APPENDIX A

REFERENCES
APPENDIX A

REFERENCES


APPENDIX B

STOP-ROP ROSTER
OF PARTICIPATING INSTITUTIONS AND COMMITTEES
SUPPLEMENTAL THERAPEUTIC OXYGEN FOR
PRETHRESHOLD RETINOPATHY OF PREMATURITY

STOP-ROP

MEMBERSHIP ROSTER

For detailed information such as names and phone numbers of certified personnel at each institution, please refer to the STOP-ROP Directory of Personnel.

JANUARY 1997
STOP-ROP
NATIONAL EYE INSTITUTE CENTERS

01
BOSTON CONSORTIUM
New England Medical Center
Newborn Medicine, NEMC # 84
750 Washington Street
Boston, MA 02111

01  New England Medical Center
02  Boston City Hospital (inactive)
03  The Children's Hospital
04  Brigham & Women's Hospital
05  Beth Israel Hospital
06  Beverly Hospital
07  Salem Hospital
08  South Shore Hospital
09  Good Samaritan Medical Center
10  Newton-Wellesley Hospital
11  Winchester Hospital
12  Lowell Hospital
13  Mount Auburn (inactive)

Principal Investigator:  Cynthia Cole, MD
Study Center Coordinator:  Brenda MacKinnon, RNC

02
COLUMBUS CHILDREN'S HOSPITAL
700 Children's Drive
Department of Pediatrics
Columbus, OH 43205

01  Children's Hospital
02  Ohio State University
03  Grant Medical Center
04  Mount Carmel Health

Principal Investigator:  Richard E. McClead, MD
Study Center Coordinator:  Rae Fellows, M.Ed.
03

PHILADELPHIA CONSORTIUM
Thomas Jefferson University
1025 Walnut Street, Suite 727
Philadelphia, PA 19107

01 Thomas Jefferson University (TJU)
02 The Children's Hospital of Philadelphia (CHOP)
03 The Hospital of the University of Pennsylvania (HUP)
04 Albert Einstein Medical Center
05 Medical College of Delaware

Principal Investigator: Alan R. Spitzer, MD
Study Center Coordinator: Bill Holt

04

UNIVERSITY OF ARKANSAS
Department of Ophthalmology
4301 West Markham, Mail Slot 523
Little Rock, AR 72205

01 Arkansas Children's Hospital
02 University Hospital of Arkansas

Principal Investigator: J. David Bradford, MD
Study Center Coordinator: Erin S. Davis, RN, NNP

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UNIVERSITY OF LOUISVILLE
School of Medicine
Department of Ophthalmology and Visual Sciences
301 East Muhammad Ali Boulevard
Louisville, KY 40292

01 University of Louisville Hospital
02 Kosair Children's Hospital
03 Norton's Hospital

Principal Investigator: Charles C. Barr, MD
Study Center Coordinator: Greg Whittington, Psy.S.
NATIONAL EYE INSTITUTE CENTERS - continued

(Former Alternative Funded Centers)

51

MAGEE-WOMENS HOSPITAL
Department of Pediatrics
300 Halket Street
Pittsburgh, PA 15213-3180

01 Magee-Womens Hospital
02 West Penn

Principal Investigator: Beverly S. Brozanski, MD
Study Center Coordinator: Judith Jones, BSN, RNC

52

UNIVERSITY OF ROCHESTER
601 Elmwood Avenue
Division of Neonatology, Box 651
Rochester, NY 14642

01 Strong Memorial Hospital
02 Children's Hospital of Buffalo

Principal Investigator: Dale L. Phelps, MD
Study Center Coordinator: Kathleen Brown, RN

54

UNIVERSITY HOSPITAL AT STONY BROOK
Department of Ophthalmology
HSC L-2, room 152
Stony Brook, NY 11794-8223

01 SUNY at Stony Brook
02 Long Island Jewish Hospital

Principal Investigator: Pamela A. Weber, MD
Study Center Coordinator: Adriann Combs, RN
NATIONAL EYE INSTITUTE CENTERS - continued

(Former Alternative Funded Centers)

56    CHICAGO CONSORTIUM
       University of Illinois at Chicago
       Department of Ophthalmology
       1905 West Taylor Street
       Chicago, IL 60612

01 University of Illinois at Chicago
02 Loyola University and Medical Center
03 Children's Memorial Hospital
04 Rush Presbyterian St Luke's Medical Center
05 Cook County Hospital
06 Illinois Masonic Medical Center
07 Christ Hospital & Medical Center
08 Northwestern University
09 Michael Reese Hospital

Principal Investigator:       Michael J. Shapiro, MD
Study Center Coordinator:    Bernadine Rupar, COT SCC
STOP-ROP
NEONATAL NETWORK CENTERS

33  INDIANA UNIVERSITY SCHOOL OF MEDICINE
James Whitcomb Riley Hospital
702 Barnhill Drive, RR 208
Indianapolis, Indiana 46202-5210

01  James Whitcomb Riley Hospital
02  Wishard Memorial Hospital
03  Indiana University Hospital

Principal Investigator: James A. Lemons, MD
Study Center Coordinator: Dee Dee Appel, RN

34  STANFORD UNIVERSITY MEDICAL CENTER
Division of Neonatology
750 Welch Road, Suite 315
Palo Alto, California 94304

01  Stanford University Medical Center

Principal Investigator: David K. Stevenson, MD
Study Center Coordinator: Bethany Ball, BS

35  UNIVERSITY OF CINCINNATI
Division of Neonatology
Department of Pediatrics
231 Bethesda Avenue ML 0541
Cincinnati, Ohio 45267-0541

01  University of Cincinnati Medical Center
02  Children's Hospital Medical Center

Principal Investigator: Edward Donovan, MD
Study Center Coordinator: Marcia Mersmann, RN
36  UNIVERSITY OF TENNESSEE AT MEMPHIS
    E.H. Crump Hospital
    853 Jefferson Avenue, Room 201
    Memphis, Tennessee  38163

    01 Regional Medical Center at Memphis

    Principal Investigator:  Sheldon Korones, MD
    Study Center Coordinator:  Tina Hudson, RN, BSN
STOP-ROP
ALTERNATIVE FUNDED STUDY CENTERS

50

KAPIOLANI MEDICAL CENTER FOR WOMEN AND CHILDREN
Bingham Bldg., 1st Floor
1319 Punahou Street
Honolulu, HI 96826

01 Kapiolani Medical Center
Principal Investigator: David Easa, MD
Study Center Coordinator: Carol Trockman, MS, RN

55

AKRON CHILDREN’S HOSPITAL
Eye Clinic
One Perkins Square
Akron, OH 44308

01 Children’s Hospital Medical Center of Akron
Principal Investigator: Frank Kokomoor, MD
Study Center Coordinator: Joyce Burton, RN

57

OREGON CONSORTIUM
Legacy Emanuel Children’s Hospital
2801 N. Gantenbein Avenue
Portland, OR 97227

01 Legacy Emanuel Children’s Hospital
02 Doernbecher Memorial Hospital for Children
Principal Investigator: Raul Banagale, MD
Study Center Coordinator: Nancy Dolphin, RN, BSN
ALTERNATIVE FUNDED STUDY CENTERS - continued

58

SHERIDAN CHILDREN'S HEALTHCARE SERVICES
Plantation General Hospital
401 NW 42nd Avenue
Plantation, FL 33317

01 Plantation General Hospital
02 Hollywood Memorial Hospital
03 West Boca Medical Center

Principal Investigator: Mitchell Stern, MD
Study Center Coordinator: Kay Wigton, RN

59

UNIVERSITY OF MARYLAND
Department of Ophthalmology
22 South Greene Street, N6W46
Baltimore, MD 21201

01 University of Maryland Medical Center
02 Greater Baltimore Medical Center
03 Mercy Medical Center
04 St-Agnes Hospital

Principal Investigator: Mark Preslan, MD
Study Center Coordinator: Tamara Tanbusch, RN, BSN

60

VANDERBILT UNIVERSITY
Department of Ophthalmology
8000 Medical Center East
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01 Vanderbilt University Medical Center

Principal Investigator: Stephen Feman, MD
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JACKSONVILLE CONSORTIUM  
University of Florida Health Sciences Center  
Department of Neonatology  
655 W. 8th Street  
Jacksonville, FL 32209

01 University Medical Center  
02 Baptist Medical Center  

Principal Investigator: Michael Stewart, MD  
Study Center Coordinator: Laurie Ott, RNC

NORFOLK CONSORTIUM  
Children’s Hospital of the King’s Daughters  
Neonatal Medicine  
601 Children’s Lane  
Norfolk, VA 23507

01 Children’s Hospital of the King’s Daughters  

Principal Investigator: Glen A. Green, MD  
Study Center Coordinator: Marilyn Reining, RN

MINNESOTA CONSORTIUM  
University of Minnesota  
Department of Ophthalmology  
420 Delaware Street SE, Box 493  
Minneapolis, MN 55455-0591

01 Hennepin County Medical Center  
02 Children’s Health Care - St.Paul  
03 Fairview-Riverside Hospital  

Principal Investigator: Terri Young, MD  
Study Center Coordinator: Sally Cook, BA
64

OKLAHOMA CONSORTIUM
Dean A. McGee Eye Institute
608 Stanton L. Young Blvd
Oklahoma City, OK 73104

01 Children's Hospital of Oklahoma
02 Mercy Health Center

Principal Investigator: Mark Scott, MD
Study Center Coordinator: Janie Shofner, COA

65

CHILDREN'S MEDICAL CENTER OF NORTHWEST OHIO
Toledo Hospital
Division of Neonatology
2142 North Cove Blvd
Toledo, OH 43606

01 Children's Medical Center of Northwest Ohio

Principal Investigator: Malini Satish, MD
Study Center Coordinator: Vicky Gall, RNC, NNP

66

COOK INSTITUTE FOR RESEARCH AND EDUCATION
East Paris Medical Center
1000 East Paris Avenue, SE
Grand Rapids, MI 49546

01 Butterworth Hospital
02 Blodgett Medical Memorial Center

Principal Investigator: Patrick J. Droste, MD
Study Center Coordinator: Nancy Finnegan, RN
STOP-ROP
INACTIVE STUDY CENTERS

30  BROWN UNIVERSITY
Women & Infants' Hospital
Department of Pediatrics
Room 2219
101 Dudley Street
Providence, RI 02905

01  Women and Infants' Hospital

Principal Investigator:  William Oh, MD
Study Center Coordinator:  Angelita Hensman, RN

31  CASE WESTERN RESERVE UNIVERSITY
Rainbow Babies and Childrens Hospital
Division of Neonatology
11100 Euclid Avenue, Room 3100
Cleveland, Ohio  44106

01  Rainbow Babies and Children's Hospital

Principal Investigator:  Avroy Fanaroff, MD
Study Center Coordinator:  Nancy Newman, RN

32  EMORY UNIVERSITY
Division of Neonatal-Perinatal Medicine
80 Butler Street
Atlanta, Georgia  30335

01  Crawford Long Hospital
02  Grady Memorial

Principal Investigator:  Barbara Stoll, MD
Study Center Coordinator:  Cathy Goulding, RN
INACTIVE STUDY CENTERS - continued

37

UNIVERSITY OF TEXAS SOUTHWESTERN MEDICAL CENTER
Department of Pediatrics
5323 Harry Hines Boulevard, E3 404
Dallas, Texas 75235

01 St Paul Medical Center

Principal Investigator: Jon E. Tyson, MD
Study Center Coordinator: Gay Hensley, RN

38

WAYNE STATE UNIVERSITY
Children’s Hospital of Michigan
Division of Neonatal and Perinatal Medicine
3901 Beaubien Boulevard, Room 405
Detroit, Michigan 48201

01 Children’s Hospital of Michigan
02 Hutzel Hospital
03 Grace Hospital
04 St John’s Hospital

Principal Investigator: Mary Bedard, MD
Study Center Coordinator: Gerry Muran, RN

39

YALE UNIVERSITY SCHOOL OF MEDICINE
Department of Pediatrics
333 Cedar Street
P.O. Box 208064
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01 The Children's Hospital at Yale New Haven

Principal Investigator: Richard A. Ehrenkranz, MD
Study Center Coordinator: Patricia Gettner, RN
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Department of Ophthalmology
1430 Tulane Avenue, SL-69
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01 Tulane University School of Medicine

Principal Investigator: Robert Gordon, MD
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<td>Meredith Wiltse, BS</td>
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### STOP-ROP
### EXECUTIVE COMMITTEE

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<tr>
<td><strong>Chair</strong></td>
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<td>Dale Phelps, MD</td>
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| Cynthia Cole, MD                        | 617/636-5322| 617/636-1456 |
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<td>Anita Yaffe, MSN, MPH</td>
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<td>301/299-3991</td>
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<td>The EMMES Corporation</td>
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<td>11325 Seven Locks Road, suite 214</td>
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<tr>
<td>Potomac, MD 20854</td>
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## EXECUTIVE COMMITTEE - continued

### Rotating Members - 2 year term

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<thead>
<tr>
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<td>Beverly Brozanski, MD</td>
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<td>412/641-5313</td>
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<tr>
<td>Magee-Womens Hospital</td>
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<td>Department of Pediatrics</td>
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<td>300 Halket Street</td>
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<td>James Lemons, MD</td>
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<td>James Whitcomb Riley Hospital</td>
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<td>Indiana University Medical Center</td>
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<td>Dean A. McGee Eye Institute</td>
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<td>University of Illinois at Chicago</td>
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<td>1905 West Taylor Street, L109</td>
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### Rotating Members - 1 year term

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<tr>
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<td>Bethany Ball, BS</td>
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<td>Stanford University Medical Center</td>
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<td>Portland, OR 97227</td>
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APPENDIX C

PROCEDURE FOR ALTERNATIVE FUNDED CENTERS
APPENDIX C

ALTERNATIVE FUNDED CENTER DESIGNATION AND PROCEDURE

The National Eye Institute, the primary funding agency, with additional support from the National Institute for Child Health and Human Development and the National Institute for Nursing Research, provides funding for five NEI participating centers, ten NICHD Neonatal Network centers, Study Headquarters, and the Coordinating Center. The STOP-ROP Executive Committee supports the designation of additional Study Centers as Alternative Funded Centers provided that adherence to study protocol is upheld. Non-funded potential Study Centers who wish to participate are required to fulfill the objectives of the study and successfully complete the procedure for application. It is recommended that a center considering application as an Alternative Funded Center have a minimum of 10-12 newborns for potential enrollment in a 12-month period. Resources provided by Study Headquarters and the Coordinating Center are described below. Specific requirements for personnel, training and support space which Alternative Funded Centers must provide are indicated. Study Centers not previously reviewed by the NEI are required to submit a modified grant application.

RESOURCES provided by the National Eye Institute, Study Headquarters, and the Coordinating Center include the following:

- Equipment such as pulse oximeter, probes and laptop computer
- *Manual of Procedures and Data Management Handbook* (copies are limited), data forms and inclusion in all formal mailings and communications
- Training support, phone consultations and site visits
- $3,000 per patient enrolled and followed.

RESOURCES provided by the Study Center must include:

[See Chapter 3, Manual of Procedures for further details]

1. Salary support must be provided for:
   a. PRINCIPAL INVESTIGATOR: Each Study Center must be headed by a Principal Investigator (PI) who will represent the center at meetings of the Technical Group, assure compliance with the *Manual of Procedures*, and facilitate enrollment of all eligible infants into the study.
   b. STUDY CENTER COORDINATOR: The PI will designate one person, the Study Center Coordinator (SCC), with adequate time commitment for supervision of day-to-day study operations. The SCC
must attend training and Study Center coordinator meetings at the Technical Group.

2. PERSONNEL: There must be at least one neonatologist and two ophthalmologists certified by the Training and Certification Faculty.

- TRAINING REQUIREMENTS: Travel expenses will be required for the following meetings.

  1. Training Meeting - 4 individuals (PI, SCC, NICU RN, and one non-PI physician) to attend training session for 3 days. This will be an expense only for the first year.

  2. Annual Meetings - 2 or 3 individuals (PI, SCC, non-PI physician) to attend for 1-2 days.

- ADDITIONAL REQUIREMENTS: To adhere to protocol objectives, appropriate office space, adequate phone lines, and mailing expenses for data forms, diskettes, and queries from the Coordinating Center or Study Headquarters must be assumed by the Alternative Funded Center.

Procedure for attaining Alternative Funded Center status for centers which were previously reviewed and approved by the NEI but did not receive funding.

1. Notify Study Headquarters of intention to participate and solicit additional study protocol requirements (if any).

2. Request a copy of the current Manual of Procedures from the Coordinating Center (301/299-8655) and review to determine feasibility of compliance with study objectives.

3. Submit a formal letter of intent to the NEI and Study Headquarters and indicate the following information within the content of this letter.

   • Sources of financial support (conditional or not) and likelihood of receiving such funding

   • Statement indicating intent to comply with requirements of the study protocol including but not limited to, attendance at training sessions, annual meetings, and assurance of enrollment of eligible infants in a timely fashion

   • Changes in personnel, study plans, or patient enrollment projections which are different from the original grant application
Study Headquarters will notify the potential Alternative Funded Centers of approval or rejection to participate in the STOP-ROP protocol. Alternative Funded Centers are eligible to receive $3,000 per patient enrolled and followed. Limited funding may be provided to Alternative Funded Centers for travel support to attend training and annual meetings. The National Eye Institute will notify Study Headquarters and the Coordinating Center if/when additional funding becomes available for the STOP-ROP protocol.

Procedure for attaining Alternative Funded Center status for Study Centers which were not previously reviewed by the NEI.

1. Notify Study Headquarters of intent to participate and discuss feasibility with Study Chair. This will include the potential Study Center’s knowledge of the following:
   - Expected number of newborns weighing <1250 grams surviving to discharge in a recent 12 month period
   - If available, expected number of newborns at Prethreshold ROP as defined by the CRYO-ROP study
   - If available, proportion of infants who receive oxygen in a recent 12 month period

2. Request copy of the current Manual of Procedures from the Coordinating Center (telephone # 301/299-8655) and review study protocol.

3. Request instructions from Study Headquarters for completion of a modified grant application.

4. Determine source(s) of alternative funding based upon study protocol expectations.

5. Submit protocol for IRB review and approval.

6. Prepare and submit a modified grant application as stated in the instructions.

Study Headquarters will notify the potential Alternative Funded Centers of approval or rejection to participate in the STOP-ROP protocol. Alternative Funded Centers are eligible to receive $3,000 per patient enrolled and followed. Limited funding may be provided to Alternative Funded Centers for travel support to attend training and annual meetings. The National Eye Institute will notify Study Headquarters and the Coordinating Center if/when additional funding becomes available for the STOP-ROP protocol.
APPENDIX D

INFORMATION LEAFLET REGARDING ROP AND STOP-ROP
STOP-ROP
Supplemental Therapeutic Oxygen for Prethreshold
Retinopathy of Prematurity

STOP-ROP is a nationwide research study to improve understanding of how Retinopathy of Prematurity can be treated.
What is Retinopathy of Prematurity (ROP)?

ROP is an eye disease that occurs commonly in premature babies. In this disease, the blood vessels in the retina of a baby's eye do not develop normally. We do not know why this happens, but it is more likely to happen in very small babies who have had many medical problems while they were in the Neonatal Intensive Care Unit (NICU).

What is the RETINA?

The retina is the lining on the inside of the eyeball that receives light, turns it into visual messages, and sends these messages to the brain so that you can see (see figure 1). If you think of the eye as a camera, the retina is like the film in the camera—it's very thin and it captures the "picture." The blood vessels that supply blood to the retina are one of the last parts of the eye to develop in an unborn child (fetus). These vessels usually complete their development around the time a full-term baby is born. If a baby is born too early (prematurely), these vessels do not finish growing until weeks after birth. During this time, the vessels may develop normally or abnormally. That is why doctors examine your baby's eyes often while your baby is in the nursery.

What happens when your baby has ROP?

Your baby's eyes need to be examined regularly to determine how the blood vessels are growing. When ROP develops, several events may occur:

1. Usually, the abnormal blood vessels will completely heal themselves.

2. Sometimes, the abnormal blood vessels will partially heal. This might cause nearsightedness ("myopia"), which would
require that your baby wear glasses at an early age. Partial healing might also cause lazy eye ("amblyopia") or wandering eye ("strabismus"). Doctors must correct these problems with patching therapy, glasses, or surgery. Babies who develop any of these problems need to have regular examinations throughout childhood. In some cases, a scar remains on the retina, causing visual problems which may be uncorrectable. These babies will have to receive life-long treatment from an eye specialist.

3. Occasionally, the abnormal blood vessels create scar tissue that can pull the retina loose from its normal position on the inner part of the eyeball. This condition, which is very serious, is called "retinal detachment." It causes significant loss of eyesight and may leave your baby partially or completely blind. If your doctor thinks that your baby's ROP is very serious and that retinal detachment might happen, the doctor will suggest surgery for your baby's eyes. In this surgery, the doctor destroys the part of the retina that has still not developed any blood vessels. This is done by freezing (cryotherapy) or using a laser. By destroying part of the retina, the doctor is able to decrease the chance by about one half (or 50 percent) that retinal detachment will happen in the retina that remains.

[PHOTO OF RETINA]

What is STOP-ROP?

STOP-ROP stands for Supplemental Therapeutic Oxygen for Prethreshold Retinopathy of Prematurity. It is a study that will be conducted in many hospitals throughout the United States. The major goal of STOP-ROP is to learn whether we can decrease the number of babies who develop severe ROP each year.
In this study, doctors will give slightly more oxygen to premature babies who have abnormal retinal blood vessels than would be given normally in their treatment for prematurity. This extra oxygen may be able to prevent the development of very serious cases of ROP which need cryotherapy or laser surgery.

Studies in animals show that too much oxygen soon after birth can cause ROP. The studies also show, however, that too little oxygen later can make ROP much worse if it has already started. In the animals, a little bit of extra oxygen helps to "quiet down" the abnormal blood vessels and make them disappear.

We do not know whether the same thing will happen in human babies. The extra oxygen may help, as it does in the animals, or it may not have any effect, or it may make ROP worse. That is the reason for this study. STOP-ROP will help us find out if the extra oxygen helps babies as it helps animals.

STOP-ROP is being supported by three institutes at the National Institutes of Health -- the U.S. Government agency that supports most of the medical research conducted in this country. The three institutes are the National Eye Institute, the National Institute for Child Health and Human Development, and the National Institute of Nursing Research.

How can your baby be in STOP-ROP?

By now, your baby's eyes are showing signs of ROP that is slightly worse than in the average baby who develops ROP. If your baby's doctors find that the abnormal blood vessels continue to grow, your baby may be eligible for the STOP-ROP study. If your baby is eligible and you agree to enroll your baby in the study, we will ask you to read and sign a CONSENT FORM that explains how the study works. There will be 880 babies across the United States participating in this study.
What happens if you decide that your baby should be in STOP-ROP?

If you decide to enter your baby into the study, he or she will receive either the normal amount of oxygen given to premature babies or slightly more oxygen. A computer will make this selection randomly. We do not know which treatment will work better, but your baby will have a 50/50 chance of receiving either treatment.

If you do not choose to participate, your baby will receive the normal amount of oxygen given to premature babies.

The doctors and nurses will monitor the oxygen level in your baby's blood by using a special pulse oximeter taped to your baby's hand or foot. A computer connected to the oximeter will collect and display oxygen readings, and the nurses will review these readings to make decisions about adjusting your baby's oxygen. The doctors will examine your baby's eyes every week until the ROP has healed or has become so serious that your baby needs cryotherapy or laser surgery.

After you take your baby home, you will be asked to bring your baby back to the hospital for another examination 10 to 12 weeks after the time your baby should have been born.

Who will monitor the study nationwide?

Information from all of the 880 babies in the study will be entered into a computer so that we can review the effects of the ROP treatment for all babies in this study. A "Data and Safety Monitoring Committee" that is independent of all the STOP-ROP hospitals will monitor this information as it comes in and oversee the entire study. The members of this committee are very experienced in handling ethical, medical, and statistical parts of clinical studies like STOP-ROP. They will review all of the
information collected. If they find that one treatment is more helpful or harmful than the other during the study, you will be notified at once and your baby's oxygen treatment will be changed so that he or she receives the best treatment.

_Do you want your baby to participate in STOP-ROP?_

We hope that you will decide that you and your baby should participate in STOP-ROP. By allowing your baby to be part of the study, you can help us learn which treatment is better, and make an important contribution to understanding how to treat Retinopathy of Prematurity.

If you have any questions, please talk with the doctor in charge of STOP-ROP or the Study Coordinator for STOP-ROP and the doctors caring for your baby. They can answer any questions you have. There is also a videotape about STOP-ROP that you can see at the hospital.

The doctor in charge of STOP-ROP is:

______________________________

Your Study Coordinator for STOP-ROP is:

______________________________

You can talk to the Study Coordinator by calling:

______________________________

THANK YOU for thinking about participating in this study.
APPENDIX E

MODEL INFORMED CONSENT FOR STOP-ROP
CONSENT FORM: Oxygen Therapy for Moderately Severe ROP

Investigator: Dale Phelps, M.D.

We understand that our premature child has an eye condition called Retinopathy of Prematurity, abbreviated ROP. This is a common problem in the smallest premature infants because the blood vessels that nourish the eye are not fully developed. Usually this ROP will heal without any side effects. However, our infant's ROP is worse than average. At this point, there is a one in three chance that the blood vessels will grow out of control and need surgery to try and prevent scars inside the eye which could cause severe vision loss.

We are being asked to allow our infant to be a part of a multicentered research investigation being conducted throughout the United States to learn if a small amount of extra oxygen treatment can prevent moderate ROP from going on to become severe ROP. Research done in animals shows that this is helpful, but it has not been tested in humans yet. The doctors believe that the extra oxygen might tell the abnormal growing vessels to quiet down and "go away" since this is what happens in animals.

If our infant joins the study (s)he will receive either 1) normal oxygen therapy or 2) slightly more than normal oxygen. This will be decided by chance (random assignment).

What is Normal Oxygen Therapy?

In infants as old as ours, oxygen in the blood is usually measured with a pulse oximeter several times a day if the baby needs oxygen. Normal infants who do not need oxygen usually measure 95% to 100%. Infants who have had breathing problems are usually a little lower, and if they are less than 90% they are given oxygen to keep their measurements over 90%. Because doctors always want to stop oxygen or any other drug as soon as possible, oxygen is often stopped if the measurement is between 90% and 95%, even if this is not as high as a normal baby.
One of several important reasons to stop oxygen as soon as possible is that this disease, ROP, happens much more often if premature infants are given high amounts of oxygen that they don’t need for long periods of time (weeks).

What is a “Small Amount of Extra Oxygen”?

This is enough extra oxygen to make the infant’s pulse oximetry measurements be as high as normal infants. Specifically, they will be given enough oxygen to have measurements of 96-99%.

The doctors testing this extra oxygen do not believe that it will increase the risk of the ROP getting worse. However, it is possible that it may make the ROP worse. This is exactly why it is so important to test the new treatment in a small number of infants before recommending it throughout the country.

What Happens to our Infant if (s)he joins the Study?

1. A computer program will decide, by chance, to have our infant be in the usual oxygen or extra oxygen treatment group. Extra oxygen could possibly mean going back on oxygen if (s)he already is off oxygen and could prolong the length of hospitalization and length of time on oxygen.

2. Continuous monitoring of blood oxygen with a pulse oximeter. This has no known risk or discomfort, but may mean using the monitor at home or staying in the hospital for monitoring.

3. Eye examinations. When ROP gets moderately severe, it is necessary to examine the eyes every week and this would not change. If the ROP gets even worse, exams get more frequent, and surgery might be recommended, but again, this is a part of usual care.

4. Follow-up: We’ll be asked to bring our infant back for regular ROP follow-up eye examinations on the usual schedule until 6 months of age or until the ROP has completely settled down. The only different things will be that one of the study doctors will do the examination and there may be some extra tests of vision (non-harmful).

5. Future Studies: Because of being involved in this study, we are asked to give the physicians permission to contact us in the future about possible other studies in ex-premature infants. We would, of course, be free to make a yes or no decision at that time.
6. The information from our infant's case will be combined with the results of treatment from up to 880 infants across the United States and those results will be put in a central computer to be analyzed.

Possible Benefits:

If the treatment works, our infant's ROP will be helped.

If the treatment is not helpful, the only benefit is that there has been extra attention and communication with us because of the study.

Possible Risks:

Infants with the extra oxygen might have an increased cost of additional oxygen and possible extra days in the hospital or extra days on oxygen at home. The research project will provide the monitor and educational support for us, our insurance will be asked to cover the additional medical care since it may truly be beneficial for both the eyes and the lungs. If there are any costs not covered by our insurance that are only because of this research, we understand that there are not funds available from the research grant to cover these. Because of this, it is possible that my infant may not be able to continue receiving treatment even if I prefer that my infant remain in the study. This should be a rare occurrence, however, because most infants are able to be monitored at home without extending the hospital stay if they are otherwise ready for discharge.

There is a small risk that extra oxygen could make the ROP worse. To monitor this as closely as possible, the information from all of the many participating centers across the United States will be examined frequently to learn if a good or bad trend is developing. That way, the study can be stopped as soon as an answer is known, good or bad.

The alternative to joining the study is to continue with usual medical care. We realize that the ROP could get worse whether our infant joins the study or not. If it does get worse, then a retinal surgeon will be asked to examine our infant about possible surgery which is not a part of this study.

It has been explained that we are free to refuse participation in this study or to withdraw from the study at any time without jeopardy to our infant's continued care. We also understand that our infant's eyes may get worse in spite of any treatment. If the design of the study or the use of the data are changed in any way, this will be explained to us and our consent obtained again. The results of the study will be published so that other infants may benefit from the knowledge, but neither our infant's name nor our names will be disclosed unless we give our separate specific consent, unless as required by law. If new information becomes available about these treatments, we will be informed and if there is reason to stop the study, the doctors in charge may do so even if we wish to continue.
We understand that the Strong Memorial Hospital will provide emergency medical care for incurred physical injuries which the hospital determines to have been a direct result of participation in this study. Compensation for injury is not available from the Strong Memorial Hospital.

If you have any questions about the protocol or wish to withdraw your infant from the study, you may contact Dr. Dale Phelps at 275-5884 or ask the nursery secretary to find her. If you have any questions about your rights as a patient or concerns about your infant's care whether or not (s)he joins the study, you should discuss these with Dr. Phelps (275-5884) or the attending Neonatologist in charge of your infant's care. (275-2268)

I/we have read the above description of this research and have had all of my questions answered. I agree to have my infant participate, and I have received a copy of this consent form to keep for myself.

_________________________  __________________________  ________________
signature of parent/guardian  relationship  date

The contents of this consent form were orally presented to the family and I believe they understand them and are consenting voluntarily.

_________________________  ________________
signature of witness  date

The research project has been satisfactorily explained to the parent(s) and all questions have been addressed.

_________________________  ________________
signature of principal investigator  date

copy given to patent(s)/guardian (date)
APPENDIX F

OPHTHALMOLOGY EXAMINATION SCHEDULE
APPENDIX F

OPHTHALMOLOGY EXAMINATION SCHEDULE

With consideration of the current, but incomplete understanding of the effects of oxygen therapy, the following recommendations are proposed by the Fetus and Newborn Committee of the American Academy of Pediatrics and the American College of Obstetricians and Gynecologists in Guidelines for Perinatal Care, Third Edition, 1992, page 203, paragraph 3.

"An individual experienced in neonatal ophthalmology and indirect ophthalmoscopy should examine the retinas of all premature neonates (i.e., those who are delivered at less than 35 weeks of gestation or who weigh less than 1,800g) who require supplemental oxygen. Infants who are less mature at birth (i.e., those delivered at less than 30 weeks of gestation or who weigh less than 1300g) should be examined regardless of oxygen exposure. The examination is best done prior to discharge, or at 5-7 weeks of age if the infant is still hospitalized, and should be repeated according to the schedule appropriate to the original findings. Follow-up is recommended for those who have had significant active disease."

The STOP-ROP Study Examination Schedule is outlined as follows:

- Examine all qualifying premature infants prior to discharge home and no later than 5-6 weeks after birth. Qualifying premature infants are defined by the following criteria:
  - less than 35 weeks of gestation at delivery and received oxygen for 6 or more hours
  - less than 1800 grams at delivery and received oxygen for 6 or more hours
  - less than 30 weeks of gestation at delivery, irrespective of oxygen exposure
  - less than 1300 grams at delivery, irrespective of oxygen exposure

- Repeat examinations: based on worst eye
  - Zone 3 vessels or ROP - every 2-3 weeks until mature/regressed
  - Zone 2 vessels or ROP - every two weeks if less than Prethreshold
  - Zone 2 Prethreshold (2 plus or Stage 3) - weekly
  - Zone 1 vessels or ROP - weekly
APPENDIX G

OHMEDA PRODUCT INFORMATION
This 3740 Service Manual describes service procedures for International 3740 Pulse Oximeters. Software revision F or later is described first in the text. Information pertaining to prior revisions is in parentheses.

This chapter provides a general description of the 3740 Pulse Oximeter and its use, as well as providing detailed product specifications.

1.1 Product Description

The Ohmeda Biox 3740 Pulse Oximeter is a stand-alone, noninvasive, arterial oxygen saturation monitor. It provides continuous, real time $\text{SaO}_2$ and pulse rate readings.

The 3740 Oximeter determines a patient's arterial oxygen saturation and pulse rate by measuring the absorption of selected wavelengths of light.

The light generated in the probe passes through the tissue and is converted to an electronic signal by the photodetector (some light is absorbed by the tissue). The electronic signal passes to the oximeter and is amplified. The oximeter's circuitry processes the signal, converting the light intensity information to $\text{SaO}_2$ and pulse rate values. A liquid crystal display (LCD) presents patient data and oximeter status information.

1.2 International Electrotechnical Commission (IEC) Classifications

1. Type of protection against electric shock: Class I/Internal Electrical Power Source

2. Degree of protection against electric shock: Type BF

3. Degree of protection against ingress of liquids: Ordinary

4. Mode of Operation: Continuous

5. Recommended methods of sterilizing or disinfecting: See Section 3.7, Cleaning and Sterilizing, in this manual and appropriate sections in the Ohmeda Probes Manual (0380-0900-085, BX# 1000-304) for recommended safety procedures when cleaning and sterilizing this equipment.

6. Degree of safety of application in the presence of flammable anesthetic mixed with air or with oxygen or nitrous oxide: Equipment not suitable for use in the presence of a flammable anesthetic mixture with air or with oxygen or nitrous oxide.

Note: The release of Rev F software coincided with the release of Rev L of both the Power Supply and SMT II boards. Information for the current Rev is described first in the text. Prior revision information is in parentheses.
1.3 Specifications

This section describes specifications important for servicing the oximeter. All specifications subject to change without notice.

**SaO2 Accuracy (1 Standard Deviation)**
- 60% - 100%  2.4% (Overall Range)
- 90% - 100%  1.5%
- 80% - 89.9%  2.1%
- Below 60%  Unspecified

**Note:** These accuracy measurements are statistically derived and correlated to simultaneous oxygen averaging readings measured on an Ohmeda Biox 3700 Pulse Oximeter, which in turn was calibrated with co-oximeters.

**Pulse Rate Accuracy (1 Standard Deviation)**
± 1.7% of current reading (assuming a constant pulse rate)

**Interfering Substances**
- Carboxyhemoglobin and other hemoglobins may erroneously increase readings. The increase is approximately equal to the amount of carboxyhemoglobin present.
- Dyes, or any substances containing dyes that change usual arterial pigmentation, may cause erroneous readings.

**SaO2 Range**
0% to 100%

**Pulse Rate Range**
- 40 to 235 Beats Per Minute (BPM)
- Display Shows 0 to 255 Beats Per Minute (BPM)

**Alarm Limits and Default Values**
- High SaO2= 70% to 100%, Default = OFF (indicated by "---")
- Low SaO2 = 50% to 100%, Default = 90%
- High Pulse= 70 to 250 Beats Per Minute, Default = OFF
- Low Pulse = 40 to 200 Beats Per Minute, Default = OFF

**Alarm and Pulse Volumes**
- Alarm Volume Range = 1 to 10, Default = 4
- Pulse Volume Range = OFF to 10, Default = 4

**Audible Alarms**
- Volume Setting = 5: = 60 dB (1 meter in front of oximeter)
- Volume Setting = 10: = 68 dB (1 meter in front of oximeter)

**Note:** The release of Rev F software coincided with the release of Rev L of both the Power Supply and SMT II boards. Information for the current Rev is described first in the text. Prior revision information is in parentheses.
Real-time Clock
4-hour Clock - Time and Date

Oximeter Dimensions
- Height: 6.99 cm (2.75 in)
- Width: 20.32 cm (8.00 in)
- Depth: 22.30 cm (8.78 in)
- Weight: 2.5 kg (5.5 lb)

Analog Connector
- Type: 1/8-inch miniature phone plug
- Plug Polarity: tip = signal (+), sleeve = ground (-)
- Output Checks: 0, 0.5, 1.0 volts

Digital Connector
- Connector Type: 25-pin, standard D female, RS-232C compatible
- Baud Rate: 1200 BPS, ASCII format
- Bits per Character: 7
- Parity: Odd
- Stop Bits: 1
- Pin Out:
  Pin 1 = Chassis ground
  Pin 2 = Receive data
  Pin 3 = Transmit data
  Pin 7 = Signal ground
  Pin 11 = See the following CAUTION.
  Pin 18 = See the following CAUTION.
  Pin 25 = See the following CAUTION.

CAUTION: Pins 11, 18, and 25 of the rear panel RS-232C connector are TTL signals and must not be wired to RS-232C signals. The oximeter will be permanently damaged if these signals are connected to RS-232C voltage levels.

Electrical Requirements
Oximeter Input Power Maximum: 15.5 volts AC ±10%, 50 or 60 Hz at 1.4 A

Leakage Current
Maximum: 100 microamperes.

Note: The oximeter should be added to the hospital's electrical safety program.

Note: The release of Rev F software coincided with the release of Rev L of both the Power Supply and SMT II boards. Information for the current Rev is described first in the text. Prior revision information is in parentheses.
Power Supplies

WARNING: Electric Shock Hazard. Use only with Ohmeda Model 15 power supplies of correct input voltage.

CAUTION: Equipment damage may result if the incorrect power supply is used.

- 100 Volt
  Input: (AC Mains): 100 Vac ±10%
  Output: 15.5 Vac @ 1.4 A, 50/60 Hz

- 120 Volt
  Input (AC Mains): 120 Vac ±10%
  Output: 15.5 Vac @ 1.4 A, 50/60 Hz

- 220/240 Volt
  Input (AC Mains): 220/240 Vac ±10% 50/60 Hz
  Output: 14.7/16.0 Vac @ 1.5/1.4 A

Fuses

- Rear Panel F1, F2 Fuses: Fast Acting, 2A @ 250 volts, 2AG 4.5 x 14.5 mm

- Power Supply Board F1 Fuse: Fast Acting, 2A @ 250 volts, 8AG/AGX 5 x 20 mm (Rev level J or earlier 6.35 x 25.4 mm)

Battery

- Sealed lead-acid, 12 volt, 1.9 Ampere-Hours
- Charge Time: 80% capacity = 4.0 hours (unit on or off)
  100% capacity = 6.5 hours (unit on or off)
- Operation Time: = 3.5 hours from a fully charged battery to automatic shutoff (25% capacity, = 10.0 Vdc)
- Low Battery Indicator: LOW BATT message appears at approximately 50% battery capacity (~ 11.5 Vdc), approximately 30 minutes of operating time remain.

Environmental Requirements

Operating:  
Temperature: 32° F to 89° F (0° C to 32° C)
Relative Humidity: 0% to 100% (noncondensing)
Atmospheric Pressure: 500 mmHg to 812 mmHg (667 kPa to 1083 kPa)

Transport/Storage:  
Temperature: 14° F to 122° F (-10° C to 50° C)
Relative Humidity: 0% to 100% (noncondensing)
Atmospheric Pressure: 375 mmHg to 812 mmHg (500 kPa to 1083 kPa)

Note: At temperature extremes, the LCD screen may exhibit reduced contrast, ghosting, or darkening. When returning from temperature extremes, allow the oximeter to return to room temperature before use.

Note: The release of Rev F software coincided with the release of Rev L of both the Power Supply and SMT II boards. Information for the current Rev is described first in the text. Prior revision information is in parentheses.
1.4 Precautions

Following is a summary of all of the warnings and cautions for the 3740 oximeter that appear in this manual.

A **WARNING** indicates the possibility of injury to a patient or an operator.
A **CAUTION** indicates a condition that may lead to equipment damage or malfunction.

⚠️ Warnings

Do **not** under any circumstances, perform any testing or maintenance on medical instruments, cables, or probes while they are being used to monitor a patient.

Patient Safety. For this oximeter, use only the Ohmeda probes specified in the *Ohmeda Probes Manual* (0380-0900-085, BX#1000-304); otherwise, patient injury or equipment damage may result.

Patient Safety. Prolonged monitoring or patient condition may require changing the probe test site periodically. Change the probe site at least every four hours to reduce the risk of blistering, skin erosion, or ischemia necrosis (especially if the site is poorly perfused.) Refer to the *Ohmeda Probes Manual* (0380-0900-085; BX#1000-304) for complete warning information for probes.

Electrical Shock and Flammability Hazard. Always turn the oximeter off and disconnect it from AC mains power before servicing or cleaning.

Proper Grounding. For protection against shock hazards, connect this equipment only to a three-wire, grounded, hospital grade (USA) receptacle. The three-prong plug must be inserted into a properly wired three-wire receptacle. Where a two-wire receptacle is encountered, a qualified electrician must replace it with a properly grounded three-wire receptacle in accordance with the National Electrical Code, or appropriate local code. Do **not**, under any circumstances, remove the grounding prong from the power plug. Do not use extension cords or adapters of any type. The power cord and plug must be intact and undamaged.

Electric Shock Hazard. Use only with Ohmeda Model 15 Power Supplies of correct input voltage.

Electric Shock Hazard. Measure the leakage current whenever an external device is connected to either the analog or digital ports. Forward and Reverse Polarity: 100 microamperes maximum.

**Note:** The release of Rev F software coincided with the release of Rev L of both the Power Supply and SMT II boards. Information for the current Rev is described first in the text. Prior revision information is in parentheses.
1/1.Product Overview

Explosion Hazard. Do not use in the presence of flammable anesthetics or other flammable substances.

Data Validity. The digital voltmeter must be accurately calibrated. If the reference voltage is improperly calibrated, the displayed SaO2 values will be inaccurate.

Failure of Operation. If the oximeter fails to respond as described, do not use it until the situation has been corrected by qualified personnel.

Battery Replacement. Unauthorized personnel should not attempt to install, connect, or replace the battery of the oximeter. Removing the cover and/or faulty battery connections could be hazardous and will void the warranty. Reversing the battery connections could result in injury and will permanently damage the circuitry. If trained technical personnel are not available, obtain this service by calling Ohmeda for assistance. For proper operation, Ohmeda recommends replacing only with an Ohmeda battery: part number 0380-0200-129 for US hospitals, BX#4790-002 for International and US nonhospitals.

Data Validity. Do not operate the oximeter unless it is properly calibrated. Inaccurate patient SaO2 readings will result.

Fuse Replacement. For continued protection against fire hazard, replace only with the same type and rating of fuse.

Connect only equipment that complies with IEC or local country safety standards (such as ETL, CSA, BSI, TUV) to the signal input and output ports on the rear panel.

Note: The release of Rev F software coincided with the release of Rev L of both the Power Supply and SMT II boards. Information for the current Rev is described first in the text. Prior revision information is in parentheses.
% Cautions

After performing any repair or calibration procedure, perform a final electrical safety check and leakage current test.

The interior side of this oximeter is coated with conductive nickel paint. When servicing the oximeter, use extreme care to avoid chipping or scraping the coated surface.

Equipment damage may result if the incorrect power supply is used.

Electrostatic discharge through the printed circuit boards will damage the components of the oximeter. Handle all circuit boards (replacement and defective) by their nonconductive edges and use the antistatic containers when transporting them. Before servicing the equipment, ground yourself and any tool to discharge any accumulated static charge by wearing a static-control wrist strap.

Connect only a high impedance device (1K ohm or higher) to the analog output jacks; otherwise, improper loading will upset the correspondence between the measured voltage and the intended output voltage.

Do not turn the oximeter on after the RECHARGE BATTERY message is displayed without first connecting it to AC mains power. This may damage the lead-acid battery.

Whenever possible, connect the oximeter to AC mains power when operating or in storage.

Always wear a ground strap when handling static sensitive electronic components; otherwise, electrostatic discharge can damage sensitive electronic components.

To disinfect this oximeter, do not:
- Autoclave
- Pressure sterilize
- Soak or immerse in any liquid
- Gas sterilize

Ensure that the power supply is disconnected from the oximeter before starting fuse replacement.

Do not cross the battery connections. The circuitry may be permanently damaged.

Note: The release of Rev F software coincided with the release of Rev L of both the Power Supply and SMT II boards. Information for the current Rev is described first in the text. Prior revision information is in parentheses.
Use nonconductive tools when adjusting the internal controls on the oximeter.

Pins 11, 18, and 25 of the rear panel RS-232C connector are TTL signals and must not be wired to RS-232C signals. The oximeter will be permanently damaged if these signals are connected to RS-232C voltage levels.

Be careful not to spread the probe socket pin connectors apart. If these connectors are spread, the probe will not function reliably.

Be careful, running the RAM Test erases any existing Trend Data.

To prevent damage to the EPROM, be sure to install the EPROM with the notch toward the rear panel.

Note: The release of Rev F software coincided with the release of Rev L of both the Power Supply and SMT II boards. Information for the current Rev is described first in the text. Prior revision information is in parentheses.
Ohmeda 3740 Pulse Oximeter
Operation and Maintenance Manual
To Our Customers

This manual describes the 3740 oximeter with software Revision F, Revision 7, and Revision 8 or later. Revision F software has SaO₂ throughout the software and manual. Revision 8 software and later has SpO₂ throughout the software and manual. If a revision level earlier than Rev F appears on your oximeter display, please consult the manual or addendum released with that software revision for more complete information.

Software Revision Level Note: Ohmeda has changed from alpha characters to numeric characters for software revision level identification. For example, if the prior software revision level was F, the next revision level (instead of G) will be 7.0. See the following conversion guide. When instructions call for Revision F or later, the numeric revision level will always be later than the alpha character.

<table>
<thead>
<tr>
<th>A</th>
<th>B</th>
<th>C</th>
<th>D</th>
<th>E</th>
<th>F</th>
<th>G</th>
<th>H</th>
<th>...</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
<td>6</td>
<td>7</td>
<td>8</td>
<td></td>
</tr>
</tbody>
</table>

User Responsibility

When operated, maintained, and repaired according to the instructions provided, this product operates as described in this manual and in any accompanying labels and/or inserts.

Do not use a defective product. Replace broken, missing, plainly worn, distorted, or damaged parts immediately.

This product and any of its components must be repaired by service personnel trained by Ohmeda. The user of this product shall have the sole responsibility for any losses incurred during unauthorized maintenance or repair as a result of improper repair, damage, or alteration.

CAUTION: Federal law in the USA and Canada restricts this device to sale by or on the order of a licensed medical practitioner.

Product Improvement

Ohmeda reserves the right to change or improve its products and accompanying technical literature without specific notice to customers who have purchased products prior to these changes/improvements. All specifications are subject to change without notice.

The technical literature accompanying your product corresponds to the product as manufactured at that time. Technical literature produced at later dates may not exactly correspond to earlier products.

Ohmeda has no obligation and absolves itself from improving or retrofitting earlier production units unless the product improvement or change directly affects the safety of the patient or proper functioning of the product. Customers who have purchased earlier production units and wish to have them updated should contact their local Ohmeda Sales Representative to determine which improvements are available.

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Table of Contents

Front Matter

User Responsibility ........................................... ii
Manufacturer's Liability .................................. ii
Product Improvement ........................................ ii
Table of Contents ............................................ iii
List of Figures ................................................ vii
Precautions ................................................... viii
Warnings ....................................................... viii
    Battery Replacement Warnings ......................... viii
    Device Failures Warnings ............................... viii
    Hazard Warnings ....................................... viii
    Patient Safety Warnings ................................ ix
    Data Validity Warnings ................................ ix
    Cautions ................................................ x

Chapter 1/Introduction

Description of 3740 Oximeter .............................. 1-1
Oximeter Operation .......................................... 1-1
Functional Components .................................... 1-3
Signal Processing .......................................... 1-4

Chapter 2/Operator Features and Controls

Oximeter Features and Controls .......................... 2-1
Screen Features ............................................ 2-2
Rear Panel .................................................. 2-4
Menu Features .............................................. 2-5
     Screen 1 ............................................. 2-5
     Screen 2 ............................................. 2-6
     Screen 3 ............................................. 2-6

Chapter 3/Operating the Oximeter

Checking the Oximeter before Use ....................... 3-1
Visual Inspection ........................................... 3-1
Functional Inspection .................................... 3-1
Alarm Verification ......................................... 3-2
     Alarm Function During Poweron ....................... 3-3
Preparing to Monitor a Patient ......................... 3-3
Modifying Operational Settings ........................ 3-4
     General Steps ....................................... 3-4
     Special Menus ....................................... 3-5
Setting the Low Pulse Rate Alarm Limit ............... 3-5
Setting the Clock ........................................ 3-6
     Setting the Time ................................... 3-6
     Setting the Date ................................... 3-7
# Table of Contents

## Chapter 4/Troubleshooting
- Patient Alarm Limit Violations ............................................. 4-1
- Signal and User Correctable Problems ................................... 4-2
- Staged Alarm System .......................................................... 4-6
  - Oximeter Alarms and Messages ........................................ 4-7
  - Computer Interface Display and Message ............................. 4-7
  - Warning Remedies .......................................................... 4-8
- Probe Alarm Messages ....................................................... 4-8
- Alarm Function During Poweron .......................................... 4-8
- Device Failure Messages ................................................... 4-10

## Chapter 5/Maintenance and Service
- Routine Maintenance ......................................................... 5-1
- Cleaning the Oximeter ....................................................... 5-1
  - Cleaning Probes ........................................................... 5-2
- Recharging the Battery ..................................................... 5-2
  - Battery Alarm Messages ............................................... 5-3
  - Recharging Periods ...................................................... 5-3
  - Replacing the Battery .................................................. 5-3
- Calibrating the Oximeter ................................................... 5-4
- Repair Policy ..................................................................... 5-5
  - Malfunctioning Equipment .............................................. 5-5
  - Authorized Service ....................................................... 5-5
  - Obtaining Service ........................................................ 5-5
    - Monitors .................................................................... 5-5
    - Probes ...................................................................... 5-5
  - Packaging and Return Procedure ...................................... 5-6
    - Everyone ..................................................................... 5-6
    - Inside the USA ........................................................... 5-6
    - Outside the USA ......................................................... 5-6
- Parts and Accessories ......................................................... 5-7
# Table of Contents

## Appendix A/Product Specifications

<table>
<thead>
<tr>
<th>Section</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>Safety Classifications</td>
<td>A-1</td>
</tr>
<tr>
<td>Oximeter Specifications</td>
<td>A-1</td>
</tr>
<tr>
<td>SpO2 Accuracy</td>
<td>A-1</td>
</tr>
<tr>
<td>Pulse Rate Accuracy</td>
<td>A-2</td>
</tr>
<tr>
<td>Interfering Substances</td>
<td>A-2</td>
</tr>
<tr>
<td>SpO2 Range</td>
<td>A-2</td>
</tr>
<tr>
<td>Pulse Rate Range</td>
<td>A-2</td>
</tr>
<tr>
<td>Alarm Limits and Default Values</td>
<td>A-2</td>
</tr>
<tr>
<td>Alarm and Pulse Volumes</td>
<td>A-2</td>
</tr>
<tr>
<td>Audible Alarms</td>
<td>A-2</td>
</tr>
<tr>
<td>Real-time Clock</td>
<td>A-2</td>
</tr>
<tr>
<td>Oximeter Dimensions</td>
<td>A-2</td>
</tr>
<tr>
<td>Analog Connector</td>
<td>A-2</td>
</tr>
<tr>
<td>Digital Connector</td>
<td>A-3</td>
</tr>
<tr>
<td>Electrical Requirements</td>
<td>A-3</td>
</tr>
<tr>
<td>Leakage Current</td>
<td>A-3</td>
</tr>
<tr>
<td>Fuses</td>
<td>A-3</td>
</tr>
<tr>
<td>Battery</td>
<td>A-3</td>
</tr>
<tr>
<td>Environmental Requirements</td>
<td>A-4</td>
</tr>
<tr>
<td>Line Cord Specifications</td>
<td>A-4</td>
</tr>
<tr>
<td>Power Supply Specifications</td>
<td>A-4</td>
</tr>
</tbody>
</table>

## Appendix B/References

B-1
# List of Figures

<table>
<thead>
<tr>
<th>Figure</th>
<th>Description</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>Figure 1-1</td>
<td>Extinction versus Wavelength Graph</td>
<td>1-2</td>
</tr>
<tr>
<td>Figure 1-2</td>
<td>Signal Composite</td>
<td>1-3</td>
</tr>
<tr>
<td>Figure 1-3</td>
<td>Functional Components</td>
<td>1-3</td>
</tr>
<tr>
<td>Figure 1-4</td>
<td>Response Mode versus Displayed Averages Tables</td>
<td>1-4</td>
</tr>
<tr>
<td>Figure 2-1</td>
<td>Front Panel</td>
<td>2-1</td>
</tr>
<tr>
<td>Figure 2-2</td>
<td>Rear Panel</td>
<td>2-4</td>
</tr>
<tr>
<td>Figure 5-1</td>
<td>Rear Panel Charging Jack and Power Supplies</td>
<td>2-2</td>
</tr>
<tr>
<td>Figure 5-2</td>
<td>Oximeter Bottom</td>
<td>5-4</td>
</tr>
<tr>
<td>Figure 5-3</td>
<td>Power Supply Models</td>
<td>5-8</td>
</tr>
<tr>
<td>Figure 5-4</td>
<td>Power Cord Plugs</td>
<td>5-9</td>
</tr>
</tbody>
</table>
Chapter 1: Introduction

This manual describes proper operation and maintenance for the Ohmeda 3740 Pulse Oximeter. Please read this manual before using this product, paying attention to all details for correct operation and recommended precautionary measures. All maintenance procedures in this manual are designed for the oximeter operator.

This manual describes operation of a 3740 oximeter containing software Revision F, Revision 7, and Revision 8 or later. If your oximeter displays another revision level, please consult the manual or manual addendum released with that software for more complete information.

WARNING: Patient Safety — The correct use of the 3740 oximeter is to measure only arterial oxygen saturation (SpO₂) and pulse rate.
- A pulse oximeter does not measure respiration and under no circumstances should be used as a substitute for an apnea monitor.
- The 3740 oximeter must not be used as the primary monitor for infants being monitored for apnea, either in the hospital or in the home setting. It measures SpO₂ and pulse rate, and only in conjunction with other appropriate monitoring techniques.
- A pulse oximeter is often used during sleep studies with adults, but must be used only to gather information regarding SpO₂ and pulse rate during these studies.
- A pulse oximeter is to be used only by or on the order of medically trained personnel.

WARNING: Patient Safety — To avoid the possibility of patient discomfort or injury during magnetic resonance imaging:
- Do not allow the oximeter probe cable to come in contact with the patient's body. Keep the cable off the patient or place a blanket or other insulating material between the patient and the probe cable.
- Position the oximeter probe and probe cable as far from the center of the magnetic field as possible.

Description of the 3740 Oximeter

The 3740 oximeter is a standalone, noninvasive, arterial oxygen saturation monitor. It provides continuous, real-time SpO₂ and pulse rate readings. Trend information is available through both the analog and digital output ports.

Oximeter Operation

The 3740 oximeter indicates a patient's arterial oxygen saturation and pulse rate by measuring the absorption of selected wavelengths of light. The light generated in the probe, passes through the tissue and is converted to an
electronic signal by the photodetector. (Some light is absorbed by the tissue.) The electronic signal passes to the oximeter and is amplified. The oximeter's circuitry processes the signal, converting the light intensity information to \( \text{SpO}_2 \) and pulse rate values. A liquid crystal display (LCD) presents patient data and oximeter status information.

Function of the 3740 oximeter is based on the assumption that hemoglobin exists in two principle forms in the blood:
- Oxygenated (HbO\(_2\)) with \( \text{O}_2 \) molecules loosely bound
- Reduced (Hb) with no \( \text{O}_2 \) molecules bound.

As shown in Figure 1-1, different amounts of light are absorbed by HbO\(_2\) and Hb. The oximeter measures the relative absorption of red light at 660 nm and infrared light at 940 nm by HbO\(_2\) and Hb. Because HbO\(_2\) and Hb allow different amounts of light to pass at these wavelengths, the oximeter can convert this relative light intensity information to \( \text{SpO}_2 \) and pulse rate values.

Note: Arterial oxygen saturation readings are displayed in some systems as \( \text{SaO}_2 \). \( \text{SpO}_2 \) is becoming the industry standard abbreviation for arterial oxygen saturation as measured by a pulse oximeter. \( \text{SaO}_2 \) is becoming the industry standard abbreviation for arterial saturation as measured by a co-oximeter.

![Extinction versus Wavelength Graph](image)

- Oxygenated hemoglobin (HbO\(_2\)) and reduced hemoglobin (Hb) exhibit markedly different absorption (extinction) characteristics to red light at 660 nm and infrared light at 940 nm.

**Figure 1-1. Extinction versus Wavelength Graph**

Note: See information about interfering substances in Appendix A, Product Specifications.

The oximeter differentiates between light absorption of hemoglobin and other fluid and tissue constituents using a patented two-wavelength,
pulsatile system. This system relies on the observation that arterial blood flow pulsates and other fluids and tissues do not. The pulsation of the arterial blood flow modulates the light passing through it. Nonpulsing fluids and tissues do not modulate the light, but have a fixed value of absorption. Therefore, the change of light energy due to arterial blood flow can be detected and isolated. See Figure 1-2.

![Diagram](image)

**Figure 1-2. Signal Composite**

**Functional Components**

The 3740 oximeter uses electrical components to determine SpO₂ and pulse rate values. The key elements are the:

- Probe
- Processing of the probe signal
- Calculations made by the microprocessor

![Diagram](image)

**Figure 1-3. Functional Components**

The probe consists of two components:

- Light source. This consists of a red and infrared LED (light emitting diode).
- Photodetector. This is an electronic device that detects light then produces an electrical current for signal processing.
The two wavelengths of light generated by the LEDs pass through the tissue at the probe site. This light, which is partially absorbed and modulated, is then collected by the photodetector and converted into an electronic signal. This signal is sent to the oximeter for further processing.

**Signal Processing**

The oximeter's electronic circuitry takes the current generated by the photodetector, processes it, and passes it to the microprocessor for calculation of the SpO₂ and pulse rate.

The microprocessor calculates the SpO₂ 30/25 (60/50 Hz) times per second. These calculations are averaged by a running-weighted-average method to determine the displayed SpO₂. This method assigns a weight (value) to each calculation based on the signal strength and the current average saturation. The displayed average is based on specific time periods and is updated at specific intervals depending on the Response Mode (see Figure 1-4).

### 60 Hz

<table>
<thead>
<tr>
<th>Response Mode</th>
<th>Display Data Updated</th>
<th>SpO₂ Averaging Time</th>
<th>Pulse Interval (See note)</th>
</tr>
</thead>
<tbody>
<tr>
<td>&quot;S&quot; Slow</td>
<td>4/3 seconds</td>
<td>12 seconds</td>
<td>12 seconds</td>
</tr>
<tr>
<td>&quot;N&quot; Normal</td>
<td>2/3 seconds</td>
<td>6 seconds</td>
<td>12 seconds</td>
</tr>
<tr>
<td>&quot;F&quot; Fast</td>
<td>1/3 seconds</td>
<td>3 seconds</td>
<td>5 seconds</td>
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### 50 Hz

<table>
<thead>
<tr>
<th>Response Mode</th>
<th>Display Data Updated</th>
<th>SpO₂ Averaging Time</th>
<th>Pulse Interval (See note)</th>
</tr>
</thead>
<tbody>
<tr>
<td>&quot;S&quot; Slow</td>
<td>3/2 seconds</td>
<td>12 seconds</td>
<td>12 seconds</td>
</tr>
<tr>
<td>&quot;N&quot; Normal</td>
<td>3/4 seconds</td>
<td>12 seconds</td>
<td>12 seconds</td>
</tr>
<tr>
<td>&quot;F&quot; Fast</td>
<td>3/8 seconds</td>
<td>12 seconds</td>
<td>5 seconds</td>
</tr>
</tbody>
</table>

**Figure 1-4. Response Mode versus Displayed Averages Tables**

The running-weighted-average method allows erroneous SpO₂ values to be discarded when the displayed SpO₂ is determined. Erroneous values result from probe movement, electrosurgery, and other sources of signal interference. This method of averaging provides a stable reading, with low sensitivity to interference, while retaining the ability to respond quickly to saturation changes.
Chapter 2: Operator Features and Controls

This chapter describes the following:
- Front panel controls, indicators, and displays.
- Rear panel connectors for the external power supply and digital and analog output devices.
- Screens and the operating features that you can access through these screens. See Chapter 3/Operating the Oximeter, for more detailed instructions and examples for using the menu features.

Oximeter Features and Controls

![Oximeter Display](image)

**Figure 2-1. Front Panel**

**Power/Standby Switch:** Powers on the oximeter (Operational mode) and off (Standby mode). In the Standby mode, Trend Data is maintained. The shining green LED indicates that the power supply is connected.

**Symbol:** Indicates the oximeter conforms with the International Electrotechnical Commission Standard 601-1 (Safety of Medical Electrical Equipment) for patient isolation-type BF devices. **Note:** Scandinavian power supplies do not have this symbol.

**Probe Plug Connector:** Probes, supplied with the oximeter, plug into this nine-hole connector.
2/Operator Features and Controls

WARNING: Patient Safety · For this oximeter, use only the Ohmeda probes specified in the Ohmeda Probes Manual; otherwise, patient injury or equipment damage may result.

Alarm Silence Key: Silences all audible alarms for 120 seconds. If other alarm conditions occur during this interval, the audible alarm will not sound.

Note: All alarms are disabled during TREND OUTPUT.

When you press this key, the flashing red alarm light changes to a steady red light to indicate alarm silence. If an alarm condition still exists after the 120-second alarm silence period, the audible tone and flashing light resume.

Display Select Key: Switches the display between Large Waveform display and the Large Number display. Press this key again to change back the previous display.

Menu/Enter Key: Enters an item from the menu, accesses another menu item, or enters a new value. A description of menu functions follows in the Menu Features section.

Up and Down Arrow Keys: Adjusts level of the pulse volume. When viewing a menu, these keys select a menu item or change an item parameter.

Contrast Adjust Lever: Adjusts the display for readability at different vertical levels. Range = 50 degrees.

Screen Features

Large Waveform Display: The plethysmographic waveform shown represents the blood volume change of the hemodynamic system assuming no other factors (such as motion artifact) are present. The plethysmographic waveform autoscales (automatically adjusts) according to the strength of the signal.

Large Number Display: The screen with large numbers is used to confirm a good quality signal during normal monitoring.
Signal Strength Indicator: Indicates strength of the received pulsatile signal. The higher the bar, the stronger the signal.

The height of the bar is determined by several factors, including tissue perfusion at the probe site and the ability of the tissue to pass the incident light.

Low Quality Signal Indicator: Displayed if the Signal Strength Indicator bar is continuously at 5 pixels or less for 5 seconds or more. When displayed, the SpO₂ reading on the oximeter may not be accurate.

Note: When the bar shows 1 pixel or less for 5 seconds or more and/or pulse rate readings are less than or equal to 20 beats per minute (BPM) for 5 seconds or more, an audible alarm sounds and the alarm light flashes; and NO PULSE message appears.

Response Mode: Indicates the SpO₂ and pulse rate averaging time. (Seen only in Large Waveform display.)

<table>
<thead>
<tr>
<th>Response Mode</th>
<th>Display Data Updated</th>
<th>SpO₂ Averaging Time</th>
<th>Pulse Interval (See note)</th>
</tr>
</thead>
<tbody>
<tr>
<td>&quot;S&quot; Slow</td>
<td>4/3 seconds</td>
<td>12 seconds</td>
<td>12 seconds</td>
</tr>
<tr>
<td>&quot;N&quot; Normal</td>
<td>2/3 seconds</td>
<td>6 seconds</td>
<td>12 seconds</td>
</tr>
<tr>
<td>&quot;F&quot; Fast</td>
<td>1/3 seconds</td>
<td>3 seconds</td>
<td>5 seconds</td>
</tr>
</tbody>
</table>

Note: The pulse-rate update is based on the previous 5- or-12 second interval. During each interval the oximeter measures the time between the plethysmographic waveform peaks to calculate the pulse rate. Pulse rate and SpO₂ calculations are based on independent time intervals.

Low Battery Indicator: Indicates approximately 30 minutes of operating time. See Chapter 5/Maintenance and Service under Battery Alarm Messages and Recharging Periods for instructions.

Note: This message appears only on the monitoring screen.

High SpO₂ Alarm Limit: Threshold for high SpO₂ alarm (Large Number display only). Default = OFF, indicated by --- (dashes).

Low SpO₂ Alarm Limit: Threshold for low SpO₂ alarm (Large Number display only). Default = 90%.
Rear Panel

WARNING: Electric Shock Hazard - Measure the leakage current whenever an external device is connected to either the analog or digital output jacks. Forward and Reverse Polarity: 100 micro-amperes maximum.

WARNING: Connect only equipment that complies with a relevant IEC or local country safety standard (such as ETL, CSA, BSI, and TUV) to the signal input/output jacks on the rear panel.

CAUTION: Maximum Voltage - Apply no more than ±15 volts to any analog or digital connector. Exception: Pins 11, 18, and 25 of the rear panel RS-232C connector are TTL signals. Apply only 0 to +5 volts to these pins. The oximeter will be permanently damaged if these signals are connected to RS-232C voltage levels.

Pulse Rate Analog Output: Provides a 0-(zero) to 1-volt linear analog representation of the displayed pulse rate. A zero-volt output is equivalent to a pulse rate of zero. A 1-volt output is equivalent to a pulse rate of 250 beats per minute (BPM).

SpO₂ Analog Output: Provides a 0 (zero) to 1-volt linear analog representation of the displayed saturation. A zero-volt output is equivalent to a saturation of zero percent. A 1-volt output is equivalent to a saturation of 100 percent. This provides a chart recorder output in trend mode (see Chapter 6).

CAUTION: Connect only a high-impedance device (1K Ohm or higher) to the analog output jacks, otherwise improper loading will upset the correspondence between the measured voltage and the intended output voltage.

Digital Interface Connector: Provides serial digital information of the SpO₂ readings, pulse rate readings, and oximeter conditions. This 25-pin connector is compatible with most RS-232C devices capable of accepting a 1200-bits-per-second input. For more information, see Chapter 7/Using the Computer Interface.
Equipotentiality Connector: Complies with DIN specification 42-801 for grounding the oximeter when using the battery, or as an auxiliary ground.

Power Supply Connector: Connects the oximeter to the power supply (charger) for charging of the battery and continuous operation.

Power Supply: Use a hospital-grade (USA) grounded receptacle only. Whenever possible, connect to AC mains power when the oximeter is operating or in storage. For long-term storage, recharge the battery every six months by plugging into AC mains power. If recharging is not possible, have battery pack removed by qualified service personnel.

WARNING: Electric Shock Hazard — Use only with Ohmeda Model 15 power supplies of correct input voltage.

CAUTION: Equipment damage may result if the incorrect power supply is used.

Symbol for "Indoor Use Only" (located on top cover of Power Supply)

Symbol for thermal fuse (located on top cover of Power Supply)

Menu Features

The oximeter’s settings and features appear on three screens. All settings revert to the default values when the oximeter is turned off.

<table>
<thead>
<tr>
<th>Screen 1</th>
<th>Screen 2</th>
<th>Screen 3</th>
</tr>
</thead>
<tbody>
<tr>
<td>PULSE VOLUME</td>
<td>LOW PULSE ALARM</td>
<td>CALIBRATE RECORDER</td>
</tr>
<tr>
<td>ALARM VOLUME</td>
<td>HIGH PULSE ALARM</td>
<td>SET TIME hh:mm</td>
</tr>
<tr>
<td>LOW SpO2 ALARM</td>
<td>RESPONSE TIME</td>
<td>SET DATE dd/mm/yyyy</td>
</tr>
<tr>
<td>HIGH SpO2 ALARM</td>
<td>TREND OUTPUT</td>
<td>DIAGNOSTIC</td>
</tr>
</tbody>
</table>

Screen 1

- PULSE VOLUME: Volume range: 1 to 10 and OFF. Default is 4.
- ALARM VOLUME: Volume range: 1 to 10. Default is 4.
- LOW SpO2 ALARM: Limit range: OFF, 50% to 100%. Default is 90%.
  (Large Number display.)
- HIGH SpO2 ALARM: Limit range: OFF, 70% to 100%. Default is OFF
  (Large Number display.)
Screen 2

- LOW PULSE ALARM: Limit Range: OFF, 40 to 200 beats per minute, in increments of 5. Default is OFF.
- HIGH PULSE ALARM: Limit Range: OFF, 70 to 250 beats per minute in increments of 5. Default is OFF.
- RESPONSE TIME: Designates the SpO₂ and pulse rate averaging time. The response indicator is displayed in the Large Waveform display only.

<table>
<thead>
<tr>
<th>Response Mode</th>
<th>Display Data Updated</th>
<th>SpO₂ Averaging Time</th>
<th>Pulse Interval (See note)</th>
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<tr>
<td>&quot;S&quot; Slow</td>
<td>4/3 seconds</td>
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</tr>
<tr>
<td>&quot;F&quot; Fast</td>
<td>1/3 seconds</td>
<td>3 seconds</td>
<td>5 seconds</td>
</tr>
</tbody>
</table>

- TREND OUTPUT: Accesses trend information for output on recording devices and computers.
- CURRENT DATA: Data stored from current "power on."
- 8 HOURS OF DATA: Data stored from the last 8 hours of operation.

Screen 3

- CALIBRATE RECORDER: Supplies 0, 0.5, and 1.0 volts to the analog output jacks on the rear panel for calibrating recording devices connected to the oximeter.
- SET TIME: Sets time on real-time clock: hh:mm
- SET DATE: Sets date on real-time clock: dd/mm/yy
- DIAGNOSTICS: Verifies and calibrates the electronic circuitry of the oximeter.

**Note:** The time and date are displayed on the computer screen during digital TREND OUTPUT only. The time and date are displayed to the right of the SpO₂ and pulse rate values according to the date and time set when the data were collected.
Chapter 3: Operating the Oximeter

This chapter provides procedures to check the oximeter before use and steps for using the oximeter to monitor patients. Also included are examples and steps that will help you use the menu features to modify operating features. Refer to information in Chapter 2/Operator Features and Controls for more detail on oximeter controls and menu options.

Checking the Oximeter before Use

Perform the following tests daily to ensure proper operation of the oximeter.

Visual Inspection

1. Inspect the oximeter case for damage.

2. Ensure the display windows are clean. (To clean, see the Cleaning the Oximeter section of Chapter 4/Maintenance and Service.)

3. Check probes for foreign material such as tape or cotton. Remove any substances that may interfere with transmission of light between the light source and the detector. (See the Ohmeda Probes Manual for more detail.)

4. Verify that the probe opens and closes smoothly (FingerClip, Finger Probe, and EarProbe). If there is any unevenness or variations in the closing motion, replace the probe.

Functional Inspection

1. Check that the probe is the correct model before connecting it to the oximeter.

   WARNING: Patient Safety — Use Only the Ohmeda probes specified in the Ohmeda Probes Manual; otherwise, patient injury or equipment damage may result.

2. Connect the probe to the oximeter. Make sure that the probe is firmly connected to the oximeter.

3. Check that the probe cable is not twisted or damaged.

4. Verify that the power supply indicator light on the Power/Standby switch is illuminated.
3/Operating the Oximeter

5. Turn on the oximeter.

6. Check that the red LED in the probe is illuminated.

7. Attach the probe to the patient.

**WARNING:** Electric Shock Hazard — Use only with Ohmeda Model 15 power supplies of correct input voltage.

**CAUTION:** Equipment damage may result if the incorrect power supply is used.

8. Connect the supplied AC power adapter to the rear panel connector and plug in the oximeter to the wall outlet.

9. Verify that the oximeter runs the self-diagnostic test during power on and that the following appears:

   OHMEDA
   3740 (T125-016)
   REVISION: X
   SYS AND CAL CHECK ...

**Note:** X is the level of the software revision.

10. Verify that the following appears after the diagnostic self-test:

    CALIBRATION PASSED
    SYSTEM OPERATIONAL

11. Adjust the display with the View Adjust lever on the bottom of the monitor if necessary.

12. After a few seconds, the following appears:

![Image]

**Alarm Verification**

1. After the probe is on the patient for 30 seconds, remove the probe from the patient. Ensure that the alarm message PROBE OFF PATIENT appears, an alarm tone sounds, and the red alarm light flashes.

**Note:** Other messages or a dashed display may appear with the Flex II Probe, SoftProbe, or EasyProbe.

2. Unplug the probe from the oximeter.

3. Ensure the Alarm Message NO PROBE CONNECTED TO UNIT appears, an alarm tone sounds, and the red alarm light flashes.

4. Turn the oximeter off. The display should be blank.
Alarm Function During Poweron

During initial poweron, if the probe is off the patient or the probe is not connected to the oximeter, the following occurs:

- The alarm light turns on and stays on
- The appropriate alarm message, PROBE OFF PATIENT or NO PROBE CONNECTED, appears on the monitor display
- Audible alarm is silent

When the condition that causes the alarm is cleared (probe is placed on patient or connected to the oximeter), the oximeter checks for a returning alarm condition for 30 seconds.

- If an alarm condition occurs within the 30 seconds (probe is removed from patient or disconnected from oximeter), the following occurs:
  - The alarm light turns on and stays on
  - PROBE OFF PATIENT or NO PROBE CONNECTED appears across the display

- If an alarm condition occurs after the 30 seconds, the following occurs:
  - An alarm tone sounds
  - The alarm light turns on and flashes
  - PROBE OFF PATIENT or NO PROBE CONNECTED appears across the display

Preparing to Monitor a Patient

WARNING: Danger Explosion Hazard — Do not use in the presence of flammable anesthetics or other flammable substances.

WARNING: Electric Shock Hazard — Use Only with Ohmeda Model 15 power supplies of correct input voltage.

1. Optional: Plug the power supply into AC power outlet and the oximeter.

2. Turn on the oximeter.

3. Determine which probe to use, connect the probe to the oximeter, and attach the probe to the patient. See the Ohmeda Probes Manual.

WARNING: Patient Safety — Prolonged monitoring or patient condition may require periodically changing the probe test site. To reduce the risk of blistering, skin erosion, or ischemic skin necrosis, check the probe site at least every four hours, especially with neonates, infants, and patients with conditions characterized by poor perfusion or sensitive skin. If any evidence of the above conditions appears (for example, discoloration or reddening), change the probe site.
4. Optional: Press the Display Select key to change the display format.

   Note: Use the Large Waveform display to help place the probe and confirm signal quality. Use the Large Number display for routine monitoring.

5. To determine if the probe is correctly attached to the patient and that the data can be verified, see the Ohmeda Probes Manual.

Modifying Operational Settings

This section provides general steps and examples for changing operational settings. For more details about using 3740 oximeter menus, see the Menu Features section of Chapter 2/Operator Features and Controls.

General Steps

Use the following as general steps to access the oximeter’s menu, select menu items, and change limits or values. See Setting the Low Pulse Rate Alarm Limit, Setting the Clock, and other examples on the following pages for details about changing a specific setting.

<table>
<thead>
<tr>
<th>1. Enter Menu</th>
<th>Press the Menu/Enter key.</th>
</tr>
</thead>
<tbody>
<tr>
<td>2. Select Item</td>
<td>Hold down an arrow key until the cursor is on the desired item, then press the Menu/Enter key. Note: To move more than one item at a time, continuously press the Arrow key.</td>
</tr>
<tr>
<td>3. Change Limit or Value</td>
<td>Press the Arrow keys to move the cursor to the desired limit/volume.</td>
</tr>
<tr>
<td>4. Enter Item and Return to Menu</td>
<td>Press the Menu/Enter key.</td>
</tr>
<tr>
<td>or Enter Item and exit Menu</td>
<td>Press the Display Select key.</td>
</tr>
</tbody>
</table>

Next time the menu is entered the cursor will be at the previously selected item. The cursor is only reset to PULSE VOLUME (top of screen 1) on the next power on.

Press the Up or Down arrow keys to raise or lower the pulse volume.

Note: From the monitoring display screen, the Up and Down arrow keys can be used to increase or decrease pulse volume.

Special Menus

- For SET TIME and SET DATE, see "Setting the Clock" in this chapter.
- For TREND OUTPUT, see Chapter 6/Using the Chart Recorder Interface or Chapter 7/Using the Computer Interface.
For CALIBRATE RECORDER, see Chapter 6/Using the Chart Recorder Interface.

Setting the Low Pulse Rate Alarm Limit

Use the following steps to set a lower pulse rate alarm.

1. Press the Menu/Enter key.
   - If you have not changed a setting since the last time you powered off and on, screen 1 (shown on the following table) appears with the cursor at PULSE VOLUME.
   - If you have changed a setting since the last time you powered off and on, the screen and cursor appear where you last changed settings.

<table>
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<tr>
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<th>Screen 3</th>
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<tr>
<td>ALARM VOLUME</td>
<td>HIGH PULSE ALARM</td>
<td>SET TIME hh:mm</td>
</tr>
<tr>
<td>LOW SpO2 ALARM</td>
<td>RESPONSE TIME</td>
<td>SET DATE dd/mm/yy</td>
</tr>
<tr>
<td>HIGH SpO2 ALARM</td>
<td>TREND OUTPUT</td>
<td>DIAGNOSTIC</td>
</tr>
</tbody>
</table>

Note: hh:mm and mm/dd/yy are the time and date stored in memory.

2. Select LOW PULSE ALARM using one or all of these steps:
   a. If screen 2 appears, step through each menu item on the screen using the Up or Down arrow key to select LOW PULSE ALARM.
   b. If screen 2 does not appear, do one of the following:
      - Press the Down arrow key when the cursor is on the last item to display the next screen. For example, pressing the Down arrow key when the cursor is on HIGH SpO2 ALARM displays screen 2.
      - Press the Up arrow key when the cursor is on the first item of a screen to display the previous screen. For example, pressing the Up arrow key when the cursor is on PULSE VOLUME displays Screen 3. Pressing the Up arrow key while the cursor is on CALIBRATE RECORDER displays screen 2.

3. When you select LOW PULSE ALARM, press the Menu/Enter key.

   The following screen appears:

   LOW PULSE ALARM

   (OFF, 40 - 200)
   ** OFF **
4. Press the Up arrow key once.

The following screen appears to show that the pulse rate limit is at 40:

LOW PULSE ALARM

(OFF, 40 - 200)

** 40 **

Note: You can change the low pulse rate limit in increments of 5.

5. Press the Down arrow key once. The pulse rate limit changes to OFF.

6. Press the Down arrow key again. The pulse rate limit changes to 200.

7. Continuously press the Down arrow key. The limit continuously changes. Set the limit to your desired value.

8. To save changes and return to either the menu screen or the monitoring display use one of the following steps:
   - To enter the item and return to the monitoring display, press the Display Select key.
   - To enter the item and return to the menu, press the Menu/Enter key.

Setting the Clock

The clock is provided to mark data during digital trend output.

Setting the Time

If you do not know how to use the menu, please read the Modifying Operational Settings section of this chapter.

1. Press the Menu/Enter key.

   - If you have not changed a setting since the last time you powered off and on, screen 1 (as shown on the following table) appears with the cursor at PULSE VOLUME.

   - If you have changed a setting since the last time you powered off and on, the screen and cursor appear where you last changed settings.

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<tr>
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<td>CALIBRATE RECORDER</td>
</tr>
<tr>
<td>ALARM VOLUME</td>
<td>HIGH PULSE ALARM</td>
<td>SET TIME hh:mm</td>
</tr>
<tr>
<td>LOW SpO2 ALARM</td>
<td>RESPONSE TIME</td>
<td>SET DATE dd/mm/yyyy</td>
</tr>
<tr>
<td>HIGH SpO2 ALARM</td>
<td>TREND OUTPUT</td>
<td>DIAGNOSTIC</td>
</tr>
</tbody>
</table>
2. Using the Arrow keys, select SET TIME (changing screens as necessary).

3. Press the Menu/Enter key.

   The following appears:
   
   MINUTE
   HOUR

4. Using an Arrow key, move the cursor to the desired item.

5. Press the Menu/Enter key.

   One of the following screens appear, depending on what item you select:

   ARROW KEY ADJUST, ARROW KEY ADJUST,
   ANY OTHER EXITS ANY OTHER EXITS
   MINUTE HOUR
   " xx " " xx "

   Note: xx = minutes or hours (24-hour clock)

6. Press either Arrow key to adjust to current time.

   Note: To move more than one number at a time, continuously press the Arrow key.

7. Press the Menu/Enter key. The new time is entered and the following appears:

   MINUTE
   HOUR

8. Press the Display Select key. The following appears:

   CALIBRATE RECORDER
   SET TIME  hh:mm
   SET DATE  dd/mm/yy
   DIAGNOSTICS

Setting the Date

1. If you are not at a menu, press the Menu/Enter key.

2. Move cursor to screen 3 (if necessary) and select SET DATE using an Arrow key.

3. Press the Menu/Enter key. The following appears:

   MONTH
   DATE
   YEAR

4. Move the cursor to the desired item using an Arrow key.
5. Press the Menu/Enter key.

One of the following screens should appear, depending on the item you select:

ARROW KEY ADJUST, ANY OTHER EXITS
ARROW KEY ADJUST, ANY OTHER EXITS
ARROW KEY ADJUST, ANY OTHER

MONTH " xx " DATE " xx " YEAR " xx "

Note: xx = month, day, or year

6. Press either Arrow key to adjust to current date.

Note: To move more than one number at a time, continuously press the Arrow key.

7. Press the Menu/Enter key.

The new date is entered and the following appears:

MONTH
DATE
YEAR

8. Press the Display Select key.

The following appears:

CALIBRATE RECORDER
SET TIME hh:mm
SET DATE dd/mm/yy
DIAGNOSTICS
Chapter 4: Troubleshooting

This chapter provides instructions to follow in the event of instrument or signal problems. It is divided into five parts:

- Patient Alarm Limit Violations
- Signal and User Correctable Problems
- Staged Alarm System
- Probe Alarm Messages
- Device Failure Messages

Patient Alarm Limit Violations

Patient Alarm Messages alert you to conditions needing immediate attention. Check the patient and the oximeter whenever any alarm condition occurs. You can silence the alarm for 120 seconds by pressing the alarm silence key. When patient alarm limit conditions occur, some or all of the following occur:

- An alarm tone sounds
- The red alarm light flashes
- The violated alarm limit flashes (if displayed)
- The out-of-range $\text{SpO}_2$ or pulse rate reading flashes
## Signal and User Correctable Problems

<table>
<thead>
<tr>
<th>Problem or Display Message</th>
<th>Possible Causes</th>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>Low Quality Signal</td>
<td>1. Poorly perfused site</td>
<td>1. Rub site vigorously for 20 to 30 seconds</td>
</tr>
<tr>
<td></td>
<td>2. Tissue sample too thick</td>
<td>2. Select thinner application site (decrease distance between probe's light source and detector)</td>
</tr>
<tr>
<td></td>
<td>3. Tape securing probe wrapped too tightly</td>
<td>3. Loosen tape</td>
</tr>
<tr>
<td></td>
<td>4. Alarm stage 1</td>
<td>4. See the Staged Alarm System section of this chapter</td>
</tr>
<tr>
<td></td>
<td>5. Bar graph on graphic display is a five pixels or less continuously for 5 seconds or more</td>
<td>5. Check patient and oximeter setup</td>
</tr>
<tr>
<td>Low Quality Signal (alarm tone sounds and alarm light flashes)</td>
<td>Alarm stage 2</td>
<td>See the Staged Alarm System section of this chapter</td>
</tr>
<tr>
<td>CHECK PROBE SITE</td>
<td>Inadequate Signal (alarm tone sounds and alarm light flashes)</td>
<td>See the Staged Alarm System section of this chapter</td>
</tr>
<tr>
<td>Electronic Interference</td>
<td>Alarm stage 3</td>
<td>See the Staged Alarm System section of this chapter</td>
</tr>
<tr>
<td></td>
<td>Electrosurgery, MRI (NMR), or other electrical/electronic devices</td>
<td>Data questionable during this period. Move the unit and probe cable away from other electrical devices. Operate unit on battery or try plugging power supply into a different electrical outlet (AC Mains Power).</td>
</tr>
</tbody>
</table>
Signal and User Correctable Problems (cont.)

<table>
<thead>
<tr>
<th>Problem or Display Message</th>
<th>Possible Causes</th>
<th>Action</th>
</tr>
</thead>
</table>
| ![Probe Motion](image)    | 1. Probe detector not flush with tissue  
                            2. Patient movement          | 1. Tape probe and/or cable  
                            2. Select another probe site |
| **NO PULSE**               | 1. Signal strength at one pixel or less for five seconds or more  
                            2. Perfusion at probe site insufficient for valid readings  
                            3. Pulse rate of 20 BPM or less for five seconds or more | 1. Check patient and oximeter setup  
                            2. Check patient and oximeter setup  
                            3. Check patient and oximeter setup |
| Display blank or difficult to read | 1. Display contrast requires adjustment  
                                        2. Power switch off  
                                        3. Battery needs recharged or replaced  
                                        4. Blown fuse or internal circuit failure | 1. Adjust display with view adjust lever  
                                        2. Turn on power switch  
                                        3. Plug oximeter into power supply  
                                        4. Plug oximeter into power supply. If LED on Power/Standby switch isn't illuminated, have unit serviced. |
| Oximeter alarms and then shuts off | Oximeter detected probe or circuit failure and automatically shut off | See the possible causes and action in this table under the following message:  
                                PROBE OR CIRCUIT FAILURE, REPLACE PROBE OR SERVICE UNIT |
| ![XX](image)               | Oximeter out of calibration | Calibrate oximeter. (See the Calibrating the Oximeter section in Chapter 5/Maintenance and Service) |
Signal and User Correctable Problems (cont.)

<table>
<thead>
<tr>
<th>Problem or Display Message</th>
<th>Possible Causes</th>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>Digital readings on display dash. Waveform and signal strength bar both good.</td>
<td>Motion artifact</td>
<td>Select another probe site</td>
</tr>
</tbody>
</table>
| INSUFFICIENT LIGHT DETECTED | 1. Dirt on probe’s light source, probe detector, or test site  
2. Tissue sample too thick  
3. Misaligned or malpositioned probe  
4. Light source blocked by fingernail polish  
5. Light source blocked by dark pigmentation  
6. Detector failure failure  
7. Light source blocked by tape | 1. Clean probe and/or test site  
2. Select thinner test site  
3. Reposition probe or select an alternate test site  
4. Use an alternate test site  
5. Use an alternate test site with less coloration  
6. Replace probe  
7. Reapply probe or move tape | |
| INTERFERENCE SpO₂ & PULSE RATE MAY BE INVALID | 1. Strong electromagnetic interference  
2. Electrocautery | 1. See Interference Present next page  
2. See Interference Present next page | Note: Data is not collected when interference is detected |
### Signal and User Correctable Problems (cont.)

<table>
<thead>
<tr>
<th>Problem or Display Message</th>
<th>Possible Causes</th>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>INTERFERENCE</strong>&lt;br&gt;SpO₂ &amp; PULSE RATE MAY BE INVALID</td>
<td><strong>Interference Present</strong>&lt;br&gt;When strong interference is detected by the oximeter, the SpO₂ and pulse rate readings do not change. If interference persists beyond the time periods indicated below, the INTERFERENCE DETECTED message is displayed. After the interference has stopped, the oximeter begins collecting data again. The SpO₂ and pulse rate readings return to the display in approximately 2 seconds.</td>
<td><strong>Response</strong>&lt;br&gt;Time period before display of the INTERFERENCE DETECTED message&lt;br&gt;&lt;br&gt;Slow</td>
</tr>
<tr>
<td><strong>LOW BATT</strong></td>
<td><strong>Battery is getting low</strong></td>
<td><strong>Recharge battery or operate from AC mains power</strong></td>
</tr>
<tr>
<td>Noncorrelating SpO₂ (Oximeter readings do not correspond to co-oximeter readings)</td>
<td>1. Excessive ambient light&lt;br&gt;2. High concentration of carboxyhemoglobin or other dysfunctional hemoglobin</td>
<td>1. Shield probe from ambient light&lt;br&gt;2. For dyshemoglobins &gt; 3%, see Appendix A, Specifications. Use oximeter only to monitor SpO₂ trends.</td>
</tr>
<tr>
<td>Noncorrelating or erratic pulse</td>
<td>Excessive patient motion</td>
<td><strong>Select alternate probe site, or tape probe and/or probe cable</strong></td>
</tr>
<tr>
<td>Power/Standby Switch on, but oximeter off</td>
<td>1. Oximeter turned off and back on too quickly&lt;br&gt;2. Oximeter detected probe or circuit failure and automatically shut off&lt;br&gt;3. Battery failure</td>
<td>1. Turn Power/Standby switch off. Wait 2 seconds and turn oximeter back on.&lt;br&gt;2. See the following alarm message in this table:&lt;br&gt;<strong>PROBE OR CIRCUIT FAILURE,</strong>&lt;br&gt;<strong>REPLACE PROBE OR SERVICE UNIT</strong>&lt;br&gt;3. Have oximeter serviced</td>
</tr>
</tbody>
</table>
### Signal and User Correctable Problems (cont.)

<table>
<thead>
<tr>
<th>Problem or Display Message</th>
<th>Possible Causes</th>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>PLEASE CONNECT POWER SUPPLY TO DETERMINE LINE FREQUENCY</td>
<td>Oximeter has lost battery-backed RAM</td>
<td>Plug power supply into oximeter</td>
</tr>
<tr>
<td>PLEASE CONNECT POWER SUPPLY TO RECHARGE BATTERY</td>
<td>Battery needs recharging (oximeter alarms continuously and automatically shuts off in approximately 10 seconds)</td>
<td>Recharge battery (see Recharging the Battery in Chapter 6/Maintenance and Service) or operate from AC mains</td>
</tr>
<tr>
<td>PROBE OR CIRCUIT FAILURE, REPLACE PROBE OR SERVICE UNIT</td>
<td>Oximeter detected probe or circuit failure (oximeter alarms continuously and automatically shuts off in approximately 2 seconds)</td>
<td>Turn Power/Standby switch off. Remove probe from patient and disconnect from oximeter</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Turn oximeter on. If oximeter shuts off, have it serviced</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Connect probe to oximeter. If oximeter shuts off, replace it</td>
</tr>
<tr>
<td>RAM DATA INVALID RE-INITIALIZING</td>
<td>Oximeter memory has been erased. Trend Data lost.</td>
<td>Oximeter automatically reinitializes and is ready for use</td>
</tr>
</tbody>
</table>

### Staged Alarm System

The staged alarm system warns you that data might be unreliable and that you may need to check the probe site or how the probe is applied to the patient. The heart of this system is an algorithm that checks signal quality from the probe site. This algorithm notes a low quality signal "event" when the signal quality deteriorates due to motion of the probe site, poor probe placement, electrical noise, or other factors. The oximeter initiates messages, then increases alarm/message severity according to the number of these events that occur over a period of time.

The following tables provide an overview of the staged alarm system. They list alarms and messages output by the oximeter and a computer interface (if used) during the alarm stages.
Oximeter Alarms and Messages

<table>
<thead>
<tr>
<th>Stage</th>
<th>Oximeter Display and Alarms</th>
</tr>
</thead>
</table>
| 1     | • LOW SGNL appears on Display (see Low Quality Signal under "Problem or Display Message" in the Signal and User Correctable Problems section of this chapter)  
• SpO₂ and Pulse Rate readings continue on the display |
| 2     | • LOW SGNL appears on the display  
• Audible alarm sounds and alarm light flashes  
• SpO₂ and Pulse Rate readings continue |
| 3     | • CHECK PROBE SITE appears on the display  
• Audible alarm sounds and alarm light flashes  
• SpO₂ and Pulse Rate analog output on graph of chart recorder, polygraph, or other recording equipment read zero volts |

Computer Interface Display and Message

<table>
<thead>
<tr>
<th>Stage</th>
<th>Auto Output</th>
<th>Trend Output</th>
<th>Slave and Waveform</th>
</tr>
</thead>
</table>
| 1     | • LOW QUALITY SIGNAL message appears  
• SpO₂ and PR readings continue | • LQ message appears  
• SpO₂ and PR readings appear | • 14 (error code) appears  
• SpO₂ and PR readings continue |
| 2     | • LOW QUALITY SIGNAL message appears  
• SpO₂ and PR readings continue | • LQ message appears  
• SpO₂ and PR readings appear | • 14 (error code) appears  
• SpO₂ and PR readings continue |
| 3     | • CHECK PROBE SITE message appears  
• SpO₂ and PR readings dashed | • CK message appears  
• SpO₂ and PR readings dashed | • 09 (error code) appears  
• SpO₂ and PR readings dashed |

As shown in the preceding tables, the type of messages, displays, and alarms indicates the severity of signal deterioration from the probe site. When signal quality improves to acceptable levels, alarms and warning messages cease, and displays return to normal.
Warning Remedies

To alleviate the warning condition, try these techniques in sequence until alarms, messages, and other warnings cease.

1. Check attachment and placement of the probe model you are using against instructions in the Ohmeda Probes Manual. Make sure that the probe is used according to instructions.

2. Have the patient remain as motionless as possible.

3. Massage probe site and reapply the probe.

4. Select another probe site, if possible.

5. Try using another probe.

Probe Alarm Messages

Probe Alarm Messages occur when the oximeter detects conditions affecting the probe. The alarm can be silenced for 120 seconds by pressing the alarm silence key.

When PROBE OFF or NO PROBE alarms occur:

- An alarm tone sounds.
- The red alarm light flashes.
- PROBE OFF PATIENT or NO PROBE CONNECTED appears on the display.
- The Alarm Silence key silences the audible alarm until the specific alarm condition is remedied.

Alarm Function During Poweron

During initial poweron, if the probe is off the patient or the probe is not connected to the oximeter, the following occurs:

- The alarm light turns on and stays on.
- The appropriate alarm message, PROBE OFF PATIENT or NO PROBE CONNECTED, appears on the display.
- Audible alarm is silent.

When the condition that causes the alarm is cleared (probe is placed on patient or connected to the oximeter), the oximeter checks for a returning alarm condition for 30 seconds.
4/ Troubleshooting

- If an alarm condition occurs within the 30 seconds (probe is removed from patient or disconnected from oximeter), the following occurs:
  - The alarm light turns on and stays on
  - PROBE OFF PATIENT or NO PROBE CONNECTED appears on the display.

- If an alarm condition occurs after the 30 seconds, the following occurs:
  - An alarm tone sounds.
  - The alarm light turns on and flashes.
  - PROBE OFF PATIENT or NO PROBE CONNECTED appears on the display.

<table>
<thead>
<tr>
<th>Display Message</th>
<th>Possible Causes</th>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>NO PROBE CONNECTED TO UNIT</td>
<td>1. Incorrect probe or probe not plugged in or fully inserted into probe connector.</td>
<td>1. Use only the probes specified in the Ohmeda Probes Manual for this oximeter. Insert all probe cable plugs fully into probe connector.</td>
</tr>
<tr>
<td></td>
<td>2. Probe failure</td>
<td>2. Replace probe</td>
</tr>
<tr>
<td>CANNOT IDENTIFY PROBE (SEE MANUAL)</td>
<td>Oximeter unable to identify probe</td>
<td>Use only probes specified in the Ohmeda Probes Manual. Replace probe.</td>
</tr>
<tr>
<td>PROBE OFF PATIENT (Other messages may occur with the Flex II Probe, SoftProbe, or EasyProbe)</td>
<td>1. Probe off patient</td>
<td>1. Attach probe to patient</td>
</tr>
<tr>
<td></td>
<td>2. Excessive light detected by probe detector</td>
<td>2. Shield probe site from ambient light</td>
</tr>
<tr>
<td></td>
<td>3. Extremely thin tissue at test site</td>
<td>3. Select an alternate test site</td>
</tr>
</tbody>
</table>
### Device Failure Messages

Whenever any of the following messages appear:

1. Note the message and turn off the unit.
2. Have the unit serviced by qualified service personnel. See the Repair Policy section of Chapter 6/Maintenance and Service.

<table>
<thead>
<tr>
<th>A/D CONVERTER FAILURE, SERVICE UNIT (Unit alarms continuously and then automatically shuts off in = 2 seconds)</th>
<th>RAM CHECK ERROR, SERVICE UNIT</th>
<th>ROM TEST ERROR LOW BYTE, SERVICE UNIT</th>
</tr>
</thead>
<tbody>
<tr>
<td>ANALOG SYNCHRONIZATION ERROR, SERVICE UNIT</td>
<td>RAM TEST ERROR HIGH &amp; LOW BYTES, SERVICE UNIT</td>
<td>STACK ERROR PLEASE NOTE CONDITIONS AND SERVICE UNIT</td>
</tr>
<tr>
<td>CHARGING CIRCUIT FAILURE, SERVICE UNIT</td>
<td>RAM TEST ERROR LOW BYTE, SERVICE UNIT</td>
<td>SYSTEM ERROR — X, PLEASE NOTE ERROR CODE AND SERVICE UNIT (Note: X represents an alphanumeric value)</td>
</tr>
<tr>
<td>MICRO-PROCESSOR ERROR, SERVICE UNIT</td>
<td>RAM TEST ERROR TREND CHECKSUM, SERVICE UNIT</td>
<td>TEST SIGNAL DC REFERENCE ERROR, SERVICE UNIT</td>
</tr>
<tr>
<td>MICRO-PROCESSOR INTERRUPT ERROR, SERVICE UNIT</td>
<td>ROM TEST ERROR HIGH BYTE, SERVICE UNIT</td>
<td>VOLTAGE REFERENCE FAILURE, SERVICE UNIT</td>
</tr>
<tr>
<td>POWER SUPPLY FAILURE, SERVICE UNIT</td>
<td>ROM TEST ERROR HIGH &amp; LOW BYTES, SERVICE UNIT</td>
<td></td>
</tr>
</tbody>
</table>
Chapter 5: Maintenance and Service

This chapter provides instructions for the following:

- Routine Maintenance
- Cleaning the oximeter and probes
- Recharging and maintaining the battery
- Calibrating the oximeter
- Ohmeda repair policy
- Packaging and returning products to Ohmeda
- Orderable parts and accessories

Routine Maintenance

Neither the pulse oximeter nor the probes require maintenance on a routine basis other than that suggested in Chapter 3/Operating the Oximeter, (Checking the Oximeter Before Use section). Service the oximeter whenever a Device Failure Alarm message appears. See Device Failure Messages in Chapter 4/Troubleshooting for a list of these messages.

Cleaning the Oximeter

WARNING: Electrical Shock and Flammability Hazard — Always turn off the oximeter and disconnect it from the AC power outlet before cleaning.

CAUTION: To clean this oximeter, do not:
- Autoclave
- Pressure sterilize
- Soak or immerse in any liquid
- Gas sterilize

The outer surface of the oximeter can be cleaned with a soft cloth dampened in a mild soap and water solution or isopropyl alcohol (70%). Ensure that the oximeter is unplugged prior to cleaning and the unit is completely dry before use.

Do not touch, press, or rub the display panel with abrasive cleaning compounds, instruments, brushes, rough surfaced materials or make contact with anything that can scratch the panel.

Do not use solutions containing acetone to clean the display panel. Use a cotton swab saturated with 70% isopropyl alcohol and gently wipe the panel.
Cleaning Probes

See the Ohmeda Probes Manual for cautions about cleaning probes.

Recharging the Battery

To recharge the battery, plug the external power supply into the AC power outlet and into the power supply connector on the rear panel of the oximeter.

![Diagram of power supplies]

Figure 5-1. Rear Panel Charging Jack and Power Supplies

WARNING: Electric Shock Hazard — Use Only with Ohmeda Model 15 power supplies of correct input voltage. Otherwise, patient injury or equipment damage may result.

CAUTION: Equipment damage may also result if the wrong power supply (charger) is used.

WARNING: Electric Shock hazard — If the integrity of the protective earth conductor is in doubt, operate the oximeter only on its internal battery.

CAUTION: Use a US hospital-grade grounded receptacle only.

CAUTION: Whenever possible, connect the oximeter to an AC power outlet when the oximeter is operating or in storage. For long-term storage, recharge the battery every six months by plugging it into an AC power outlet. If recharging is not possible, have battery pack removed by qualified service personnel.

WARNING: Proper Grounding — For protection against shock hazards, connect this equipment only to a three-wire, grounded, hospital grade receptacle. The three-connector plug must be inserted into a properly wired three-wire receptacle. If a two-wire receptacle is encountered, a
qualified electrician must replace it with a properly grounded three-wire receptacle in accordance with the governing electrical code. Do not, under any circumstances, remove the grounding connector from the power plug. Do not use extension cords or adapters of any type. The power cord and plug must be intact and undamaged.

Battery Alarm Messages

The following alarm message (with no alarm tone) indicates the battery has approximately 30 minutes of power remaining. When this message appears, promptly recharge the battery:

LOW BATT

The following alarm message (with continuous alarm tone) appears for approximately 10 seconds, then the oximeter automatically shuts off. When this message appears, immediately connect the oximeter to the power supply (which is plugged into the AC power outlet).

PLEASE CONNECT
POWER SUPPLY
TO
RECHARGE BATTERY

CAUTION: Do not turn the oximeter on after the RECHARGE BATTERY alarm message is displayed without first connecting it to an AC power outlet. Damage to the lead-acid battery may result.

Recharging Periods

80% capacity = 4.0 hr (oximeter on or off)
100% capacity = 6.5 hr (oximeter on or off)

Under normal conditions, the battery pack lasts for several hundred "charge-discharge" cycles. To obtain maximum battery life, recharge the battery pack whenever it is not in use by plugging into an AC power outlet. The battery pack will not overcharge.

During long-term storage, recharge the battery every six months, if possible. If this is not possible, have service personnel remove battery pack.

Replacing the Battery

WARNING: Battery Replacement — Unauthorized personnel should not attempt to install, connect, or replace the battery of the oximeter. Removing the cover and/or faulty battery connections could be hazardous and voids the warranty. Reversing the battery connections could result in injury and permanently damage the circuitry. If trained technical personnel are not available, obtain service by calling Ohmeda. For proper operation, replace only with an Ohmeda Battery. Refer to the 3740 Service Manual for correct replacement procedure.
qualified electrician must replace it with a properly grounded three-wire receptacle in accordance with the governing electrical code. Do not, under any circumstances, remove the grounding connector from the power plug. Do not use extension cords or adapters of any type. The power cord and plug must be intact and undamaged.

Battery Alarm Messages

The following alarm message (with no alarm tone) indicates the battery has approximately 30 minutes of power remaining. When this message appears, promptly recharge the battery:

LOW BATT

The following alarm message (with continuous alarm tone) appears for approximately 10 seconds, then the oximeter automatically shuts off. When this message appears, immediately connect the oximeter to the power supply (which is plugged into the AC power outlet).

PLEASE CONNECT
POWER SUPPLY
TO
RECHARGE BATTERY

CAUTION: Do not turn the oximeter on after the RECHARGE BATTERY alarm message is displayed without first connecting it to an AC power outlet. Damage to the lead-acid battery may result.

Recharging Periods

80% capacity = 4.0 hr (oximeter on or off)
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WARNING: Battery Replacement — Unauthorized personnel should not attempt to install, connect, or replace the battery of the oximeter. Removing the cover and/or faulty battery connections could be hazardous and voids the warranty. Reversing the battery connections could result in injury and permanently damage the circuitry. If trained technical personnel are not available, obtain service by calling Ohmeda. For proper operation, replace only with an Ohmeda Battery. Refer to the 3740 Service Manual for correct replacement procedure.
Calibrating the Oximeter

WARNING: Data Validity — Do not operate the oximeter unless it is properly calibrated. Inaccurate patient SpO₂ readings will result.

Whenever the following message appears on the display you should calibrate the oximeter:

±XX  
ADJUST POT AT BOTTOM  
HOLE TO VALUE = 0±.1  
HIT DISP SEL TO END  

XX = calibration reading

To calibrate, perform the following steps:

1. Remove probe from the oximeter (if connected).

2. Locate the calibration screw inside the calibration port on the bottom of the oximeter (see Figure 5-2).

![Figure 5-2. Oximeter Bottom](image)

3. Using a small, flat-blade screwdriver (plastic or nonconductive), slowly turn the calibration screw until the calibration reading on the display is 0.0 ± 0.1.

   Note: Turn the screw clockwise to increase the reading and counterclockwise to decrease the reading.

   If the oximeter does not calibrate, do not use it. Contact an authorized Ohmeda service representative for assistance. See the Repair Policy and Procedure section of this chapter.
4. After the reading stabilizes, press the Display Select key. The following message indicates the oximeter is ready for use:

CALIBRATION PASSED
SYSTEM OPERATIONAL

Repair Policy

This section outlines the repair policy for Ohmeda products. Make sure you follow these recommendations for efficient and reliable service.

Malfunctioning Equipment

Do not use malfunctioning equipment. Make necessary repairs, or have the equipment serviced by Ohmeda Service Personnel. After repair, test the equipment to ensure that it functions according to the manufacturer's published specifications.

Authorized Service

To ensure full reliability, have all repairs and service done by an Authorized Ohmeda Service representative. If this cannot be done, replacement and maintenance of those parts listed in the service manual may be undertaken by a competent, trained individual having expertise in the repair of devices of this nature. Replace damaged parts with components manufactured or sold by Ohmeda. After repair or service, test the unit to ensure that it complies with the manufacturer's published specifications.

WARNING: Electrical Shock Hazard — Only qualified service personnel should remove the cover from the oximeter.

Obtaining Service

Use the following information to obtain service for specific Ohmeda products:

Inside the USA:

Monitors
- Hospitals and Clinics: Contact the nearest Ohmeda Regional Service Office listed on the back cover for assistance.
- Nonhospitals: Contact the Ohmeda Service and Distribution Center (OSDC) at 800-999-6277.

Probes

Outside the USA—Monitors and Probes:
Contact the nearest Ohmeda Service Representative or office.
Packaging and Return Procedure

If returning equipment to Ohmeda, use the following procedures:

**Everyone:**
Please clean and properly decontaminate the equipment.

Package the equipment securely—in the original shipping container if possible—and enclose the following with the returned item:

- A letter describing the problem in detail.
- Warranty information (a copy of the invoice or other applicable documentation must be included).
- Purchase order number to cover repairs.
- "Ship To" and "Bill To" information.
- Person (Name, Telephone or Telex Number, and Country) to contact for questions and necessary repairs.

When Ohmeda's warranty is not applicable, repairs are made at Ohmeda's current list price for replacement parts, plus a reasonable labor charge.

**Inside the USA:**
Hospitals, clinics, and nonhospitals call OSDC (800-999-6277) for instructions for your specific product, then ship it prepaid to the following address:

Ohmeda Service and Distribution Center
7750 The Bluffs NW
Austell, GA 30001

**Outside the USA:**
Send to your local authorized service office.
Parts and Accessories

The following parts may be ordered through Ohmeda.

For Probes and Probe Accessories, see the Ohmeda Probes Manual.

<table>
<thead>
<tr>
<th>Description</th>
<th>US Hospital</th>
<th>US Nonhospital/ International</th>
</tr>
</thead>
<tbody>
<tr>
<td>Power Supplies (see Figure 5-3)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>100 Volt Power Supply (50/60 Hz, Wall Mount)</td>
<td></td>
<td>4610-030</td>
</tr>
<tr>
<td>120 Volt Power Supply (50/60 Hz, Desktop)</td>
<td>0380-1500-100</td>
<td>4610-032</td>
</tr>
<tr>
<td>120 Volt Power Supply (50/60 Hz, Wall Mount)</td>
<td>0380-1500-102</td>
<td>4610-031</td>
</tr>
<tr>
<td>220/240 Volt Power Supply (50/60 Hz, Desktop)</td>
<td>0380-1500-103</td>
<td>4610-033</td>
</tr>
<tr>
<td>220/240 Volt Power Supply (50/60 Hz, Desktop, Scandinavian)</td>
<td></td>
<td>7000-203</td>
</tr>
<tr>
<td>DC Vehicle Power Supply</td>
<td></td>
<td>6051-0000-028</td>
</tr>
<tr>
<td>Power Cords (see Figure 5-4)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Continental European</td>
<td></td>
<td>7000-200</td>
</tr>
<tr>
<td>United Kingdom</td>
<td></td>
<td>7000-201</td>
</tr>
<tr>
<td>North American</td>
<td>0208-0943-300</td>
<td>7000-088</td>
</tr>
<tr>
<td>Scandinavian</td>
<td></td>
<td>7000-203</td>
</tr>
</tbody>
</table>

Literature

<table>
<thead>
<tr>
<th>Description</th>
<th>US Hospital</th>
<th>US Nonhospital/ International</th>
</tr>
</thead>
<tbody>
<tr>
<td>3740 Operating/Maintenance Manual</td>
<td>0380-0900-074</td>
<td>1125-311</td>
</tr>
<tr>
<td>3740 Operation Instructions Decall</td>
<td>0380-0900-021</td>
<td>1125-100</td>
</tr>
<tr>
<td>3740 Reference Card</td>
<td>0380-0900-022</td>
<td>1125-101</td>
</tr>
<tr>
<td>3740 International Service Manual</td>
<td>0380-0900-081</td>
<td>1125-314</td>
</tr>
</tbody>
</table>
### Parts and Accessories (cont.)

<table>
<thead>
<tr>
<th>Description</th>
<th>US Hospital</th>
<th>US Nonhospital/International</th>
</tr>
</thead>
<tbody>
<tr>
<td>Miscellaneous</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Oxyhemoglobin Dissociation Curve Decal</td>
<td>0380-0900-011</td>
<td>1000-144</td>
</tr>
<tr>
<td>Battery*</td>
<td>0380-0200-129</td>
<td>4790-002</td>
</tr>
<tr>
<td>3740 Carrying Case</td>
<td>0380-1500-098</td>
<td>8125-008</td>
</tr>
<tr>
<td>3740 Carrying Case (heavy duty)</td>
<td>0380-1500-120</td>
<td>7900-253</td>
</tr>
<tr>
<td>Fuse* (Rear Panel F1, F2) 2A @ 250 V, 2 AG, Fast Acting</td>
<td>See note following</td>
<td>See following note</td>
</tr>
<tr>
<td>Fuse* (Power Supply Board, F1) 2A @ 250 V, 8 AG/AGX, Fast Acting, Instrument Type</td>
<td>See note following</td>
<td>See following note</td>
</tr>
</tbody>
</table>

* Refer to trained service personnel to replace this fuse. See the *3740 International Service Manual.*

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![Index of power supply models](image)

**Figure 5-3. Power Supply Models**
Figure 5-4. Power Cord Plugs
Notes
Appendix A: Product Specifications

This appendix covers the following information about the 3740 oximeter:

- Safety Classifications
- Oximeter Specifications
- Line Cord Specifications
- Power Supply Specifications

Safety Classifications

1. Type of protection against electric shock: Class I/International Electrical Power Source

2. Degree of protection against electric shock: Type BF

3. Degree of protection against ingress of liquids: Ordinary

4. Mode of Operation: Continuous

5. Recommended methods for cleaning: See Chapter 5/Maintenance and Service and appropriate sections in the Ohmeda Probes Manual 0380-099-084 (1000-304) for recommended cleaning procedures.

6. Degree of safety of application in the presence of flammable anesthetic mixed with air or with oxygen or nitrous oxide: Equipment not suitable for use in the presence of a flammable anesthetic mixture with air or with oxygen or nitrous oxide.

Oximeter Specifications

This section describes specifications important for servicing the oximeter. All specifications are nominal and subject to change without notice.

SpO₂ Accuracy

- 60% - 100% 2.4% (Overall Range)
- 90% - 100% 1.5%
- 80% - 89.9% 2.1%
- Below 60% Unspecified

Accuracy at 1 Standard Deviation

Note: These accuracy measurements are statistically derived and correlated to simultaneous oxygen averaging readings measured on an Ohmeda 3700 oximeter. The 3700 oximeter was calibrated with co-oximeters.
Appendix A/Product Specifications

Pulse Rate Accuracy

± 1.7% of current reading (assuming a constant pulse rate)
Accuracy at 1 Standard Deviation

Interfering Substances

- Carboxyhemoglobin may erroneously increase readings. The increase is approximately equal to the amount of carboxyhemoglobin present.
- Dyes, or any substances containing dyes that change usual arterial pigmentation, may cause depressed (lower) readings.
- Methemoglobin tends to drive the reading toward 85%.

Also see the Appendix B/References.

SpO2 Range

0% to 100%

Pulse Rate Range

- 40 to 235 beats per minute (BPM)
- Display Shows 0 to 255 beats per minute (BPM)

Alarm Limits and Default Values

- High SpO2 = 70% to 100%, Default = OFF (indicated by "--")
- Low SpO2 = 50% to 100%, Default = 90%
- High Pulse = 70 to 250 beats per minute, Default = OFF
- Low Pulse = 40 to 200 beats per minute, Default = OFF

Alarm and Pulse Volumes

- Alarm Volume Range = 1 to 10, Default = 4
- Pulse Volume Range = OFF to 10, Default = 4

Audible Alarms

- Volume Setting = 5: = 60 dB (1 meter in front of oximeter)
- Volume Setting = 10: = 68 dB (1 meter in front of oximeter)

Real-time Clock

- 24-Hour Clock - Time and Date

Oximeter Dimensions

- Height: 6.99 cm (2.75 in)
- Width: 20.32 cm (8.00 in)
- Depth: 22.30 cm (8.78 in)
- Weight: 2.5 kg (5.5 lb)

Analog Connector

- Type: 1/8-inch miniature phone plug
- Plug Polarity: tip = signal (+), sleeve = ground (-)
- Output Checks: 0, 0.5, 1.0 volts
CAUTION: Maximum Voltage—Apply no more than ±15 volts to any analog or digital connector. Exception: Pins 11, 18, and 25 of the rear panel RS-232C connector are TTL signals. Apply only 0 to +5 volts to these pins. The oximeter will be permanently damaged if these signals are connected to RS-232C voltage levels.

Digital Connector

- Connector Type: 25-pin, standard D female, RS-232C compatible
- Baud Rate: 1200 BPS, ASCII format
- Bits Per Character: 7
- Parity: Odd
- Stop Bits: 1
- Pin Out:
  - Pin 1 = Chassis ground
  - Pin 2 = Receive data
  - Pin 3 = Transmit data
  - Pin 7 = Signal ground
  - Pin 11 = See CAUTION following.
  - Pin 18 = See CAUTION following.
  - Pin 25 = See CAUTION following.

CAUTION: Pins 11, 18, and 25 of the rear panel RS-232C connector are TTL signals and must not be wired to RS-232C signals. The oximeter will be permanently damaged if these signals are connected to RS-232C voltage levels.

Electrical Requirements

- Oximeter Input Power Maximum: 15.5 volts AC ±10%, 50 or 60 Hz at 1.4 A

Note: The oximeter should be added to the hospital’s electrical safety program.

Leakage Current

- Maximum: 100 micro-amperes.

Fuses

- Rear Panel: F1, F2 Fuses: Fast Acting, 2 A Ø 250 volts, 2 AG
- Power Supply Board F1 Fuse: Fast Acting, 2 A Ø 250 volts, 8 AG/AGX 6.35 x 25.4 mm.

Battery

- Sealed lead-acid, 12-volt, 1.9 Amperé-Hours
- Charge Time: 80% capacity = 4.0 hours (unit on or off)
  100% capacity = 6.5 hours (unit on or off)
- Operation Time: = 3.5 hours from a fully charged battery to automatic shutoff (25% capacity, = 10.0 Vdc)
Appendix A/Product Specifications

- Low Battery Indicator: LOW BATT message appears at approximately 50% battery capacity (= 11.5 Vdc), approximately 30 minutes of operating time remain.

Environmental Requirements

Operating: Temperature: 32°F to 89°F (0°C to 32°C)
Relative Humidity: 0% to 100% (noncondensing)
Atmospheric Pressure: 500 mmHg to 812 hPa to 1083 hPa

Transport/Storage: Temperature: 14°F to 122°F (-10°C to 50°C)
Relative Humidity: 0% to 100% (noncondensing)
Atmospheric Pressure: 375 mmHg to 812 mmHg (500 hPa to 1083 hPa)

Note: At temperature extremes, the LCD read-out may exhibit reduced contrast, ghosting, or darkening. When returning from temperature extremes, allow the oximeter to return to room temperature before use.

Line Cord Specifications

<table>
<thead>
<tr>
<th></th>
<th>International</th>
<th>North American</th>
<th>Scandinavian</th>
</tr>
</thead>
<tbody>
<tr>
<td>Conductor Size</td>
<td>1.5 mm²</td>
<td>.75 mm²</td>
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<tr>
<td>Color Codes</td>
<td>Brown (line)</td>
<td>Black (line)</td>
<td>Brown (line)</td>
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<td></td>
<td>Blue (neutral)</td>
<td>White (neutral)</td>
<td>Blue (neutral)</td>
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<td></td>
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<td>Green (ground)</td>
<td>Green/Yellow (ground)</td>
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<td>9.8 ft</td>
<td>2.5 meters</td>
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<td>CEE-22</td>
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<td>Hospital Grade</td>
<td>CEE 7-7</td>
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<td></td>
<td>BS-1363A (United Kingdom)</td>
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</tbody>
</table>

Power Supply Specifications

- 100-Volt
  Input (AC power outlet): 100 Vac ±10%
  Output: 15.5 Vac @ 1.4 A, 50/60 Hz

- 120-Volt
  Input (AC power outlet): 120 Vac ±10%
  Output: 15.5 Vac @ 1.4 A, 50/60 Hz

A-4
3740 Operation and Maintenance Manual
Appendix A/Product Specifications

- 220/240-Volt
  Input: (AC power outlet): 220/240 Vac ±10% 50/60 Hz
  Output: 14.7/16.0 Vac @ 1.5/1.4 A

WARNING: Electric Shock Hazard. Use only with Ohmeda Model 15 power supplies of correct input voltage.

CAUTION: Equipment damage may result if the incorrect power supply is used.

Probe Specifications

See the Ohmeda Probes Manual.
Appendix B: References


Manual Correction Bulletin

To our 3700, 3700e, 3710, and 3740 customers:

The output you'll see on a device connected to the serial port—
printer, computer, etc.—is incorrectly described in your monitor's
manual. In all cases, blood oxygen saturation will appear as SaO2
or SAO2, rather than SpO2 or SPO2 as shown.
Manual Bulletin

To all users of our probes and sensors:

We have discontinued publication of the Ohmeda Probes Manual in all language versions.

Complete information for using Ohmeda probes appears in the User Instructions that accompany each of them.

If the Operation Manual or Service Manual you received with your instrument refers to the Ohmeda Probes Manual, refer to the User Instructions for the probe you’re using.

Please put this bulletin with your manual. Thank you.

Ohmeda Monitoring

Advertencia para añadir al manual

A todos los usuarios de nuestras sondas y sensores:

Hemos suspendido la publicación del Manual de Sondas Ohmeda en idiomas distintos del inglés.

En las Instrucciones para el Usuario que acompañan cada una de las sondas Ohmeda ya se suministra información completa acerca de cómo utilizarlas.

Si en el Manual de Funcionamiento o en el Manual de Servicio de Reparaciones que usted ha recibido con su instrumental se menciona el Manual de Sondas Ohmeda, acuda en cambio a las Instrucciones para el Usuario que vinieron con su sonda.

Por favor, guarde esta advertencia junto con su manual. Muchas gracias.

Ohmeda Monitoring

Bulletin du manuel

A tous les utilisateurs des différents capteurs Ohmeda :

La publication du Manuel d’utilisation des capteurs, dans toutes les langues, a été interrompue.

Des informations complètes d’utilisation accompagne chaque capteur Ohmeda.

Si le manuel d’utilisation et d’entretien que vous avez reçu se réfère au Manuel d’utilisation des capteurs, consultez, à la place, les informations fournies avec le capteur que vous utilisez.

Insérer ce bulletin dans le manuel. Merci.

Ohmeda Monitoring
Mitteilung für Handbuch

An alle Benutzer unserer Sonden und Sensoren:

Das Ohmeda Sondenhandbuch wird nicht mehr in übersetzten Versionen herausgegeben.

Vollständige Informationen zur Verwendung der Ohmeda Sonden beinhaltet die Gebrauchsanleitung, die jeder Sonde beiliegt.

Verweist das den Instrumenten beiliegende Bedienungs- und Wartungshandbuch auf das Ohmeda Sondenhandbuch, beziehen Sie sich statt dessen auf die der jeweiligen Sonde beiliegende Gebrauchsanleitung.

Diese Mitteilung bitte dem Handbuch hinzufügen. Danke.

Ohmeda Monitoring

Bollettino del manuale

A tutti gli utenti delle sonde e dei sensori della Ohmeda:

La pubblicazione, in tutte le lingue, del Manuale delle Sonde è stata interrotta.

Per informazioni complete sull'uso delle sonde della Ohmeda, fare riferimento alle istruzioni per l'utente allocate ad ogni sonda.

Se, con lo strumento, si è ricevuto un manuale operativo (o un manuale di assistenza) che fa riferimento al Manuale delle Sonde, si consiglia di consultare invece le istruzioni allocate alla sonda in uso.

Allegare questo bollettino al manuale.

Ohmeda Monitoring

Tillägg till handboken

Till användare av våra probes och givare:

Ohmeda Probes Handbok ges inte längre ut på något annat språk än engelska.

I användarhandböckerna som medföljer de olika instrumenten finns fullständig information om användning av probes från Ohmeda.

Om den användar- eller servicehandbok som medföljde utrustningen hänvisar till Ohmeda Probes Handbok, se användarhandboken för det instrument som du använder.

Förvara detta tillägg med din handbok.

Ohmeda Monitoring
APPENDIX H

REPRINT - INTERNATIONAL CLASSIFICATION OF ROP
SPECIAL ARTICLES

An International Classification of Retinopathy of Prematurity

As a result of advances in technology, particularly in life support systems capable of keeping tiny premature infants alive, and better observation of the premature infant fundus with improved ophthalmoscopic techniques, including the indirect ophthalmoscope, much has been learned about the early active stages of retinopathy of prematurity (ROP). This term is preferred because it can be utilized to describe all phases of the retinal changes observed in premature infants. The traditional term, retrolental fibroplasia, is inappropriate in the acute phase of this disorder, for it describes solely those later cicatricial changes which involve the eyes of only the most severely affected infants. Much of what has been learned over the past two decades about the disease in its modern form fails to fit with the Reese classification system, or any other classification system extant. Furthermore, the real incidence of the disease may be increasing although the evidence on this point is inconclusive and treatment of the disease in its active and cicatricial form has been advocated but it is not always clear whether disease stage is being treated and what the results of such treatment are. Hence, the need for a new classification system of the acute stages of ROP at this time, with a classification of the cicatricial stages to follow.

THE CLASSIFICATION

The system presented here differs from previous systems in that it permits the examiner to specify at the outset two parameters of the disease not recognized in other classification systems. These are the location of the disease in the retina and the extent of the developing vasculature involved. In addition, the examiner grades the retinopathy according to a system more consistent with current clinical observations.

Location

For the purpose of defining this variable, three zones of retinal involvement are recognized (Fig 1). Each zone is centered on the optic disc rather than the macula, contrary to standard retinal drawings. The new scheme was selected because normal retinal vascular growth proceeds outward from the disk toward the ora serrata in an orderly fashion. The first two zones occupy that portion of the fundus that lies behind a circle drawn using the disk as the center and the distance to the nasal ora serrata at the horizontal meridian as its radius. Therefore, any ROP that is circumferential must, by definition, fall into one of these two posterior zones.

Zone I (posterior pole or inner zone) consists of a circle (Fig 1) the radius of which subtends an angle of 30 degrees and extends from the disk to twice the distance from the disk to the center of the macula. The limits of the zone are consequently defined as twice the disk-fovea distance in all directions from the optic disk, i.e., an arc of 60 degrees.

Zone II extends from the edge of zone I peripherally to a point tangential to the nasal ora serrata (at 3 o’clock in the right eye, 9 o’clock in the left eye) and around to an area near the temporal anatomic equator. The temporal edge of zone II cannot be more accurately defined clinically as the anatomic landmarks needed to determine the equator in a premature infant are obscured. Indeed, these landmarks are sufficiently varied in humans to render precise locations difficult at any age.

Zone III is the residual crescent of retina anterior to zone II. This is the zone that is last vascularized in the premature eye and it is the zone, by common agreement of clinicians, most frequently involved with ROP.

Extent of the Disease (Fig 1)

This is specified as hours of the clock. As the
Fig 1. Scheme of retina of right eye (RE) and left eye (LE) showing zone borders and clock hours employed to describe location and extent of retinopathy of prematurity.

Staging the Disease

In addition to the above two parameters, the final one to be specified is the level of abnormal vascular response observed. Here, four stages are recognized and staging for the eye as a whole is by the most severe manifestation present. However, for purposes of recording the complete examination, each stage is defined and the extent of each stage by clock hours is recorded.

Stage 1. Demarcation Line (Fig 2). This line is a thin but definite structure that separates the avascular retina anteriorly from the vascularized retina posteriorly. There are recognizable abnormal branching or arcing of vessels leading up to it. It is relatively flat, lies within the plane of the retina and is white in color. There have been described vascular changes that can be apparent prior to the development of the demarcation line. However, these more subtle vascular changes vary considerably, cause no known ocular morbidity by themselves, and are difficult to quantitate. They may be noted, but do not justify a diagnosis of early ROP.

Stage 2. Ridge (Fig 3). The line of stage 1 now has grown, has height and width, occupies a volume, and extends up out of the plane of the retina. The ridge may change in color from white to pink and vessels may leave the plane of the retina to enter it. Small isolated tufts of new vessels lying on the surface of the retina may be seen posterior to this ridge structure. Such lesions do not constitute the fibrovascular growth that is a necessary condition for stage 3.

Stage 3. Ridge with Extraretinal Fibrovascular Proliferation (Fig 4). To the ridge of stage 2 is added the presence of extraretinal fibrovascular proliferative tissue. The characteristic locations where this proliferating tissue may be found are: (1) contiguous to the posterior aspect of the ridge, causing a ragged appearance of the ridge as proliferation becomes more extensive; (2) immediately posterior to the ridge but not always appearing to be connected with it; (3) into the vitreous perpendicular to the retinal plane. Fibrovascular proliferation may be seen in any or all of these locations in stage 3 ROP.

Stage 4. Retinal Detachment (Fig 5). To the above is added unequivocal detachment of the retina. It may be caused by an exudative effusion of fluid, traction, or both, even in this early stage. In any case, the examiner should specify its location, extent, and nature. It may be particularly difficult to differentiate shallow posterior retinal detachments, as the loss of choroidal pattern may be subtle and difficult to distinguish through the increasing vitreous haze of severe disease. Serial examinations may be required to be certain of a true detachment. It should be emphasized that the presence of elevated retinal vessels running from the retinal plane...
to the height of the ridge does not constitute a posterior detachment.

**"PLUS" DISEASE**

Progressive vascular incompetence, occurring along with the changes described at the edge of the abnormally developing retinal vasculature, is noted by increasing dilation and tortuosity of the peripheral retinal vessels, iris vascular engorgement, pupillary rigidity, and vitreous haze. When, and only when the vascular changes are so marked that the posterior veins are enlarged and the arterioles tortuous, then the designation "plus" is added to the ROP stage number (Fig 6). For example, the ridge of stage 2 ROP combined with posterior vascular dilation and tortuosity would be written, stage 2+ ROP. When the ROP is located in zone I or posterior zone II and "plus" disease is present, progression may be very rapid.

**RECORDING THE RESULTS**

For purposes of recording the results of the examination, the appended examination record is recommended (Table). The scheme is computer compatible.

**PROBLEMS CONFRONTED**

The committee recognizes that no classification, including the present one, is perfect. During the course of our deliberations, several problem areas were encountered for which approximate solutions were developed while realizing that, with time and experience in the use of the classification, better solutions for its users will emerge. The problems were:

**Definition of Zone**

Anatomic landmarks, other than the disk and the ora, may be difficult to discern in the premature eye and therefore, the boundaries of the zones I and II for example, are only approximate. The same can be said of zones II and III, except that if vascularization has reached the nasal ora, any disease found elsewhere is by definition in zone III. The committee recommends that when doubt exists as to the appropriate zone to locate the disease, it be located in the more posterior zone.

**Stage 3 Disease**

The committee clearly recognizes the need to further subdivide stage 3 disease for its potential prognostic significance. To do so, it chose as its yardstick the amount of fibrovascular proliferative tissue present. If only limited amounts can be rec-ognized by the examiner, this would constitute "mild" stage 3 (Fig 7). If, on the other hand, significant amounts of tissue are seen infiltrating the vitreous, proliferating posterior from the ridge, then this is "moderate" stage 3 (Fig 8). Finally, if massive infiltration of the tissues surrounding the ridge is occurring, the threshold for "severe" stage 3 has been reached (Fig 9).

**Overlap with Cicatricial Disease**

It is clearly recognized that in this classification, traction detachment forms part of the description of stage 4. Classically, this has been reserved for the cicatricial phase of the disease. Retinopathy of prematurity is a continuum and not easily fitted into any arbitrary man-made scheme. Nevertheless, the description of stage 4 would be incomplete without allowing for the occurrence of traction detachments as part of it. For the time being, the committee recommends the retention and use of the Reese classification of cicatricial disease to describe disease changes beyond those described in this classification.

**SPONSORSHIP**

The classification is the product of the joint effort of 23 ophthalmologists from 11 countries. Although the committee was an ad hoc body, it obtained sponsorship for its deliberations from the American Academy of Ophthalmology, the American Academy of Pediatrics, the American Association of Pediatric Ophthalmology and Strabismus, the National Eye Institute, the Division of Maternal and Child Health of the Bureau of Health Care Delivery and Assistance, the March of Dimes, the Alberta Heritage Foundation for Medical Research, and Ross Laboratories. In no small measure, this support has provided the encouragement necessary to complete work on this classification. The success or failure of this classification will be judged by its use within the ophthalmologic and pediatric communities.

**SUMMARY CONCLUSIONS**

The unifying principle underlying this classification system is: The more posterior the disease and the greater the amount of involved retinal vascular tissue, the more serious the disease. The staging of the disease at any given location expresses the natural history and evolution of events at the border between vascularized and avascular retina. The classification system is designed to permit the examiner full latitude in transcribing his observations so that they will be immediately inter-
Fig 2. Fundus photograph and line drawing show demarcation lines of stage 1 retinopathy of prematurity.

Fig 3. Fundus photograph and line drawing show development of ridge characteristic of stage 2.

Fig 4. Fundus photograph and line drawing of extra-retinal fibrovascular proliferative tissue of stage 3.

Fig 5. Fundus photograph and line drawing of shallow exudative retinal detachment characteristic of stage 4 involvement.
Fig 6. Fundus photograph of posterior venous dilation and arteriolar tortuosity characteristic of "plus" disease.

Fig 7. Fundus photograph and line drawing show amount of extraretinal fibrovascular proliferative tissue judged to be "mild" stage 3 retinopathy of prematurity.

Fig 8. Fundus photograph and line drawing of "moderate" proliferation of extraretinal fibrovascular tissue from ridge.

Fig 9. Fundus photograph and line drawing of extraretinal fibrovascular proliferation of amount of tissue judged to be characteristic of "severe" stage 3 retinopathy of prematurity.
TABLE. Retinopathy of Prematurity (ROP). Ophthalmic Examination Record

**BIOGRAPHICAL DATA**
- Name ___________________________  Hospital # ___________________________
- Birthdate (MM/DD/YY) __/__/__  Sex (M/F) __
- Birthweight (grams) __________  Gestational Age (weeks) ______
- Multiple births (Singles, Twins, Triplets+) ______

**EXAMINATION**
- Date of Exam __/__/__  Examiners Initials or # ________

---

**NOTE**
- Mark with 'X'

---

**STAGE AT CLOCK HOURS**

---

Mark highest stage at every clock hour

- If Stage 3: [ ] mild, [ ] moderate, [ ] severe
- If Stage 4: [ ] exudative, [ ] tractional, [ ] combined

---

**OTHER FINDINGS**
- Mark with 'X'

- O.R.  A Dilatation/tortuosity posterior vessels [ ]
- O.R.  B Iris vessel dilatation [ ]
- O.R.  C Pupil rigidity [ ]
- O.R.  D Vitreous haze [ ]
- O.R.  E Hemorrhages [ ]

---

**Circumferential MLP (Roosa, 1993)**
- Mark with 'X'

- O.R.  I. Small mass opaque tissue in periphery without detachment [ ]
- O.R.  II. Larger mass opaque tissue in periphery with localized detachment [ ]
- O.R.  III. Larger mass in periphery with traction held to disc [ ]
- O.R.  IV. Retrolental tissue covering part of pupil [ ]
- O.R.  V. Retrolental tissue covering entire pupillary area [ ]

**COMMENTS:**

---

**Signature**

---

*Format permits complete recording of detailed examination results both graphically employing retinal drawing and numerically for later analysis if desired.*
eligible to another examiner who may not have had the opportunity to examine the specific infant.

ACKNOWLEDGMENT

This work was supported in part by the Alberta Heritage Foundation for Medical Research Conference Support Grant 1932: Public Health Service Research Grants EY03513, EY01723, EYO3473; National Eye Institute and Grant 5C1-123373. US Department of Health and Human Services. Public Health Service. Division of Maternal and Child Health. Bethesda, MD; March of Dimes Birth Defects Foundation. White Plains, NY, and Ross Laboratories. Columbus, OH.

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REFERENCE


FIFTH ASIAN CONGRESS OF PAEDIATRICS

The Fifth Asian Congress of Paediatrics will be held in Kuala Lumpur, Malaysia on August 5-9, 1985.

Further information may be obtained from:
The Organising Secretary
5th Asian Congress of Paediatrics
4th Floor, MMA House
124 Jalan Pahang
Kuala Lumpur 02-14
Malaysia
APPENDIX I

STANDARD PHOTOGRAPHS
APPENDIX I

STANDARD PHOTOGRAPHS

[to be distributed]

PLUS DISEASE

MILD, MODERATE, AND SEVERE STAGE 3 ROP

MILD, MODERATE, AND SEVERE IRIS VESSEL DILATATION
APPENDIX J

STOP-ROP SAMPLE DATA FORMS
APPENDIX J
DATA FORMS

CONTENTS:

STOP 00  Patient register Form
STOP 01  Baseline, Eligibility and Randomization Form
STOP 02  Retinal Examination Form
STOP 03  Weekly Outcome Form
STOP 04  Three Month Ophthalmic Outcome Examination Form
STOP 05  Three Month Neonatal Outcome Form
STOP 06  Protocol Anomaly Form
STOP 07  Transfer Form
STOP 08  Adverse Experience Form
STOP 09  Revised Denver Prescreening Developmental Questionnaire
STOP 10  Initial Discharge Form
STOP 10A Parent/Caretaker Interview
STOP 11  Rehospitalization Form
STOP 12  Death
STOP 13  CRYO Outcomes Prediction for STOP-ROP Enrollees
To be completed for each infant - at the time the infant first reaches Prethreshold as modified from CRYO-ROP.

<table>
<thead>
<tr>
<th>1) Name</th>
<th>2) Hospital ID #</th>
<th>3) Date of Birth M/D/Y</th>
<th>4) Birth Weight (in grams)</th>
<th>5) Gender (M-male, F-female, A-ambiguous)</th>
<th>6) Race of Mother (in weeks)</th>
<th>7) Gest. Age (M/D/Y)</th>
<th>8) Date of Exam</th>
<th>9) Examination Results</th>
<th>10) Right Eye</th>
<th>11) Left Eye</th>
<th>12) Pulse Oximetry Saturation</th>
<th>13) Oxygen Code</th>
<th>14) Exclusion Criteria</th>
<th>15) Treatment Assignment</th>
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</table>

**Notes:**

1. This column will not copy through to page two of NCR form, to protect confidentiality of patient.
2. Race Code: W-White, not of hispanic origin, B-Black, not of hispanic origin, H-Hispanic, A-Asian, P-Pacific Islander, N-Native American, O-Other, specify
3. Oxygen Code: 0-No oxygen, 1-Nasal cannula or hood, 2-Nasal CPAP (prongs) 3-ETT (vent or CPAP), 4-Other, specify
4. Exclusion Criteria: 0-No exclusion criteria apply, 1-Parent refusal, 2-Physician refusal, 2-Infant enrolled in conflicting study, 31-Sats >94% in room air, 32-Too ill to maintain sats >96% in O2, 4-Infant transferred to non-STOP-ROP center, 5-Fatal congenital anomaly, 6-Congenital eye anomaly, 7-Second exam does not confirm Prethreshold, 8-Threshold ROP OU, 9-Unable to maintain follow-up if enrolled, 99-Other, specify on log.
5. Treatment Assignment code: C-Conventional, S-Supplemental, H-Hope-Rop.
MODIFIED CRYO-ROP DEFINITION OF PRETHRESHOLD ROP

The modified CRYO-ROP definition of prethreshold ROP is used to define zones and stages.

Prethreshold ROP is defined as follows:

ZONE 1
- Any number of clock hours of stage 1 or 2 without PLUS disease

ZONE 2
- Any number of clock hours of stage 3 without PLUS disease
- Any number of clock hours of stage 2 with PLUS disease
- PLUS disease with less than 5 contiguous and less than 8 composite clock hours of stage 3

ZONE 3
- ROP that is in Zone 3 cannot be Prethreshold
Complete this form to confirm eligibility for infants with Prethreshold ROP. Answer questions 1-13. If randomizing by telephone, call the Coordinating Center at 301/299-8655 and complete questions 14-20 while on the telephone. If randomizing by sealed envelope alone, complete questions 14-20, and fax questions 1-20 to the Coordinating Center. For both methods of randomization, complete question 21 and mail original form to the Coordinating Center.

1. Date of Birth __________ M D Y

2. Infant’s Gender
   (M-male
   F-female
   A-ambiguous) ________________

3. Birth weight __________ grams

4. Gestational age at birth __________ and __/7 days
   weeks

5. Race or ethnic background of mother
   (W-White, not of Hispanic origin
   B-Black, not of Hispanic origin
   H-Hispanic
   A-Asian
   P-Pacific Islander
   N-Native American
   O-Other, specify __________________) __

6. FIRST STUDY EXAMINATION
   a) Date __________ M D Y
   b) Time of first exam
      (24 hour clock) __________ : __________
      Hours Minutes
      Right Eye Left Eye
   c) Study Eye Status
      (1-Before Prethreshold
      2-Prethreshold
      3-Threshold or beyond
      4-Fully vascularized or Zone 3
      9-Other, specify __________________)

   __________________
   Name of Ophthalmologist
d) Cert. #

7. CONFIRMATORY STUDY EXAMINATION
   a) Date __________ M D Y
   b) Time of second exam
      (24 hour clock) __________ : __________
      Hours Minutes
      Right Eye Left Eye
   c) Study Eye Status
      (1-Before Prethreshold
      2-Prethreshold
      3-Threshold or beyond
      4-Fully vascularized or Zone 3
      9-Other, specify __________________)

   __________________
   Name of Ophthalmologist
d) Cert. #

8. Growth Assessment
   a) Current weight __________ grams
   b) Length __________ cm
   c) Head circumference __________ cm

9. Apnea Assessment
   a) Is the infant on an apnea monitor?
      (N-No, Y-Yes) __
   b) Is the infant on any methylxanthines?
      (N-No, Y-Yes) __
   c) Number of apnea/bradycardia episodes requiring stimulation in past 24 hours __________
10. Respiratory Support
   a) Is the infant currently on oxygen? (1-No, skip to c)
      (2-Yes, but intermittently
      3-Yes, on nasal cannula
      4-Yes, on hood
      5-Yes, on nasal CPAP [prongs]
      6-Yes, on ETT (vent or CPAP)
      9-Yes, other, specify ____________________

   b) Pulse oximeter saturation on O₂ ____________________

   c) Pulse oximetry in room
      air recorded today

      If infant is on oxygen with sits ≥90%,
      discontinue for 20 minutes before recording
      saturation. If saturation drops below 85%,
      return to ordered oxygen immediately, and
      record 84%.

      Record 993 if the infant is medically unstable
      to place in room air.

11. Is the infant on diuretics?
   (1-No
    2-Intermittently
    3-Daily) ____________________

12. Within the past week, has the infant received
    steroids that were other than topical?
   (1-No
    2-Systemic for BPD
    3-Systemic, not for BPD
    4-Inhaled
    5-Unknown, enrolled in masked steroid
       clinical trial) ____________________

13. All of the following must be verified prior to
    randomization. Code: (N-No, Y-Yes)

      To be eligible, question 13.a-d must be answered
      Yes and either e or f must be answered Yes.

      a) Consent form for randomization
         signed by parent or legal guardian,
         infant not on conflicting study, AND
         infant likely available for study followup.

      b) Does the neonatologist caring
         for the infant agree that both
         study saturation ranges (89-94%
         and 96-99%) can be attained
         without medical complications?

          [Signature of Neonatologist]
          Cart. #
          (if applicable)

      c) A pulse oximeter and laptop are
         available within 24 hours
         for full time study use

      d) Infant was verified to have
         Prethreshold ROP by two examiners
         at least one of whom was certified

      e) Infant was first diagnosed with
         Prethreshold ROP within the
         the past 24 hours
         [if Yes, skip to 14]

      f) Late Entry. The last certified
         ophthalmic examination which
         confirmed Prethreshold ROP was
         performed within the past 48
         hours but the first exam diagnosing
         Prethreshold ROP occurred more
         than 24 hours ago

14. Is infant eligible to be randomized?
    (N-No, Y-Yes) ____________________

15. Method of randomization
    (1-Telephone call,
    2-No telephone call) ____________________
STOP-ROP
BASELINE, ELIGIBILITY AND RANDOMIZATION [01]

STOP-ROP ID: ____________

NOTE: Certified ophthalmologist must complete Retinal Examination Form (STOP 02) and provide the following for last certified examination:

<table>
<thead>
<tr>
<th>ROP SEVERITY</th>
<th>No stage</th>
<th>Stage 1</th>
<th>Stage 2</th>
<th>Stage 3</th>
<th>Stage 4/5</th>
</tr>
</thead>
<tbody>
<tr>
<td>Plus disease</td>
<td>N/A</td>
<td>-</td>
<td>+</td>
<td>-</td>
<td>+</td>
</tr>
<tr>
<td>Zone 1</td>
<td>&lt;P</td>
<td>P</td>
<td>T</td>
<td>P</td>
<td>T</td>
</tr>
<tr>
<td>Zone 2</td>
<td>&lt;P</td>
<td>&lt;P</td>
<td>&lt;P</td>
<td>&lt;P</td>
<td>P</td>
</tr>
<tr>
<td>Zone 3</td>
<td>&lt;P</td>
<td>&lt;P</td>
<td>&lt;P</td>
<td>&lt;P</td>
<td>&lt;P</td>
</tr>
</tbody>
</table>

Key:

+  plus disease (at least 2 quadrants)
3+ <5 contiguous and <8 composite clock hours of stage 3 with plus disease
3++ ≥5 contiguous hours or ≥8 composite clock hours of stage 3 with plus disease
<P less than Prethreshold
P Prethreshold
T Threshold
> T Beyond Threshold

STRATUM DEFINITIONS

<table>
<thead>
<tr>
<th>STRATUM A</th>
<th>Fellow Eye</th>
</tr>
</thead>
<tbody>
<tr>
<td>One Eye</td>
<td></td>
</tr>
<tr>
<td>Prethreshold ROP any zone</td>
<td>AND</td>
</tr>
<tr>
<td>OR Prethreshold ROP zone 1</td>
<td>AND</td>
</tr>
<tr>
<td>AND Prethreshold ROP any zone</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>STRATUM B</th>
<th>Fellow Eye</th>
</tr>
</thead>
<tbody>
<tr>
<td>One Eye</td>
<td></td>
</tr>
<tr>
<td>Prethreshold ROP zone 2</td>
<td>AND</td>
</tr>
<tr>
<td>OR Prethreshold ROP zone 2</td>
<td></td>
</tr>
<tr>
<td>AND Lead than Prethreshold ROP (includes no ROP)</td>
<td></td>
</tr>
</tbody>
</table>

16. PRETHRESHOLD SEVERITY STRATUM .............................................. (Code A or B) ___

17. TREATMENT ASSIGNMENT
(C-Conventional, S-Supplemental) ..................................................... ___

18. ASSIGNED STOP-ROP ID NUMBER ................................................. ____________

19. Randomization Completed

Date ................................................................. M D Y

Time (24 hour clock) ........................................ Hours: Minutes

Signature of Study Center Coordinator ____________________________

ON COMPLETION OF ITEMS 1-21, MAIL TO: DATA MANAGER, STOP-ROP COORDINATING CENTER, 11325 SEVEN LOCKS ROAD, SUITE 214, POTOMAC, MD 20854. IF RANDOMIZING BY SEALED ENVELOPE ALONE, ALSO FAX FORM TO COORDINATING CENTER AT 301/299-3991 ON COMPLETION OF ITEMS 1-20.

STOP 01 V03, 01/01/96
21. COMPLETE THIS FORM USING DATA OBTAINED AT TIMES SHOWN

<table>
<thead>
<tr>
<th>Randomization date:</th>
<th>READING 1 (4 hrs prior to randomization)</th>
<th>READING 2 (8 hrs post randomization)</th>
<th>READING 3 (16 hrs post randomization)</th>
<th>READING 4 (24 hrs post randomization)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Randomization time:</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

| a) Month/Day/Year |                                         |                                      |                                       |                                      |
|-------------------|-----------------------------------------|--------------------------------------|                                       |                                      |

| b) Hour: Minutes (24 hour clock) |                                         |                                      |                                       |                                      |
|---------------------------------|-----------------------------------------|--------------------------------------|                                       |                                      |

| c) Is infant Receiving Oxygen by hood? N = No, Skip to e, Y = Yes |                                         |                                      |                                       |                                      |
|------------------------------------------------------------------|-----------------------------------------|--------------------------------------|                                       |                                      |

| d) Oxygen Concentration (%) |                                         |                                      |                                       |                                      |
|----------------------------|-----------------------------------------|--------------------------------------|                                       |                                      |

| e) Is infant Receiving Oxygen by Cannula? N = No, Skip to h, Y = Yes |                                         |                                      |                                       |                                      |
|------------------------------------------------------------------|-----------------------------------------|--------------------------------------|                                       |                                      |

| f) Cannula Oxygen Concentration (%) |                                         |                                      |                                       |                                      |
|-----------------------------------|-----------------------------------------|--------------------------------------|                                       |                                      |

| g) Cannula Oxygen Flow L/min |                                         |                                      |                                       |                                      |
|-------------------------------|-----------------------------------------|--------------------------------------|                                       |                                      |

| h) Is the infant on vent? N = No, if No skip to l, Y = Yes |                                         |                                      |                                       |                                      |
|----------------------------------------------------------|-----------------------------------------|--------------------------------------|                                       |                                      |

| i) Vent PIP/PEEP, cm H₂O |                                         |                                      |                                       |                                      |
|--------------------------|-----------------------------------------|--------------------------------------|                                       |                                      |

| j) Vent Rate/min |                                         |                                      |                                       |                                      |
|------------------|-----------------------------------------|--------------------------------------|                                       |                                      |

| k) Oxygen Concentration (%) |                                         |                                      |                                       |                                      |
|----------------------------|-----------------------------------------|--------------------------------------|                                       |                                      |

| l) Is the infant on CPAP? (N = No, skip m and n, Y = Yes) |                                         |                                      |                                       |                                      |
|----------------------------------------------------------|-----------------------------------------|--------------------------------------|                                       |                                      |

| m) Oxygen Concentration (%) |                                         |                                      |                                       |                                      |
|----------------------------|-----------------------------------------|--------------------------------------|                                       |                                      |

| n) CPAP, cm H₂O |                                         |                                      |                                       |                                      |
|----------------|-----------------------------------------|--------------------------------------|                                       |                                      |

- Submit original to Coordinating Center by mail.
- RETAIN COPY FOR YOUR FILES.

REMINDER: Enter STOP-ROP ID Number, Name Code and Date of Randomization in the RANDOMIZATION LOG.
Certified ophthalmologist: complete entire form at Baseline and when each eye first reaches an endpoint.

1. Visit number ............... (Code 00-Baseline, 01-Week 1, 02-Week 2, 88-Treatment Completion) __________

2. Date of Examination ___________________________ M D Y

3. EYE EXAMINATION SKETCH (to be completed by certified ophthalmologist)

Provide Findings by Clock Hours
[Mark highest stage in each sector]

(CODE: 0-No information 5-Avascular
1-Demarcation line 6-Incompt. vessels
2-Ridge 7-Fully vascularized
3-Extraretal prolif 8-Regressing
4-Retinal detach 9-Regressed)

STOP 02 V02, 01/01/96
STOP-ROP
RETINAL EXAMINATION FORM [02]

STOP-ROP ID: [Center #] [Hosp. Code] [Patient #]

4. Stage 3 disease .................................. (Code: 0-None, 1-Mild, 2-Moderate, 3-Severe)  
   RIGHT EYE  LEFT EYE

5. Hemorrhages (vitreous/retinal) ... (Code: 0-None, 1-Small, retina, 2-Large, retina, 3-Vitreous) 
   RIGHT EYE  LEFT EYE

6. Is active ROP present in Zone 1 or Zone 2? ............... (Code N-No Skip to 8, Y-Yes) 
   RIGHT EYE  LEFT EYE

7. STOP-ROP ophthalmic summary of active ROP
   a) Lowest zone with ROP ...................................  
   RIGHT EYE  LEFT EYE
   b) Worst stage in lowest zone with ROP ................. 
   RIGHT EYE  LEFT EYE
   c) Total clock hours of worst stage in lowest zone with ROP 
   RIGHT EYE  LEFT EYE
   d) Longest number contiguous hours of worst stage in lowest zone with ROP 
   RIGHT EYE  LEFT EYE
   e) Plus disease (at least two quadrants) ................ 
   (N-No, Y-Yes)  
   RIGHT EYE  LEFT EYE

8. Study Eye Status (use codes 01-99 below) ......................  
   RIGHT EYE  LEFT EYE

   Adverse Eye Endpoint
   01) * Threshold ROP *
   02) * Beyond Threshold ROP *  
      (retinal fold, detachment, or obscuring hemorrhage)

   Favorable Eye Endpoint
   03) * Fully Vascularized within 1 disc diameter of ora  
       (may be quiescent old disease present) - No active ROP *
   04) ** In zone 3 for the 2nd time in a row or more: immature vessels 
       or less than Prethreshold ROP with/without regression **

Eye not yet at endpoint - continue to examine weekly
   05) Zone 3 for the 1st time: immature vessels or less than Prethreshold ROP with/without regression
   06) Zone 1 or 2: immature vessels or less than Prethreshold ROP with/without regression
   07) Prethreshold present with or without some regressing ROP
   08) Status post cryo or laser (no detachment)
   99) Other (comment) 

   * If present for FIRST TIME, submit Retinal Examination form
   ** If in zone 3 for the SECOND TIME, submit Retinal Examination form

THRESHOLD VERIFICATION

Complete the first time answer to question 8 = 01 or 02 for an eye

Verification of Threshold disease or retinal fold or detachment was performed by: ____________________________

Name of Certified Ophthalmologist

Certification Number 9. [ ]

Signature of Examining Certified Ophthalmologist

Certification Number 10.

Signature of Study Center Coordinator

Certification Number 11.
WEEKLY OUTCOME FORM [03]

STOP-ROP ID: 
Center # Hosp. Code Patient #

HOSPITAL ID NUMBER: _________________________

NAME CODE: _________________________

1. Date of Examination ........................................................... M D Y

2. Status of infant at time of form completion
   (1) Routine weekly examination prior to oxygen treatment completion
   (2) Routine treatment completion: both eyes at endpoint, and at least 2 weeks post randomization
   (3) Treatment prematurely terminated, but weekly follow-up continues
   (4) Treatment prematurely terminated and weekly follow-up will not continue
   (9) Other, please specify ____________________________

3. Follow-up visit number ........................................ (Code: 01-week 1, 02-week 2, 99-not weekly exam) __________

RESPIRATORY SUPPORT

4. Is the infant on oxygen? .................................................. (N-No, Y-Yes) ______
   If NO, enter the last date the infant received oxygen and skip to e

   a) Mode of delivery
      (1) Yes, but intermittently, skip to d
      (2) Yes, on naso cannula
      (3) Yes, on hood
      (4) Yes, on nasal CPAP [prongs]
      (5) Yes, on ET (vent or CPAP)
      (9) Yes, other, specify ____________________________

   b) Oxygen concentration .................................................. % ______

   c) If on cannula, enter cannula flow .................................... L/min ___ • ___

   d) Pulse oximeter saturation on O₂ .....................................

   e) Pulse oximetry in room air recorded today

If infant is on oxygen with sats ≥90%, discontinue for 20 minutes before recording saturation. If saturation drops below 85% return to ordered oxygen immediately, and record 84%.

Record 999 if the infant is too medically unstable to place in room air.

APNEA ASSESSMENT

5. a) Is the infant on an apnea monitor? .................................. (N-No, Y-Yes) ______

   b) Number of apnea and/or bradycardia episodes requiring stimulation recorded in past 24 hours __________

   c) Is the infant on any methylxanthines? .............................. (N-No, Y-Yes) ______

PHARMACOLOGICAL SUPPORT

6. Is the infant on diuretics?
   (1) No
   (2) Intermittently
   (3) Daily

STOP 03 V03, 01/01/96
7. Within the past week, has the infant received any steroids other than topical? (1-No, 2-Yes, systemic for BPD, 3-Yes, systemic, not for BPD, 4-Yes, inhaled, 5-Unknown, infant enrolled in masked steroid clinical trial)

GROWTH ASSESSMENT

8. a) Current weight ................................................................. grams
   b) Length ................................................................. cms
   c) Head circumference ............................................... cms
      Right eye
      Left eye

9. Study Eye Status (use codes 01-99 below) ........................................

The ophthalmologist will use conventional eye examination form/chart notes to record the weekly eye findings for clinical purposes and determine the current eye status as below. The purpose is to determine if an eye has reached either the adverse or favorable endpoint, or needs to continue in follow-up. Confirm study eye status with the ophthalmologist and record below. If answer is 1, 2, 3, or 4, Retinal Examination form must be submitted.

Adverse Eye Endpoint
01) * Threshold ROP *
02) * Beyond Threshold ROP *
   (retinal fold, detachment, hole or obscuring hemorrhage)

Favorable Eye Endpoint
03) * Fully Vascularized within 1 disk diameter of ora
   (may be quiescent old disease present) - No active ROP *
04) ** In zone 3 for the 2nd time in a row or more: immature vessels or less than Prethreshold ROP with/without regression **

Eye not yet at endpoint - continue to examine weekly
05) Zone 3 for the 1st time: immature vessels or less than Prethreshold ROP with/without regression
06) Zone 1 or 2: immature vessels or less than Prethreshold ROP with/without regression
07) Prethreshold present with or without some regressing ROP
08) Status post cryo or laser (not detached)
09) Other (comment)

* If present for FIRST TIME, submit STOP 02 form *
** If in zone 3 for the SECOND TIME, submit STOP 02 form **

10. Was ophthalmologist masked to treatment assignment at the time of the exam? (N-No, Y-Yes)

11. Name of Examining Certified Ophthalmologist

12. Has a new episode of any of the following occurred since completion of the last STOP-ROP weekly outcome form? (N-No, Y-Yes)

Excessive Apnea and Bradycardia (number of episodes in a 24 hour period is triple the baseline and > 3)
Documented hyperoxia (paO₂ >120 torr) while in the target range
Documented hypoxia (paO₂ <45 torr) while in the target range
Seizures (new onset)
Necrotizing Enterocolitis
Pneumonia/Sepsis with positive culture or requiring antibiotic treatment for more than five days
Other serious events or events thought to be treatment-related

Reminder: If YES, complete an Adverse Experience (STOP 08) for each item.

13. Certification Number

Signature of Study Center Coordinator

Date
THREE MONTH OPHTHALMIC OUTCOME
EXAMINATION FORM [04]

(To be completed by a Certified Ophthalmologist)

STOP-ROP ID: _____________________________

Center #  Hosp. Code  Patient #

HOSPITAL ID NUMBER: _____________________________

NAME CODE: _____________________________

1. Date of Examination _____________________________  M  D  Y

2. Is this visit outside the three-month examination window? [10-14 weeks post due date] (N-No, Y-Yes) ___

   If YES, code REASON:

   (1-Infant unable to maintain scheduled appointment due to illness or hospitalization,
   2-Parents unable to maintain scheduled appointment,
   3-Certified ophthalmologist not available,
   9-Other, specify _____________________________)

   RIGHT EYE  LEFT EYE

3. Vitreous opacity on or near visual axis

   a) Hemorrhage .... (0-Absent, 1-Slight, 2-Moderate, 3-Extensive, 9-View obscured) ___ ___

   b) Membranes/organization (0-Absent, 1-Slight, 2-Moderate, 3-Extensive, 9-View obscured) ___ ___

4. Fundus

   a) Macular heterotopia .... (0-Absent, 1-Questionable, 2-Present, 9-View obscured) ___ ___

   b) Optic nerve atrophy .... (0-Absent, 1-Questionable, 2-Present, 9-View obscured) ___ ___

   c) Other _____________________________ (0-Absent, 1-Present, 9-View obscured) ___ ___

   If other is present in RIGHT EYE, specify: _____________________________

   If other is present in LEFT EYE, specify: _____________________________

STOP 04 V03, 01/01/96
STOP-ROP
THREE MONTH OPHTHALMIC OUTCOME EXAMINATION [04]

STOP-ROP ID:  [Table]
Center #  Hosp. Code  Patient #

RIGHT EYE  LEFT EYE

d) Retina

1) Fold ..........................  (0-Absent, 1-Present*, 9-View obscured)  \____  \____
   * If present, record clock hour orientation and extent.
   Always indicate clock hour limit clockwise.
   a. Radial  ......................  (clock hours)  \_____ to \_____
   b. Zones involved  (0-Absent, 1-Present)  \___ Z1 \___ Z2 \___ Z3  \___ Z1 \___ Z2 \___ Z3
   c. Circumferential .............  (clock hours)  \_____ to \_____
   d. Zones involved  (0-Absent, 1-Present)  \___ Z1 \___ Z2 \___ Z3  \___ Z1 \___ Z2 \___ Z3

2) ROP cicatrix (old line) without fold  (0-Absent, 1-Present, 9-View obscured)  \____  \____

3) Chorioretinal scars [document by drawings on pages 4 and 5 of this form]
   a. Cryo or laser  ..................  (0-Absent, 1-Present, 9-View obscured)  \____  \____
   b. Other than cryo or laser ....  (0-Absent, 1-Present, 9-View obscured)  \____  \____

4) Detachment or retinoschisis .......  (0-Absent, 1-Present, 9-View obscured)  \____  \____
   If detachment or retinoschisis, code location as follows: if some but not all hours detached, leave "all" blank and code 0 (absent), 1 (present), or 9 (View obscured) under each hour. If no (or all) hours detached, code 0 (or 1) under "all" and leave hours 1-12 blank.

RIGHT EYE

<table>
<thead>
<tr>
<th>Zone 1</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
<th>7</th>
<th>8</th>
<th>9</th>
<th>10</th>
<th>11</th>
<th>12</th>
</tr>
</thead>
<tbody>
<tr>
<td>Zone 2</td>
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<td></td>
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<td></td>
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</tr>
<tr>
<td>Zone 3</td>
<td></td>
<td></td>
<td></td>
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<td></td>
<td></td>
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<td></td>
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</tbody>
</table>

LEFT EYE

<table>
<thead>
<tr>
<th>Zone 1</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
<th>7</th>
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<td></td>
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<tr>
<td>Zone 3</td>
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</tr>
</tbody>
</table>

STOP 04 V03, 01/01/96
STOP-ROP
THREE MONTH OPHTHALMIC OUTCOME EXAMINATION [04]

STOP-ROP ID: ___________ ___________ ___________
Center # Hosp. Code Patient #

5. Summary [Note: codes differ from CRYO-ROP forms]
   a. View (1-Complete to ora serrata, 2-Out to vortex veins, 3-Only zone 1, 4-No fundal view) __ __

   b. Most severe abnormality found for each eye ___________
      01-Essentially normal
      02-Minor findings(s) (e.g. cicatrix, laser cryo scars) and/or abnormal angle of temporal vessels
      03-Macular ectopia
      04-*Partial retinal detachment, retinoschisis, or fold in near periphery (sparing fovea)*
      05-*Partial retinal detachment, schisis, or fold involving fovea*
      06-Cataract, retrolental membrane, or corneal opacity blocking view of macula (draw if possible)
      07-Total retinal detachment or schisis, or total retrolental membrane
      08-Status post vitrectomy
      09-Enucleation
      88-Unable to determine (e.g., corneal opacity unrelated to ROP, or miotic pupil making view impossible). Explain:
      RIGHT EYE: __________________________________________
      LEFT EYE: __________________________________________

   99-Other, specify: RIGHT EYE: __________________________________________
      LEFT EYE: __________________________________________

   * Complete appropriate Fundus Sketches on pages 4 and 5 of this form

6. Are fundus drawings prepared? ___________ (N-No, Y-Yes) __ __
   If partial detachment or chorioretinal scars, but no drawings, specify reasons:
   RIGHT EYE: __________________________________________
   LEFT EYE: __________________________________________

7. Are you masked to the assigned oxygen treatment of this infant? ___________ (N-No, Y-Yes) __ __

8. Whether or not you think you know the treatment assignment, what is your best guess, or intuition? ___________ (C = Conventional, S = Supplemental) __ __

9. Did infant have cryotherapy? ___________ (N-No, Y-Yes) __ __
   If Yes, specify initial date ___________ ___________ ___________
   M D Y M D Y

10. Did infant have argon or diode laser therapy? ___________ (N-No, Y-Yes) __ __
    If Yes, specify: type of laser ___________ (A = Argon, D = Diode) __ __
    initial date ___________ ___________ ___________
    M D Y M D Y

11. Did infant have any other surgical treatment on the eyes? ___________ (N-No, Y-Yes) __ __
    If YES, specify:
    RIGHT EYE: __________________________________________ DATE: ___________ ___________ ___________
                      M D Y M D Y
    LEFT EYE: __________________________________________ DATE: ___________ ___________ ___________
                      M D Y M D Y

Signature of Certified Ophthalmologist

Signature of Study Center Coordinator

STOP 04 V03, 01/01/96
14. DRAWINGS AT THREE MONTH EXAMINATION

COMPLETE IF PARTIAL DETACHMENT OR CHORIORETINAL SCAR PRESENT, OR AT THE DISCRETION OF THE OPHTHALMOLOGIST. Use Figure 1 of instructions for symbols. Black pen or dark colored pencils may be used.

RIGHT EYE

Sagittal View
15. DRAWINGS AT THREE MONTH EXAMINATION

COMPLETE IF PARTIAL DETACHMENT OR CHORIORETINAL SCAR PRESENT, OR AT THE DISCRETION OF THE OPHTHALMOLOGIST. Use Figure 1 of instructions for symbols. Black pen or dark colored pencils may be used.

LEFT EYE

---

Sagittal View
THREE MONTH NEONATAL OUTCOME FORM [05]

STOP-ROP ID: ____________________________

HOSPITAL ID NUMBER: __________________

NAME CODE: _____________________________

Infant examination should be performed 10-14 weeks post due date.

1. Date of Examination ________________________________  M  D  Y

2. Weeks post due date ________________________________  weeks ______

CURRENT PHYSICAL STATUS

3. a) Weight ________________________________  grams ______

   b) Length ________________________________  cms ______  •  ___

   c) Head circumference ________________________  cms ______  •  ___

RESPIRATORY SUPPORT

4. Is the infant currently on oxygen? ____________________________  (N-No, Y-Yes) ______

   If NO, enter last date the infant received oxygen, and skip to 5 ______  M  D  Y

   a) Mode of delivery

      (1-Yes, but intermittently, skip to 5

      2-Yes, on nasal cannula

      3-Yes, on hood

      4-Yes, on nasal CPAP [prongs]

      5-Yes, on ETT (vent or CPAP)

      9-Yes, other, specify ____________________________) ______

   b) Oxygen concentration ____________________________  % ______

   c) If on cannula, enter cannula flow rate ____________________________  L/min ______  •  ___

   d) Pulse oximeter saturation on O₂ ____________________________

5. Pulse oximetry in room air recorded today ____________________________

Code 999 if infant is medically unstable to place in room air.

If infant is on oxygen with sats ≥90%, discontinue oxygen for 20 minutes before recording lowest saturation value.

If saturation drops below 85% at any time, return to ordered oxygen immediately and record 84%.

6. Status of home apnea monitor use

   (1-Never used

   2-Currently on monitor

   3-Previously used

   4-Infant never discharged to home) ____________________________

   If 3-Previously used, provide: ____________________________  Date ended ______  M  D  Y

STOP 05 VO4, 01/01/96
7. Since the week before randomization, when did the infant last receive any steroids, other than topical?
   (1-Never, 2-Currently daily or every other day, 3-In the past 2 weeks, 4-Since the last weekly study
   examination, but more than 2 weeks ago, 5-Before or on the last weekly study examination,
   6-Unknown, infant enrolled in masked steroid trial) ............................................
   If 4, estimate the date last received ......................................................... M D Y

8. Since randomization, when did the infant last receive any methylxanthines?
   (1-Never, 2-Currently daily or every other day, 3-In past 2 weeks, 4-Since the last weekly study
   examination, but more than 2 weeks ago, 5-Before or on the last weekly study examination) ............................................
   If 4, estimate the date last received ......................................................... M D Y

9. Since randomization, when did the infant last receive any diuretics?
   (1-Never, 2-Currently daily or every other day, 3-In past 2 weeks, 4-Since the last weekly study
   examination, but more than 2 weeks ago, 5-Before or on the last weekly examination) ............................................
   If 4, estimate the date last received ......................................................... M D Y

10. **REMINDER:** Initial Discharge Form (STOP 10) must be completed for initial hospitalization,
    and Rehospitalization Form (STOP 11) must be completed for each hospitalization following
    initial discharge.
    a) Is the infant currently at home? .............................................................. (N-No, Y-Yes)  
    b) Including initial discharge, how many times has the infant been discharged to home?
       (If never discharged to home, code 00 and skip to 11) .................................
    c) Since initial discharge to home, did the infant:
       1-Have any illness or breathing problem, but no oxygen was required .......... (N-No, Y-Yes)
       2-Require oxygen to be started or increased, but did not need to be hospitalized .. (N-No, Y-Yes)
       3-Require oxygen to be started or increased and needed to be hospitalized for a
          cardio-pulmonary condition ....................................................................... (N-No, Y-Yes)
       4-Require hospitalization for a non-cardio-pulmonary condition ................. (N-No, Y-Yes)

NEURO/DEVELOPMENTAL STATUS

11. a) Have parents and SCC completed the modified RPDQ Form (STOP 09)? ......................... (N-No, Y-Yes)
    b) Was the infant able to maintain oral feedings for 3 consecutive days
       at the time of initial discharge to home? ....................................................... (N-No, Y-Yes)
    c) Is the infant able to maintain oral feedings for 3 consecutive days now? .............. (N-No, Y-Yes)
       Provide the first date of the first 3 consecutive days at which the infant was
       able to maintain oral feedings, if not previously provided. Leave blank if
       previously provided. ..................................................................................... M D Y

_____________________________ ____________________________
Signature of Study Center Coordinator or Neonatologist Date Completed

12. ____________________________
Certification Number

STOP 05 VO4, 01/01/96
PROTOCOL ANOMALY [06]

1. Date of anomaly ........................................... M D Y

2. Cause(s) of anomaly ........................................
   a) Signed consent, infant randomized, weekly or 3 month follow-up possible, but parents refuse assigned treatment or monitoring ........................................
      if Yes, indicate treatment plan

   b) Signed consent, infant randomized, but parents refuse follow-up

   c) Scheduled STOP-ROP weekly examination or its ophthalmic portion not performed
      if YES,
      1) which weekly exam?  ............................................ (Code: 01-Week 1, 02-Week 2, 03-Week 3, etc)
      2) reason for not performing exam
         1-Medically unstable
         2-Unavailability of certified ophthalmologist
         3-Parents unable to keep scheduled appointment
         4-Transferred to a non STOP-ROP facility on a temporary basis
         9-Other, please specify

   d) Permanent transfer to non-STOP-ROP facility, no follow-up of infant is possible
      if YES, where:

   e) Infant not permanently transferred to non-STOP-ROP facility, but temporarily off study oxygen treatment monitoring equipment for over 4 hours
      if YES, code reason:
         0-In operating room
         1-Prolonged radiology examination
         2-Transportation to/from home
         3-Transportation to/from other facility
         4-Medically unstable
         9-Other, please specify

   f) Oxygen treatment prematurely permanently terminated, but not by parent
      if YES, indicate why:

   g) Laser/cryo treatment of ROP in an eye not yet at Threshold

   h) Moved/lost to follow-up without explicit refusal/termination

   z) Other cause(s) ...........................................
      if YES, specify:

Signature of Certified Neonatologist/Ophthalmologist ...........................................
Date ...........................................
Certification Number ...........................................

Signature of Study Center Coordinator ...........................................
Date ...........................................
Certification Number ...........................................

STOP 06 V04, 01/15/98
TRANSFER FORM [07]

STOP-ROP ID: ____________

Center #  Hosp. Code  Patient #

HOSPITAL ID NUMBER: __________________

NAME CODE: ____________

This form is used to document arrival of an infant transferred from one STOP-ROP Study Center to another STOP-ROP Study Center. The receiving SCC will submit the original to the Coordinating Center, copy to the sending SCC, and retain a copy for their files. When an infant is transferred from one hospital to another hospital within the same Study Center, NO transfer form is required.

1. TRANSFERRED FROM ONE STOP-ROP STUDY CENTER TO ANOTHER STOP-ROP STUDY CENTER

Call the Coordinating Center at 301/299-8655 to obtain the NEW IDENTIFIERS for the participant’s NEW STOP-ROP ID NUMBER. Then enter the numbers below.

NEW STOP-ROP ID NUMBER: ____________

Center #  Hosp. Code  Patient #

NEW HOSPITAL ID NUMBER: __________________

Obtain from Network Coordinating Center: (if applicable)

NEW NETWORK ID NUMBER: ____________

Number  Center #

Signature of Study Center Coordinator __________________ Date __________________

2. Certification Number __________________
Complete this form whenever an adverse experience occurs. A separate report should be submitted to the Coordinating Center for each type of adverse event.

1. Date first observed or first reported

2. Type of adverse experience

If 06 is coded, answer question 3, otherwise skip to 4

- Excessive apnea and bradycardia episodes (triple the baseline in a 24 hour period and > 3 episodes)
- Documented hyperoxia (pO2 > 120 torr) while in the target range
- Documented hypoxia (pO2 < 45 torr) while in the target range
- Seizures (new onset)
- Necrotizing enterocolitis
- Pneumonia/sepsis with positive blood culture or requiring antibiotic treatment for more than five days
- Other serious events or events thought to be treatment-related (specify all such)

3. Respond to both the following questions if question 2 is coded 06: pneumonia/sepsis
   a) Is there evidence of sepsis? (1-No, 2-Definite, 3-Probable)
   b) Is there evidence of pulmonary disease? (1-No, 2-Definite pneumonia, 3-Probable pneumonia, 4-No pneumonia, but BPD exacerbation, 5-BPD exacerbation or pneumonia, cannot differentiate, 6-Other, [specify])

4. Was this type of adverse experience ever noted prior to STOP-ROP enrollment? (0-Uncertain, 1-No, 2-Yes)

5. How was the adverse experience reported? (1-By clinician, 2-By parent[s], 3-By someone else)

6. Is there a relationship between this adverse experience and STOP-ROP treatment assignment? (1-Probably No, 2-Unable to judge, 3-Probably Yes, 4-Definitely Yes)

7. Is the adverse experience ongoing? (N-No, Y-Yes, If Yes skip to 9)

8. Date adverse experience resolved (or monitoring completed)

9. What was (is) the worst severity grade of this adverse experience? (1-Mild, no therapy needed, monitoring only, 2-Moderate, may require minimal or no medical intervention, except monitoring, 3-Severe, requires medical intervention, 4-Life-threatening, requires intensive medical intervention, 5-Death has occurred [complete STOP 12 form])

10. Certification Number

11. Date of report

12. Certification Number
CONTINUE ANSWERING UNTIL 3 "NOs" ARE CIRCLED

1. Equal Movements
When your baby is lying on his/her back, can (s)he move each of his/her arms as easily as the other and each of the legs as easily as the other? Answer No if your child makes jerky or uncoordinated movements with one or both of his/her arms or legs.

Yes No

2. Stomach Lifts Head
When your baby is on his/her stomach on a flat surface, can (s)he lift his/her head off the surface?

Yes No

3. Regards Face
When your baby is lying on his/her back, can (s)he look at you and watch your face?

Yes No

4. Follows To Midline
When your child is on his/her back, can (s)he follow your movement by turning his/her head from one side to facing directly forward?

Yes No

5. Responds To Bell
Does your child respond with eye movements, change in breathing or other change in activity to a bell or rattle sounded outside his/her line of vision?

Yes No

6. Vocalizes Not Crying
Does your child make sounds other than crying, such as gurgling, cooing, or babbling?

Yes No

7. Smiles Responsively
When you smile and talk to your baby, does (s)he smile back at you?

Yes No

8. Follows Past Midline
When your child is on his/her back, does (s)he follow your movement by turning his/her head from one side almost all the way to the other side?

Yes No

9. Stomach, Head Up 45°
When your baby is on his/her stomach on a flat surface, can (s)he lift his/her head 45°?

Yes No

10. Stomach, Head Up 90°
When your baby is on his/her stomach on a flat surface, can (s)he lift his/her head 90°?

Yes No

11. Laughs
Does your baby laugh out loud without being tickled or touched?

Yes No

12. Hands Together
Does your baby play with his/her hands by touching them together?

Yes No

13. Follows 180°
When your child is on his/her back, does (s)he follow your movement from one side all the way to the other side?

Yes No

14. Grasps Rattle
It is important that you follow instructions carefully. Do not place the pencil in the palm of your child's hand. When you touch the pencil to the back or tips of your baby's fingers, does your baby grasp the pencil for a few seconds?

Yes No
INITIAL DISCHARGE FORM [10]

STOP-ROP ID: ____________________________

Center #  Hosp. Code  Patient #

HOSPITAL ID NUMBER: ____________________

NAME CODE: ____________________________

Complete this form at the earliest of: initial discharge to home, transfer to non STOP-ROP Study Center, death of the infant, or continuous hospitalization until 3 months corrected age. The Study Center Coordinator is responsible for completion of the form. The top copy of the form should be submitted to the Coordinating Center and the other two copies should be maintained in the infant and Study Center Coordinator files.

1. Date of earliest event in 1.a) ........................................... M  D  Y

   a) Status of the infant [if codes 3 or 4, skip to question 3]
      (1-Initial discharge to home
      2-Permanent transfer to a non STOP-ROP hospital,
      3-Death
      4-Remains hospitalized at 3 months corrected age) .....................................

2. If discharge to home or permanent transfer to non STOP-ROP hospital, complete the following:

   a) Discharged home or to non STOP-ROP hospital on apnea monitor ................. (N-No, Y-Yes)

   b) Discharged home or to non STOP-ROP hospital on oxygen  ......................... (N-No, Y-Yes)

3. Was infant able to maintain oral feedings for three consecutive days? ............. (N-No, Y-Yes)

   If YES, record the first date of the 3 consecutive days the infant was able to maintain feedings
   M  D  Y

Note that questions 4-10 should reflect the status of the infant only after randomization.

4. Number of days from randomization date ..............................................

5. Number of days in ICU with ventilator or CPAP ....................................

6. Number of days in ICU with oxygen but no ventilator or CPAP ...................

7. Number of days in ward with a ventilator or CPAP ................................

8. Number of days in ICU without oxygen, ventilator or CPAP ......................

9. Number of days in ward with oxygen, but no ventilator or CPAP ...............

10. Number of days in ward without oxygen, ventilator or CPAP ...................

11. Was the entire hospitalization in a STOP-ROP institution? ....................... (N-No, Y-Yes)

STOP 10 VO2, 01/05/95
STOP-ROP
INITIAL DISCHARGE FORM [10]

ADVERSE EXPERIENCES

12. Has a new episode of any of the following occurred since completion of the last STOP-ROP weekly outcome form? .......................................................... (N-No, Y-Yes) □

- Excessive apnea and bradycardia (number of episodes in a 24 hour period is triple the baseline and > 3)
- Documented hyperoxia (paO₂ >120 torr) while in the target range
- Documented hypoxia (paO₂ <45 torr) while in the target range
- Seizures (new onset)
- Necrotizing enterocolitis
- Pneumonia/sepsis with positive culture or requiring antibiotic treatment for more than five days
- Other serious events or events thought to be treatment-related

Reminder: If YES, complete an Adverse Experience (STOP 08) for each item.

________________________
Signature of Study Center Coordinator

Certification Number
INITIAL DISCHARGE FORM [10A]
PARENT/CARETAKER INTERVIEW

STOP-ROP ID: ____________
Center # Hosp. Code Patient #

HOSPITAL ID NUMBER: ____________

NAME CODE: ____________

Perform interview with parent, if parent lives with the child. If the parent does not live with the child, perform interview with primary caretaker(s): legal guardian, adoptive mother or father, etc.

I would like to ask you some general questions about your personal history. You are free to refuse to answer any of the questions. Remember that this information is important to the study and will remain confidential.

1. Interview performed by (1 = personal interview, 2 = telephone call, 3 = other, specify _______________) __

2. What is your relationship to the infant?
   (0 = not applicable
   1 = mother [biol.]
   2 = father [biol.]
   9 = other, specify ________________) ........ Caretaker 1 __ Caretaker 2 __

3. What is the highest level of education completed by the infant’s caretaker(s)?
   (0 = not applicable
   1 = less than 7 years
   2 = 7-9 years
   3 = 10 or more years without diploma
   4 = high school graduate or GED
   5 = some college/business/vocational
   6 = college degree
   7 = graduate work
   8 = refused to answer) ................. Caretaker 1 __ Caretaker 2 __

4. What is the primary occupation of the infant’s caretaker(s)?
   Caretaker 1: Occupation ____________________________________________
   Caretaker 2: Occupation ____________________________________________

5. ___________________ Date of interview

Signature of Study Center Coordinator

STOP 10A/INTERVIEW VO1, 01/05/95
**REHOSPITALIZATION FORM [11]**

**STOP-ROP ID:**

Center #  Hosp. Code  Patient #

**HOSPITAL ID NUMBER:**

**NAME CODE:**

Complete this form at discharge for each hospitalization excluding the initial hospitalization. Submit the top copy to the Coordinating Center, and maintain the other two copies in the infant and Study Center Coordinator files. The Study Center Coordinator is responsible for completion of this form.

1. Date of rehospitalization .............................................................. M  D  Y

2. Date of discharge to home, permanent transfer to non STOP-ROP hospital, death of the infant, or 3-month corrected age visit .............................................................. M  D  Y

   a) Status of the infant .................................................. (1-Discharge to home, 2-Transfer to a non-STOP-ROP hospital, 3-Death, 4-Rehospitalized at 3 months corrected age visit)

3. If discharge to home or permanent transfer to non STOP-ROP hospital, complete the following:

   a) Discharged home or to non STOP-ROP hospital on monitor .................................................. (N-No, Y-Yes)

   b) Discharged home or to non STOP-ROP hospital on oxygen .................................................. (N-No, Y-Yes)

4. Was infant able to maintain oral feedings for three consecutive days? .................................................. (N-No, Y-Yes, P-Previously answered)

   If YES, record the first date of the 3 consecutive days the infant was able to maintain feedings.

   M  D  Y

   Note that questions 5-11 should reflect the status of the infant only during this rehospitalization.

5. Number of days infant rehospitalized ..............................................................

6. Number of days in ICU with ventilator or CPAP ..............................................................

7. Number of days in ICU with oxygen but no ventilator or CPAP ..............................................................

8. Number of days in ward with ventilator or CPAP ..............................................................

9. Number of days in ICU without oxygen, ventilator or CPAP ..............................................................

10. Number of days in ward with oxygen but no ventilator or CPAP ..............................................................

11. Number of days in ward without oxygen, ventilator or CPAP ..............................................................

12. What is the primary reason for this hospitalization? ..............................................................

   (01-Pulmonary condition, 02-Surgical procedure, 03-Apnea, 04-Seizures, 05-Gastroenteritis, 06-Failure to thrive, 07-ENT-related illness, 08-Child protective reason, 99-Other, specify ) ..............................................................

13. Indicate the number of visits to any doctor since the last hospitalization .............................................................. (N-No, Y-Yes)

14. Was the entire rehospitalization in a STOP-ROP institution? .............................................................. (N-No, Y-Yes)

15. Certification Number .................................

   Signature of Study Center Coordinator
DEATH FORM [12]

STOP-ROP ID: __________________________

Center #  Hosp. Code  Patient #

HOSPITAL ID NUMBER: ____________________

NAME CODE: ____________________________

Complete when death occurs at or before 3 months corrected age. Fax copy of this form to the Coordinating Center at 301/299-3991 within 24 hours of notification, and mail the original to the Coordinating Center within 3 days. Submit copy of Discharge Summary when it becomes available. If parents have agreed to an autopsy, consent for an eye examination should be requested (see section 9.3.1 of the Manual of Procedures).

1. Date of death .................................................. M  D  Y

2. Autopsy .................................................. (N-No, Y-Yes, U-Undecided or unknown) __________

3. Status of primary cause of death .............. (F-Final, autopsy based; N-Final, not autopsy based; P-Provisional) __________

4. Primary cause of death
   1-Cardio-vascular
   2-Respiratory (including sudden unexpected death in BPD infants)
   3-Accident
   4-Unknown
   5-Pneumonia/sepsis
   6-Sudden infant death syndrome without chronic lung disease
   9-Other, please specify ____________________________

5. Date infant last received assigned oxygen treatment .................................................. M  D  Y

6. Was death possibly associated with assigned oxygen treatment? ............................. (N-No, Y-Yes) __________

7. Excluding the death, has a new episode of any of the following occurred since the last weekly exam? (N-No, Y-Yes) __________
   Excessive apnea and bradycardia (number of episodes in a 24 hour period is triple the baseline and >3)
   Documented hypoxia (pao2 >120 torr) while in the target range
   Documented hypoxia (pao2 <45 torr) while in the target range
   Seizures (new onset)
   Necrotizing enterocolitis
   Pneumonia/sepsis with positive culture or requiring antibiotic treatment for more than five days
   Other serious events or events thought to be treatment-related

   Reminder: If answer to 6 or 7 is YES, complete an Adverse Experience (STOP 08) for each item.

   Reminder: If death occurs during initial hospitalization, complete Initial Discharge Form (STOP 10). If death occurs during a rehospitalization, complete Rehospitalization Form (STOP 11).

8. Did the death occur at a STOP-ROP institution? .................................................. (N-No, Y-Yes) __________

______________________________
Signature of Neonatologist

______________________________
Signature of Study Center Coordinator

9. __________
Certification Number

10. __________
Certification Number

STOP 12  VO1, 11/11/94
CRYO Outcomes Prediction for STOP-ROP Enrollees [13]

IDENTIFICATION:
STOP-ROP ID# ______ | ______ | ______ STOP-ROP name code: ______ | ______ | ______

BASELINE CHARACTERISTICS:

Birth Weight: ______ grams Check here if Birth Weight >1250 grams______(data sheet optional)

Birth place ____________
1. Inborn
2. Outborn

Multiple Birth ________
1. Single Birth
2. Multiple Birth

OPHTHALMOLOGY EXAMS:

RIGHT EYE

Date of 1st eye exam: ____/____/____
Did vessels end in zone 1? (y or n) ____

Date of 1st onset of ROP: ____/____/____
Was ROP in zone 1? (y or n) ____

Date of 1st onset of Prethreshold ROP:
____/____/____
Was there Plus Disease? (y or n) ____

This Eye (check one):
1 ____ Reached Threshold ROP by CRYO def.
On ____/____/____
Was ROP in zone 1? (y or n) ____
# of Hours of Stage 3? ______

2 ____ Was treated without reaching CRYO Threshold

3 ____ Regressed without reaching CRYO Threshold or receiving any ablative treatment

4 ____ Unknown - child died before ophthalmic endpoint

5 ____ Unknown - Follow-up Refused

6 ____ Unknown - Lost to Follow-up

9 ____ Other ________________________________

LEFT EYE

Date of 1st eye exam: ____/____/____
Did vessels end in zone 1? (y or n) ____

Date of 1st onset of ROP: ____/____/____
Was ROP in zone 1? (y or n) ____

Date of 1st onset of Prethreshold ROP:
____/____/____
Was there Plus Disease? (y or n) ____

This Eye (check one):
1 ____ Reached Threshold ROP by CRYO def.
On ____/____/____
Was ROP in zone 1? (y or n) ____
# of Hours of Stage 3? ______

2 ____ Was treated without reaching CRYO Threshold

3 ____ Regressed without reaching CRYO Threshold or receiving any ablative treatment

4 ____ Unknown - child died before ophthalmic endpoint

5 ____ Unknown - Follow-up Refused

6 ____ Unknown - Lost to Follow-up

9 ____ Other ________________________________

Threshold by STOP-ROP Definition

Zone 1: Any Stage 1+ or 2+ or Any Stage 3, with or without plus disease (2 quadrants).

Zone 2: > 5 Contiguous or ≥ 8 Composite clock hours of stage 3 with plus disease (2 quadrants).

Threshold by CRYO-ROP Definition

Zone 1: ≥ 5 Contiguous or ≥ 8 Composite clock hours of stage 3 with plus disease

Zone 2: ≥ 5 Contiguous or ≥ 8 Composite clock hours of stage 3 with plus disease

SCC Signature __________________________ Date __________________________ Certification #
INDEX
2 weeks ............................................... 7-10, 9-3
24 hours ............................................. 4-12, 6-1, 6-4, 6-5, 6-8, 6-9, 6-11, 6-15, 6-16, 7-5, 7-13, 8-4, 9-7, 9-8, 10-3
3 months ............................................ 1-2, 8-1, 11-11
3 successive examinations ......................... 6-17, 9-3
3-month .............................................. 6-17, 6-18, 6-19, 8-8, 9-1, 9-3, 9-4, 9-5, 9-6, 11-11
48 hours ............................................. 6-16, 8-4, 9-7
84% ..................................................... 7-14
85% ..................................................... 1-5, 7-3, 7-14
94% ..................................................... 1-2, 4-2, 5-2, 6-7, 7-2, 7-3, 7-6, 7-10
96% ..................................................... 2-4, 6-7, 7-3, 7-6
99% ..................................................... 1-2, 7-2, 7-3, 7-4, 7-10
abstracts ............................................. 3-16, 4-5, 4-9, 4-10
acceptance .......................................... 4-1, 4-4, 11-3, 11-5, 11-6, 11-9
accrual .............................................. 3-1, 3-14, 3-15, 10-1, 11-3, 11-4, 11-5, 11-6, 11-7
accuracy ............................................. 3-15, 7-4, 8-4, 10-7
acidosis ............................................. 2-3
acknowledge ........................................ 4-6
admission .......................................... 6-19, 9-5
adverse ............................................. 1-3, 1-4, 2-6, 3-9, 3-10, 3-15, 4-2, 4-11, 4-12, 5-3, 5-4, 6-17, 8-1, 8-6, 8-7, 9-1, 9-2, 9-3, 9-4, 9-7
adverse experience ................................ 4-11, 4-12, 9-7
Adverse Experience form ......................... 9-7
adverse outcome .................................. 8-6, 8-7, 9-1, 9-2
alcohol ............................................. 8-3
Alternative Funded Center ......................... 3-7, 3-16, 3-18
amblyopia .......................................... 1-3
American Academy of Pediatrics ................ 8-3
aminophylline ..................................... 9-4
ancillary ............................................ 3-7, 3-12, 4-1, 4-5, 4-6, 4-7, 4-8, 4-9, 7-13
angiogenic ........................................ 7-2
animal .............................................. 1-1, 1-2, 2-6, 2-7, 5-3
anomalies ......................................... 10-5, 10-6
anomaly ............................................ 5-2, 6-10, 6-17, 8-8, 9-7, 9-8, 10-6, 10-7
anomaly exception ................................. 10-6
another study ...................................... 6-10, 6-13
antioxidants ....................................... 2-3
antiseptic ......................................... 8-3
anxiety ............................................. 6-18
apnea .............................................. 4-11, 4-12, 6-17, 9-4
apnea assessment ................................ 6-17
arterial blood gases ............................... 7-13
arterial oxygen saturation ....................... 7-1, 7-4
arterial PaO2 ..................................... 2-7, 2-8, 7-1, 7-2
asphyxia .......................................... 2-3
asymmetric ........................................ 9-1, 11-3
atopy .............................................. 9-6
audit ............................................... 10-5, 10-7
aunts .............................................. 6-19
authorship ........................................ 4-5
autopsy ................................................. 9-7
axis ...................................................... 1-9, 1-10, 5-8
back transferred ..................................... 6-19
baseline .............................................. 3-15, 4-11, 6-11, 6-13, 6-14, 6-15, 6-16, 8-1, 8-4, 11-11, 11-12
Baseline, Eligibility and Randomization form 6-11, 6-13, 6-14, 6-15, 6-16, 8-4
beneficial ............................................. 1-2, 1-3, 3-9, 3-10, 4-4, 5-4
benefit ............................................... 1-3, 1-4, 1-5, 1-9, 2-6, 3-11, 5-3, 5-4, 7-6, 11-3
betadine .............................................. 8-3
bilateral .............................................. 1-8
binomial .............................................. 11-9
biographical sketch .............................. 10-1, 10-2, 10-3
birth weight ........................................ 1-1, 1-4, 2-1, 2-2, 2-3, 5-2, 6-4, 6-11, 11-2, 11-8
black .................................................. 5-3, 8-4, 11-2
blind .................................................. 2-3, 2-4
blindness ............................................. 1-11, 2-1, 2-3
blood gases ......................................... 2-5, 7-13
boundary ............................................. 11-3
BPD ..................................................... 9-5, 11-11, 11-12
bradycardia ......................................... 4-11, 9-4
brain .................................................. 2-7
bronchodilators .................................... 9-6, 11-11
cable .................................................. 7-10
cable lock .......................................... 7-10
caffeine ............................................. 9-4
calibration .......................................... 10-4
 cannula ............................................. 7-6, 7-14
carboxy hemoglobin ............................. 7-4
case control ........................................ 1-2, 2-1, 2-3, 2-5, 5-3
Caucasian ........................................... 5-3, 11-2
cell culture ......................................... 2-6
censoring ............................................ 11-11
certification ....................................... 3-13, 3-14, 5-1, 6-11, 6-12, 6-14, 6-17, 8-4, 8-7, 10-1, 10-2, 10-3, 10-4, 10-5
certified ............................................. 3-17, 4-3, 6-4, 6-10, 6-11, 6-16, 6-17, 6-18, 8-4, 8-5, 8-6, 8-7, 8-8, 9-2, 10-1, 10-2, 10-3
certified examiner ......................... 6-10, 6-11, 6-17, 6-18, 8-4, 8-5, 8-7
certified ophthalmologist .................. 3-17, 6-4, 6-10, 6-11, 6-16, 6-17, 6-18, 8-4, 8-6, 8-7, 8-8, 9-2, 10-2, 10-3
certify ............................................... 3-7, 10-5
cicatricial .......................................... 1-3, 2-1, 2-3, 2-4, 2-6
Clinical Centers ................................. 3-5
clock hour .......................................... 6-5, 6-6, 8-2, 8-5, 8-7, 9-2
CNS ................................................... 2-7
cold stress ......................................... 2-3
communication .................................... 2-5, 3-1, 3-13, 3-15, 6-4, 10-4, 10-5
completion ......................................... 4-10, 5-1, 6-16, 6-18, 7-13, 8-1, 8-4, 8-8, 10-2, 10-3, 10-5
composite .......................................... 6-5, 6-6, 8-5, 8-7, 9-2
computer .......................................... 1-12, 3-14, 3-15, 5-1, 5-2, 6-8, 6-9, 6-16, 7-5, 7-9, 7-10, 7-11, 7-13, 8-1, 10-6
<table>
<thead>
<tr>
<th>Term</th>
<th>Pages</th>
</tr>
</thead>
<tbody>
<tr>
<td>confirmed</td>
<td>3-1, 6-10, 6-11, 6-17, 7-4, 8-4, 8-5, 8-6, 8-7, 9-3</td>
</tr>
<tr>
<td>confirming examination</td>
<td>6-4, 6-11, 8-7, 10-2</td>
</tr>
<tr>
<td>congenital</td>
<td>6-10</td>
</tr>
<tr>
<td>Congress</td>
<td>3-6</td>
</tr>
<tr>
<td>consent</td>
<td>1-12, 3-10, 4-1, 4-2, 4-7, 4-9, 5-2, 5-4, 6-1, 6-4, 6-7, 6-8, 6-10, 6-11, 8-4, 9-7, 9-8, 10-1, 10-3, 11-8</td>
</tr>
<tr>
<td>contact</td>
<td>3-8, 3-13, 3-17, 6-1, 6-4, 6-18</td>
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<td>contiguous</td>
<td>6-5, 6-6, 7-6, 8-5, 8-7, 9-2</td>
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<td>conventional</td>
<td>1-1, 1-2, 1-5, 1-7, 1-11, 1-12, 3-1, 4-2, 4-3, 4-11, 5-4, 6-7, 6-10, 6-11, 5-16, 7-2, 7-6, 7-7, 7-8, 7-9, 7-10, 7-11, 7-13, 8-6, 9-1, 11-1, 11-3, 11-4, 11-6, 11-7, 11-9, 11-11</td>
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<td>conventional oxygen</td>
<td>1-7, 1-12, 3-1, 4-2, 4-3, 7-2, 7-8, 7-9, 7-10, 7-13, 11-1, 11-9, 11-11</td>
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<td>Coordinating Center</td>
<td>3-1, 3-5, 3-6, 3-7, 3-8, 3-9, 3-10, 3-12, 3-13, 3-14, 3-15, 3-16, 3-17, 4-2, 4-4, 4-5, 4-6, 4-7, 4-8, 4-12, 6-4, 6-9, 6-11, 6-12, 6-13, 6-14, 6-15, 6-16, 6-18, 7-5, 7-13, 8-4, 8-5, 9-7, 9-8, 10-1, 10-2, 10-3, 10-4, 10-5, 10-6, 10-7, 11-9</td>
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<td>Coordinators group</td>
<td>3-9</td>
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<td>correlation</td>
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<td>correspondence</td>
<td>10-4</td>
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<td>cost</td>
<td>1-1, 1-2, 1-3, 1-4, 1-5, 1-7, 1-8, 1-9, 1-10, 1-11, 3-15, 5-3, 11-11</td>
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<tr>
<td>cost-effectiveness</td>
<td>1-9, 11-11</td>
</tr>
<tr>
<td>costs</td>
<td>1-2, 1-3, 1-4, 1-8, 1-9, 1-10, 1-11, 5-1, 5-3, 6-19, 10-3, 11-11</td>
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<td>CPAP</td>
<td>7-14</td>
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<td>crying</td>
<td>7-11</td>
</tr>
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<td>cryo-rop</td>
<td>1-2, 1-5, 1-7, 1-8, 2-4, 3-1, 3-5, 6-5, 9-2, 10-2, 11-1, 11-8</td>
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<td>cryotherapy</td>
<td>1-1, 1-2, 1-3, 1-4, 1-5, 1-7, 1-8, 1-10, 1-12, 2-1, 2-3, 2-4, 2-5, 2-6, 6-7, 8-7, 11-2</td>
</tr>
<tr>
<td>Cyclomydril</td>
<td>8-1, 8-8</td>
</tr>
<tr>
<td>Cyclopentolate Hydrochloride</td>
<td>8-1</td>
</tr>
<tr>
<td>darkly pigmented</td>
<td>8-1</td>
</tr>
<tr>
<td>Data and Safety Monitoring Committee</td>
<td>3-1, 3-5, 3-6, 3-9, 3-10, 3-15, 4-1, 4-4, 4-5, 4-11, 5-1, 11-9</td>
</tr>
<tr>
<td>data audit</td>
<td>1-10-5</td>
</tr>
<tr>
<td>data forms</td>
<td>6-11, 6-13, 6-16, 10-2, 10-3, 10-4, 10-5, 10-6, 11-12</td>
</tr>
<tr>
<td>Data Management Handbook</td>
<td>3-14, 3-16, 6-16, 7-13, 9-5</td>
</tr>
<tr>
<td>data quality</td>
<td>3-11, 10-6</td>
</tr>
<tr>
<td>Database Administrator</td>
<td>10-6</td>
</tr>
<tr>
<td>date of birth</td>
<td>6-4</td>
</tr>
<tr>
<td>death</td>
<td>1-1, 4-11, 4-12, 9-7, 9-8, 11-11</td>
</tr>
<tr>
<td>decision analysis</td>
<td>1-3</td>
</tr>
<tr>
<td>decision tree</td>
<td>1-4, 1-5, 1-6, 1-9</td>
</tr>
<tr>
<td>delinquent</td>
<td>10-6</td>
</tr>
<tr>
<td>demarcation line</td>
<td>6-5</td>
</tr>
<tr>
<td>Denver</td>
<td>6-18, 7-7, 9-6, 11-12</td>
</tr>
<tr>
<td>desaturation</td>
<td>7-11, 9-4</td>
</tr>
<tr>
<td>detachment</td>
<td>1-2, 1-3, 2-1, 2-3, 2-6, 8-7, 9-1, 9-2, 9-3</td>
</tr>
<tr>
<td>developmental</td>
<td>6-18, 9-6</td>
</tr>
</tbody>
</table>
exclusion 3-1, 6-4, 6-7, 6-10, 6-11
exclusion criteria 3-1, 6-7, 6-10, 6-11
Executive Branch 3-6
Executive Committee 3-1, 3-5, 3-6, 3-7, 3-8, 3-9, 3-10, 3-13, 4-1, 4-3, 4-4, 4-5, 4-6, 4-7, 4-8, 4-9, 4-10, 5-4, 10-5
Extramural and Collaborative Program 3-6
eye drops 8-8
families 6-18, 6-19, 9-7, 11-8
family 6-1, 6-4, 6-19, 7-11, 8-4
fetal congenital anomaly 6-10
favorable 1-3, 1-7, 2-5, 4-2, 6-17, 7-10, 8-1, 8-6, 8-8, 9-1, 9-3, 9-4, 11-11
favorable outcome 1-7, 9-1, 9-3, 11-11
feedings 9-5
fellow eye 6-12, 8-8, 11-1, 11-8
female 5-3, 7-7, 11-2
Fetus and Newborn Committee 8-3
financial counselors 6-19
financial support 3-18
first name 6-13
folding back 1-9
folds 1-3, 2-3, 8-7, 9-2
fovea 9-2, 9-2
frequency distribution 7-10
fully vascularized 6-17, 8-1, 8-8, 9-2, 9-3
funding 3-1, 3-5, 3-6, 3-9, 3-16, 3-17, 4-3, 4-9, 10-2
funds 3-6, 4-7, 4-9
tfundus 8-2
gender 5-3, 6-4, 11-12
gestation 6-18, 8-3, 9-3, 9-5
gestational 2-3, 5-2, 6-4, 7-7, 9-1, 9-3, 9-5
gestational age 2-3, 5-2, 6-4, 7-7, 9-1, 9-6, 11-11, 11-12
gloves 8-3
grams 1-3, 2-1, 5-2, 7-7, 8-3
grandparents 6-19
grant application 4-9
graph 1-3, 1-10, 1-11, 6-8, 7-9
growth 1-1, 1-2, 1-12, 1-3, 2-6, 2-7, 6-4, 7-2, 9-1, 9-3, 9-4, 9-6, 11-11
head circumference 6-17, 9-4, 9-6, 11-11
Headquarters 3-1, 3-5, 3-6, 3-7, 3-8, 3-9, 3-10, 3-13, 3-17, 4-2, 4-7, 4-8, 6-1, 8-3, 9-4, 9-7, 10-1, 10-2, 10-3, 10-5
hemoglobin 7-1, 7-4
hemorrhage 9-2, 9-3
histograms 7-10
hold 5-4
home 1-4, 1-8, 5-1, 5-2, 5-3, 6-4, 6-9, 6-17, 6-18, 7-11, 8-3, 9-1, 9-5, 9-6, 10-3, 11-12
home monitoring 7-11
hood 7-6, 7-14
hospital code 6-12, 6-13, 6-14
hospital ID number 6-13
<table>
<thead>
<tr>
<th>Term</th>
<th>Pages</th>
</tr>
</thead>
<tbody>
<tr>
<td>hospital record</td>
<td>1-4, 1-6, 1-9, 1-11, 4-9, 5-1, 5-3, 9-5, 11-11</td>
</tr>
<tr>
<td>hospitalization</td>
<td>2-3, 4-11, 6-17</td>
</tr>
<tr>
<td>hyperoxia</td>
<td>1-1, 2-5, 2-7, 4-11, 6-17</td>
</tr>
<tr>
<td>hyphenated</td>
<td>6-13</td>
</tr>
<tr>
<td>hypotony</td>
<td>8-2</td>
</tr>
<tr>
<td>hypoxemia</td>
<td>2-6, 7-2</td>
</tr>
<tr>
<td>hypoxia</td>
<td>5-2, 10-3</td>
</tr>
<tr>
<td>hypoxic</td>
<td>4-11, 7-1</td>
</tr>
<tr>
<td>ID</td>
<td>6-13, 6-14, 6-15, 10-6, 10-7</td>
</tr>
<tr>
<td>Identification</td>
<td>6-1, 6-12, 6-13, 10-6</td>
</tr>
<tr>
<td>Identify</td>
<td>4-1, 6-1, 6-4, 9-8, 10-7, 11-12</td>
</tr>
<tr>
<td>immature vessels</td>
<td>8-3</td>
</tr>
<tr>
<td>ineligible</td>
<td>5-2, 10-3</td>
</tr>
<tr>
<td>infection</td>
<td>4-11, 7-1</td>
</tr>
<tr>
<td>initial discharge</td>
<td>6-17, 9-5</td>
</tr>
<tr>
<td>Initial Discharge form</td>
<td>6-17</td>
</tr>
<tr>
<td>Instillation</td>
<td>8-1</td>
</tr>
<tr>
<td>insurance</td>
<td>5-1</td>
</tr>
<tr>
<td>integrity</td>
<td>3-14, 3-15, 4-7, 10-5, 10-7</td>
</tr>
<tr>
<td>intensive Care Nursery</td>
<td>2-1, 7-10</td>
</tr>
<tr>
<td>intention to treat</td>
<td>4-2</td>
</tr>
<tr>
<td>interim</td>
<td>3-10, 4-4, 5-3, 5-4, 9-6, 11-3, 11-9, 11-11</td>
</tr>
<tr>
<td>interim results</td>
<td>4-4, 5-4, 11-3</td>
</tr>
<tr>
<td>intervention</td>
<td>1-9, 3-1, 5-2, 6-1, 8-1, 9-1, 11-8</td>
</tr>
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<td>iodophor</td>
<td>8-3</td>
</tr>
<tr>
<td>IRB</td>
<td>4-1, 4-2, 4-7, 4-8, 5-4, 10-3</td>
</tr>
<tr>
<td>ischemia</td>
<td>1-1, 2-1, 2-7</td>
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<td>justification</td>
<td>5-3</td>
</tr>
<tr>
<td>key</td>
<td>1-3, 1-4, 1-8, 1-9, 2-1, 6-5, 7-10, 8-5, 10-1, 10-6, 10-7, 11-12</td>
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<td>10-7, 11-12</td>
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<td>2-6</td>
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<td>6-7, 8-7</td>
</tr>
<tr>
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<td>6-7</td>
</tr>
<tr>
<td>last day</td>
<td>7-14</td>
</tr>
<tr>
<td>last name</td>
<td>6-13</td>
</tr>
<tr>
<td>late entrant</td>
<td>6-11, 6-16</td>
</tr>
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<td>late entry</td>
<td>6-5, 6-16</td>
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<td>4-1, 4-2, 6-4, 8-4</td>
</tr>
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<td>1-2, 1-8, 1-11, 4-9, 6-8, 6-13, 6-17, 9-4, 9-6, 11-11</td>
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<td>lesion</td>
<td>2-6</td>
</tr>
<tr>
<td>letter of intent</td>
<td>10-1, 10-2</td>
</tr>
<tr>
<td>lid speculum</td>
<td>8-2, 8-3</td>
</tr>
<tr>
<td>life-threatening</td>
<td>4-11, 4-12</td>
</tr>
<tr>
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<td>1-1, 2-5, 2-6, 2-7, 4-2, 5-1, 6-7, 9-4, 9-5, 9-6, 11-11</td>
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</tr>
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<td>4-3, 6-16, 6-17, 6-18, 8-1, 8-4, 8-6, 9-2, 10-2</td>
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<td>masking</td>
<td>4-3, 8-1</td>
</tr>
<tr>
<td>mature vessels</td>
<td>8-6, 8-8, 10-3</td>
</tr>
<tr>
<td>media</td>
<td>4-3, 4-4</td>
</tr>
<tr>
<td>medical record</td>
<td>6-13, 6-17, 8-8</td>
</tr>
<tr>
<td>medically unstable</td>
<td>4-2, 6-17, 8-8</td>
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<td>meetings</td>
<td>3-7, 3-9, 3-13, 3-14, 3-15, 3-16, 3-17, 4-5, 4-9</td>
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<td>methemoglobin</td>
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<td>6-13</td>
</tr>
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<td>minorities</td>
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</tr>
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<td>minority</td>
<td>3-10</td>
</tr>
<tr>
<td>minority opinion</td>
<td>3-10</td>
</tr>
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<td>minutes</td>
<td>3-8, 3-16, 6-9, 7-6, 7-10, 7-14, 8-1, 8-3, 10-6</td>
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<tr>
<td>MOP</td>
<td>3-5</td>
</tr>
<tr>
<td>morbidity</td>
<td>1-3, 2-4, 11-9</td>
</tr>
<tr>
<td>most frequent</td>
<td>6-8, 6-9</td>
</tr>
<tr>
<td>myopia</td>
<td>1-3, 2-1</td>
</tr>
<tr>
<td>name</td>
<td>4-12, 6-4, 6-12, 6-13, 6-14, 6-15, 6-19, 8-4, 8-7, 10-6, 10-7</td>
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<td>name code</td>
<td>6-13, 6-15, 10-6, 10-7</td>
</tr>
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<td>nasal</td>
<td>7-5, 7-6, 7-6, 7-7</td>
</tr>
<tr>
<td>National Eye Institute</td>
<td>3-1, 3-6, 3-9, 3-10, 3-16, 3-18, 4-3, 4-4, 4-6, 5-1</td>
</tr>
<tr>
<td>National Institute of Child Health and Human Development</td>
<td>3-1, 3-6, 4-6</td>
</tr>
<tr>
<td>National Institute of Nursing Research</td>
<td>3-1, 3-6, 3-10, 4-3, 4-6</td>
</tr>
<tr>
<td>Natural History Cohort</td>
<td>1-4, 11-1</td>
</tr>
<tr>
<td>Natural History Study</td>
<td>1-5</td>
</tr>
<tr>
<td>NEI</td>
<td>3-1, 3-5, 3-6, 3-8, 3-9, 3-10, 3-12, 3-13, 3-15, 4-4, 4-7, 4-8, 4-9</td>
</tr>
<tr>
<td>Nellcor</td>
<td>6-7, 6-9, 7-2, 7-4, 7-5</td>
</tr>
<tr>
<td>Neonatal Network</td>
<td>3-16, 6-13</td>
</tr>
<tr>
<td>Neonatal Outcome form</td>
<td>6-18, 9-5, 9-6</td>
</tr>
<tr>
<td>neonatologist</td>
<td>3-6, 3-9, 3-17, 3-18, 5-2, 6-1, 6-4, 6-7, 6-17, 6-18, 6-19, 7-11, 8-5, 8-8, 9-7, 10-1, 10-2, 10-3</td>
</tr>
<tr>
<td>Neonatologists</td>
<td>1-1, 2-5, 2-6, 3-7, 3-9, 3-13, 4-3, 5-1, 6-18, 10-1</td>
</tr>
<tr>
<td>neovascular</td>
<td>2-1</td>
</tr>
<tr>
<td>neovascularization</td>
<td>2-1</td>
</tr>
<tr>
<td>network</td>
<td>3-15, 3-16, 6-13, 6-19</td>
</tr>
<tr>
<td>Network center number</td>
<td>6-13</td>
</tr>
<tr>
<td>Network number</td>
<td>6-13</td>
</tr>
<tr>
<td>neurological maturation</td>
<td>9-4, 9-5</td>
</tr>
<tr>
<td>Term</td>
<td>Page(s)</td>
</tr>
<tr>
<td>-------------------------------</td>
<td>---------</td>
</tr>
<tr>
<td>newsletter</td>
<td>3-8, 3-16, 6-18</td>
</tr>
<tr>
<td>NICHD</td>
<td>3-1, 3-6, 3-7, 3-8, 3-13</td>
</tr>
<tr>
<td>NICU</td>
<td>3-7, 3-9, 4-3, 6-10, 6-18, 7-5, 7-6, 7-11, 8-1, 10-3</td>
</tr>
<tr>
<td>NICU nurse</td>
<td>3-9, 4-3, 6-18, 7-5, 8-1, 10-3</td>
</tr>
<tr>
<td>NINR</td>
<td>3-1, 3-8</td>
</tr>
<tr>
<td>nipple</td>
<td>9-5, 11-12</td>
</tr>
<tr>
<td>Nothing by Mouth</td>
<td>8-1</td>
</tr>
<tr>
<td>NPO</td>
<td>8-1</td>
</tr>
<tr>
<td>null hypothesis</td>
<td>11-1, 11-3</td>
</tr>
<tr>
<td>nystagmus</td>
<td>1-3</td>
</tr>
<tr>
<td>Ohmeda</td>
<td>6-7, 6-8, 6-9, 6-16, 7-2, 7-4, 7-5, 7-11, 10-1</td>
</tr>
<tr>
<td>open label treatment</td>
<td>5-4</td>
</tr>
<tr>
<td>Operations Committee</td>
<td>3-1, 3-6, 3-7, 3-8, 3-9, 4-1, 4-7, 9-8, 10-7</td>
</tr>
<tr>
<td>ophthalmic examination</td>
<td>5-2, 6-1, 6-4, 6-16, 6-18, 8-1, 8-6, 9-2, 9-3, 9-7, 9-9</td>
</tr>
<tr>
<td>ophthalmologic</td>
<td>3-18, 6-1, 11-9, 11-10</td>
</tr>
<tr>
<td>ophthalmologist</td>
<td>3-6, 3-7, 3-9, 3-17, 4-3, 5-2, 6-1, 6-4, 6-10, 6-11, 6-16, 6-17, 6-18, 7-11, 8-1, 8-2, 8-4, 8-6, 8-7, 8-9, 9-2, 10-1, 10-2, 10-3</td>
</tr>
<tr>
<td>Ophthalmologists</td>
<td>3-7, 3-9, 3-13, 3-17, 4-3, 5-1, 6-11, 6-18, 10-1, 10-2, 10-3, 10-5</td>
</tr>
<tr>
<td>ophthalmoscope</td>
<td>8-2</td>
</tr>
<tr>
<td>ophthalmoscopy</td>
<td>5-2</td>
</tr>
<tr>
<td>ora serrata</td>
<td>8-2, 8-6, 9-2, 9-3</td>
</tr>
<tr>
<td>other studies</td>
<td>4-9, 11-9</td>
</tr>
<tr>
<td>other study</td>
<td>3-9, 3-14</td>
</tr>
<tr>
<td>outcome1-2, 1-4, 1-5, 1-7, 1-8, 1-9, 1-10, 1-11, 2-4, 2-7, 3-1, 4-2, 4-8, 6-15, 6-17, 6-18, 7-10, 8-6, 8-7, 8-8, 9-1, 9-2, 9-3, 9-4, 9-5, 9-6, 11-1, 11-9, 11-10, 11-11</td>
<td></td>
</tr>
<tr>
<td>oxygen management</td>
<td>6-16, 6-17, 9-1</td>
</tr>
<tr>
<td>oxygen toxicity</td>
<td>2-7, 9-5</td>
</tr>
<tr>
<td>oxygen treatment</td>
<td>1-3, 1-7, 1-9, 1-12, 2-5, 2-6, 4-2, 4-3, 4-10, 4-11, 6-7, 6-11, 6-16, 6-17, 6-18, 7-1, 7-2, 7-10, 7-11, 8-4, 8-7, 8-8, 9-2, 9-3, 9-4, 11-3, 11-11</td>
</tr>
<tr>
<td>PaO2</td>
<td>1-2, 2-6, 2-7, 2-8, 4-11, 7-1, 7-2, 7-13</td>
</tr>
<tr>
<td>parallel</td>
<td>4-5, 4-6, 4-7, 4-8, 4-9, 4-10</td>
</tr>
<tr>
<td>parent</td>
<td>3-17, 4-1, 4-10, 5-2, 6-4, 6-19, 7-11, 7-13</td>
</tr>
<tr>
<td>parents</td>
<td>1-12, 3-13, 3-17, 4-1, 4-3, 4-7, 4-9, 4-10, 5-1, 5-2, 5-3, 5-4, 6-1, 6-4, 6-7, 6-9, 6-10, 6-18, 6-19, 7-11, 7-13, 8-4, 8-6, 9-6, 9-7, 10-4, 11-8, 11-12</td>
</tr>
<tr>
<td>participant number</td>
<td>6-13, 6-14, 6-15</td>
</tr>
<tr>
<td>pathology</td>
<td>1-1</td>
</tr>
<tr>
<td>Patient Register</td>
<td>3-17, 6-4, 6-11, 6-15</td>
</tr>
<tr>
<td>pay</td>
<td>1-10, 1-11</td>
</tr>
<tr>
<td>payment</td>
<td>10-3</td>
</tr>
<tr>
<td>pediatric outcomes</td>
<td>9-1, 9-4</td>
</tr>
<tr>
<td>pediatrician</td>
<td>6-7, 6-10, 6-19, 7-11</td>
</tr>
<tr>
<td>peer review</td>
<td>4-4</td>
</tr>
<tr>
<td>peripheral retina</td>
<td>7-2, 7-8</td>
</tr>
<tr>
<td>Phenytoin Hydrochloride</td>
<td>8-1</td>
</tr>
<tr>
<td>phone</td>
<td>3-8, 5-4, 6-4, 6-19, 9-5</td>
</tr>
<tr>
<td>PI</td>
<td>3-17, 4-1, 4-3, 4-6, 4-9, 6-1, 6-10, 10-1, 10-3, 10-5</td>
</tr>
<tr>
<td>pilot</td>
<td>3-5, 7-5, 7-6, 7-8, 11-8</td>
</tr>
<tr>
<td>plus disease</td>
<td>6-5, 6-6, 8-2, 8-5, 8-7, 9-2</td>
</tr>
</tbody>
</table>
pneumonia ................................................. 4-11, 6-17
policy ...................................................... 3-6, 3-12, 4-2, 6-8, 8-3
positive pressure ventilation ......................... 7-14
post due date ............................................ 6-17, 6-18, 6-1, 9-8, 9-3, 9-5
post-discharge .......................................... 6-18
postcard .................................................... 6-12
posterior pole ........................................... 6-5, 8-2
potentially eligible ...................................... 5-2, 5-4
pounds ...................................................... 1-12
power ....................................................... 11-3, 11-4, 11-7, 11-9, 11-11
practice ................................................... 2-7, 4-2, 6-7, 6-8, 7-10, 8-8, 10-3
precision ................................................... 7-4
premature ................................................. 1-1, 1-2, 1-3, 1-11, 1-12, 2-1, 2-3, 2-6, 2-7, 4-5, 4-8, 5-2, 5-3, 7-1, 7-2, 8-3
presentations ............................................. 3-10, 3-12, 3-16, 4-5, 4-10
prethreshold .............................................. 1-1, 1-2, 1-4, 1-5, 1-6, 1-8, 2-4, 3-1, 3-17, 4-1, 5-1, 6-1, 6-4, 6-5, 6-6, 6-7, 6-10, 6-11, 6-12, 6-16, 7-6, 8-3, 8-4, 8-5, 8-8, 9-1, 11-1, 11-2, 11-8, 11-11
primary nurses .......................................... 6-19
PRN .......................................................... 9-6
probe ....................................................... 7-5
probes ...................................................... 3-17, 6-15, 7-5, 7-11, 10-1
profox ..................................................... 7-5, 7-10
program .................................................... 3-6, 3-8, 3-13, 6-8, 7-5, 7-10, 7-11, 10-7
progress ................................................... 1-2, 1-4, 1-5, 1-7, 2-1, 3-6, 3-8, 3-12, 3-13, 5-4, 6-16, 9-2, 10-1, 10-3
progresses .............................................. 2-3, 3-1, 4-1, 6-4, 6-16, 8-7, 9-2
progressing ............................................. 1-1, 1-2, 6-1, 11-1
progression ............................................ 1-4, 2-3, 5-3, 6-1, 8-7, 9-2, 9-3, 11-1, 11-3, 11-4, 11-6, 11-7, 11-9, 11-13
progression fraction ................................... 11-1, 11-4, 11-6
progression probability ............................... 11-4, 11-7
Project Officer ........................................... 3-16, 3-18
protocol .................................................. 1-11, 2-1, 3-1, 3-6, 3-7, 3-8, 3-9, 3-10, 3-11, 3-12, 3-14, 3-15, 3-16, 3-17, 3-18, 4-1, 4-6, 4-7, 4-11, 5-2, 6-10, 6-17, 7-11, 8-8, 9-1, 9-7, 9-8, 10-1, 10-3, 10-4, 10-5, 10-7
protocol adherence ...................................... 10-1, 10-3, 10-5
Protocol Anomaly form .................................. 5-2, 6-17, 8-8, 9-7, 9-8
protocol monitor ....................................... 3-6, 3-8, 3-9, 3-10, 3-14, 3-17, 4-1, 10-4, 10-7
protocol monitoring .................................... 3-14, 3-15, 10-4
publication .............................................. 1-8, 3-10, 3-15, 3-16, 4-4, 4-5, 4-9, 4-10, 5-4
publications ............................................. 4-5
publicity .................................................. 4-3
published .................................................. 1-8, 4-5, 4-6, 5-4
pulmonary ............................................... 1-1, 1-2, 2-7, 7-2, 7-6, 11-11
pulmonary hypertension ............................... 1-1, 7-2, 7-6
pulse oximetry ......................................... 1-2, 2-5, 5-2, 6-4, 6-7, 6-8, 6-9, 7-1, 7-2, 7-4, 7-5, 7-6, 7-10, 7-11, 7-13, 7-14, 9-6, 9-8
qualifying premature infants ......................... 8-3
race ....................................................... 5-3, 6-4, 11-2, 11-12
randomization .......................................... 3-5, 3-10, 3-14, 4-2, 4-3, 6-1, 6-4, 6-8, 6-10, 6-11, 6-12, 6-13, 6-14, 6-15, 6-16, 6-17, 7-13, 8-1, 8-4, 9-1, 9-2, 9-3, 10-2, 10-6, 11-1, 11-8, 11-10, 11-12
<table>
<thead>
<tr>
<th>Term</th>
<th>Pages</th>
</tr>
</thead>
<tbody>
<tr>
<td>randomization log</td>
<td>6-12, 6-14, 6-15</td>
</tr>
<tr>
<td>randomize</td>
<td>3-14, 6-11, 6-12, 6-15, 10-3</td>
</tr>
<tr>
<td>randomized</td>
<td>1-1, 2-6, 4-2, 4-3, 4-10, 5-4, 6-4, 6-7, 6-11, 6-16, 6-17, 7-10, 7-11, 8-4, 8-8, 9-1, 9-3, 9-5, 9-8, 11-9, 11-12</td>
</tr>
<tr>
<td>recruitment</td>
<td>3-7, 3-10, 3-15, 3-16, 5-2, 11-8</td>
</tr>
<tr>
<td>refer</td>
<td>3-9, 4-3, 6-5, 6-8, 9-2, 11-10</td>
</tr>
<tr>
<td>referral</td>
<td>3-18</td>
</tr>
<tr>
<td>referred</td>
<td>3-10, 3-17, 4-4, 6-10, 8-7, 9-2</td>
</tr>
<tr>
<td>referring hospitals</td>
<td>6-19, 9-5</td>
</tr>
<tr>
<td>refuse consent</td>
<td>6-7</td>
</tr>
<tr>
<td>register</td>
<td>3-17, 6-1, 6-4, 6-10, 6-11, 6-15, 8-5</td>
</tr>
<tr>
<td>registered</td>
<td>3-7, 6-10</td>
</tr>
<tr>
<td>registration</td>
<td>6-11, 6-15</td>
</tr>
<tr>
<td>regress</td>
<td>1-2, 1-4, 1-6, 1-7, 1-11, 2-5</td>
</tr>
<tr>
<td>progresses</td>
<td>1-5, 1-10, 6-11, 6-16, 8-5, 9-2</td>
</tr>
<tr>
<td>regressing</td>
<td>1-11, 8-8</td>
</tr>
<tr>
<td>regression</td>
<td>1-5, 1-7, 1-8, 2-5, 2-6, 2-7, 4-6, 6-4, 6-11, 6-17, 8-1, 8-5, 8-6, 8-8, 9-3, 11-10</td>
</tr>
<tr>
<td>Rehospitalization</td>
<td>6-17, 9-5</td>
</tr>
<tr>
<td>Rehospitalization form</td>
<td>9-5</td>
</tr>
<tr>
<td>reimburse</td>
<td>3-15, 6-19</td>
</tr>
<tr>
<td>rejection</td>
<td>11-3, 11-4, 11-9</td>
</tr>
<tr>
<td>reschedule</td>
<td>6-17, 8-8</td>
</tr>
<tr>
<td>resources</td>
<td>4-7, 4-8</td>
</tr>
<tr>
<td>resuscitation</td>
<td>9-4</td>
</tr>
<tr>
<td>retina</td>
<td>1-12, 2-1, 2-5, 2-7, 7-2, 8-1, 8-2, 8-7, 8-8, 9-2</td>
</tr>
<tr>
<td>retinal detachment</td>
<td>1-2, 1-3, 2-1, 2-6, 6-7, 9-1, 9-2, 9-3</td>
</tr>
<tr>
<td>retinal examination</td>
<td>6-11, 6-12, 6-13, 6-14, 6-15, 6-17, 8-2, 8-4, 8-6, 8-7, 8-8</td>
</tr>
<tr>
<td>Retinal Examination form</td>
<td>6-11, 6-12, 6-13, 6-14, 6-15, 6-17, 8-2, 8-4, 8-6, 8-7, 8-8</td>
</tr>
<tr>
<td>retinal examinations</td>
<td>4-3, 8-1, 10-5</td>
</tr>
<tr>
<td>retinal fold</td>
<td>8-7, 9-2, 9-3</td>
</tr>
<tr>
<td>retinopathies</td>
<td>1-2, 1-12, 2-1, 2-5</td>
</tr>
<tr>
<td>retinopathy</td>
<td>1-1, 1-2, 1-11, 1-12, 2-1, 2-3, 2-5, 2-6, 2-7, 3-13, 3-17, 8-2, 9-1, 11-2</td>
</tr>
<tr>
<td>retrolental</td>
<td>1-11, 2-1, 2-3</td>
</tr>
<tr>
<td>retrolental fibroplasia</td>
<td>1-11, 2-1, 2-3</td>
</tr>
<tr>
<td>revascularization</td>
<td>2-3</td>
</tr>
<tr>
<td>Revised Denver Developmental Questionnaire</td>
<td>6-18</td>
</tr>
<tr>
<td>Revised Denver Pre-screening Developmental Questionnaire</td>
<td>9-6</td>
</tr>
<tr>
<td>ridge</td>
<td>8-7, 9-2</td>
</tr>
<tr>
<td>RLF</td>
<td>1-11, 2-1, 2-3</td>
</tr>
<tr>
<td>Rochester</td>
<td>2-1, 2-2, 3-1, 3-10, 3-13, 4-1, 7-6, 7-7, 9-7</td>
</tr>
<tr>
<td>room air</td>
<td>2-6, 5-1, 5-2, 6-7, 6-9, 6-16, 7-14, 9-6, 11-11, 11-12</td>
</tr>
<tr>
<td>ROP severity</td>
<td>6-5, 6-8, 6-14, 8-5</td>
</tr>
<tr>
<td>roster</td>
<td>3-15, 3-16</td>
</tr>
<tr>
<td>RPDQ</td>
<td>11-12</td>
</tr>
<tr>
<td>rush</td>
<td>1-4</td>
</tr>
<tr>
<td>sample size</td>
<td>1-2, 2-5, 3-1, 3-11, 5-4, 11-1, 11-3, 11-4, 11-6, 11-8, 11-11</td>
</tr>
<tr>
<td>sample sizes</td>
<td>11-4, 11-7</td>
</tr>
<tr>
<td>SaO2</td>
<td>7-4, 7-6, 7-8</td>
</tr>
</tbody>
</table>
saturated ........................................... 7-1
saturation ......................................... 6-16, 11-12
saturation in room air .............................. 5-2, 6-1, 6-5, 8-1, 8-3, 8-4, 9-6, 10-2
saturation monitoring ............................. 3-14, 6-8, 7-10, 7-12, 8-1, 9-6, 10-6
saturation values .................................. 5-2, 6-1, 6-5, 8-1, 8-3, 8-4, 9-6, 10-2
scars .................................................. 3-10
SCC .................................................. 3-7, 4-1, 4-3, 6-1, 6-4, 6-10, 6-11, 6-12, 6-16, 6-18, 7-11, 7-14, 8-4, 8-6, 8-7, 9-4, 9-5, 9-6, 9-8, 10-1, 10-3, 10-4, 10-5, 10-7
scleral depression ................................. 6-5, 8-2
scleral depressor ................................... 8-2
screen .............................................. 3-14, 6-8, 7-10, 7-12, 8-1, 9-6, 10-6
screening .......................................... 5-2, 6-1, 6-5, 8-1, 8-3, 8-4, 9-6, 10-2
second opinion ..................................... 3-10
seizures ........................................... 4-11, 6-17
sensitivity analysis .............................. 1-4, 1-9
sequential ......................................... 6-13, 11-3, 11-9
severity ........................................... 4-12, 5-4, 5-6, 6-12, 6-14, 8-5, 9-1, 9-4, 11-8
shock ............................................... 2-3
siblings ............................................ 9-6
sickle cell ......................................... 1-2, 1-12, 2-1
site visits .......................................... 3-5, 3-7, 10-4, 10-5
sketch ............................................. 10-1, 10-2, 10-3
smoking ............................................ 9-6
Social Security Number ........................... 6-19
social workers ..................................... 6-19
software ............................................ 3-14, 7-5, 7-10, 10-1, 10-6, 11-3, 11-4
space ............................................... 3-18, 6-12, 10-5
spending rate function ............................ 11-3
stage ............................................... 2-3, 6-1, 6-5, 6-6, 8-1, 8-2, 8-5, 8-7, 9-2
status ................................................ 1-1, 1-2, 1-3, 3-1, 6-4, 6-7, 6-8, 6-15, 6-18, 7-13, 8-1, 8-6, 8-7, 9-1, 9-4, 9-6, 9-8, 10-4, 10-5, 11-11, 11-12
stepdown ........................................... 6-19
sterile water ....................................... 8-3
sterilization ....................................... 8-3
sterilized .......................................... 8-3
stimulation ........................................ 8-3
STOP 00 ............................................ 3-17, 6-4, 6-15
STOP 01 ............................................ 6-11, 6-13, 6-14, 6-15, 6-16, 8-4
STOP 02 ............................................ 6-11, 6-12, 6-13, 6-14, 6-15, 6-17, 8-2, 8-4, 8-6, 8-7, 8-8, 10-3
STOP 03 ............................................ 6-16, 6-17, 8-6
STOP 04 ............................................ 6-18, 8-8, 9-3
STOP 05 ............................................ 6-18, 9-5, 9-6
STOP 06 ............................................ 5-2, 6-17, 8-8, 9-8
STOP 08 ............................................ 4-12, 9-7
STOP 09 ............................................ 6-18, 9-6
STOP 10 ............................................ 6-17
STOP 11 ............................................ 6-17, 9-5
STOP-ROP Cooperative Group ................. 4-5, 4-6
thrombosis ........................................... 7-1
timeline .................................................. 3-1, 3-5
tissue ..................................................... 9-7
tortuosity .............................................. 6-5, 8-2
toxicity .................................................... 2-7, 4-11, 9-5
trained .................................................. 1-12, 3-17, 5-2, 10-1, 10-2, 10-3, 10-5
training .............................................. 3-5, 3-9, 3-13, 3-14, 3-17, 7-11, 10-1, 10-2, 10-3, 10-4, 10-5, 10-6
Training and Certification Faculty .................. 3-13, 10-2, 10-5
transcutaneous ........................................ 7-1
transferred ............................................. 4-2, 6-4, 6-10, 6-13, 6-19, 7-10, 11-8
transportation ......................................... 7-11
transported ............................................. 5-2
treatment assignment ................................. 6-10, 6-14, 6-15, 6-16, 7-13, 9-3, 9-4
treatment policy ....................................... 4-2
two weeks .............................................. 1-1, 6-16, 8-3, 8-6, 8-7, 8-8, 9-2
ultrasound .............................................. 6-4
uncies .................................................... 6-19
uncontrolled .......................................... 1-1, 2-5, 5-3
unmasked .............................................. 6-17, 6-18, 8-6
unstable ................................................. 4-2, 5-17, 7-14, 8-8
utilities ................................................. 1-9
utility ..................................................... 1-7, 1-8
vascularized ........................................... 2-1, 6-17, 8-1, 8-7, 8-8, 9-2, 9-3
ventilation ............................................. 7-14
ventilator .............................................. 1-8, 6-7, 7-6, 7-11, 7-14, 11-11
ventilatory stability ................................. 9-4
ventilatory stimulants ................................ 9-4
vessels .................................................. 1-12, 6-1, 6-4, 6-5, 6-17, 6-2, 8-3, 8-5, 8-6, 8-7, 8-8, 9-3, 10-3
visual impairment ..................................... 9-4
visual loss ............................................. 2-3
weekly .................................................. 4-1, 6-11, 6-14, 6-16, 6-17, 6-18, 7-11, 7-14, 8-3, 8-4, 8-5, 8-6, 8-7, 8-8, 9-1, 9-4, 11-11
weekly examinations ................................. 6-11, 6-17, 6-18, 8-3, 8-4, 8-5, 8-6, 8-8
Weekly Outcome form ................................ 6-16, 6-17, 8-6
weigh ..................................................... 5-2, 9-6
weight .................................................. 1-1, 1-3, 1-4, 2-1, 2-2, 2-3, 5-2, 6-4, 6-11, 6-17, 9-4, 11-2, 11-8, 11-11
window .................................................. 6-17, 7-10, 9-3, 9-5
withdrawal ............................................ 2-5, 9-7, 9-8, 11-11
women .................................................. 5-3
writing teams .......................................... 3-11, 4-5
zone ..................................................... 1-3, 6-1, 6-4, 6-5, 6-6, 6-12, 6-16, 6-2, 8-3, 8-5, 8-6, 8-7, 8-8, 9-2, 9-3, 11-8