



MS
8920038

Memorandum

Date . SEP 29 1995
From Director, Office of Device Evaluation (HFZ-400)
Center for Devices and Radiological Health (CDRH)
Subject Premarket Approval of Healthdyne, Inc.
Healthdyne System 37[®] Home Uterine Activity Monitoring System
To The Director, CDRH
ORA _____

ISSUE. Publication of a notice announcing approval of the subject PMA.

FACTS. Tab A contains a FEDERAL REGISTER notice announcing:

- (1) a premarket approval order for the above referenced medical device (Tab B); and
- (2) the availability of a summary of safety and effectiveness data for the device (Tab C).

RECOMMENDATION. I recommend that the notice be signed and published.

Susan Alpert
Susan Alpert, Ph.D., M.D.

Attachments

- Tab A - Notice
- Tab B - Order
- Tab C - S & E Summary

DECISION

Approved _____ Disapproved _____ Date _____

Prepared by Kathy Daws-Kopp, CDRH, HFZ-470, 9/22/95:, 594-1180

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FOOD AND DRUG ADMINISTRATION

[DOCKET NO. _____]

Healthdyne, Inc.: PREMARKET APPROVAL OF System 37[®] Home Uterine
Activity Monitoring System

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing its approval of the application by Healthdyne, Inc., Marietta, GA 30067, for premarket approval, under section 515 of the Federal Food, Drug, and Cosmetic Act (the act), of System 37[®] Home Uterine Activity Monitoring System. FDA's Center for Devices and Radiological Health (CDRH) notified the applicant, by letter on September 29, 1995, of the approval of the application.

DATE: Petitions for administrative review by (insert date 30 days after date of publication in the FEDERAL REGISTER).

ADDRESS: Written requests for copies of the summary of safety and effectiveness data and petitions for administrative review to the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 1-23, 12420 Parklawn Drive, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

Colin Pollard,
Center for Devices and Radiological Health (HFZ-470)
Food and Drug Administration
9200 Corporate Blvd.
Rockville, MD 20850
301-594-1180.

SUPPLEMENTARY INFORMATION: On July 24, 1992, Healthdyne, Inc., Marietta, GA 30067, submitted to CDRH an application for premarket approval of System 37[®] Home Uterine Activity Monitoring System. The device is a Home Uterine Activity Monitor and is indicated for use, in conjunction with standard high risk care, for the daily at-home measurement of uterine activity in pregnancies \geq 24 weeks gestation for women with

previous preterm delivery. Uterine activity data are displayed at a remote location to aid in the early detection of preterm labor.

In accordance with the provisions of section 515(c)(2) of the act as amended by the Safe Medical Devices Act of 1990, this PMA was not referred to the Obstetrics and Gynecology Devices Panel, an FDA advisory panel, for review and recommendation because the information in the PMA substantially duplicates information previously reviewed by this panel.

On September 29, 1995, CDRH approved the application by a letter to the applicant from the Director of the Office of Device Evaluation, CDRH.

A summary of the safety and effectiveness data on which CDRH based its approval is on file in the Dockets Management Branch (address above) and is available from that office upon written request. Requests should be identified with the name of the device and the docket number found in brackets in the heading of this document.

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OPPORTUNITY FOR ADMINISTRATIVE REVIEW

Section 515(d)(3) of the act (21 U.S.C. 360e(d)(3)) authorizes any interested person to petition, under section 515(g) of the act (21 U.S.C. 360e(g)), for administrative review of CDRH's decision to approve this application. A petitioner may request either a formal hearing under part 12 (21 CFR part 12) of FDA's administrative practices and regulations or a review of the application and CDRH's action by an independent advisory committee of experts. A petition is to be in the form of a petition for reconsideration under 10.33(b) (21 CFR 10.33(b)). A petitioner shall identify the form of review requested (hearing or independent advisory committee) and shall submit with the petition supporting data and information showing that there is a genuine and substantial issue of material fact for resolution through administrative review. After reviewing the petition, FDA will decide whether to grant or deny the petition and will publish a notice of its decision in the FEDERAL REGISTER. If FDA grants the petition, the notice will state the issue to be reviewed, the form of the review to be used, the persons who may participate in the review, the time and place where the review will occur, and other details.

Petitioners may, at any time on or before (insert date 30 days after date of publication in the FEDERAL REGISTER), file with the Dockets Management Branch (address above) two copies of each petition and supporting data and information, identified with the name of the device and the docket number found in brackets in the heading of this document. Received petitions may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

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This notice is issued under the Federal Food, Drug, and Cosmetic Act (secs. 515(d), 520(h), (21 U.S.C. 360e(d), 360j(h)) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10) and re delegated to the Director, Center for Devices and Radiological Health (21 CFR 5.53).

Dated: _____.

A handwritten mark or signature, possibly a stylized 'Y' or a similar character, located in the bottom right corner of the page.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 29 1995

Mr. Timothy Cowart
Special Counsel/Director of Quality Assurance
Healthdyne, Inc.
1850 Parkway Place, 12th Floor
Marietta, Georgia 30067

Re: P920038
Healthdyne System 37® Home Uterine Activity Monitoring System
Filed: July 24, 1992
Amended: August 24, October 6, and December 11, 1992;
March 4 and 25, April 5, 6 and 22, May 18, September 28,
October 12 and 26, and December 13, 1993; January 28, May 23,
August 29 and 30, September 19, October 7, 12 and 14, 1994;
January 12, March 14 and 22, May 10, June 9 and 13,
July 20, August 23, September 6, 13, and 20, 1995

Dear Mr. Cowart:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed its review of your premarket approval application (PMA) for the System 37® Home Uterine Activity Monitor. This device is indicated for use, in conjunction with standard high risk care, for the daily at home measurement of uterine activity in pregnancies greater than or equal to 24 weeks gestation for women with previous preterm delivery. Uterine activity data is displayed at a remote location to aid in the early detection of preterm labor. We are pleased to inform you that the PMA is approved subject to the conditions described below and in the "Conditions of Approval" (enclosed). You may begin commercial distribution of the device upon receipt of this letter.

The sale, distribution and use of this device are restricted to prescription use in accordance with 21 CFR 801.109, within the meaning of section 510(e) of the Federal Food, Drug, and Cosmetic Act (the act) under the authority of section 515(d)(1)(B)(ii) of the act. FDA has also determined that to ensure the safe and effective use of the device that the device is further restricted within the meaning of section 520(e) under the authority of section 515(d)(1)(B)(ii), (1) insofar as the labeling specifies the requirements that apply to the training of practitioners who may use the device as approved in this order and, (2) insofar as the sale, distribution and use must not violate sections 502(q) and (r) of the act.

CDRH will publish a notice of its decision to approve your PMA in the FEDERAL REGISTER. The notice will state that a summary of the safety and effectiveness data upon which the approval is based is available to the public upon request. Within 30 days of publication of the notice of approval in the FEDERAL REGISTER, any interested person may seek review of this decision by requesting an opportunity for administrative review, either through a hearing or review by an independent advisory committee, under section 515(g) of the Federal Food, Drug, and Cosmetic Act (the act).

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Failure to comply with the conditions of approval invalidates this approval order. Commercial distribution of a device that is not in compliance with these conditions is a violation of the act.

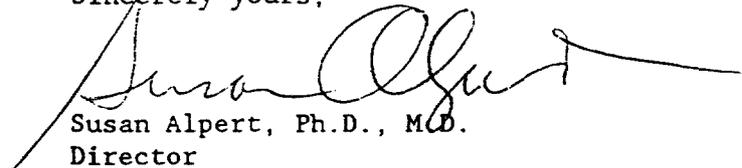
You are reminded that as soon as possible, and before commercial distribution of your device, that you must submit an amendment to this PMA submission with copies of all approved labeling in final printed form.

All required documents should be submitted in triplicate, unless otherwise specified, to the address below and should reference the above PMA number to facilitate processing.

PMA Document Mail Center (HFZ-401)
Center for Devices and Radiological Health
Food and Drug Administration
9200 Corporate Boulevard
Rockville, Maryland 20850

If you have any questions concerning this approval order, please contact Ms. Kathy Daws-Kopp at (301) 594-1180.

Sincerely yours,



Susan Alpert, Ph.D., M.D.
Director
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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SUMMARY OF SAFETY AND EFFECTIVENESS INFORMATION

I. GENERAL INFORMATION

Device Generic Name: Home Uterine Activity Monitor

Device Trade Name: System 37® Home Uterine Activity Monitoring System

Applicant's Name and Address:

Healthdyne, Inc.
1850 Parkway Place, 12th Floor
Marietta, Georgia 30067

Premarket Approval Application (PMA) No.: P920038

Date of Notice of Approval to Applicant: September 29, 1995

II. INDICATIONS FOR USE

The System 37® Home Uterine Activity Monitoring System (hereinafter referred to as the System 37) is indicated for use, in conjunction with standard high risk care, for the daily at-home measurement of uterine activity in pregnancies ≥ 24 weeks gestation for women with previous preterm delivery. Uterine activity data is displayed at a remote location to aid in the early detection of preterm labor.

III. DEVICE DESCRIPTION

The System 37 consists of a tocodynamometer, a Data Acquisition Unit (DAU), a Base Station, and a Receiving Computer. The tocodynamometer uses Smythe Guard Ring technology to detect pressure changes across the external surface of the maternal abdomen and outputs the data to the Data Acquisition Unit (DAU). The DAU records the output of the tocodynamometer, stores up to 240 minutes of continuous data, and provides this data to the Base Station. The Base Station receives data from the DAU, stores and transfers data via a modem to the receiving computer, and charges the internal battery of the DAU and Base Station. The Receiving Computer receives data from the Base Station and displays and prints data for review by attending medical personnel.

The tocodynamometer of the System 37 is a pressure sensing transducer that uses the Smythe Guard Ring principle of operation. The patient positions the tocodynamometer on her abdomen and secures the position by tightening an elastic belt. The DAU receives the output from the tocodynamometer and stores the information to memory. At the completion of the monitoring period, the patient connects (docks) the DAU with the Base Station, and the data is transferred from the DAU to the Base Station. Once the Base Station has received and stored the

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data, the patient or medical practitioner can transfer the data via a modem to the receiving computer.

The receiving computer, which is at a remote location, receives, stores, and displays the information to either hard disk or diskette. A printer interfaces via cable with the receiving computer through a dedicated port on the computer. The hardware of the receiving computer is an NEC 386SX, 16/20 MHz or other equivalent computer conforms to the Healthdyne specifications. The software includes a commercially available DOS operating system and a proprietary software package for transferring the data via a telephone modem from the Base Station to the receiving computer. In addition, a proprietary software package is used to receive, store, access, display, and print the data.

IV. CONTRAINDICATIONS, WARNINGS AND PRECAUTIONS

There are no known contraindications for the System 37.

Warnings and precautions can be found in the System 37 labeling (See Attachment 1).

V. ALTERNATE PRACTICES AND PROCEDURES

Current practices for detecting uterine contractions require patient education programs designed to increase the patient's awareness of the signs and symptoms of preterm labor. As part of the educational program, patients may be instructed manually to monitor (palpate) uterine contractions. In addition, frequent assessment of cervical status and intensive nursing services have also been used to assist in the detection of preterm labor (PTL). Further, the use of other legally marketed HUAM devices for monitoring PTL has been available since 1989.

VI. MARKETING HISTORY

The System 37 has not been marketed for preterm labor use in the United States or any foreign country. In January of 1990, the System 37 was cleared via 510(k) Premarket Notification for home monitoring of low risk pregnancies *at term*.

VII. POTENTIAL ADVERSE EFFECTS OF THE DEVICE ON HEALTH

Within the studies that have been performed to date, there have been no reported adverse effects on health.

Even though no adverse effects were reported, the potential exists for mild discomfort associated with overtightening the belt. The potential for this occurrence is remote since the belt is easily adjusted to fit a wide range of girths. Also, the Data Acquisition Unit (DAU) provides a visual indication to the patient/health care provider to show that the belt is sufficiently tight. In addition, the potential is

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present to cause skin irritation as a result of external contact between the surface of the tocodynamometer and the patient's abdomen. To date, there have been no cases of skin irritation reported during any of the studies. This potential is considered remote since the tocodynamometer is generally worn only 2 hours per day. In conjunction, the potential is further reduced since the patient contacting material is silicone rubber that is considered safe for skin contact.

The DAU is completely battery-powered (rechargeable from the Base Station) and the Base Station is also powered by rechargeable batteries. The battery charger used by the Base Station is listed and approved by the Canadian Standards Association (CSA). The potential for electric shock while using either the DAU or Base Station is remote since it would require unscrewing and removing the housing cover that shields and protects the internal electronic subassemblies. As with any electronic device, a patient should not use the device while bathing or near water. There were no adverse events reported regarding electrical hazards, and labeling cautions the patient not to remove the housing cover or use the device while bathing or near water. In addition, the patient is cautioned not to send data via telephone modem from the Base Station to the Receiving Computer during an electrical storm.

VIII. SUMMARY OF PRECLINICAL STUDIES

LABORATORY STUDIES

The objectives of the laboratory studies were to test the performance of the software and hardware. This testing included development techniques used for verification of performance involving emulation of the software modules, integration testing of the modules linked together, system testing of the hardware and software, and clinical testing of the hardware and software.

Module level and integration testing of the software program included testing as follows: (1) under normal systems operation within the normal systems environment; (2) at data input extremes, both inside and outside of the allowed ranges.

System level or bench testing of the System 37 included data integrity checks of the system. This was accomplished by providing controlled, simulated input signals to the tocodynamometer and the DAU, transferring the input data to the Base Station and Receiving Computer, and printing the data for comparison to the known input signals. In addition, system level testing of the System 37 included word error rate testing of the datalinks within the System 37.

ADDITIONAL STUDIES

The objectives of the additional studies were to investigate compliance with the electromagnetic compatibility standards, electrical safety standards, and other standards specified within the Premarket Testing Guidelines for Home Uterine Activity Monitors (Guide).

Electromagnetic Compatibility (EMC) Testing. This testing evaluated the compliance of the device to various EMC standards. Emissions and Immunity were performed on the entire device. The device met the requirements for the expected environment for the various components of the device.

Electrical Safety Testing. The Base Station within the System 37 is powered by rechargeable batteries and uses a battery charger specifically designed for medical applications. The electrical safety of the battery charger was evaluated and was found to meet generally accepted safety requirements.

Other Testing. The objective of this testing was to reach compliance with requirements from our Guide for Mechanical Vibration and Shock Resistance, Fluid Spill, High and Low Temperature and Humidity, and Reliability Tests. These tests were performed on the entire device. The device met the requirements for the various components of the device.

IX. SUMMARY OF CLINICAL STUDIES

CLINICAL FEASIBILITY STUDIES

The applicant performed two clinical tests to verify that the System 37 could record, transmit, and display uterine activity data with women experiencing active labor in the hospital environment. The first test compared the performance of the System 37 with the performance of a commercially marketed product using an external tocodynamometer. The results show that the System 37 detected 98.7% (0.962 correlation coefficient) of the uterine contractions detected by the other product.

The objective of the second phase of clinical feasibility testing was to determine whether the System 37 with an external tocodynamometer could accurately record the uterine contraction frequency, amplitude, duration, and peak time when compared with a commercially available perinatal monitor with an internal uterine catheter. The mean frequency of uterine activity was nearly identical (17.9). In addition, the System 37 recorded an average of 88% of the uterine contraction amplitudes detected by an internal catheter.

PIVOTAL CLINICAL TRIAL

The objective of this clinical study was to assess the safety and effectiveness of the System 37 in use with standard high risk care as an aid in the early detection of preterm labor.

Study Design

Clinical investigations were conducted at four sites: Hutzel Hospital, Detroit, Michigan; LAC/USC Medical Center, Los Angeles, California; Jefferson Medical Center, Philadelphia, Pennsylvania; and Our Lady of Lourdes, Camden, New Jersey.



The study was a prospective, randomized, controlled, multi-center single blind study. The inclusion criteria for all study participants were as follows:

1. A pregnancy between 24 and 36 weeks gestation;
2. A Creasy score of ≥ 10 ;
3. Written consent to participate; and
4. A diagnosis of a previous history of preterm delivery;
or
5. Multiple gestation;
or
6. Preterm labor in the current pregnancy.

The exclusion criteria were as follows:

1. Fetal distress,
2. Intrauterine death,
3. Abruption Placenta,
4. Pre-eclampsia, or
5. Any and all medical diseases or conditions that require termination of the pregnancy.

Study subjects were randomized to one of two arms: (a) standard high risk obstetrical care (Control) versus (b) use of the System 37 for two hour sessions per day plus standard high risk obstetrical care (Monitored) to determine if the addition of the System 37 to standard high risk care resulted in the earlier detection of preterm labor (PTL).

All subjects received the same standard obstetrical care provided to high risk subjects as part of prematurity prevention programs at each of the medical centers. Subjects in each group received identical educational sessions regarding signs and symptoms of preterm labor and techniques of self-palpation of uterine contractions.

All subjects were scheduled for routine evaluation by their obstetrician at least every four weeks until 30 weeks gestation, at least every two weeks between 30 and 36 weeks gestation, and at least weekly thereafter.

Subjects were scheduled for a non-routine medical visit if the frequency of uterine contractions (each contraction > 40 seconds) was four or more per hour (as determined by the monitor or self palpation) or if the patient noticed other signs or symptoms of preterm labor described to her in the initial educational sessions.

The applicant chose to request approval only for use on subjects with previous preterm delivery (PPTD). Therefore, the labeling claims for this device concern only those subjects enrolled with PPTD. Statistical analyses were reported for this

subgroup only. The remaining subjects in the study were included in the safety analysis of the device.

Patient Assessments

The diagnosis of preterm labor was determined by clinical examination under the following preterm labor study definition:

- a. Gestational age between 24 and 36 completed weeks;
 - b. Four (4) or more uterine contractions per 60 minutes and ruptured membranes;
- or
- c. Four (4) or more uterine contractions per 60 minutes and intact membranes and documented cervical change occurring during the current visit, or intact membranes and cervical effacement of 80% or cervical dilation of 2 centimeters or more.

No sham monitoring was conducted in the control group, and the protocol did not standardize the use of specific medical interventions for PTL such as the frequency of bedrest, cervical examinations, or specific tocolytic regimens.

The outcome measures for this study were:

Primary

1. Cervical status (dilation and effacement) at time of PTL diagnosis;

Secondary

2. Average gestational age at delivery;
3. Neonatal weight at delivery; and
4. Neonatal length of hospital stay.

Study Population

The total population of subjects enrolled for all risk factors was 586. Of those, 231 (121 control and 110 monitored) were multiple gestations and 355 were singletons (186 control and 169 monitored). The single and multiple gestations were randomized separately. A total of 137 (73 control and 64 monitored) singletons were enrolled with PTL in the current pregnancy. For that subgroup, 81 (60 control and 21 monitored) completed the study and 22 (16 control and 6 monitored) experienced PTL. For the twin's subgroup, 109 (80 control and 29 monitored) completed the study and 39 (25 control and 14 monitored) experienced PTL.

218 Subjects Enrolled with PPTD	
105 Control	113 Monitored
101 Completed study to Delivery	86 Completed study to Delivery
19 PTL Diagnosis	21 PTL Diagnosis

A total of 218 high risk women with a PPTD met the entry criteria and consented to participate in the study. Independent randomization at each site resulted in 105 women in the control group and 113 women in the monitored group. From these 218 women, the preterm status is known for 187 members of the group. Among the women for whom preterm labor was known, 40 subjects with PPTD (19 or 19% control, 21 or 24% monitored) experienced preterm labor.

At FDA request, three control subjects were removed from the analysis due to data discrepancies. Exclusion of these subjects from the analysis did not change the conclusion drawn from the clinical study.

Data Analysis and Results

Of the enrolled and randomized study subjects who met the entry criteria with PPTD and experienced an event of preterm labor, monitored women had statistically less cervical dilation at the time of diagnosis of PTL when compared with the control group (Table 1).

TABLE 1

Mean (SD) Cervical Dilation (cm) at Time of PTL Diagnosis

Monitored (N = 21)	Control (N = 19)	p-value
1.71 (.90)	2.68 (1.3)	0.014

If tocolytic therapy for PTL is initiated before cervical dilation reaches 2 cm, it is considered more likely to be successful. The number of subjects with a history of a PPTD from the monitored and control group with < 2 cm in dilation at the time of diagnosis of PTL were compared (Table 2).

TABLE 2

Percent with < 2 cm Dilated at the Time of PTL Diagnosis

Monitored (N = 21)	Control (N = 19)	p-value
52.3%	21.0%	0.041

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The primary outcome measure for this study was cervical status at time of PTL diagnosis. Since some subjects had cervical dilation before the onset of labor, a comparison of the change in dilation from the examination immediately before the onset of preterm labor was completed (Table 3).

TABLE 3

Mean (SD) Change in Cervical Dilation (cm) at Time of PTL Diagnosis

Monitored (N = 21)	Control (N = 19)	p-value
1.29 (0.64)	1.84 (1.3)	0.11

The mean change in cervical dilation at the time of the diagnosis of preterm labor for women with PPTD was 1.29 in the monitored group and 1.84 in the control group (p = 0.11). While the difference between the two groups is not significant, the data shows a trend toward a significant difference between the two groups. Data tables are not presented on safety analysis, since no adverse events of any kind were reported.

XI. CONCLUSIONS DRAWN FROM THE CLINICAL STUDIES

The System 37 can be used to detect, record, and transmit uterine contraction data to qualified medical professionals for evaluation.

Analysis of the PPTD study population ($N_m = 21$, $N_c = 19$) revealed that there was a statistically significant difference between the mean cervical dilation of the monitored population (1.71 cm) versus the control population (2.68 cm) at the time of diagnosis of PTL. Further, there is a statistically significant difference in percent < 2 cm dilated at time of PTL diagnosis (52.3% versus 21.0%).

It should be noted that the System 37 was used in conjunction with a standard care regimen for women at high risk of preterm labor. Standard care as used in this study consisted of routine clinical visit every four weeks up to 30 weeks gestation and every two weeks thereafter until 36 completed weeks of gestation. This care, which did not include daily nursing contact, served as the control for the study.

Based on this outcome data, limitations in the study design did not allow for conclusions regarding the effects of treatment, sham monitoring, frequency of cervical exams, the potential benefits of frequent nursing contact, or the potential benefits of the CareFone™ HUAM when used as an addition to obstetrical care that differs significantly from the care provided as part of this study.

XII. PANEL RECOMMENDATION

Pursuant to section 515(c)(2) of the Food, Drug and Cosmetic Act (the Act), as amended by the Safe Medical Devices Act of 1990, this PMA was not referred to the Obstetrics and Gynecologic Devices Panel, an FDA advisory panel, for review and recommendation because the information in the PMA substantially duplicates information previously reviewed by this panel. However, at three consecutive Panel meetings on April 29-30, 1993; September 1-2, 1994; and April 24, 1995, FDA sought guidance on several general issues relating to this and other PMAs and to the use of HUAM devices. The issues discussed with the Panel consisted of inclusion of subjects at early and late gestational ages (GA), target study populations, clarifications on acceptable definitions of PTL, prophylactic tocolysis use, minimum standard care, cervical dilation as a primary endpoint, inclusion of specific subgroups in the analysis, significance of the results of specific subgroups, the quality of the data transmission, labeling and promotional claims, post approval studies, and the impact of other studies showing negligible effect. The issues and Panel discussion are presented in more detail below.

On April 29-30, 1993, the Panel addressed generic HUAM study design questions, as follows:

- (1) **Intra- and Inter-observer Variance for Cervical Exams.** (This addresses the variance that occurs in these inexact measurements between observers and between exams for the same observer). The Panel concluded that, within reason, this must be tolerated because there are no known alternatives to this system of clinical management.
- (2) **Definition of Preterm Labor.** In several variations of this discussion, it was determined that nearly any definition, within reason, is acceptable if it is applied equally to study and control arms, regardless of whether the subject delivers in a timely manner.
- (3) **Prophylactic Tocolysis use.** It was noted that prophylactic tocolysis (i.e., use of tocolytics before PTL is diagnosed) might influence the primary study endpoint, cervical dilation at PTL diagnosis. The Panel indicated that cases where tocolysis is used, both before and after PTL diagnosis, should not be excluded, as long as such use is evenly balanced between the control and study arm.
- (4) **Medically Indicated Preterm Deliveries.** At one point, it was suggested that medically indicated preterm deliveries should be excluded from analysis because these subjects could not have benefited from such HUAM monitoring. The Panel indicated that it would be appropriate to include these subjects in analysis for cervical dilation, but they should be excluded from the analysis for perinatal outcome.

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- (5) **Subgroup Analysis by Gestational Age.** It was noted that, in a significant portion of the study, PTL diagnosis occurred after 34 weeks gestation. Subgroup analysis of the women diagnosed in PTL before this point might be very useful. The Panel commented that such analysis was beyond the scope of the original hypothesis, and thus, should not be required.
- (6) **Data Transmission Quality.** The FDA asked the Panel to comment on appropriate review criteria for assessing the quality of data transmission resulting from the combination of transducer, signal processing, telephone transmission, and data display. The Panel commented that the resulting display of the uterine contraction tracing should not be so distorted as to cause misinterpretation.

On September 2, 1994, the Panel addressed generic HUAM study design questions, as follows:

- (1) **Cervical Dilation as a Primary Endpoint.** FDA argued that diagnosis of PTL can only be truly confirmed retrospectively. Thus, FDA posed, the use of cervical dilation in the definition of PTL results in a problem determining the disposition of subjects who do not continue promptly from PTL diagnosis to delivery. The Panel agreed that this study endpoint has ascertainment bias, but any other treatment of this data would undermine the prospective nature of the study. Furthermore, the Panel acknowledged that this endpoint is compatible with clinical practice and no better alternative could be identified.
- (2) **Standard Care for High-Risk Pregnancies.** FDA questioned whether the control arm of the study received adequate care, in terms of detecting PTL. If inadequate, this could lead to a misleading comparison between the monitor and control groups. The Panel acknowledged the widely varying management regimens at different clinical centers. However, they did not find that any of the current regimens used for control subjects were substandard.
- (3) **Labeling Claims.** As evidenced by reduced cervical dilation at diagnosis, HUAMs are useful for the early detection of preterm labor. FDA suggested that the Panel discuss the implied claims for the product and any resulting modifications to the consumer labeling. They discussed potential labeling changes, but did not come to any majority conclusions.
- (4) **Postapproval Studies.** FDA proposed the possibility of addressing important clinical issues that might not have been addressed in the premarket studies in a post market study. The Panel discussed the various inadequacies brought up during the discussion of question one as potential concerns for a postapproval study. However, they did not come to a consensus on any specific type of postapproval study.



On April 24, 1995, another Panel meeting was held to discuss a recent publication on a randomized controlled study that showed monitoring had no effect when compared with a sham control containing frequent nursing contact. At this meeting the Caremark study¹ was formally presented. Representatives from industry and the general public were given an opportunity to comment.

Additionally, the Panel was given a history of HUAM regulation and addressed generic HUAM study design questions, as follows:

- (1) **Preterm Labor Definition - Postdiagnosis Failure to Proceed to Labor.** This question pertains to the situation where PTL is diagnosed and no intervention is prescribed, but Delivery does not follow in a timely fashion (within 2 weeks). Should the diagnosis of PTL stand? Some members of the Panel opined that PTL could stop. It was determined that the effect would be even in both control and treatment arms and the diagnosis should stand.
- (2) **Study Populations.** FDA questioned whether specific socio-economic groups (such as tobacco smokers) should be excluded or included because of their possible effects on the data. The Panel determined that FDA should not mandate that specific target populations be included in the study populations, other than those at risk for PTL.
- (3) **Affect of Other Studies That Showed No Added Effect from HUAM Use.** FDA asked the Panel about the impact of the Caremark study on the labeling claims of other HUAM devices. The Panel stated that few issues have a record of completely positive results. Specific changes to the labeling requirements were not recommended.

¹ Devoe, et al. A Multicenter Randomized Controlled Trial of Home Uterine Monitoring (HUAM): Active Vs. Sham Device. American Journal of Obstetrics and Gynecology, SPO Abstracts 1995;172(1):253.

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XIII. CDRH DECISION

CDRH evaluated the concerns identified with the System 37 study, in light of the comments and guidance obtained from the advisory Panel. In particular, CDRH concurred with the Panel's decision that use of the PTL definition was acceptable as long as the definition was consistently applied to all study arms. CDRH removed from the data analysis those subjects that did not appear to meet the definition of PTL. In addition, the applicant was required to submit information to address the issue of potential bias in the use of tocolytics. CDRH determined that there was not sufficient evidence to conclude that bias existed.

Based upon a review of the data contained in the PMA, CDRH determined that the System 37 Home Uterine Activity Monitoring System has been shown to be effective for the indications as specified in the labeling. FDA issued an approval letter on September 29, 1995.

The applicant's manufacturing facility was inspected on August 12, 1993, and was found to be in compliance with the Good Manufacturing Practice Regulations.

XIV. APPROVAL SPECIFICATIONS

Directions for use: See attached Labeling

Warnings, Hazards to Health from the Use of the Device: See indications, contraindications, warnings, precautions and adverse reactions in the attached labeling.

Conditions of Approval: CDRH Approval of this PMA is subject to full compliance with the conditions described in the approval order.

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PHYSICIAN INFORMATION SHEET

CAUTION

Federal law restricts this device to sale, distribution or use by or on the order of a physician. The device is further restricted with respect to the training of the ~~medical practitioners~~ ^{physicians} who may use the device.

I. Device Description and Features

The System 37^R Home Uterine Activity Monitoring system consists of a tocodynamometer or sensor, a Data Acquisition Unit (DAU) or Recorder, and a Base Station or transmitter. The System 37^R is a solid state physiologic data recorder designed to collect maternal uterine activity information via tocodynamometer and transmit that data to a remote site.

II. Indications for Use

The System 37^R is indicated for use in conjunction with standard high risk care, for the daily at-home measurement of uterine activity in pregnancies ≥ 24 weeks gestation for women with a history of previous preterm delivery (PPTD). Uterine activity data is displayed at a remote location to aid in the early detection of preterm labor.

III. Contraindications

Studies have not revealed any contraindications for the System 37^R.

IV. Warnings

This device will not prevent or predict the onset of preterm labor nor will it prevent the occurrence of preterm birth. The System 37^R monitors uterine activity and provides this information to the physician for assessment and, if necessary, intervention.

The battery charger should be plugged into a properly grounded three-pronged AC outlet. Extension cords or adapter plugs should not be used. A properly grounded adapter plug - one that has a grounding wire that is attached to a properly grounded AC outlet - can be used.

Do not operate the battery charger or the Base Station if it or the cable is damaged, cut, or broken. Contact your service center for assistance.

Always keep the Data Acquisition Unit (DAU), Base Station and battery charger away from any and all heated surfaces.

Always keep the DAU, Base Station and battery charger away from children, and follow the instructions provided in this manual to ensure the proper use of the system.

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The DAU and Base Station are sensitive electronic instruments. Handle with care and do not drop either device. If you should drop either device, contact your service center for immediate assistance.

V. Precautions

The System 37^R should not be used by the patient while bathing or near water as an electrical shock hazard is present.

Do not send data during an electrical storm while the System 37^R is attached to a telephone line. A lightning strike could cause the information to be lost during transmission or damage to the equipment could occur. Recording with the DAU can be performed and completed during an electrical storm.

Do not place liquids or spill liquids on the DAU or Base Station. Although the surfaces of the equipment provide certain resistance to liquid spills, damage to the equipment could result. If liquid is spilled on either piece of equipment, contact your service center for assistance.

Do not use the System 37^R outdoors or expose it to direct sunlight, rain, or moisture. Do not operate where aerosol products are being used or when oxygen is being administered.

If the sensor belt is pulled too tight, there could be some discomfort. To avoid this problem, adjust the belt to a more comfortable fit.

Patients with acute psychiatric disorders may not be able to comply with monitoring.

Patients without a telephone may be unable to transmit data twice daily unless special arrangements are available.

VI. Adverse Reactions

To date, no adverse reactions have been reported concerning the use of the System 37^R.

As with any electrical device, the System 37^R should not be used while bathing or around water as an electrical shock hazard is present.

The tocodynamometer or sensor may possibly cause skin irritation. The sensor is generally worn two hours per day. To date there have been no reports of skin irritation.

VII. Directions for Use

A. After prescription of the System 37^R by a physician, the patient should be educated regarding the signs and symptoms of preterm labor per standard high risk care.

B. The patient should receive instructions from a qualified medical practitioner regarding the proper operation of the System 37^R. These instructions should include the appropriate location for the

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tocodynamometer or sensor placement to facilitate uterine activity detection.

- C. The patient should be instructed by a qualified medical practitioner to monitor her uterine activity for one hour in the morning and one in the evening. The patient should be reclining in a chair or bed during the data collection period. The recorded data should be transmitted shortly after each recording session. Should the patient perceive uterine activity at other times of the day, she should be instructed to contact her physician or the Healthdyne Perinatal Service Center. She may then be instructed to monitor her uterine activity and transmit this data immediately.

VIII. How Supplied

Use of the System 37^R may be provided to patients by private practice physicians, hospitals, licensed home health care services, or by Healthdyne on the prescription of a physician. The System 37^R is available for purchase by physicians, hospitals, or licensed home health care agencies. The data collected by the System 37^R can be transmitted to a Healthdyne Perinatal Service Center. Uterine activity data should be reviewed by trained perinatal nurses or physicians.

IX. Clinical Studies

A collaborative, multicenter, prospective randomized clinical trial was conducted at four sites to determine if the use of the System 37^R Uterine Activity Monitoring System in addition to high risk obstetrical care resulted in an early detection of preterm labor. Study subjects were randomized to one of two study arms: (a) standard high risk obstetrical care without sham monitoring (control) versus (b) use of the System 37^R in addition to standard high risk care (monitored).

Standard care for both groups of these high risk patients comprised (i) patient education regarding the signs and symptoms of preterm labor and the techniques of self-palpation of uterine contraction, and (ii) routine obstetric evaluations every four weeks until 30 weeks gestation, at least every two weeks between 30 and 36 weeks gestation, and at least weekly thereafter. The monitored group was required to remain at rest for two one-hour recording periods each day, while the control group was not. Both groups were advised to limit their physical activity.

Patients were scheduled for a non-routine medical visit if the frequency of uterine contractions (each contraction > 40 seconds) was four or more per hour (as determined by the monitor or by self-palpation) or if the patient noticed other signs or symptoms of preterm labor described to her in the initial educational sessions. Diagnosis of preterm labor was defined as four or more uterine contractions per hour with cervical changes as assessed by clinical examination.

A total of 218 high risk women with previous preterm delivery met the entry criteria and consented to participate in the study. Independent randomization at each site resulted in 105 women in the control group and 113 women in the monitored group. From these 218 women, the term and preterm delivery status

is known for 187 members of the group. Among the women for whom preterm labor status was known, 40 patients (21 or 24% monitored, 19 or 19% control) experienced preterm labor. Of the enrolled and randomized study subjects who met the entry criteria and experienced preterm labor, monitored women had statistically less cervical dilation at the time of diagnosis of preterm labor (Table 1).

TABLE 1

Mean (SD) Cervical Dilation (cm) at Time of PTL Diagnosis

Monitored (N = 21)	Control (N = 19)	p-value
1.71 (0.90)	2.68 (1.3)	0.014

Of the women who experienced preterm labor, more of the women in the monitored group were less than two centimeters dilated at the time of preterm labor diagnosis as compared to the women in the control group (Table 2).

TABLE 2

Percent with < 2 cm Dilated at the Time of PTL Diagnosis

Monitored (N = 21)	Control (N = 19)	p-value
52.3%	21.0%	0.041

Limitations in the study design do not allow for conclusions on device effectiveness with respect to bedrest, sham monitoring, frequency of cervical exams, or obstetric care differing significantly from that specified in the study protocol, as described above. In addition, limitations in the study design do not allow for conclusions with respect to reducing the incidence of preterm birth. Furthermore, limitations in the study design do not allow for assessing the effects of nursing care that will be used in conjunction with the device.

**SYSTEM 37^R
USERS
OPERATING
INSTRUCTIONS**

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CAUTION

United States Federal law restricts this device to sale, distribution, or use by or on the order of a physician. The device is further restricted with respect to the training of ~~medical practitioners~~ who may use the device.

physicians

UNDERSTANDING LABOR AND PRENATAL MONITORING

Anatomy of Pregnancy

Pregnancy brings many physical changes. The following brief description and drawing are to help you understand what is happening to your body during pregnancy.

The baby grows inside your uterus (womb), which is located between your bladder and rectum. Inside the uterus is an organ called the **placenta**. The placenta begins to form and grow at the time the fertilized egg implants in your uterus. The placenta delivers the nutrients the fetus (baby) needs for growth and removes waste products. The **umbilical cord** connects the developing fetus and placenta. The fetus floats inside the **amniotic sac** located in your uterus. This sac is filled with fluid which cushions the fetus. Before delivery can occur, this sac must rupture (open). The fluid leaks out through your vagina. You may have heard this referred to as your "water breaking" or "ruptured membranes".

Your **cervix** is located at the bottom of your uterus. During pregnancy, your cervix is pointed toward the back of your vagina and is firm (like the tip of your nose) and closed. When labor begins, the cervix begins to efface (thin) and dilate (open). This allows the fetus to pass from the uterus into the vagina (birth canal) and then out of your body. The mechanism for delivery of the fetus is called **labor**. Labor will be discussed in more detail later in this handbook.

Uterine Contractions

The uterus is a muscle which contracts and relaxes. When a contraction begins, your uterus becomes tight and hardens to the touch. When the contraction stops, your uterus becomes soft again--which is the normal state. It is normal for your uterus to contract at various times during your pregnancy. Contractions may occur after certain activities, such as when you lie down, after sexual activity, or after you walk up or down a flight of stairs. It is not normal for you to have frequent and regular uterine contractions before your baby is due. If you sense a feeling of frequent and regular uterine activity, for example, 4 contractions per hour, your uterus may be contracting prematurely, alerting you that preterm labor may have begun.

Labor

Labor occurs when the uterus begins to contract in a regular and frequent pattern. It is followed by the effacement and dilatation of the cervix and delivery of your baby. Labor normally takes

place approximately 280 days (40 weeks) following the onset of your last menstrual period.

Preterm Labor

Labor is considered preterm labor when it occurs more than three weeks before your expected delivery date.

The cause of preterm labor is not known. In fact, as many as one-half of all women who deliver prematurely do not have any identifiable risk factors. Preterm labor may occur in active as well as inactive women, during the first pregnancy or during a subsequent pregnancy.

There is an increased risk of preterm labor for women who have experienced preterm delivery in a previous pregnancy and women who are carrying more than one baby during pregnancy.

Warning Signs of Preterm Labor

The onset of preterm labor is often very subtle and difficult to recognize. Preterm labor is usually not painful; therefore, you must be aware of the early warning signs of preterm uterine activity and what to look for. Throughout your pregnancy, you may experience some or all of the signs and symptoms that have been associated with preterm uterine activity. These include;

- Increased uterine activity/contractions
- Menstrual-like cramps
- Intestinal cramping (with or without diarrhea)
- Low dull backache
- Pressure or pain in the lower abdomen, back or thighs
- Pelvic Pressure
- Vaginal discharge (change or increase)
- Sense of "feeling bad"

Should you have any questions or comments about these signs and symptoms, you should contact your doctor or the Healthydyne Perinatal Service Center for further information.

You should also learn to identify the following:

Uterine Contractions. The following best describes the sensation of a uterine contraction; If you flex or bend your arm, you can feel the muscle in your upper arm tighten. As you slowly relax your arm, you can feel the muscle soften. This is similar to how your uterus feels when it tightens and relaxes during a uterine contraction. A contraction usually lasts 30-90 seconds.

Menstrual-like Cramps. The menstrual-like cramps (cramping discomfort) that may be associated with the early signs of preterm labor occur in the lower abdomen. This cramping may come and go in a regular pattern, or may be continuous and radiate to your back (see below).

Low, Dull Backache. The low, dull backache that is sometimes associated with preterm labor may come and go, or it may be constant.

Pelvic Pressure. A sensation of pressure in the lower abdomen, back, or thighs (sometimes described as heaviness in the pelvis).

Vaginal Discharge. Vaginal discharge may increase or change into a mucous or watery, light, or bloody discharge. A change in discharge has been associated with preterm labor. If you experience a gush of fluid from your vagina, your water may have broken and you need to call your doctor immediately.

Should you experience any of these indications, call your doctor or the Healthdyne Perinatal Service Center and carefully follow the instructions provided to you.

If your doctor determines that you are at risk for preterm labor, or that you are experiencing any of the early warning signs of preterm labor, you may be directed to do the following:

Increase Your Rest. Resting on your side is a helpful way to keep your uterus relaxed.

Your doctor may prescribe rest periods ranging from twice a day (for 2 hours each) or modified bed rest, consisting of complete rest with activity limited to getting up to go to the bathroom and sitting for meals.

Decrease Strenuous Activity. Your doctor may request that you do not participate in strenuous activity, such as jogging, running, playing tennis, or frequent trips up and down stairs. Your doctor may also limit heavy lifting, cleaning, and long trips.

Consider Temporary Change in Job Activities. Work activities may need to be modified, decreased, or stopped depending on your doctor's evaluation of your medical condition.

Sexual Activity. Your doctor may request that you limit or stop your sexual activities.

Breast Preparation. Breast preparation may be postponed by your doctor until three (3) weeks prior to your delivery date. This delay is because of the association of breast preparation (breast massage or nipple rolling) and the stimulation of uterine activity/contractions.

Childbirth Classes. Your doctor may encourage you to attend childbirth classes but advise you to avoid all physical activities except for the breathing exercises. Always remember to follow your doctor's instructions regarding your prenatal preparation and activities.

If the following situations occur, call your doctor immediately.

Bleeding: If you notice any bleeding, report it to your doctor. A large gush or steady stream of bright red blood is an emergency. Get help immediately, lie on your side and put your feet higher than your head.

Rupture of the Bag of Water (Amniotic Fluid): Occasionally the

bag of fluid around the baby will rupture prematurely. If you notice a gush of fluid or a steady trickle of fluid you should notify your doctor. Be certain to note any color or odor that might be present in the fluid.

Intense Abdominal Pain: If you experience constant, intense pain, regardless of whether you're having contractions or not, notify your doctor.

ANY OF THE ABOVE SITUATIONS MAY INDICATE AN EMERGENCY. CONTACT YOUR DOCTOR IMMEDIATELY.

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MONITORING ACTIVITIES

Uterine Activity Monitoring

Indications for Use

The System 37^R is used in conjunction with standard high risk care, for the daily at-home measurement of uterine activity in pregnancies \geq 24 weeks gestation for women with a history of previous preterm delivery (PPTD). Uterine activity data is displayed at a remote location to aid in the early detection of preterm labor.

Description

Healthdyne's System 37^R is used to monitor uterine activity. The monitor allows you to record, store, and send your uterine activity information over a standard telephone line for review by clinical personnel.

The portion of the System 37^R used in your home consists of the following three basic components: the sensor or tocodynamometer, the Data Acquisition Unit (DAU) or Recorder, and the BaseStation or Transmitter.

The sensor or tocodynamometer detects your uterine activity and provides information to the Recorder (See Illustration One).

The DAU or Recorder receives and stores the information provided from the Sensor (See Illustration Two). The DAU stores the information until it is transferred to the BaseStation. In addition, the Recorder performs the following functions:

1. Provides an indication of good Sensor contact with your abdomen.
2. Allows you to mark uterine contractions that you feel.
3. Provides an alarm indication, when, 60 minutes of information has been recorded, the memory of the Recorder is full, or the batteries of the Recorder need recharging.

The BaseStation provides a "home for the Recorder when it is not in use, stores the information provided to the DAU, recharges the batteries in the Recorder, and sends the recorded information over the telephone for review by clinical personnel (See Illustration Three).

Contraindications

Studies have not revealed any contraindications for the System 37^R.

Warnings

This device will not prevent or predict the onset of preterm labor nor will it prevent the occurrence of preterm birth. The System 37^R monitors your uterine activity and provides this information to your physician for assessment and, if necessary, intervention.

The battery charger should be plugged into a properly grounded three-pronged AC outlet. Extension cords or adapter plugs should not be used. A properly grounded adapter plug - one that has a grounding wire that is attached to a properly grounded AC outlet can be used.

Do not operate the battery charger or the Base Station if it or the cable is damaged, cut, or broken. Contact your service center for assistance.

Always keep the Data Acquisition Unit (DAU), BaseStation and battery charger away from any and all heated surfaces.

Always keep the Data Acquisition Unit (DAU), BaseStation and battery charger away from children, and follow the instructions provided in this manual to ensure the proper use of the system.

Do not transmit information during periods of electrical storm activity. A lightning strike could cause the information to be lost during transmission or damage to the equipment could occur.

Do not place liquids or spill liquids on the Data Acquisition Unit (DAU) or Base Station. Although the surfaces of the equipment provide certain resistance to liquid spills, damage to the equipment could result. If liquid is spilled on either piece of equipment, contact your service center for assistance.

Precautions

The System 37^R should not be used by the patient while bathing or near water as an electrical shock hazard is present.

Do not send data during an electrical storm while the System 37^R is attached to a telephone line. Recording with the DAU can be performed and completed during an electrical storm.

There could be some discomfort from the sensor belt, but this can be adjusted to fit large and small abdominal girths.

Patients with acute psychiatric disorders may not be able to comply with monitoring.

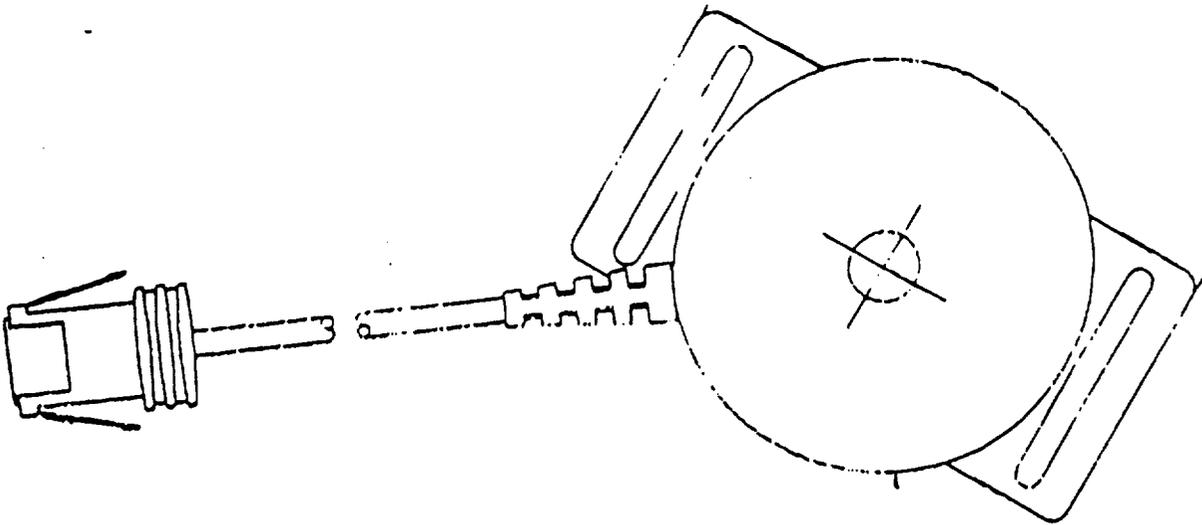
Patients without a telephone may be unable to transmit data twice daily unless special arrangements are available.

Follow your physician's instructions when using the Data Acquisition Unit (DAU). Monitoring with the DAU should be performed while you are in a comfortable position. Most patients monitor while resting comfortably in bed or sitting in a comfortable chair. Just relax while you are monitoring.

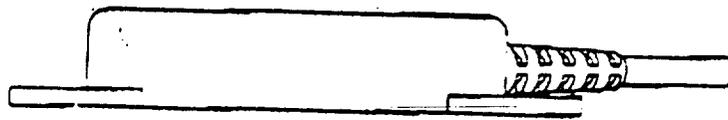
Adverse Reaction

To date, no adverse reactions have been reported concerning the use of the System 37^R.

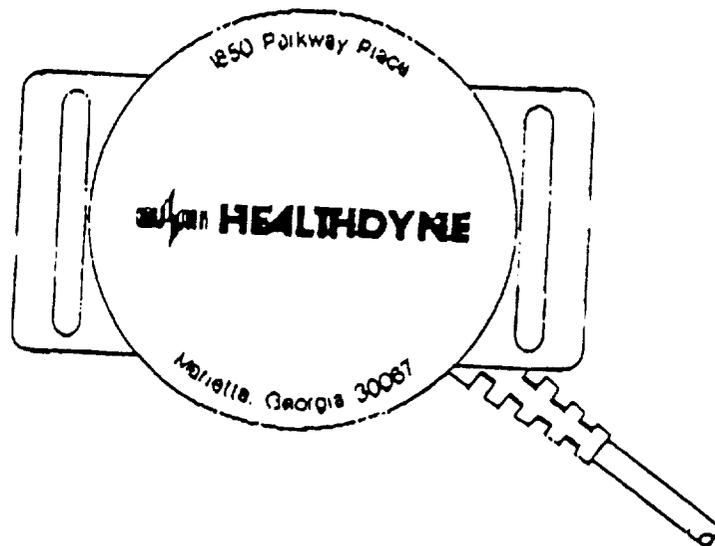
ILLUSTRATION ONE



Tocodynamometer Front View
(SENSOR)

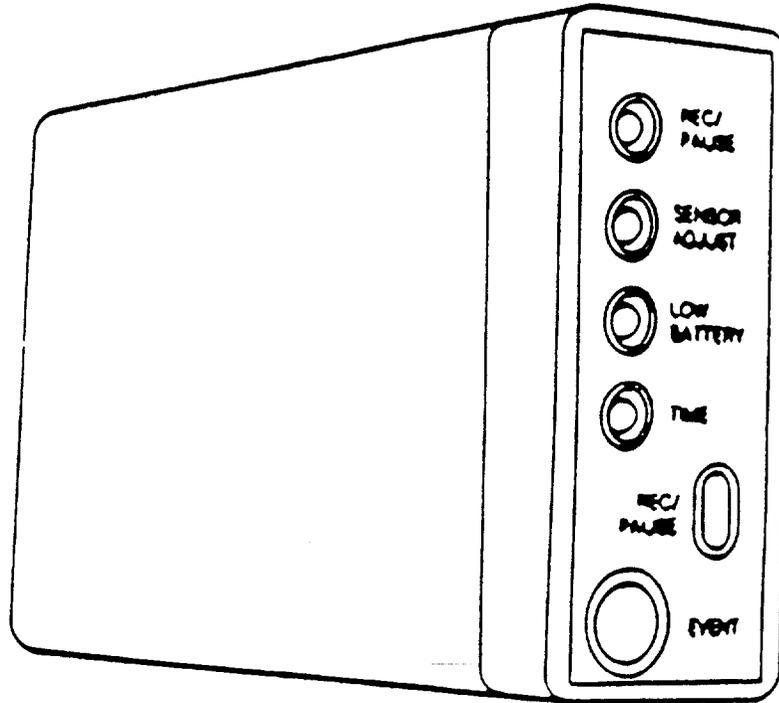


Tocodynamometer Side View
(SENSOR)

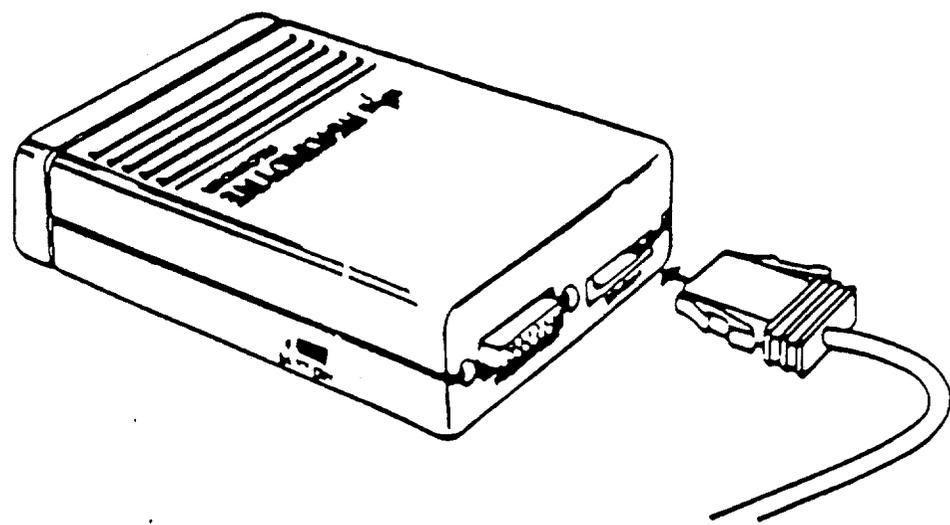


Tocodynamometer Rear View (SENSOR)

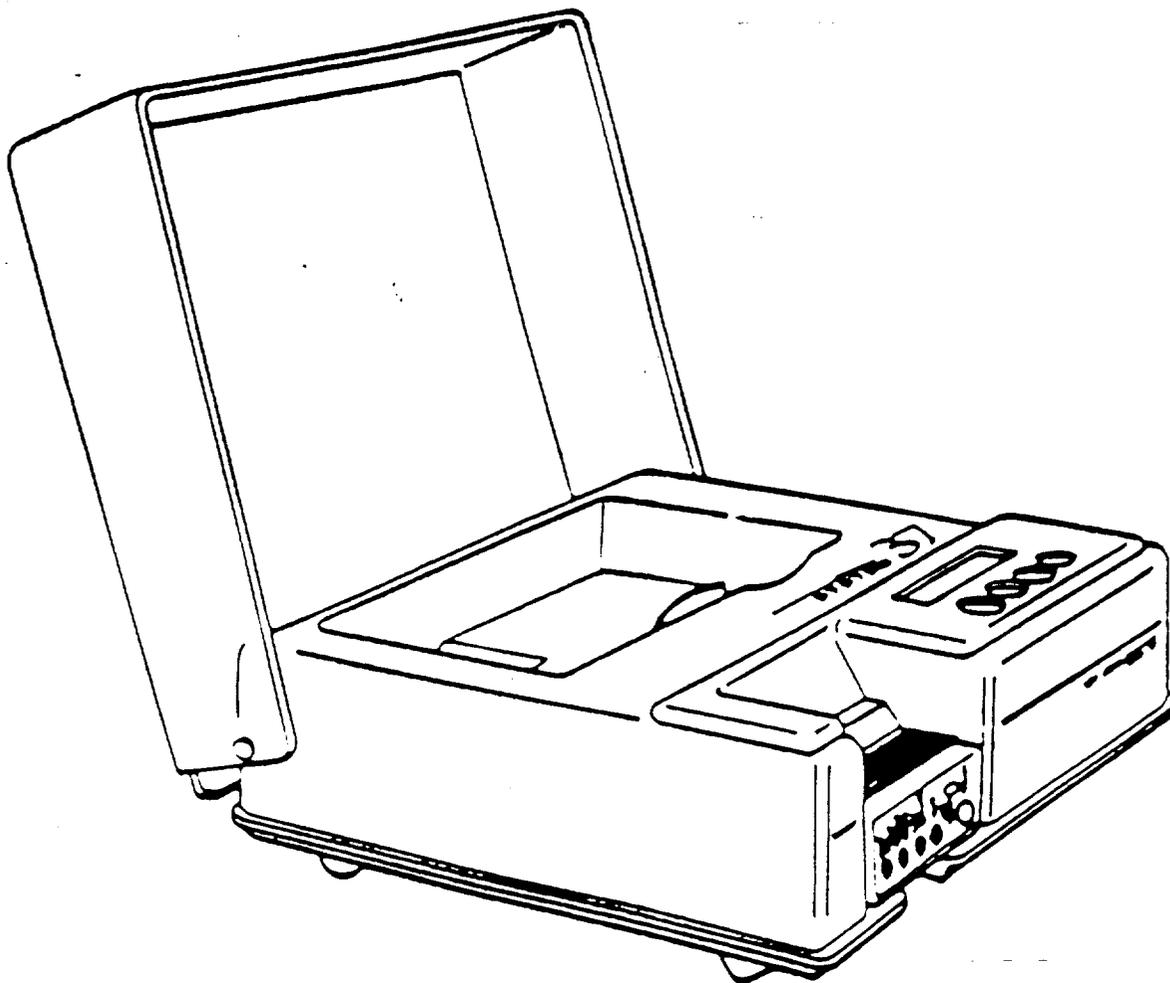
ILLUSTRATION TWO



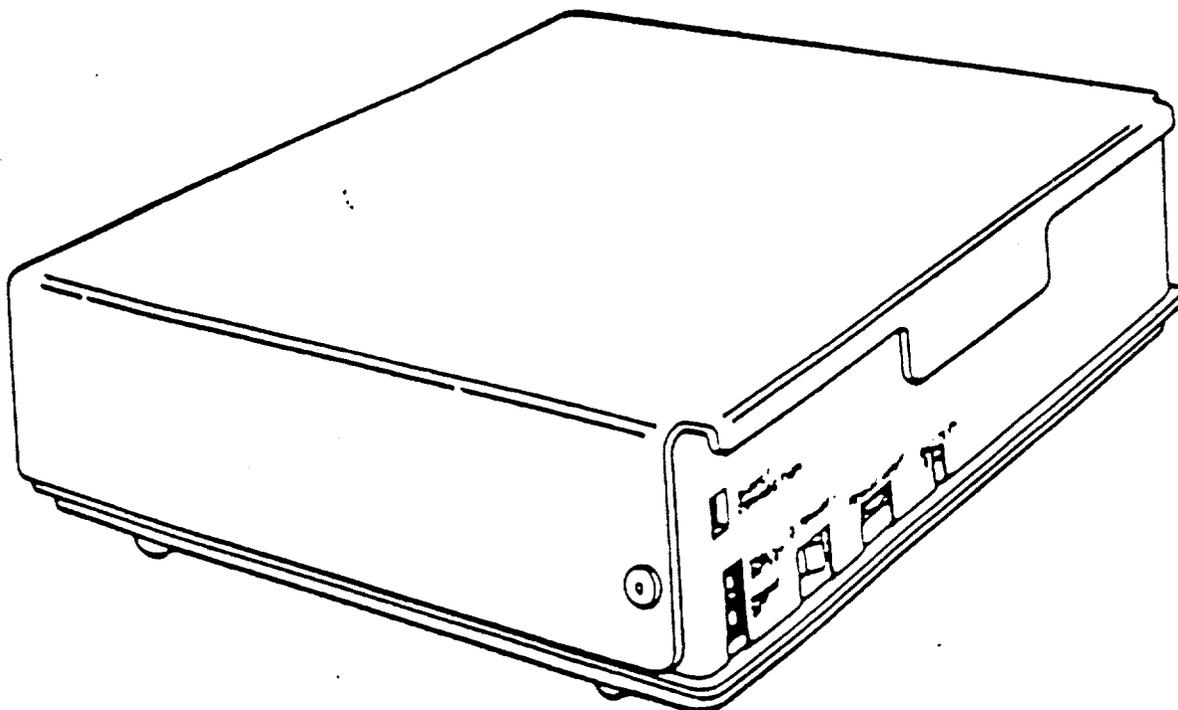
DAU Or Recorder Front Panel



DAU Or Recorder Rear Panel



BaseStation Or Transmitter Top Panel With Recorder "Docked"



BaseStation Or - Transmitter Rear Panel

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As with any electrical device, the System 37^R should not be used while bathing or around water as an electrical shock hazard is present.

The tocodynamometer or sensor may possibly cause skin irritation. The sensor is generally worn two hours per day. To date there have been no reports of skin irritation.

Monitoring Devices and Supplies

To set-up the System 37^R in your home, you should have the following equipment:

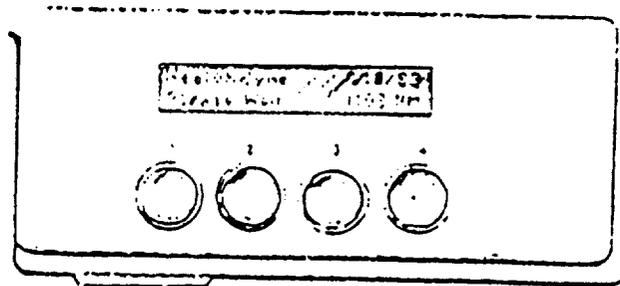
- 1 Tocodynamometer or Sensor
- 2 Patient Belts
- 1 DAU or Recorder
- 1 BaseStation or Transmitter
- 1 Telephone Line
- 1 Power Cord

If you do not receive all of this equipment in the shipping container, contact your Healthdyne Perinatal Service Center for assistance. Upon your receipt of your equipment and prior to its use, you must perform the following procedure.

Procedure

1. Place the BaseStation on a sturdy surface which is close to an electrical outlet and a telephone jack. Plug the power cord connector into a properly grounded AC outlet. Please note that extension cords should not be used. Plug the BaseStation connector into the "Power Input" receptacle on the back of the BaseStation.
2. Turn the power switch on the back of the BaseStation to the On (1) position. A message will be displayed on the screen located on the top of the BaseStation. The first message will appear as follows:

"Healthdyne (Current Date)"
"Please Wait" or "Battery Low (Current Time)"
(This message can take up to 10 seconds to appear.)



Please note that if "Please Wait" or "Battery Low" is not displayed on the BaseStation's screen, the DAU may be improperly connected to the BaseStation. Should this occur, remove the DAU from the BaseStation and reinsert

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it. If the condition continues, contact your local Healthdyne Perinatal Service Center for assistance.

A "Battery Low message on the screen of the BaseStation refers to the battery in the DAU, not the BaseStation.

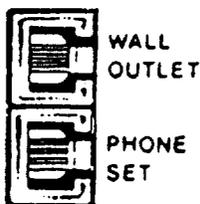
Upon charging of the DAU's battery, the BaseStation's screen will indicate the message "Battery OK". This message will remain on the screen until the DAU is removed from the BaseStation.

A "Battery OK" message means that the DAU can record a complete one hour data session and store the data for three hours without requiring the DAU battery to be recharged. Once you have completed your monitoring session and transmitted your data, always dock or connect the DAU with the BaseStation to ensure that the internal batteries of the DAU are properly charged. In cases where the DAU has been fully charged but is detached from the BaseStation for time periods less than 24 hours due to travel, power outages, etc., it is recommended that the internal battery be recharged for 1.5 hours for every hour of monitor use. In cases where the DAU has been fully charged but is detached from the BaseStation for time periods greater than 24 hours, you should contact your Healthdyne Service Center, advise them of the equipment condition, and follow the instructions that are provided to you. By following these procedures, you should always have a sufficient battery charge for DAU usage.

CAUTION

Always keep the BaseStation connected to an AC power source and power turned "on" in order to ensure that the internal batteries of the BaseStation and DAU are sufficiently charged in the event of a power loss. In addition, when the DAU is not in use, keep it connected to the BaseStation in order to ensure that the internal battery is sufficiently charged for use.

3. Remove your telephone line from the telephone connection jack on the wall and place that line into the "Phone Set" receptacle located on the back of the BaseStation. Take the telephone line provided by Healthdyne and connect one end into the "Wall Outlet" receptacle on the back of the Transmitter. Connect the other end of the line to the telephone jack on the wall. Pick-up the telephone receiver and listen for a dial tone.

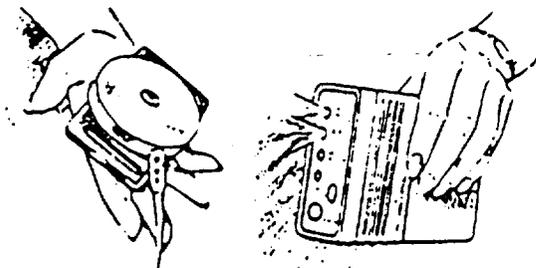


Once you have completed these instructions, you are ready to proceed to the Operating Instructions.

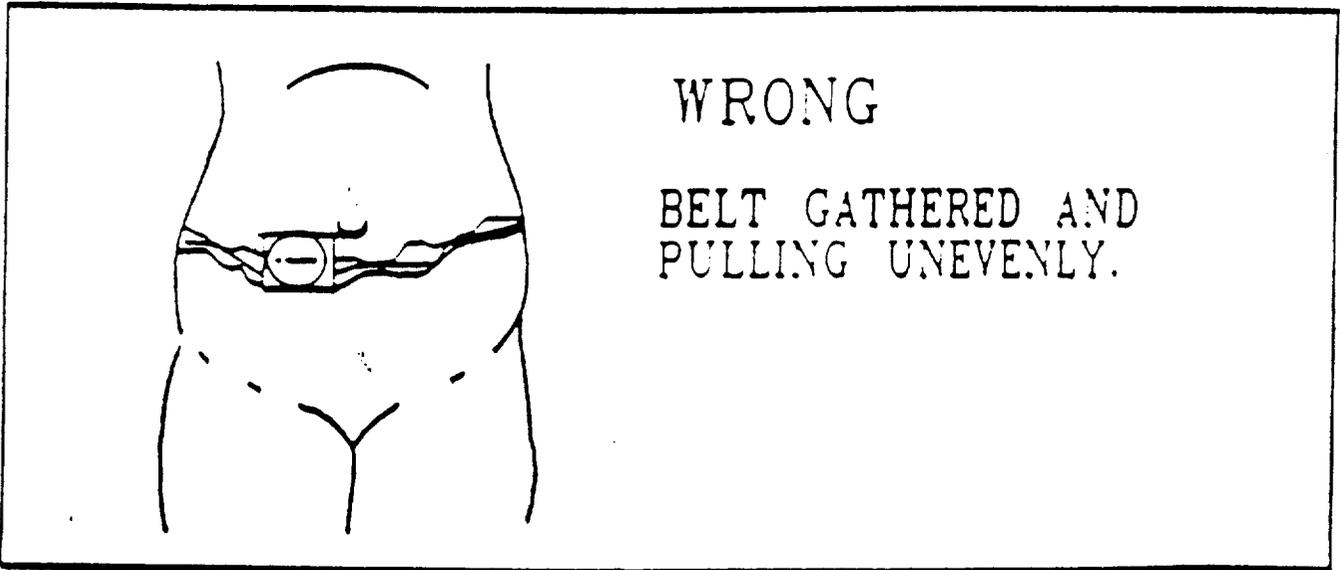
Operating Instructions

Recording Data

1. Remove the DAU from the BaseStation. Insert the Sensor's input connector into the receptacle labeled "Sensor" in the back of the DAU. Once the Sensor is connected, the "Sensor Adjust" light on the front panel of the DAU will come on. Since the Sensor has not been applied to your abdomen, the Sensor Adjust indicator light will be red.
2. Thread the belt through the slots on each side of the Sensor. Place the Sensor on a flat surface or in the palm of your hand with the blue dot facing up. This allows the Sensor to reference room pressure and "zero" itself. Press the "Rec/Pause" button on the DAU. The Rec/Pause light should be Green. Hold the sensor in your hand (blue dot up) for a minimum of twenty seconds.

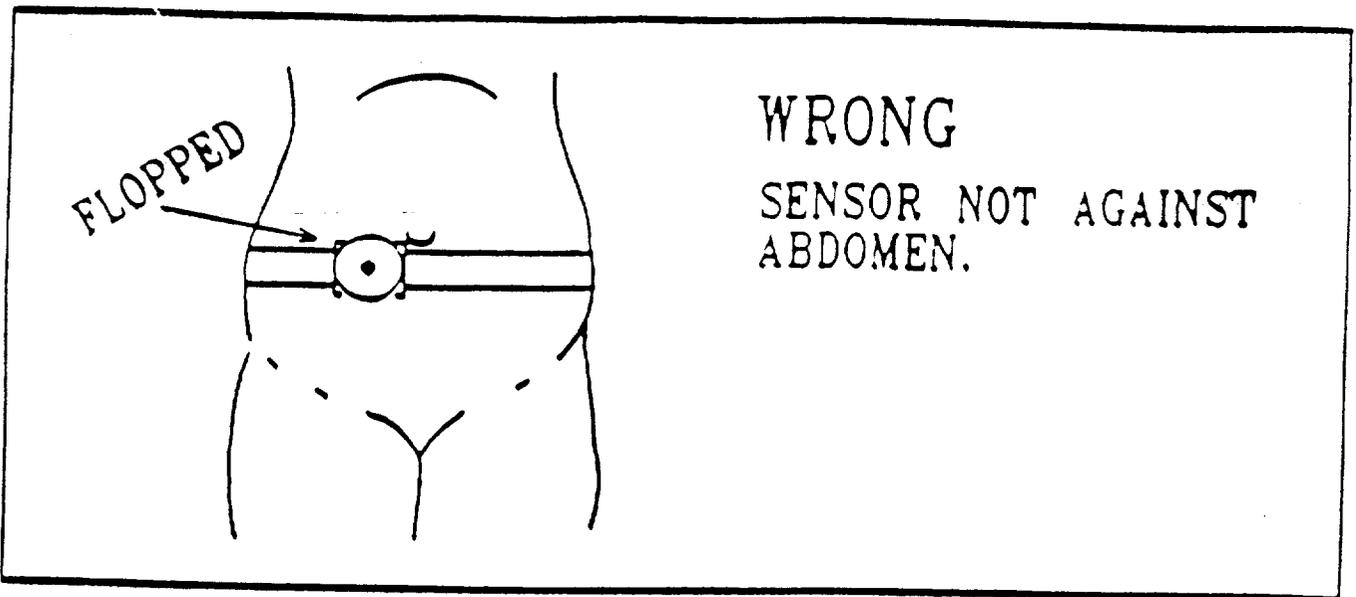


3. Place the front surface (blue dot) of the Sensor on your abdomen so that the complete surface area of the Sensor is in contact with the skin. You should follow the training instructions provided by your nurse concerning the location and placement of the sensor on your abdomen. Begin to tighten the Sensor belt slowly until the belt is snug. The recorder will provide an audible beep indicating that Sensor belt tightening is occurring, however, continue to tighten the belt until it is snug. Once again, you should follow the training instructions provided by the medical practitioner concerning the tightening of the Sensor's belt. Please refer to the following diagrams for correct positioning of the sensor.



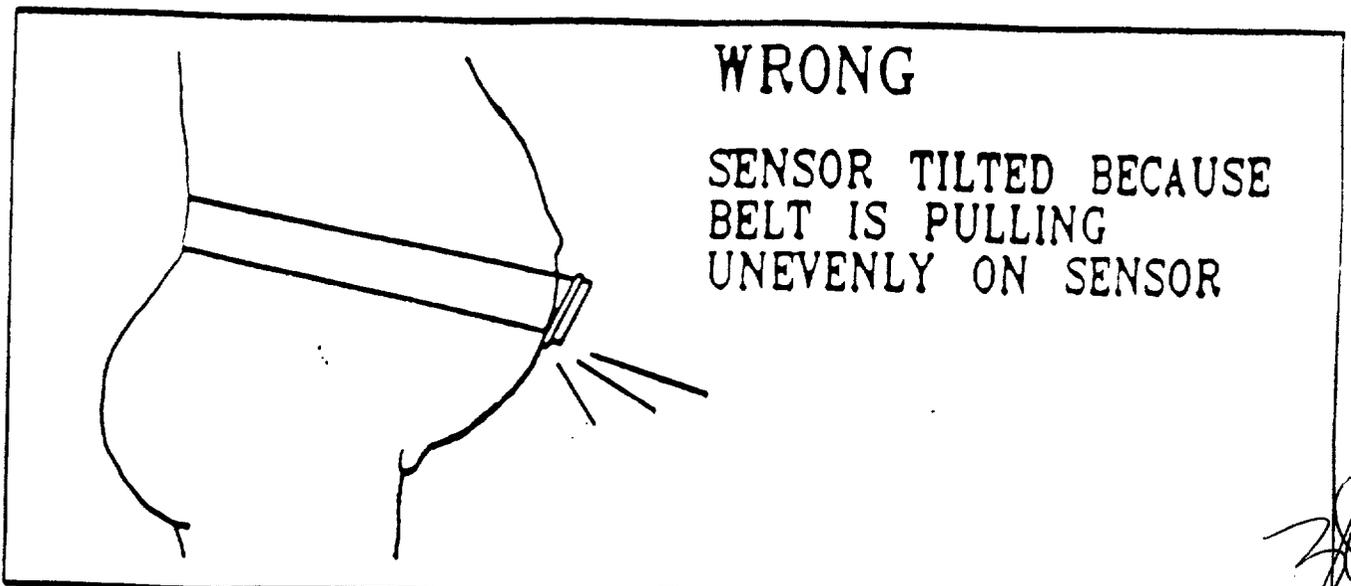
WRONG

BELT GATHERED AND
PULLING UNEVENLY.



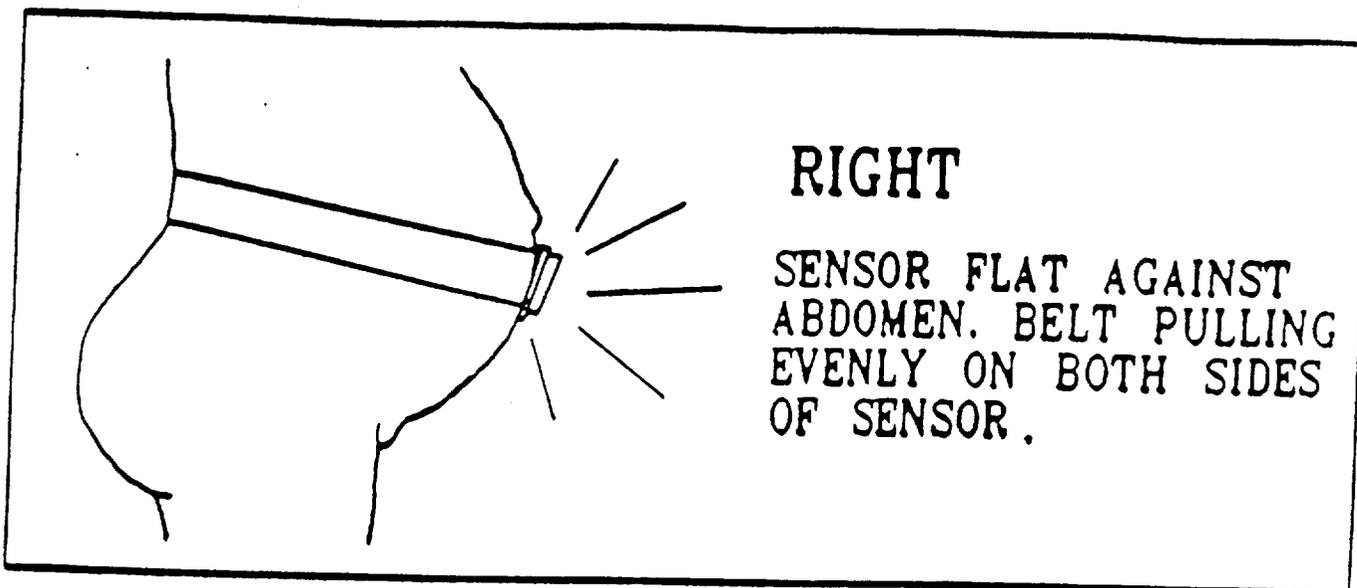
WRONG

SENSOR NOT AGAINST
ABDOMEN.



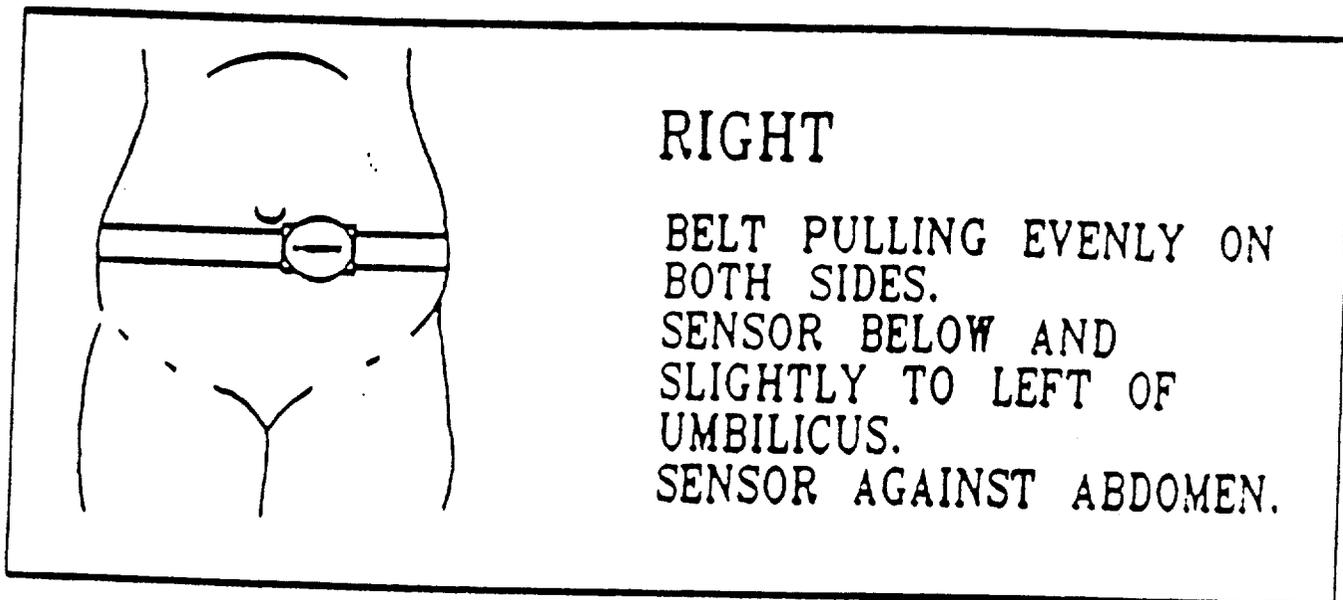
WRONG

SENSOR TILTED BECAUSE
BELT IS PULLING
UNEVENLY ON SENSOR



RIGHT

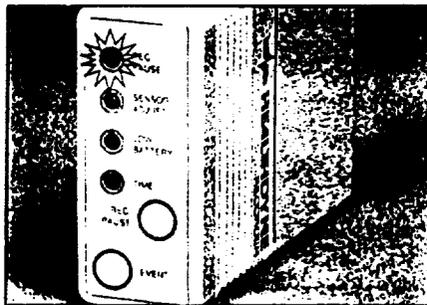
SENSOR FLAT AGAINST
ABDOMEN. BELT PULLING
EVENLY ON BOTH SIDES
OF SENSOR.



RIGHT

BELT PULLING EVENLY ON
BOTH SIDES.
SENSOR BELOW AND
SLIGHTLY TO LEFT OF
UMBILICUS.
SENSOR AGAINST ABDOMEN.

4. Check the "Sensor Adjust" indication on the front of the DAU for a green light.
5. If the Sensor Adjust light is still red after performing these instructions, reposition the Sensor and belt to another location, and tighten it again according to training instructions provided by your nurse.
6. During the recording period the Sensor Adjust light will turn red if the Sensor belt becomes loose. An audible beep will occur if the Sensor Adjust light has been red for ten seconds. If this occurs, retighten the Sensor and belt according to the instructions provided above.
7. When your Sensor has been properly positioned, the Rec/Pause light will blink green and the Sensor light will go out. During the recording session, if you desire to interrupt the session, press the Rec/Pause button. Once this occurs, the "Rec/Pause" light will blink yellow and the audible alarm will beep for five seconds every minute. During this interrupt period, you may remove the belt or disconnect the Sensor from the DAU. You may pause for a time period of up to 15 minutes without causing the DAU to reset the internal timer. Should you exceed the 15 minute time period, a full 60 minutes of new information must be recorded.



8. When the interrupt period has ended and you are ready to resume recording, the procedure to begin recording again will depend upon whether or not you unplugged the Sensor from the DAU.

If you have removed the Sensor belt from your abdomen, you can position the Sensor in the same location on the abdomen and tighten the belt snugly in the same way as you did during the initial recording set-up period. Press the "Rec/Pause" button on the front of the Recorder and check the "Sensor/Adjust" indicator for a Green light. If this light is not Green, unstrap the belt, then retighten it following the above instructions.

If you have unplugged the Sensor from the DAU, you must reconnect the Sensor to the DAU, press the "Rec/Pause"

yo

button on the front of the DAU, and perform Steps 2 through 5 again.

9. When you have recorded a complete 60 minute session, the Red "Time" light on the front of the DAU will come on and the DAU will alarm for 10 seconds. Once this occurs, disconnect the Sensor from the DAU.
10. Insert the DAU into the BaseStation to automatically transfer data from the DAU. The display on the Transmitter will read "Please Wait", and the DAU will provide a continuous "flickering" of all lights until the data is transferred to the BaseStation. If the transfer does not occur, a message will appear on the BaseStation screen advising you to reconnect the DAU to the BaseStation. Remove the DAU from the BaseStation and reconnect the DAU to the BaseStation.

Caution

If the Low Battery indicator comes on during the recording session, you should discontinue the monitoring session, connect the DAU to the BaseStation, and contact your service center for assistance.

Caution

The DAU and BaseStation are sensitive electronic instruments. Handle with care and do not drop either device. If you should drop either device, contact your service center for immediate assistance. Always keep these instruments and all accessories out of reach of children.

Transmitting Data



1. You will be contacted when it is time to send you uterine activity data.
2. On the front of the BaseStation (underneath the screen) there are four buttons identified as number 1 through 4.

Press button number 1. If you have recorded information, the screen will display the message "Data Can Be Sent." If you have not recorded information the screen will read "No Data To Send". Since we are concerned with transferring data, we will proceed with the "Data Can Be Sent" message. The next message to appear will be "Do You Want To Send?". Press button Number 1 (Yes) to send data or button Number 2 (No) if you do not want to send data.
3. The next message will be "Do you want to talk?". Press button Number 1 (Yes) or button Number 2 (No) as instructed by your nurse.
4. The next message will be "To Interrupt Press 4 - Initializing". The message will change to "Press 1 - Hang up Phone". When this occurs, press button Number 1 when instructed by your nurse and hang up the telephone.
5. Transmission of the recorded information is occurring. The message will change and read "To interrupt, push 4".
6. After data transmission is complete, the BaseStation will audibly and visually indicate that you should pick up the telephone if you pressed Number 1 (Yes) indicating that you chose to talk to a medical nurse at the Healthdyne Service Center, in step 3 above. If so, pick up the telephone and press button number 4 to stop the audible tone and speak with the nurse.

If no was selected in step 3, the telephone line will automatically disconnect and the message display will read "Healthdyne - Current Date".
7. When the transfer of information has been completed, press button Number 3 to verify that all information has been transmitted. The screen display on the Transmitter should read "No Data to Send". If the display reads "Data can be

sent" contact your medical practitioner and prepare to send the information again according to the steps identified above.

Troubleshooting Guide

If the System 37^R does not work as described above, check for the following:

1. No "Please wait" or "Battery Low message on the front display of the Transmitter.

Instruction: Remove the DAU from the BaseStation and reinsert the DAU into the BaseStation.

2. No display on the top of the BaseStation.

Instruction: Check that the power cord is properly connected and that the power switch is in the On(1) position. If the power cord is properly connected and the power switch is in the On position and the display still does not work, contact your Service Center for assistance.

3. No dial tone is present on your telephone.

Instruction: Check that the telephone is connected to the "Phone Set" input receptacle on the back of the BaseStation, and the BaseStation is connected to your telephone wall jack.

4. "Sensor Adjust" light will not stay green.

Instruction: The Sensor needs to reference to ambient pressure (zeroed). Disconnect the Sensor and start recording procedure over.

5. "Sensor Adjust" light will not stay green.

Instruction: Release the belt tension and re-tighten the belt slowly until snug. Check the Sensor Adjust indication for a green light. After this occurs, if the Sensor Adjust will not stay Green, reposition the Sensor to another location as instructed by your nurse.

6. "Do you want to get?" is provided on the front display of the BaseStation instead of "Do you want to send?"

Instruction: Press Button Number 2 indicating "No" on the front panel of the BaseStation. Remove the DAU from the BaseStation and reinsert the DAU into the BaseStation.

7. "Call Service Center" message is provided on the front display of the BaseStation with an audible tone.

Instruction: Press button number 4 on the front panel of the BaseStation to stop the audible tone and contact your service center for assistance.

8. Whenever you are asked by the Healthdyne medical practitioner or service center to perform a DAU Self-Test, you should activate an internal memory check test according to the following procedure:

Turn the Battery Switch to "OFF" (0).
Plug-in sensor input connector and lay on flat surface.
Turn Battery Switch to "On" (1)
A two (2) second audible alarm will occur and a steady green "REC/PAUSE" light will appear, indicating the unit self test is active.
This green light will stay on for about 60 seconds.
After 60 seconds the green light will go off and a red "SENSOR ADJUST" light will come on.
The unit is ready for use.

If a failure occurs during the 60 second test cycle, a random combination of indicators will come on steady with a constant audible alarm.

If this occurs, the DAU must not be used and should be replaced. Contact your service center for assistance.

Caution

Unless you are performing the internal memory check test, always leave the DAU power switch in the "On" position. This will assure that the internal battery will be charged once the DAU is connected with the BaseStation.

9. Whenever you are asked by the Healthdyne medical practitioner or service center to perform a BaseStation Self-Test, you should turn the power switch located on the side of the DAU to the "OFF" position and then back to the "ON" position. This will activate an internal memory check test according to the following procedure:
 - a. Turn Power Switch to "OFF (0)".
 - b. Depress and hold down buttons 3 and 4 on the control panel.
 - c. Turn Power Switch to "On (1)".
 - d. Release buttons 3 and 4.
 - e. Display will read:
"Part # Rev XX"
 - f. Then:
Part # Rev XX
"ROM Check Sum is XXXX"

- g. Then:
"Testing memory"
"Block 1, pattern 55"
- h. Then:
"Testing memory"
"Block 1, pattern AA"
- i. Then:
"Testing memory"
"Block 2, pattern AA"
- k. Then:
" Memory test passed"

Note: Verify that both Block 1 and Block 2 messages have appeared. If not, some memory is not being recognized as being present. In this condition, the BaseStation should not be used and you must contact your Healthdyne service center for assistance.

- l. Display will then show:
"Healthdyne Date & Time"
- m. The self test is not complete and the unit is ready for use.
- n. If at any time during the test cycle a failure occurs, the display will read either of following messages:
 - 1. "Call Service Center" or "Memory is bad"
 - 2. Or a constant alarm will occur.

If an audible alarm activates or either of the above messages is provided, the BaseStation should not be used and you must contact your Healthdyne service center for assistance.

Summary of Patient Monitoring Instructions

Set-up

1. Plug the power cord into the BaseStation and the wall outlet.
2. Turn the Power switch on.
3. Connect the phone lines to the BaseStation.
4. Make sure you have a dial tone and the message displayed on the BaseStation's screen is "BATTERY OK".

Recording

1. Remove the DAU from the BaseStation.
2. Plug the Sensor into the DAU.
3. Push the REC/PAUSE button. Make sure the green REC/PAUSE light comes on.
4. Wait 20 seconds with the Sensor in the palm of your hand. The Sensor should be face up (white surface of the Sensor visible and labeled side of the Sensor towards your hand).
5. Strap the Sensor on your abdomen (See Recording Data section, Step 3) and tighten the belt.
6. Make sure the SENSOR ADJUST light is green. When the green light goes off, and the REC/PAUSE light blinks green, you are recording properly.

Transmitting

1. When your nurse contacts you, push button # 1 to verify that data can be sent.
2. Tell your nurse that data can be sent.
3. Press button #1 (YES) to send the data and press button # 1 (YES) or button #2 (NO) to answer the message "DO YOU WANT TO TALK?".
4. Tell your nurse when the BaseStation displays "PUSH BUTTON #1 - HANG UP PHONE".
5. Press button #1 and hang up the phone when the nurse tells you. Data transmission is now occurring.

6. If "YES" to talk was chosen, pick up your phone when the BaseStation's displays instructs you to do so. Press button # 4 to eliminate transmitter noise.
7. Press button # 3 to make sure that all data was sent.

REMOTE TRANSMITTER

If your schedule requires you to travel or work outside your home, your physician may prescribe the use of the Healthdyne System 37^R Remote Transmitter. The Remote Transmitter allows for the transmission of your recorded uterine activity that is stored within the DAU from any telephone.

CAUTION

The Remote Transmitter should only be used when you and your physician have determined that the BaseStation can not be used to transmit your uterine activity data. Since the quality of the data transmission by the Remote Transmitter is not as good as the quality of the data transmission that is performed by the BaseStation, it is recommended that the uterine activity data be transmitted by both the Remote Transmitter and the BaseStation. Follow the instructions provided by your Healthdyne medical practitioner, as well as the written instructions presented within the Remote Transmitter Instruction Sheet when using the Remote Transmitter in conjunction with the BaseStation to transmit your uterine activity data.

THINGS TO REMEMBER:

Do not use critical time monitoring your contractions or calling the Healthdyne Perinatal Center if you experience the following:

1. A gush or trickle of fluid from your vagina.
2. Intense abdominal pain.
3. Bleeding from your vagina.

CALL YOUR DOCTOR IMMEDIATELY!

One of the most difficult and frustrating problems you may encounter is understanding the technical terms that are used in relation to your care and that of your baby.

To help you become familiar with this "new language", we have put together the following list of commonly used terms

with a brief explanation.

If at any time you do not understand a procedure or a term used by the professionals taking care of you and your baby, be sure to ask for further clarification.

Afterbirth: The placenta and membranes.

Amniotic Fluid: The fluid inside the amniotic sac, which surrounds the baby, (sometimes called the bag of waters).

Anemia: A condition in which the blood is deficient in red blood cells, hemoglobin (the red-colored material in your blood, which carries oxygen), or both.

Apgar Score: A simple system for assessing a baby's condition after birth. It is commonly reported at one (1) and five (5) minutes after birth. Scores range from 0 - 10. The highest score or 10 is very rare with a preterm baby and scores of four (4) to seven (7) are quite common.

Bag of Waters: A thin membrane filled with fluid in which the baby floats (amniotic sac).

Braxton-Hicks Contractions: Small, irregular, often painless contractions of the uterus during pregnancy. These contractions do not cause the cervix to dilate and are considered normal.

Breech: The condition in which the buttocks or feet of the baby are in the downward position in the uterus instead of the normal head-first position.

Cervical Incompetence: An unexplained weakening of the cervix which results in the cervix opening prior to labor.

Cervix: The lower part or neck of the uterus which opens into the vagina.

Cesarean Section: The operation of delivering the baby through an incision in the mother's abdomen.

Dilatation: The condition of the cervix during labor when it is being stretched beyond its normal size to allow for the delivery of the baby.

Due Date: The date when the baby is expected to be born.

Edema: Excessive fluid in body tissue (swelling).

Effacement: Thinning of the cervix as labor progresses.

Episiotomy: A small incision made into the tissue between the vagina and rectum at the time of delivery.

Fetus: An undelivered baby.

Gestation: The number of weeks of pregnancy that have passed since conception. Normal gestation is 40 weeks.

Growth Retardation: This refers to a slow rate of growth of the unborn baby. Growth Retardation does not mean the baby is mentally retarded.

Hyaline Membrane Disease (H.M.D.): A common cause of difficulty with breathing in a preterm baby.

Intrauterine Growth Retardation (I.U.G.R.): See growth retardation.

Labor: The process of regular uterine contractions, effacement and dilatation of the cervix which expels the fetus, placenta, and membranes from the body.

Low Birthweight: Any baby who weighs 2500 grams (5 1/2 pounds) or less at birth.

Meconium: The green material which is passed from the baby's bowels in the first few days after birth. Occasionally the baby may pass meconium before birth to produce meconium-stained amniotic fluid.

Neonatologist: A doctor specializing in caring for preterm and high-risk babies.

Perinatologist: A doctor (obstetrician) specializing in caring for high-risk pregnancies.

Placenta: The "after-birth", the spongy organ within the uterus which establishes and maintains contact through blood vessels in the umbilical cord between the mother and her unborn baby.

Pregnancy-Induced Hypertension (PIH): A disease generally occurring during the last half of pregnancy characterized by edema, high blood pressure, and protein in the urine. Also called Toxemia.

Preterm: Any infant born before the 37th week of pregnancy.

Proteinuria: Protein in the urine.

Respiratory Distress Syndrome (R.D.S.): Breathing difficulty from any cause. Common in preterm infants.

Small-For Gestation Age (S.G.A.): A baby who is small at birth because of poor growth in the uterus.

Term (Full Term): Infants born after 37 weeks completed gestation.

Toxemia: See Pregnancy-Induced Hypertension.

Umbilical Cord: The attachment of blood vessels which connect the baby to the placenta and mother.

Umbilicus: The naval.

Viable: Sufficiently mature to live.

REMOTE TRANSMITTER INSTRUCTION SHEET FOR SYSTEM 37^R

APPLICATION

Healthdyne's System 37^R Remote Transmitter allows for the transmission of your recorded uterine activity that is stored within the Data Acquisition Unit (DAU or Recorder) from any telephone. The Remote Transmitter does not need to be connected to the phone system in any matter and is battery operated. Prior to each patient use, the Remote Transmitter is checked to ensure that it works properly.

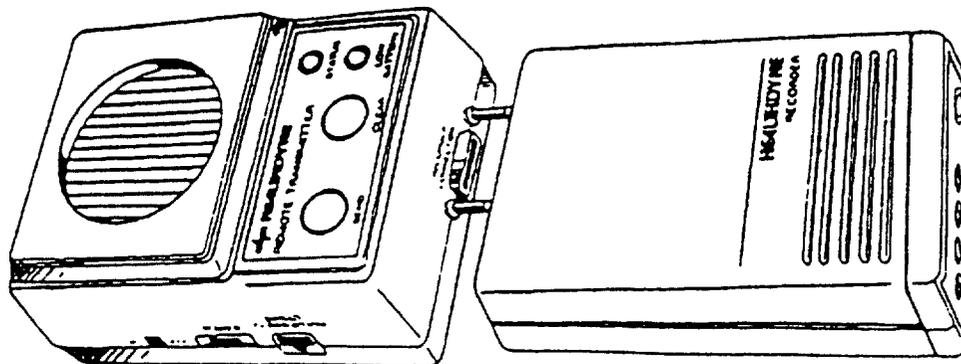
CAUTION

The Remote Transmitter should only be used when you and your physician have determined that the BaseStation can not be used to transmit your uterine activity data. Since the quality of the data transmission is not as good as the quality of the data transmission that is performed by the BaseStation, it is recommended that the uterine activity data be transmitted by both the remote transmitter and the BaseStation.

OPERATING INSTRUCTIONS

1. If you are utilizing both the BaseStation and Remote Transmitter as part of the System 37^R, any time you remove the DAU from the BaseStation and know that you are to use the Remote Transmitter to send data, you must connect the DAU to the Remote Transmitter and depress the clear switch on the Remote Transmitter for 2 seconds before recording your uterine activity. Once you depress the clear switch for 2 seconds, the status light on the remote transmitter will flash and an audible beep from the DAU will occur. If this does not occur, do not use the DAU with the Remote Transmitter and contact your service center for assistance.
2. Record your uterine activity data as previously instructed by your medical practitioner.
3. When you have completed your recording session, you will contact your medical practitioner in preparation to transmit your uterine activity data. Your medical practitioner will instruct you to connect the Remote Transmitter to the DAU as shown below.

Figure 1 - Remote Transmitter Connection to the DAU



4. Upon instruction by your medical practitioner, lay the speaker portion or mouthpiece of the telephone on the remote transmitter as shown in the figure below, and press the send button on the remote transmitter.

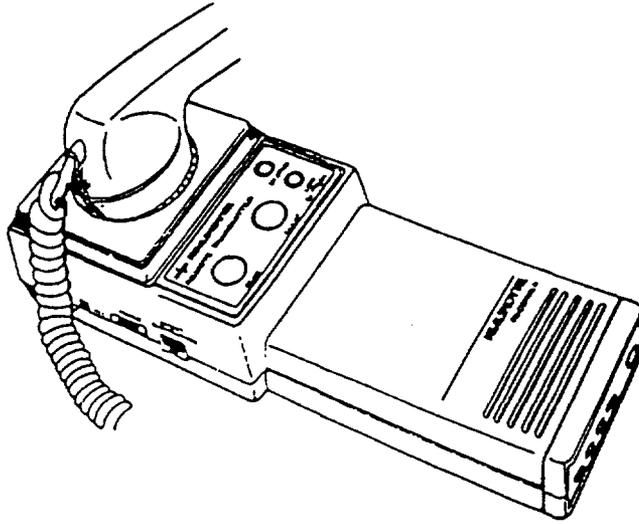


Figure 2 - Transmitting Data

5. A status light on the Remote Transmitter will flicker green while data is being transferred. When this light stops flickering, pick up the telephone and you will be able to speak to the medical practitioner and review your uterine activity data.
6. If instructed to do so by your medical practitioner, press the clear button on the remote transmitter for 2 seconds until the status light flashes and the audible reset tone can be heard from the DAU. This will clear all data from the recorder.
7. Although the remote transmitter and the DAU are battery powered, do not leave them disconnected from their battery chargers when they are not being used for either recording data, sending data, or in transit.
8. While using the DAU with the Remote Transmitter, the DAU should be left connected to the Remote Transmitter and the Remote Transmitter should be plugged into its battery charger when it is not being used to record data, send data, or while in transit. This will maintain the charge on the DAU internal battery.