<Spacebar>**.

Several boxes will be shown across the top of the screen. These boxes are called context windows, and they indicate the sleep state at a given time. Each window represents 30 seconds. When you click on a context window, the screen will move to that point of time into the study. You should verify that what is shown on the waveforms matches what is indicated in the context window.

As appropriate, you may score respiratory events by utilizing the measurement tool feature of the *ALICE 3* System to obtain detailed information about a segment of data. Align the cursor at the point where you believe an event begins. Drag the mouse across the screen to the area where you believe the event ends to highlight the data. A white box will appear in the top left portion of the screen.

If the area meets the minimum criteria, another window will be displayed listing each of the types of respiratory events. Select the appropriate event.

You will notice that the appropriate event has been indicated on the screen by a colored bar.

RULES:

Central Apnea: Refer to the definition above. The most artifact resistant channel is the CO_2; therefore use this as your primary reference to identify the breaths preceding and following the airflow cessation. The duration of apnea should be measured from the end of inspiration to the end of the next inspiration ("peak to peak"). If there is a discrepancy between CO_2 duration and THERM duration, use the channel that gives the shortest apnea duration for determining the beginning and end point of the apnea. Now consult the abdominal channel and verify whether there was a simultaneous cessation in respiratory movements. If the answer is yes, the apnea can be considered central.

NOTE 1: Cardiogenic Artifacts can be frequently observed in the CO_2 signal. In order not to confuse these with breaths, check the ECG frequency and ignore those waves that coincide with the heartbeats or SaO_2 pulse waveform. Also, the THERM may give you a clue to the first real breath or resumption of breathing after an apnea.

NOTE 2: A more accurate estimate of apnea duration is obtained by measuring the interval between the end of inspiration and the next onset of inspiration. Healthdyne uses this interval in their *ALICE 3* algorithm. For the human eye peak to peak detection is easier and this strategy is selected for the CHIME Monitor tracing and incorporated in this protocol as well. As a result, the duration values may have to be altered for each apnea.

NOTE 3: There is almost one second lag between the CO_2 signal and other respiratory signals. The term "simultaneous" presupposes that you discount that 1 second delay.

NOTE 4: In some circumstances only the THERM will be available. You can use this channel as an alternative to CO_2. The beginning and end of the apnea must be timed on the same channel.

NOTE 5: If the preceding or subsequent breath is broad, without a peak, identify the middle of that breath as the peak. If breaths are more easily identified on the THERM channel, time the apnea using this channel.

NOTE 6: The first breath or few breaths following a central apnea may be paradoxical with reduced airflow. However, the central apnea terminates at the <u>first</u> effort, even if the breath is out of phase.

NOTE 7: The first breath following a central apnea may be paradoxical without airflow (obstructed breath) yet this obstructed component may not last the 3 seconds necessary to meet criteria for mixed apnea. The termination of central apnea is timed with the return of respiratory efforts.

NOTE 8: Both the CO_2 and airflow channels are subject to displacement artifact. They also have different time lags or offsets from the respiratory effort channel. The beginning and end of apneas must be timed on the same channel and you are to use the channel that gives you the shortest apnea duration.

NOTE 9: If both the CO_2 and THERM are displaced, examine the respiratory effort channels for any cessation of effort $\geq$ 10 seconds. In this instance, you may use the RC or AB channels to score central apneas based on time from peak of last effort to peak of first effort on the same channel.

Note the different strategy for identifying "peak to peak" inspiration on the CO_2 channel vs the respiratory effort and thermistor channels.

STEP 7. SCORING OF HYPOPNEA

This protocol utilizes the same *ALICE 3* event log and the *ALICE 3* procedures that are used to verify and characterize apneic events ≥ 10 seconds. See **Step 6**.

DEFINITIONS:

Central hypopnea (CH): A 50% decrease in the amplitude of the thermistor channel lasting 10 seconds or more with the ribcage and abdominal movements in phase. In order to qualify, one of two additional criteria have to be fulfilled: the event must be followed by a drop in oxyhemoglobin saturation (SaO_2) of 4% or more or an arousal confirmed by EEG. See **Arousal Protocol, Step 5**.

Obstructive hypopnea (OH) (partial obstruction): A 50% decrease in the amplitude of the thermistor signal lasting 10 seconds or more with ribcage and abdominal movements partially or completely out of phase. In order to qualify one of two additional criteria must be fulfilled: the event must be accompanied by a drop in SaO_2 of 4% or more or an arousal confirmed on EEG. See **Arousal Protocol, Step 5**.

PROCEDURES AND DECISION MAKING RULES:

1. Choose Alternate Montage 2 which consists of ECG, cardiotachometer, ribcage and abdominal movements, sum (VT), CO_2, THERM, pulse waveform, SaO_2 and actimeter.

2. Retrieve the *ALICE 3* event log. *ALICE 3* will identify hypopnea based on drops in THERM of 50% or more. The objective is to verify these drops and to determine whether either one or both of the other two criteria are present as well. If not the event should be deleted. Hypopneic events fulfilling the criteria that *ALICE 3* failed to identify are to be added.

    a. Begin by scrutinizing each flagged hypopnea. Verify the 4% drop in SaO_2. In order to accept the validity of the SaO_2 signal, there should be at least 3 acceptable pulse waves. If artifact prevails, this latter criterion is not fulfilled and the SaO_2 cannot be used to accept or reject the hypopnea. The SaO_2 drop should occur either during the hypopneic event or within seconds after the termination of this event.

    Check whether a previously scored arousal is contingent on this event. An arousal is considered contingent if it occurs during or within 5 seconds after the termination of the hypopneic event. If at least one of the two or both criteria is not fulfilled remove the flagged hypopnea from the *ALICE 3* event table by marking it with a minus sign. Hypopnea related arousals during AS (A) will need to be identified during hypopnea scoring as they are not included in sleep state scoring.

    b. If you agree with the *ALICE 3* decision, measure the duration. If you disagree with the value in the table, rectify by inserting the correct value. The beginning of an hypopneic event is defined by the

peak of the last "full" breath, that is the breath before the amplitude dropped by 50%. The termination of an hypopneic event is defined as the peak of the first breath with an amplitude ≥50%.

c. Then consult the ribcage and abdominal channels to determine if it is central or obstructive hypopnea. If these two channels are in phase, it is a central hypopnea. A (+) will confirm that you agree the event is a central hypopnea.

   If these two channels are not in phase, it is an obstructive hypopnea. This can be scored as a user defined event. Use the (-) sign to remove the central hypopnea. Sweep the cursor across the event. When you release the mouse button, the menu of both *ALICE 3* and user defined event will appear. Click on obstructive hypopnea and the event will be added to the event table.

   NOTE: It is possible that movements prevent accurate identification of central and especially obstructive hypopnea. Check sleep states to see whether the infant was awake. If so, delete the hypopnea. If the infant was asleep, mark the hypopnea as uninterpretable on the event table. This needs to be done by hand.

d. After the *ALICE 3* identified hypopneic events have been verified, the recording has to be scanned for possible omissions. Steps (a) through (c) have to be followed and additional events must be added to the event table.

e. Enter hypopnea results as necessary.

(From: *Healthdyne ALICE 3, User Manual 1994*).

Saving Your Modifications

When you have finished Scoring the entire study and the events have been validated, you should save your modifications.

1. Press **<ESC>** from within the viewing program to access the menu.

2. From the menu, select to "**Exit to main menu**".

3. From the Main Menu, select the "**Backup current patient**" option.

The back-up process will occur automatically. When the process has been completed, you may proceed to display or print your results.

STEP 8. REMOVE ARTIFACT IN SPECIFIC CHANNELS IN ORDER TO ALLOW FOR AUTOMATED ANALYSIS AND COMPILATION OF SUMMARY VARIABLES

Elimination of Spurious Oximetry Data

The pulse waveform indicates the quality of the oximeter data. A rounded, upgoing signal should be present for each QRS complex on the ECG although the pulse waveform will be slightly delayed. Any significant decrease in amplitude may indicate a concomitant decrease in SaO_2 reliability.

When the pulse signal identifies unreliable data, the SaO_2 signal must be eliminated for that segment and 5 seconds beyond. Using the mouse, position the cursor arrow on the left-most area of the bad pulse signal. Depress and hold the left button on the mouse. Move the mouse a small distance to the right so a narrow segment of the screen (approximately 1 mm) is defined by two parallel, narrow black lines running from top to bottom. Release the button on the mouse. The area between the two lines will be black, and a menu will appear on the left side of the screen. Use the mouse to select "**Start Highlight Period**" by moving the cursor to this block on the menu and pressing the left button on the mouse one time. Now the menu and the highlighted area disappear and a green box comes up in the lower margin of the screen that says "**highlight: time ?**" Move the cursor arrow to the end of the bad area and highlight one millimeter area as before. When the menu appears, select "**End highlight period**". The green box at the bottom of the screen now shows the time for the beginning and end of the bad area. Now move the cursor arrow to the left margin of the screen and position it over the title **SaO_2**. Click on right mouse button (ESC). On drop down menu, select "**ADD FAIL PERIOD**". You should see a grey bar cover the period you selected.

Elimination of Spurious End-tidal CO_2 Data

When the end-tidal P_{CO_2} ($P_{ET}CO_2$) signal becomes artifactual, it should be removed from calculations for the overnight study. The $P_{ET}CO_2$ signal is subject to artifact, usually due to displacement or plugging of the nasal catheter leading to falsely low values. Accurate $P_{ET}CO_2$ signals are characterized by a smooth, end-expiratory plateau, with small variations in amplitude from breath to breath. With rapid respiratory rates, a smooth peak is sometimes observed rather than a plateau. $P_{ET}CO_2$ readings should be considered artifactual under the following circumstances:

a. If the oral-nasal thermistor signal shows stable baseline flow, but the $P_{ET}CO_2$ amplitude is reduced from baseline by one-third or more, then that portion of the $P_{ET}CO_2$ should be considered artifact, and the data should not be included in summary calculations.

b. If the technician notes that the catheter has been displaced or plugged and replaces the catheter, the affected data preceding the catheter replacement should be discarded.

c. If the signal is disrupted from movement secondary to catheter displacement and the signal spontaneously returns to the previous baseline, the affected data should be removed. Obstructive sleep apnea can occur in association with movement, so this data should be evaluated carefully before it is removed from the calculations.

Cardiac Signals

Observe the cardiac rate on *ALICE 3* raw data. If the rate drops precipitously due to a loose electrode or an artifact for at least 3 beats remove the signal. Healthdyne will consider adding median heart rate values which protects against isolated erroneous data.

STEP 9. UPON COMPLETION OF *ALICE 3* SCORING, PRINT OUT FINAL SUMMARY REPORT

STEP 10. COMPARISON OF *ALICE 3* and CHIME MONITOR EVENTS

The CHIME DCAC will be responsible for comparing the scored events from both the *ALICE 3* system and the CHIME Monitor.

Study sites will not be responsible for completing the following items. They are included here for documentation purposes only.

Standard Event Scoring; also see **Step 6 and Step 7**.

1. Obtain the summaries of the results of scoring of events for both *ALICE 3* and CHIME Monitor.

2. For each event scored on *ALICE 3* that meets the CHIME criteria, determine if there was a corresponding CHIME Monitor event that occurred during the same period.

AT *ALICE 3*

3. Based on CHIME Monitor scoring summary, use *ALICE 3* to review all events that included low amplitude deflections.

4. Locate each event and evaluate the airflow signals to determine the presence or absence of airflow for each low amplitude deflection. Note the total number of low amplitude deflections with airflow.

5. If any events were scored as genuine on CHIME Monitor scoring but not identified during *ALICE 3* scoring, these should be located on *ALICE 3* and rescored to accurately characterize the events. Following rescoring a new scoring summary should be printed out.

AT CHIME MONITOR BASE STATION

6. For each *ALICE 3* event utilize the CHIME scoring software to add the results of *ALICE 3* scoring to the corresponding CHIME event. Note that there are special fields in the CHIME Monitor software that allow input of the results of the *ALICE 3* scoring. Also note that it is possible that a genuine event scored on *ALICE 3* may have been labeled FALSE on original CHIME Monitor scoring. In these cases the *ALICE 3* fields should still be added.

7. If an *ALICE 3* event was not detected by the CHIME Monitor, use CHIME Monitor software to add the event to the CHIME database.

8. Print out new CHIME Monitor scoring summary.

Appendix A

Several components of the data acquisition protocol are in the final stages of testing; these include the DAS, thermometer and eye movement sensor. Descriptions of these components are in this appendix for information purposes only. When the components are ready to be integrated into the acquisition procedure, an addendum to this PSG protocol, with implementation details, will be distributed to each site.

CHIME PSG Data Acquisition System

The CHIME Data Acquisition System requires different connections between study subjects and the *ALICE 3* PSG monitor than would be used for a straight *ALICE 3* PSG. The principal difference is the use of the D.A.S. amplifier as the interface between the subject and the electronic equipment as opposed to the Calvin unit that is used when the *ALICE 3* monitor is used alone. The D.A.S. amplifier is connected to the Calvin by means of a cable that connects between the "input device" connector on the Calvin unit and the "Calvin" connector on the back of the D.A.S. amplifier. The "auxiliary input" connectors on the side of the Calvin unit labeled 1, 2, 3, 4, 5 get connected to the five connectors labeled "aux" immediately under the Calvin connector on the D.A.S. amplifier. Please note that the numbering of these connectors on the D.A.S. amplifier is not sequential and it is important that the small telephone wire connection be made between connectors of the same number on the Calvin unit and on the D.A.S. amplifier unit. Special cables with small black plastic connectors on each end are provided with the D.A.S. unit to connect the eye movement and temperature channels between the D.A.S.. amplifiers and Calvin. Connect one end of the one cable to the connector labeled "Spare 1" on Calvin and the other end to the connector on the back of the D.A.S. unit labeled "eye out". Similarly, connect the second cable to the connector labeled "Spare 2" on Calvin with the other end connected to the connector on the D.A.S. amplifier unit labeled "temp out". This completes connecting the D.A.S. to the Calvin unit.

Connecting the D.A.S. Amplifier Unit to the Patient

The patient box normally connected to the "input device" connector on Calvin is now connected to the connector labeled "patient box" on the D.A.S. amplifier unit. The cable from the NIMS monitor that normally is connected to Calvin through a special set of wires that went into the "auxiliary input" is now connected to the D.A.S. unit at the connector labeled "NIMS". A special cable has been provided with the D.A.S. unit to connect the output from your capnometer to the input connector on the D.A.S. labeled "CO_2 in". Similarly, a cable from the special CHIME eye movement sensor connects to the connector on the D.A.S. amplifier labeled "eye in". The special CHIME temperature monitor connects through its cable to the input labeled "temp in". The patient box and the capnometer, eye movement sensor, and temperature monitor are all connected to the study subject in the same way as is done with the *ALICE 3*.

Connecting the D.A.S. Amplifier Unit to the D.A.S. Computer

The D.A.S. amplifier unit has an output connector labeled "D.A.S." and this gets connected to the D.A.S. computer by means of a cable provided with the D.A.S. unit. The cable connects to the unmarked connector on the back of the computer near the right when facing the back of the computer. This is the only connector on the computer that will accept the D.A.S. cable, so do not try to force the cable into another connector on the computer where it will not fit properly. The D.A.S. amplifier must also be connected to the power supply using the connector labeled "12 VDC", and the power supply is plugged into the standard electrical outlet.

This completes the procedure for connecting the D.A.S. unit and computer to the *ALICE 3* system. It is important to note that the connections between Calvin and the *ALICE 3* unit remain the same as they were when the D.A.S. unit was not used. *ALICE 3* will not work properly if these connections are not correctly made.

Operating the D.A.S. Computer

Although the D.A.S. system is connected between the subject and *ALICE 3*, it does not interfere with any of the normal *ALICE 3* functions with the exception of measuring electrode impedance. Thus, it is possible to use *ALICE 3* without using the D.A.S. computer by merely using the connections described in the previous section and switching the D.A.S. amplifier unit on by means of the red switch on the top of the unit. You will know that the unit is switched on by the light that shines from within the switch. The only *ALICE 3* function that does not work with the D.A.S. system connected is the measurement of the EEG electrode impedances while collecting data (by depressing **<F>** on the *ALICE 3* keyboard). We had to sacrifice that function to enable the D.A.S. system to collect data not only for *ALICE 3* but also for the D.A.S. computer. A small electrode impedance meter has been designed at the CTOC to allow electrode impedances to be measured independent of the D.A.S. or *ALICE 3* monitor.

To begin collecting data, *ALICE 3* should be set up in the usual manner. Once it has been determined that *ALICE 3* is collecting the data as desired by the investigators, the D.A.S. computer can be started. This is done by first switching on the computer and waiting until the C prompt (C:\>) appears. To start the program type "**das**" and push the <Enter> key. A blue screen should appear that says "Global Lab". At this point type the letter **S** followed by the enter key and a small menu will appear at the center of the top of the screen. From this menu choose "**A/D Module**" by moving the highlighted band using the down arrow cursor key or typing the letter **A**. We are now in the data acquisition mode of the software and a new window will appear at the upper left corner of the screen. Choose the entry on this menu labeled "**Load**" and a menu that asks you to type in the name of the set-up program for the PSG will appear. At this point you should type in "**CHIME**" followed by the <ENTER> key, and this will load the CHIME montage for the data acquisition system. Once this is completed the small window in the upper left-hand corner of the screen will reappear. Now it is necessary to name the file where the data will be stored on the computer's hard disk. Select the "**Edit**" item from the menu and a new large, complicated window will appear. At the lower right-hand corner of this window is an entry called "**Filename**". A name which is usually "**CHIME.OUT**" will appear at this point, and you should use the mouse to position the cursor (small white arrow) at the "**C**" and press the left mouse button. Now you can type the name of the storage file so that it replaces the "**CHIME.OUT**" in that listing. The conventions for naming the CHIME storage file follows. After you have typed in the filename move the cursor with the mouse to the button labeled "**OK**" and depress the left mouse button. The screen will return to the small window in the upper left-hand corner.

Now choose the acquisition mode by typing "**A**". A new small window will appear under the word "**Acquisition**" at the top of the screen. The first item in this menu is the word "**Go**" and it should be highlighted in white. If for some reason it is not highlighted, use the up or down arrow curser keys to move the highlighted area to the word "**Go**". To start acquisition push the <Enter> key and the data acquisition screen will appear. This consists of a series of 20 horizontal white lines on a black background. To actually start acquiring data you must push any key on the keyboard, and you will see the waveforms being collected on the screen. These signals will be flashing by too fast to be able to be viewed and understood, but this display can be used to indicate that data is being collected. At the bottom of the screen will be a blue bar with the words "**Acquisition Running**". If you do not see this, the acquisition system is probably not running correctly and you need to repeat the previous steps to make sure that data is being acquired.

The D.A.S. computer need no further attention until the study ends.

Ending a Data Acquisition Session

Once the PSG study has been completed, you can stop the data acquisition system by pushing the escape <ESC> button on the keyboard. The blue bar at the bottom of the screen will say "**interrupted after (number) scans! Save used buffers to disk?**" and below that are listed a highlighted "**Yes**" or "**No**". If the "**Yes**" is highlighted and you wish to save the data push the <Enter> button. If you do not wish to save the data move the highlight to the "**No**" using the right arrow key, and then push the <Enter> key. Once this selection is made, data acquisition is complete. To exit the program you must push the **S** key to bring up a new menu under the word "**System**" at the top of the screen. The last item on this menu is "**Exit**" and you can either highlight this by pressing the <Down Arrow> key five times or typing the letter **E**. Once the exit is highlighted, press the <Enter> key and you will return to the C prompt.

Eye Movement Sensor Test

Before use, the batteries should be tested. This is done by depressing the battery test button (labeled "press to test") and holding the button down for at least three seconds. The battery test light should come on and remain on for the entire duration of the time the button is depressed. If the light comes on as the button is depressed, but its intensity decreases and eventually the light goes out while the button is still depressed, there is not enough power in the battery to operate the sensor for the PSG, and the batteries need to be replaced. If the light does not come on at all once the button is depressed, the batteries need to be replaced. Battery lifetime is approximately 90 hours for fresh batteries. Thus, you can expect to change batteries after seven 12-hour PSG studies. If the batteries need to be replaced, follow the instructions in the "replacement of batteries" section of these instructions.

Note: Replacement of Batteries

The following steps should be used in replacing the battery (AA, any brand).

1. Unscrew the four screws in the corners of the front panel of the CHIME eye movement sensor electronic box.

2. Lift the front panel from the box, recognizing that it is connected to the batteries by two wires. Be careful not to break these wires.

3. Remove the old batteries from the battery clip, noting their orientation. Replace these batteries with fresh batteries in the same orientation. A "+" is indicated on each side of the battery clip to show the orientation of the positive battery terminal. Make sure that the batteries are firmly installed in the battery holder.

4. Re-assemble the front panel on the box. You might want to press the battery test button to make sure that the light lights before replacing the screws in the four corners on the front panel. This completes the battery replacement procedure.

Eye Movement Sensor: The sensor should be placed over the orbit of one eye. If the infant is placed in the lateral position then place the sensor on the contralateral side. Non-allergenic tape should be used to hold the sensor in place, and the lead wire should also be taped to the cheek so that strain on the wire will not pull the sensor off the eye.

Connect the sensor cable to the input connector on the electronic box and lock the plug in place by twisting the clip located on the plug near the prongs, so that it engages the clip on the socket and keeps the plug from accidentally coming out of the socket.

Connect the output cable to the output connector on the electronics box, and connect the other end of the cable to the input marked "EYE MOVEMENT" on the CHIME data acquisition unit or "SPARE 1" on the Calvin box of the *ALICE 3* PSG machine (Figure 8.)

Switch the eye movement sensor box on by flipping the toggle switch to the "on" position. Within a few seconds recordings of eye movement should be seen on the "eye" channel of the PSG computer.

CHIME PSG Thermometer

This instrument consists of the electronics package itself, a thermistor for measuring skin temperature, and a thermistor for measuring air temperature. The skin temperature thermistor consists of a metal disk at the end of a flexible white wire connected to a longer, more robust gray wire with a plug at the other end. This plug should be connected to the connector marked "**SKIN**" on the front panel of the instrument directly beneath the digital display. Make sure that the connector is pressed all the way into the socket so that good contact is established. The air thermistor is located within a metallic cylindrical cage with oval openings on the sides. It also has a gray wire with a plug on the end that should be connected to the socket on the electronic instrument front panel marked "**AIR**'.

The output signal from this instrument is available at the smaller connector marked "**OUT**" on the right-hand side of the front panel. A special cable that connects between this connector and the CHIME data acquisition amplifier unit is provided with the instrument. One end of this cable should be plugged into the connector marked "**OUT**" and the other goes to the data acquisition amplifier to the connector marked "**TEMPERATURE IN**".

The CHIME PSG thermometer is operated on battery power and does not require any other connections for power or information transfer. Since it is battery powered, it is important that the power switch is left in the off position when the thermometer is not used so that battery energy can be conserved.

Instructions for Use with PSG
The following steps should be carried out in using the thermometer for PSG studies.

1. Make sure that the thermistors and interface cables are connected as described above.

2. The skin thermistor should be placed on the infant's abdomen in the right upper quadrant over the liver (See Section D.6.j. Application of Electrodes.) The metal side of the thermistor should be in contact with the skin. The thermistor should be held in place using non-allergenic tape. A second piece of tape should secure the lead wire to the infant so that there is no tension on the thermistor itself. Such tension could cause the thermistor to loosen from the skin and give an erroneous temperature.

3. Place the air temperature thermistor over the infant's head 30 to 70 cm above the face. The method of securing this thermistor will be dependent upon the arrangements used at the particular center where the study is being carried out, but it is important that the thermistor be in a position where it will not be bumped by care-givers during the study.

4. The instrument can then be switched on using the power switch located under the selector knob on the front panel. The switch is in the "**on**" position when the toggle is pointing upward, and the power light (PWR) is lit. This is not a bright light, so it may be difficult to see in a bright room. If this light is not lit, it is necessary to change batteries before proceeding any further. Instructions for this are given in the next section.

5. The selector knob is used to check the calibration of the instrument. After the instrument is switched on, the selector should be set to 20. This is done by pushing in on the knob and turning until the white pointer points to the number 20 on the panel. After a few seconds the digital indicator on the panel should read 20.0. Due to the least significant figure error of this type of instrument, the panel may indicate 20.1 or 19.9, but this will be within the accuracy of the instrument. If a number that is not close to 20 appears, the instrument is not working correctly, and you should contact the CHIME engineer on call. Now move the selector switch to the position labeled "**30**". The panel meter should ideally give the reading of 30.0, but 29.9 and 30.1 are equally acceptable. Now move the selector switch to the number 40, and the panel display should indicate 39.9, 40.0, or 40.1. This completes the calibration check, and the selector switch should be returned to the position labeled "**OP**". The instrument is now ready for operation.

6. The switch to the immediate right of the skin thermistor connector determines whether the instrument is measuring the air temperature and the skin temperature (the "**A/S**" position of the switch) or just measuring the air temperature (the "**A**" Position). Choose the position that you will use for the PSG study. It is recommended that the A/S position be used.

7. The digital display on the front panel will now show the temperature of either the air probe or the skin probe. Each is displayed for 20 seconds. When the instrument is set up for both air and skin temperature the first 20 second segment after it is turned on gives the air temperature, followed by 20 seconds of the skin temperature and repeating. Although it is difficult to know which is which by looking at the digital display, it will be quite clear on the *ALICE 3* screen, since the skin temperature will be at a higher level than the air temperature.

Replacement of Batteries

The CHIME PSG thermometer is operated on battery power. Periodically these batteries will need to be replaced. It is time to replace the batteries when upon turning on the instrument the red "**PWR**" light fails to illuminate even though the numbers on the digital read-out are functioning. If the batteries need to be replaced, the following steps should be taken.

1. Batteries are located in a compartment on the bottom of the CHIME PSG thermometer. The compartment cover can be identified by the word "**OPEN**". To open this cover, press down over the "**OPEN**" label and slide the cover toward the rear of the instrument.

2. Four AA size alkaline batteries are housed in the battery compartment. All four should be changed. It is sometimes difficult to remove the first battery, but this can be done by sliding a small screwdriver between the first battery and the back of the case and gently prying the battery up from its holder. It is relatively easy to remove the remaining batteries without the screwdriver.

3. Replace the batteries making sure that the positive end (marked "+") corresponds with the "+" sign written on the bottom of the battery compartment at each battery position. Note that each battery is in the opposite position from the one to which it is adjacent. Make sure that batteries are firmly seated in the battery compartment and replace the compartment cover by sliding it in from the back of the case until it snaps in place.

Appendix B
Table of Contents

R	2-6,8,9,16,18
I	7,10-15,19
BM	
+	10,12,14,15
-	1-9,13,16-19

EVENTS	**Waveforms By Number**
Apnea	
Central Apnea	25
Obstructive Apnea	
Mixed Apnea	26
Hypopnea	
Associated Desaturation of 4%	29
Associated Arousal	
Periodic Breathing	26-28
Arousal	
SA	24
AA	23
CO2 Purge Artifact	31,33
Movement Artifact	32
SaO2 Removal	30

* In order to reduce the number of sample waveforms, some may contain examples of several things such as overall state, an apneic event, and eye movement as defined by the eye movement sensor. Each waveform is numbered to help you move through the cross-referencing numbers. Contents are arranged by waveform type by waveform number. As new examples are added new numbers will be added.

For sites where PSG staff initializes cartridge: At other sites CHIME staff will provide prepared PSG and new home cartridge for each PSG.

Initialize the CHIME cartridge for PSG Use.

Enter Infant's Information:

1. For **Name**, enter infant's "Event Record Label" (**ERL**). i.e., tokj12003121893
2. Enter infant's **Date of Birth** (mm/dd/yy).
3. Enter infant's **ID#** (5-digit Study ID#).
4. Enter infant's **Sex** (M/F).
5. **Address** information may be left blank.
6. Enter in **Comments**: CHIME monitor S/N and Cartridge S/N used during the PSG.

Enter Monitor ALARM & RECORD Settings:

1. For **APNEA**, set "Alarm" to 90 seconds; and "Record" to 16 seconds.
2. For **BRADYCARDIA**, set "Alarm" to -240 (Enter a negative value to disable the alarm.) Set "Record" to 80 (<44 wks PCA) or 60 (>44 wks PCA).
3. For Hypopnea, Labored Breath, Rapid Breath, Tachycardia, and O_2 Sat: Enter negative values to disable the alarms.
4. "Event Waveform Buffers" values remain the same for all infants. Buffers should display the following values: 75, 30, 400, 25, 0, 1, and 3. "Continuous Record" should be set to **ON** (check mark).

	ALARM	**RECORD**
APNEA	90	16
Hypopnea	-25	-25
Labored Breath	-9.0	-9.0
Rapid Breath	-240	-240
BRADYCARDIA	-80	80 (<44 wks PCA)
	-60	60 (>44 wks PCA)
Tachycardia	-240	-240
O_2 Sat	-50	-50

Event Waveforms Buffers	
·Pre-Record (sec)	75
·Post-Record (sec)	30
·Calibration Values	
Def. Quan. Val.	400
·Min. Acc Vol.	25
·Periodic Recording	
Starting Hour	0
·Interval (hours)	1
·Duration (minutes)	3
·Continuous Record	ON

ON = Check Mark
OFF = No Check Mark]

5. Note: Monitor will ALARM for Band and Lead Disconnects and asystole (slow heart light).

Quality of Individual PSG Channels:

Infant's Name:_____
Study ID:_____
Date:_____

Quality of Individual PSG Channels:

	CHANNELS	GAIN SET AMPLITUDE	BOX IMPEDANCE	ALICE IMPEDANCE	COMMENTS
1	R-EOG				
2	L-EOG				
3	C_4 - M_1				
4	C_3 - M_2				
5	O_2 - M_1				
6	O_1 - M_2				
7	Chin				
8	Position				
9	Temp				
10	ECG				
11	Cardiotachometer				
12	Impedance				
13	RC				
14	Abdomen				
15	Sum				
16	CO_2				
17	CO_2 Number				
18	Thermistor				

19	Oximeter Pulse Waveform				
20	O_2 Saturation				
21	Actimeter				

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Appendix D
Approved Supply List

Parameter	Sensors	Recommended Brand
EEG	Gold cup electrodes, 48" leadwire w/ hole, 10/box, specify male pins (not female safety jacks Elefix Cream or Ten-20	Grass E5GH Nihon Kohden/D.O. Weaver or Contour IB
EOG	Gold cup (same as EEG) with paste or Contour IB. Elefix Cream or Ten-20	Grass Nihon Kohden/D.O. Weaver
Submental EMG	Miniature biopotential electrodes (AgAgCl) Kit includes 5 electrodes with 60" leads, 2 60mg tubes of electrolyte gel and 200 adhesive washers. Order standard male jacks. Gel from Gereonics is Sigma Gel (Parker)	Gereonics 450318 DM Davis also supplies adhesive collars (washers)
Respiration (Effort)	Respiband Plus Bands. 24" (set of two) or 15" (set of two) Model 107-007-24 or 107-007-15	NIMS
Respiration Airflow (thermistor)	Healthdyne, neonatal nasal thermistor (with supply of double stick adhesives) (catalog No. 6210)	Healthdyne
ECG	Contour S30 1B. Conductive solid gel ECG neonatal/pediatric disposable Ag/AgCl electrodes. (45/pouch) and Jenson Premie Solid Gel Cloth, Snap Ag/AgCl Reusable Electrodes P/N: A-3501 (30/pouch); P/N: A-3502 or P/N: A-3503	Contour Medical Technology, Inc. Jenson Medical International
SaO_2	Ohmeda SoftProbe (Reusable) 7900 - 222/F	Ohmeda

Skin Preparation - Omniprep 5oz.	D.O. Weaver & Co.
Tape - Micropore	3M *
Tape - Transpore	3M *
Tape - Coban	3M *
Cotton Tipped Applicators, 100 - 6 inch	*
CO_2 (O_2) Salter Labs, one No. 4701F, Infant (Divided Cannula) Oxygen delivery CO_2 sampling nasal cannula	Salter Labs *
Bandage - Kerlix, Disposable (single pt. use)	*
Kendall Conform Stretch Bandage, 2 or 4" X 4.1 yd. stretched. (Kling, elastic gauge)	*
Optical disks (Maxtor) OC-800 or equivalent	City Computer & Supply
Arm Restraints - Pediwrap w/o thumbhole #201 neonatal or pediatric #203	The Medi-Kid Co.
Posey Oximeter Probe Wrap 6554	Posey*

* These should be available through your medical center purchasing or central supply departments.

City Computer and Supplies 271 Schropp Ave. Akron, OH 44312 1-800-759-6868	Contour Medical Technology, Inc. 144 Southway Blvd. La Veryne, TN 37086 1-800-851-8184 Fax: 615-793-6998
DM Davis Inc. 215 West 90th St. NY, NY 10024 PH: 212-787-8519	Gereonics, Inc. 4650-143 Dulin Rd. Fallbrook, Calif. 92028 Call toll free: 1-800-654-6266, 8-3pm PST PH: 619-731-9003 FAX: 619-728-4640
Astro-Med Grass Instrument Co. 101 Old Colony Ave. P.O. Box 516 Quincy, MA 02269-0516 PH: 617-775-0002 Fax: 617-773-0415	Jenson Medical International P.O. Box 8114 The Woodlands, Texas 77387 1-800-992-5487 PH: 409-539-5544 FAX: 409-539-5533
The Medi-Kid Co. P.O. Box 716 Nueva, CA 92567 PH: 909-928-9528 FAX: 909-928-1223	Neuro Supplies Inc. 86 Boston Rd. Waterford, CN 06385 1-800-638-7693
Nihon Kohden America 1-800-325-0283	NIMS 1840 West Avenue Miami Beach, Florida 33139 1-800-654-6467
Salter Labs 100 W. Sycamore Rd. Arvin, CA 93203	D.O. Weaver & Co. 565-C Nucla Way Aurora, Co 80011