CONTINUOUS MEASUREMENT OF CERVICAL DILATATION DURING LABOUR

by

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ABSTRACT

An instrument for the continuous measurement of cervical dilatation is described. The principle of operation, being that of mutual inductance, utilises two coils, one on the posterior lip of the cervix and the other on the anterior, the axes of these coils being kept parallel by a flexible linkage. A magnetic field, from the primary coil being driven with a 10kHz alternating current of constant amplitude, induces a voltage in the secondary coil. This voltage whose magnitude decreases as the distance between the coils increases, is used by the instrument for the determination of cervical dilatation. A cervical dilatation recording from a multiparous patient is presented and discussed.

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1. INTRODUCTION

To evaluate the progress of the first stage of labour, it is necessary to measure cervical dilatation. In this age of technology, the obstetrician still relies on digital pelvic examinations. This form of intermittent measurement tends to be a little inaccurate, does not provide very much information and is not always reliable for predicting the time of delivery as will be shown later.

Repetitious pelvic examinations also increase the risk of infection for both mother and baby and increase maternal discomfort.

In order to improve the management of labour, cervical dilatation should be measured continuously, providing such information as the dilatation between contractions, the dilatation peaks, frequency of contractions, the effect of drugs, such as oxytocin, on dilatation and immediate information of any change in the dilatation pattern.

This paper describes a cervical dilatation monitor capable of providing valuable information for labour management or research purposes.

2. THE CERVIX

The size and shape of the cervix varies widely from individual to individual. The external os, with its anterior and posterior lips (labium anterius and posterius) is the opening in the vaginal portion of the cervix (portio vaginalis) which connects the cervical canal with the vagina.

The cervix is composed predominantly of fibrous connective tissue, with very little smooth muscle. Portio vaginalis is almost devoid of muscle.

Many observations suggest that the sensory system of the skin covering the portio vaginalis is much less sophisticated and, in most instances, less sensitive than that covering other exposed areas of the body.

During pregnancy, the cervix tends to swell, leading to gross enlargement with subsequent softening. During the first three months of pregnancy, the cervix is directed downward and backward, but as the uterus enlarges and rises in the abdomen, it assumes a more vertical direction.

The cervix may remain long and thin until the onset of labour, but usually in the final days/weeks, it undergoes increased softening, thins out and the cervical canal

becomes shorter. After labour has begun, thinning or effacement continues until the cervix is only from a few millimetres to 1 cm thick.

Dilatation of the cervix, during the first stage of labour, often begins before effacement is complete, and the external os eventually reaches a maximal expansion of about 10 cm. Since the cervix contains very little muscular tissue, its role in labour is a passive one, responding directly to uterine activity. It merely opens up to allow the passage of the baby, this dilatation being accomplished by direct pressure of the presenting part or the force exerted by the bag of waters.

Some cervical dilatation has usually taken place by the time labour commences. The normal cervix has about 2 cm dilatation at the onset of labour, if the patient is examined at the height of a uterine contraction. In some cases the cervix can still be firm at the beginning of labour.

The connective tissue framework of the cervix undergoes a transformation that enables it to stretch to the point where the cervical canal reaches full dilatation, namely 10 cm. It has been suggested that it is a dissociation of the collagen fibrils that results in the softening and dilatability of the cervix, and that the fundamental changes

concern the ground substance which binds the fibres together rather than the collagen itself.

The following section describes the methods that have already been developed to continuously measure the dilatation of the cervix during labour.

3. LITERATURE REVIEW

To measure cervical dilatation, Smyth (1954) had linen threads attached to cervical clips to actuate a linear differential displacement transducer, but was not very successful.

Caliper-like instruments have been used by Friedman and Von Micsky (1963), Siener (1963), Embrey and Siener (1965), Richardson, Sutherland and Allen (1978) and others. This type of instrument consists basically of a pair of caliper arms with distal ends attached to opposing rims of the external cervical os. In some cases, a potentiometer or strain gauges acted as dilatation sensors. The problems encountered were : (i) distortion of the circular dilatation of the cervix, (ii) its mechanical nature made it difficult to attach and maintain throughout labour, (iii) vaginal walls limited the motion of some devices, (iv) because of the bulkiness and weight, its position could

change, (v) not very comfortable for the patient, and (vi) does not permit digital vaginal examinations.

Wolf (1951) and Rice (1974) placed coils on opposite sides of the cervix and determined dilatation from their mutual induction but experienced problems due to angular displacement of a coil.

Kriewall (1974) and Kriewall and Work (1977) described a method of measuring dilatation using a permanent dipole as the magnetic field source and two Hall-effect magnetic field transducers as detector on the diametrically opposite edges of the cervix. They were positioned in quadrature to pick up radial and tangential components of the field from the permanent magnet. The two signals were processed to determine the spacing. The limitation was that the earth's magnetic field interferred during the end stages of dilatation. Angular displacement of the dipole also caused inaccuracy.

Kruse, Fehlauer, Holm and Volkmar (1979) developed an improved instrument which employed a combination of the Hall-effect and caliper techniques.

The ultrasonic transit-time measurement method, described by Zador, Neuman and Wolfson (1976), Kok, Wallenburg and Juriy (1976), Moss, Lauron, Roux and Neuman (1978), and Lewin

Sadoul, Beuret and Sylvain-Leroy (1978), used ultrasound crystals attached to the cervix. With this technique, the assumption must be made that the signal is transmitted uniformly throughout the medium at a constant velocity, and therefore air pockets in the vagina can upset the measurements.

4. CERVICAL DILATATION MONITOR DEVELOPED BY THE AUTHOR OF THIS PAPER

All the methods of cervical dilatation measurement described in Section 3 have problems. This section describes an instrument which does not suffer from any of these defects.

Principle of Operation

Its principle of operation is that of mutual inductance, but with this device there is no possibility of coil misalignment as experienced by Wolf and Rice.

Two cylindrical coils are attached to the cervix, one coil to the posterior lip of the external os, the other to the anterior lip. The planes of the coils correspond to the median sagittal plane of the body, i.e. the coil axes lie horizontally across the body.

To prevent misalignment of the coil axes, a special linkage was developed to keep the axes parallel. The property of the linkage is fairly similar to that of a bicycle chain in that it can bend in only one plane.

The axes of the chain 'pins' are parallel to the coil axes, thereby movement of the coils is restricted to a single plane corresponding to the planes of the coils, and coil misalignment is prevented. The linkage is discussed further on page 10 to 14.

Theory

One coil is driven with an alternating current I, causing a voltage V to be induced in the second, such that

$$V = -M\frac{dI}{dt} \qquad (1)$$

where M is the mutual inductance of the two coils. In the case where two coils lie in the same plane, have equal radii and equal number of turns, and provided the cross-sectional dimensions of the coils are small compared with the distance between the coils, then Grover states that

$$M = -0,001\left(\frac{\pi^2}{8}\right)\left(\frac{2a}{r}\right)^3 DaN^2 \ \mu H \qquad (2)$$

where a = average coil radius (cm)

r = distance between coil axes (cm)

N = number of turns in each coil

and D = factor determined by the value of $\frac{2a}{r}$

(Refer to p.181 of Grover's book)

Over the entire range of dilatation, D ≈ 1. The coils were constructed such that a = 0,3 cm and N = 225 turns. Cervical dilatation range (r) varies from 2 cm to 10 cm.

The primary coil is driven with a sinusoidal current $I = 0{,}177 \sin 2\pi ft$ amperes at a frequency (f) of 10kHz.

Substituting into equations (1) and (2) :

$V \approx 6000 \cos 2\pi ft$ μV when r = 2 cm

and $V \approx 45 \cos 2\pi ft$ μV when r = 10 cm

Experimentally, V was also found to vary with $\frac{1}{r^3}$ and the experimental curve of V vs r was close to the theoretical one.

e.g. $V_{experimental} \approx 7000 \cos 2\pi ft$ μV when r = 2 cm

and $V_{experimental} \approx 40 \cos 2\pi ft$ μV when r = 10 cm

The System

A simplified systems diagram is shown in Figure 1. A detailed systems diagram and a circuit diagram can be found in Appendices A and B respectively.

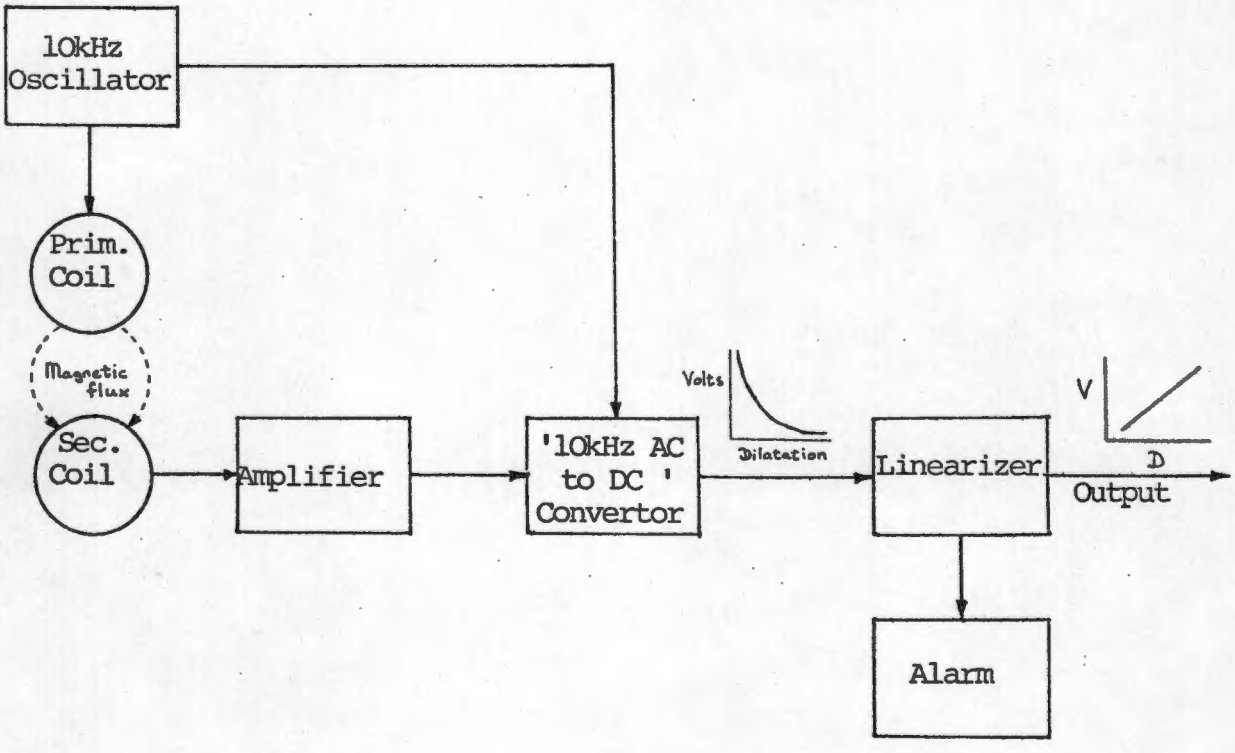

Figure 1 : Simplified Systems Diagram of Cervical Dilatation Monitor

The oscillator drives the primary coil with a sinusoidal current of constant amplitude. A voltage is induced in the secondary, the amplitude of which varies with dilatation,

which is then amplified and full-wave rectified at 10kHz, using the oscillator, in such a manner as to reduce noise. After smoothing, the signal is linearized. The DC output of the system is arranged such that the voltage (V) is equal to dilatation (cm), e.g. 7V output is equivalent to 7 cm of dilatation. There is also an alarm, visual and/or audible, presettable at different values of dilatation.

To summarise, there are two parts, namely (i) an internal device, consisting basically of two coils and a linkage, and (ii) a monitor which provides current to the primary coil, measures the induced voltage in the secondary, converts this voltage to a value of cervical dilatation, and incorporates an alarm system.

The Internal Device

As discussed previously, this consists basically of two coils and a connecting linkage to ensure alignment of the coils. See Figures 2, 3 and 4.

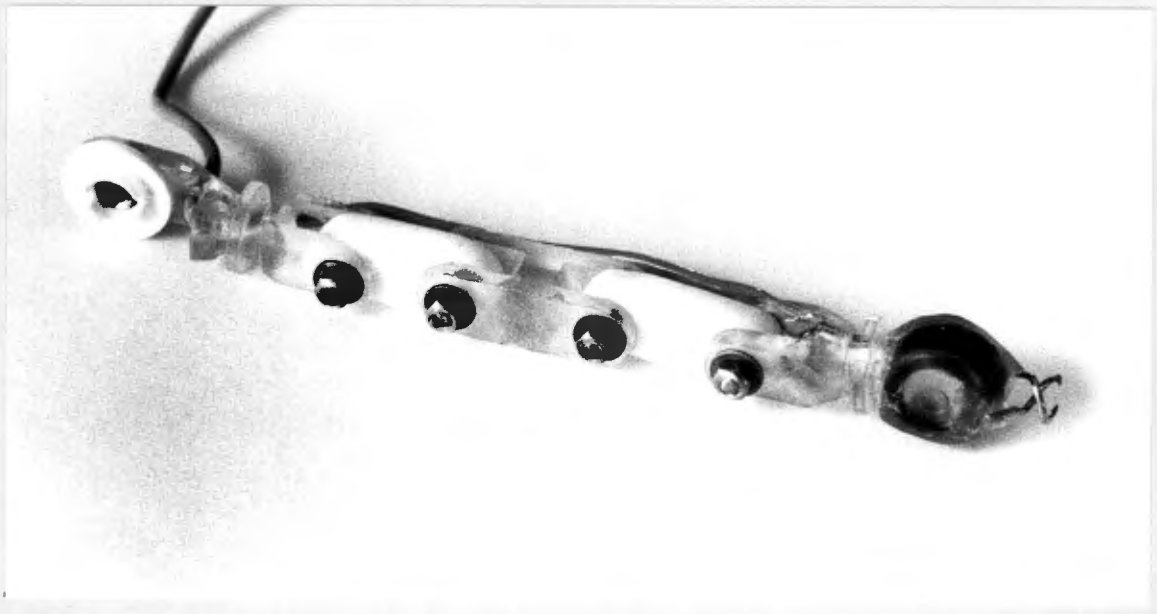

Figure 2 : Anterior part of Internal Device without sleeve or seals

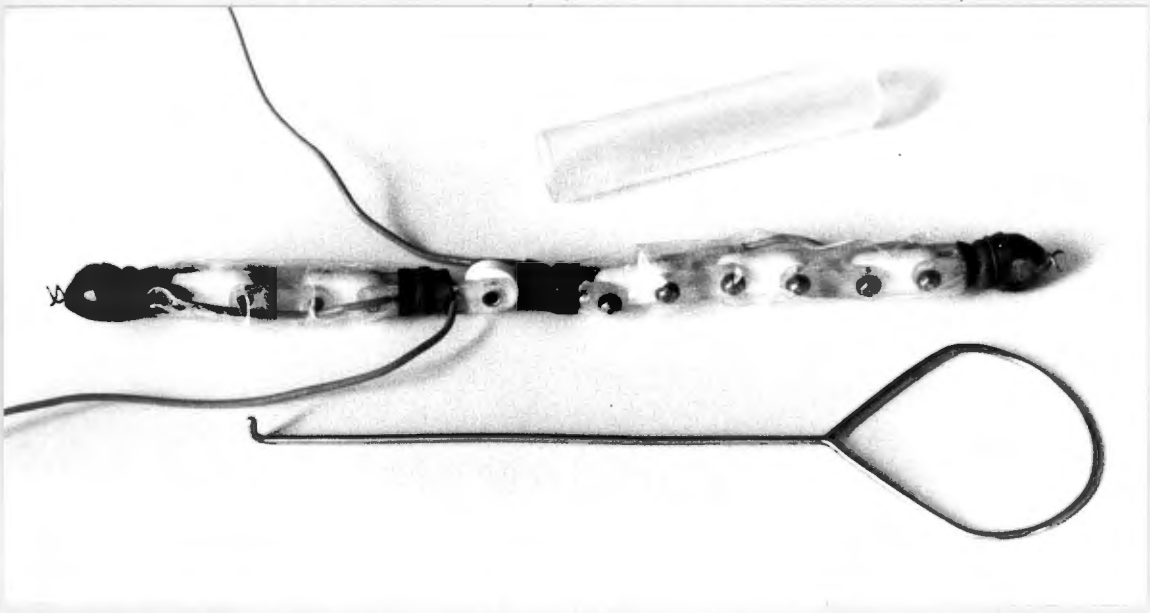

Figure 3 : Complete Internal Device : stretched out, with applicator tube and stainless steel handle

Figure 4 : Complete Internal Device : folded, as in patient

Each coil, having 225 turns of 40 SWG copper wire, was wound on a 5 mm diameter, 4 mm long 'perspex' core (resulting in each coil having an electrical impedance of 8+j15Ω at 10kHz). The windings were covered with a layer of CIBA GEIGY electrical potting epoxy, LMB542/HY2967 with silica filler, to ensure good electrical insulation, and then encapsulated with a layer of cold cure acrylic for added strength.

Each coil was fitted with a device for attachment to the cervix. The device, manufactured from spring stainless steel wire, resembles a short section of a double helical spring, being only three-quarters of a turn. It basically looks like a fetal scalp ECG electrode, the method of

attachment being similar. The base of this attachment device was cast within the layer of cold cure acrylic. This method of attaching a transducer to the cervix has been used by others, e.g. Kriewall and Work in 1977.

Each coil is connected to a length of plastic chain. The chain attached to the coil for the posterior rim of the external cervical os is slightly longer than its partner anteriorly. The total length of the two chains is $\pm$ 15 cm. The links of the chain were manufactured from 'teflon' (PTFE), polycarbonate and 'perspex'. 'Teflon' was included because of its low coefficient of friction to prevent a pair of links jamming. Brass screws and nuts (size 10BA) were utilised as the pins of the chain and secured the links together.

This brass hardware distorts the magnetic field so slightly that no significant effect can be found.

The ends of the chains are linked together using a press stud, each complementary half being fitted to an end. This press stud, allowing rotation of one half relative to the other, was arranged such that the axis of rotation was parallel to the chain axes.

The posterior length of chain was made longer so that the press stud would lie as close as possible to the vaginal opening.

Both posterior and anterior chains were enclosed in a thin disposable plastic sleeve, the ends being sealed with neoprene seals. The sleeves, which do not inhibit the movement of the chain, prevent corrosion of the brass pins, and biological matter from penetrating the linkages which would be difficult to clean. These sleeves, which also house the cables to the coils, are replaced along with the seals after each use.

The Monitor

A detailed system diagram and a circuit diagram of the monitor can be found in Appendices A and B respectively.

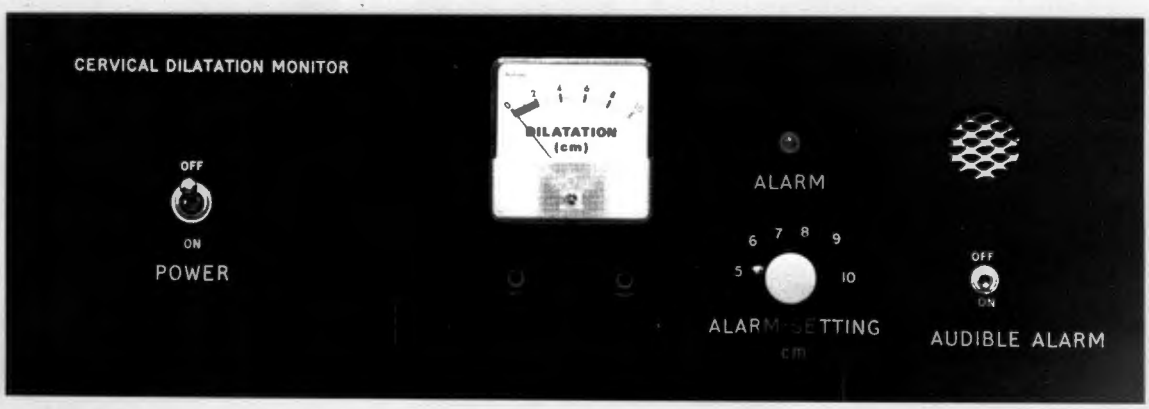

Figure 5 : Front Panel of Monitor

The front panel of the monitor, see Figure 5, is fitted with a main switch, a meter indicating cervical dilatation (in cm), and the sockets for the plugs of the Internal Device below this. To the right of these is the alarm setting

which can cause the alarm to trigger when dilatation exceeds either 5, 6, 7, 8, 9 or 10 cm depending on its setting.

The alarm consists of a visual part, namely a flashing light emitting diode, and an audible part producing a high pitched bleeping sound. The audible part of the alarm may be switched off by the operator if so desired.

The output of the monitor can be linked to a pen recorder which will give a tracing of dilatation vs time.

Safety

The safety of the patient was the main factor when this equipment was designed. The following features are included in the system for the protection of the patient from electrical dangers :

(1) Fuses on both the live and neutral of the mains supply (230 Vac).

(2) A double pole main switch.

(3) An earth conductor in the mains supply cord as well as an auxiliary earth terminal for a separate earth conductor.

(4) Earthing of all exposed metal parts of the monitor. The casing is made of 'perspex'.

(5) A low leakage current mains isolation transformer with fuses at the secondary terminals.

(6) Voltage to the primary coil in the patient is limited to a maximum of 6 volts should the oscillator circuit fail. Should the amplifier of the secondary coil fail, any voltage applied to that coil will be limited to 0,7 volts.

With the coils at mains voltage (230 Vac), the leakage current from each coil and 10 cm of screened cable is ±5µA, therefore total patient leakage current will be ±10µA under this type of fault condition. Normal patient leakage current at 10kHz is ±3µA.

Earth leakage current was measured at 32µA, and at 31µA with the power leads reversed. To ensure continued electrical safety, the equipment should be tested regularly for leakage currents.

It would be preferable if the Internal Device was a disposable unit as it is likely to become electrically unsafe after continued use. A disposable Internal Device would also be easier and less costly to manufacture.

The maximum magnetic field density to which cervical/vaginal tissue is subjected is 25 gauss (refer to book by Purcell, Ch.6, p.203, Eqn 44). This value of 25 gauss is safe, as Kriewall, referring to Pressman's book (1970), reported that only fields greater than 5000 gauss and at frequencies greater than 30kHz, have been found to be harmful.

Dilatation Measurement Range

The cervical dilatation monitor is capable of measuring dilatation over a continuous range of 2 cm to 10 cm.

Accuracy

The circuitry of the monitor includes a linearizer, which basically alters the gain of the system as dilatation varies. The gain changes at various breakpoints, these breakpoints corresponding to dilatation values of 3, 4, 5, 6, 7, 8 and 9 cm. This linearization technique assumes that the change in the induced voltage in the secondary coil with respect to a change in dilatation is linear between two consecutive breakpoints. As the induced voltage is not strictly linear between consecutive breakpoints, this could result in a $\pm$ 1 mm inaccuracy in the dilatation reading.

The main source of inaccuracy lies in the positioning of

the coils on the cervix, i.e. whether they are placed diametrically opposite each other and whether they are positioned on the edge of the external os or well back.

The system was calibrated with the Internal Device in air. Placing it in Ringer's solution caused a slight increase in the dilatation reading at values greater than 8 cm. By comparing this to the test performed on its prototype, which has no attachment device, it was found that the stainless steel causes slight inaccuracies at large dilatation values when placed in Ringer's solution. Therefore the design of the attachment device or this method of attachment must be altered.

The response time of the system is about 0,2 seconds, therefore the -3dB breakpoint is at approximately 1 Hz (governed by the filter in the linearizer). This results in the response to signals with a frequency greater than 1 Hz being reduced. As most of the dilating movements of the cervix are at frequencies less than 1 Hz, very little information of the dilatation pattern will be lost.

If the monitor is calibrated at a mean ambient temperature of, say, 25^{o}C, the output, indicating dilatation, will deviate by a maximum of 2 mm over the ambient temperature range of 15^{o}C to 35^{o}C. This 2 mm drift is quite acceptable when compared with the possible errors resulting from incorrect positioning of the coils on the cervix.

As it was impossible to manufacture the chain without any 'play' between the linkages, slight misalignment of the coils can result. Because this misalignment is very little, it has negligible effect on the accuracy of the system.

5. ATTACHMENT OF THE INTERNAL DEVICE TO THE CERVIX AND THE RESULTS OBTAINED USING THE CERVICAL DILATATION MONITOR

At the time this paper was written, only one cervical dilatation pattern had been monitored by the system.

Sterilization of the Internal Device was achieved by gassing it for 4 hours in ethylene oxide, after which a 6 day period was allowed for degassing.

The coils were attached to the cervix with the aid of an applicator tube and a stainless steel handle (see Figure 3). The tube was positioned purely by feel so that the coil, followed by its linkage system, was slid down the tube to the appropriate part of the cervix. The end of the linkage was given a ¾ turn clockwise causing the attachment device to be 'screwed' into the cervix. To help with this ¾ turn, the stainless steel handle was manufactured which fits through the press stud.

Both coils were attached in this manner and in such a way

that the two press stud halves faced one another and could be snapped closed. The closing of the press stud ensures proper alignment of the coils and prevents unscrewing of the coils.

The 'test patient' was a 30 year old multipara. Her history included two miscarriages, one still birth, one successful delivery and this being her second. She was given Pitocin, diluted 2 units/litre of 5% dextrose solution, initially at a rate of 30 drops/minute being decreased later to 15 drops/minute. As the cervix was already $\pm$ 4 cm dilated when the device was fitted, some difficulty was experienced in attaching the coil to the posterior lip of the cervix, resulting in a fair amount of haemorrhaging. Fitting the anterior coil presented no problems. The membranes were already ruptured at the time of fitting.

The cervical dilatation monitor was switched on at 11h17 and monitored dilatation until almost 13h00, being minutes before delivery. The dilatation recordings of Figures 6, 7 and 8 were plotted on a Beckman 10" linear recorder which was connected to the output of the monitor via matching circuitry. These are only samples of a long continuous tracing. Figures 9 and 10 show a summary of the entire recording.

The monitor indicated a dilatation of ± 4 cm at 11h17, which agreed with a vaginal examination that was performed just prior to the fitting of the Internal Device.

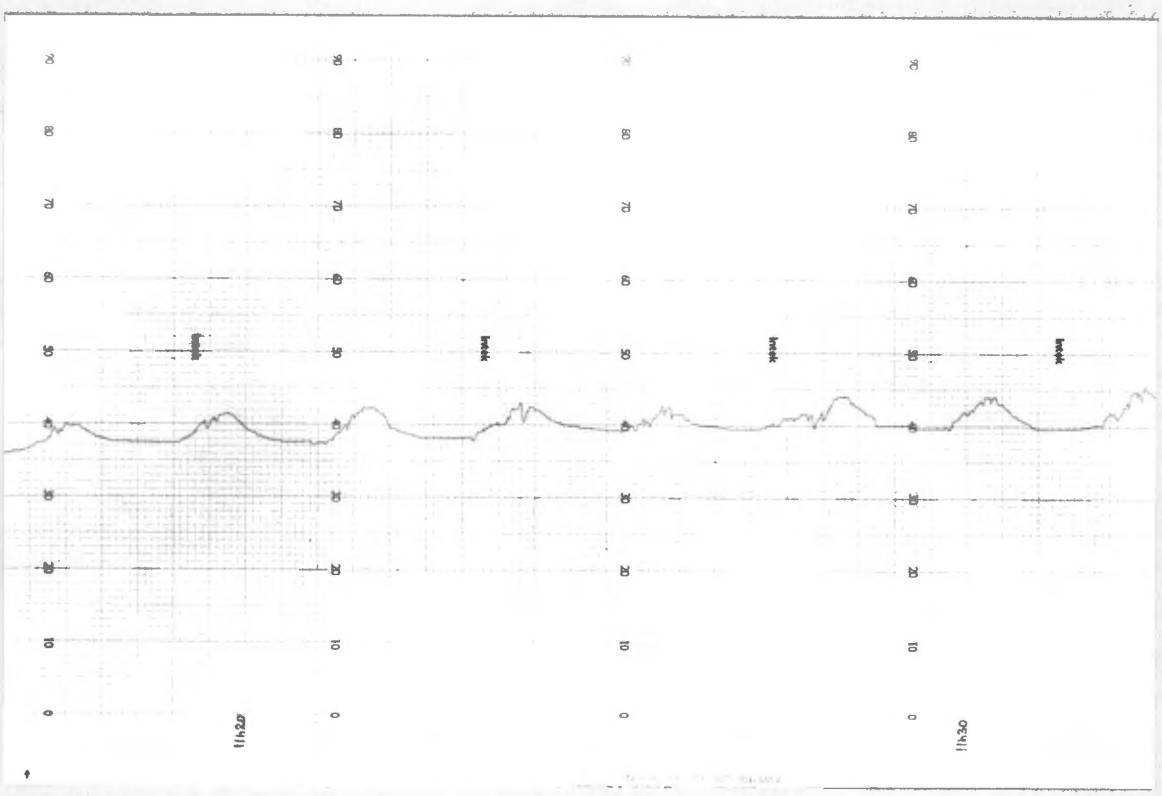

Figure 6 : Recording of cervical dilatation from 11h17 until 11h32. (Dilatation is in mm.)

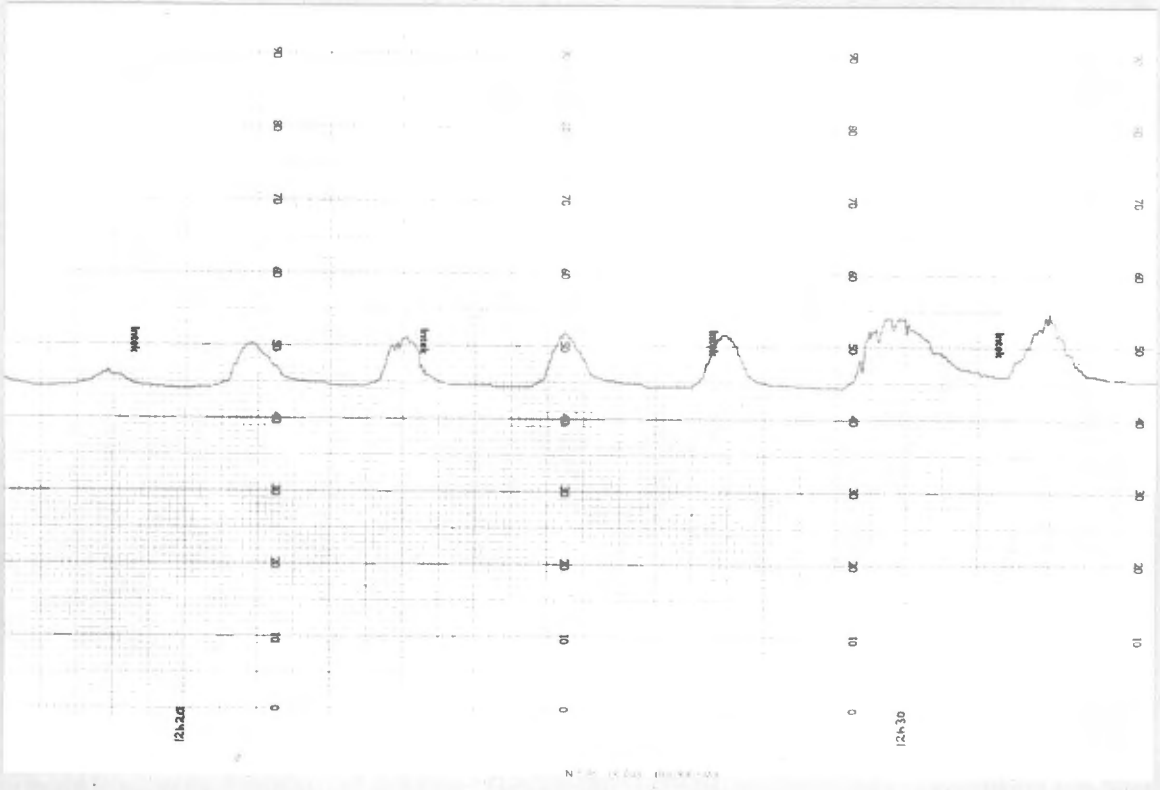

Figure 7 : Recording of cervical dilatation from 12h18 until 12h33

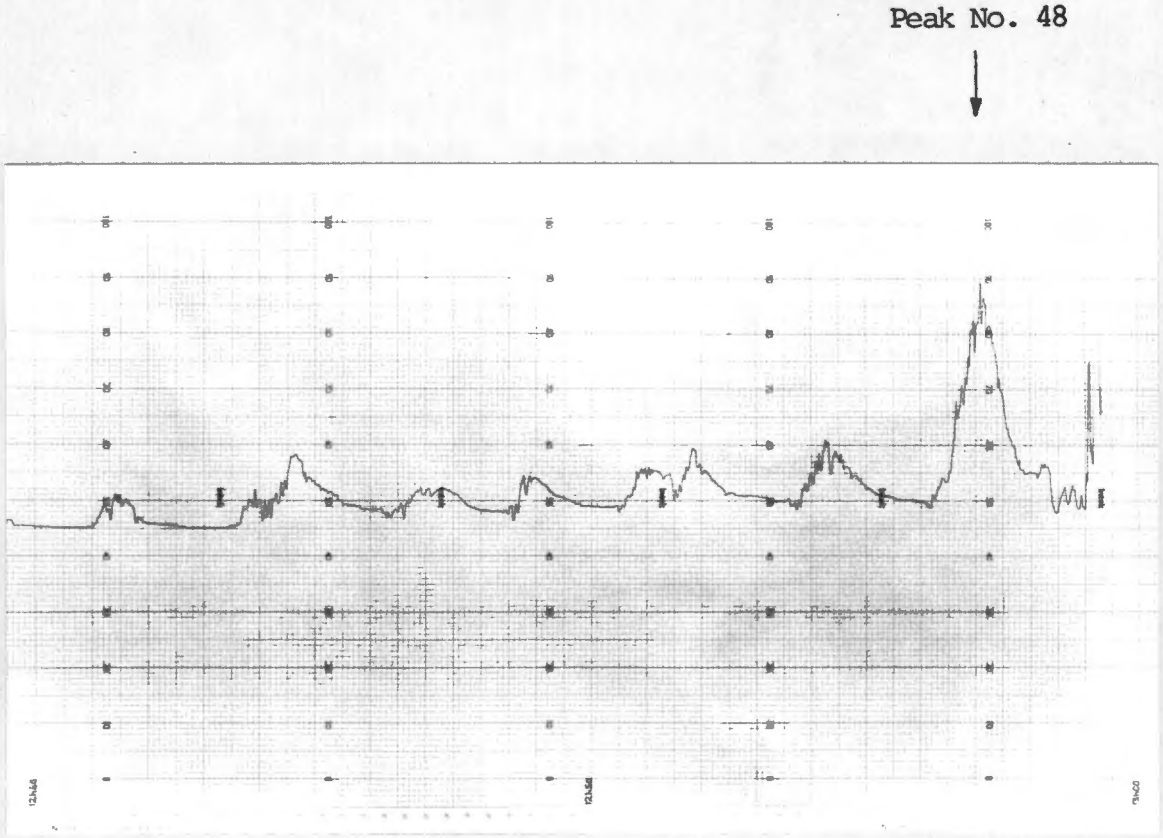

Figure 8 : Recording of cervical dilatation from 12h40 until 13h00

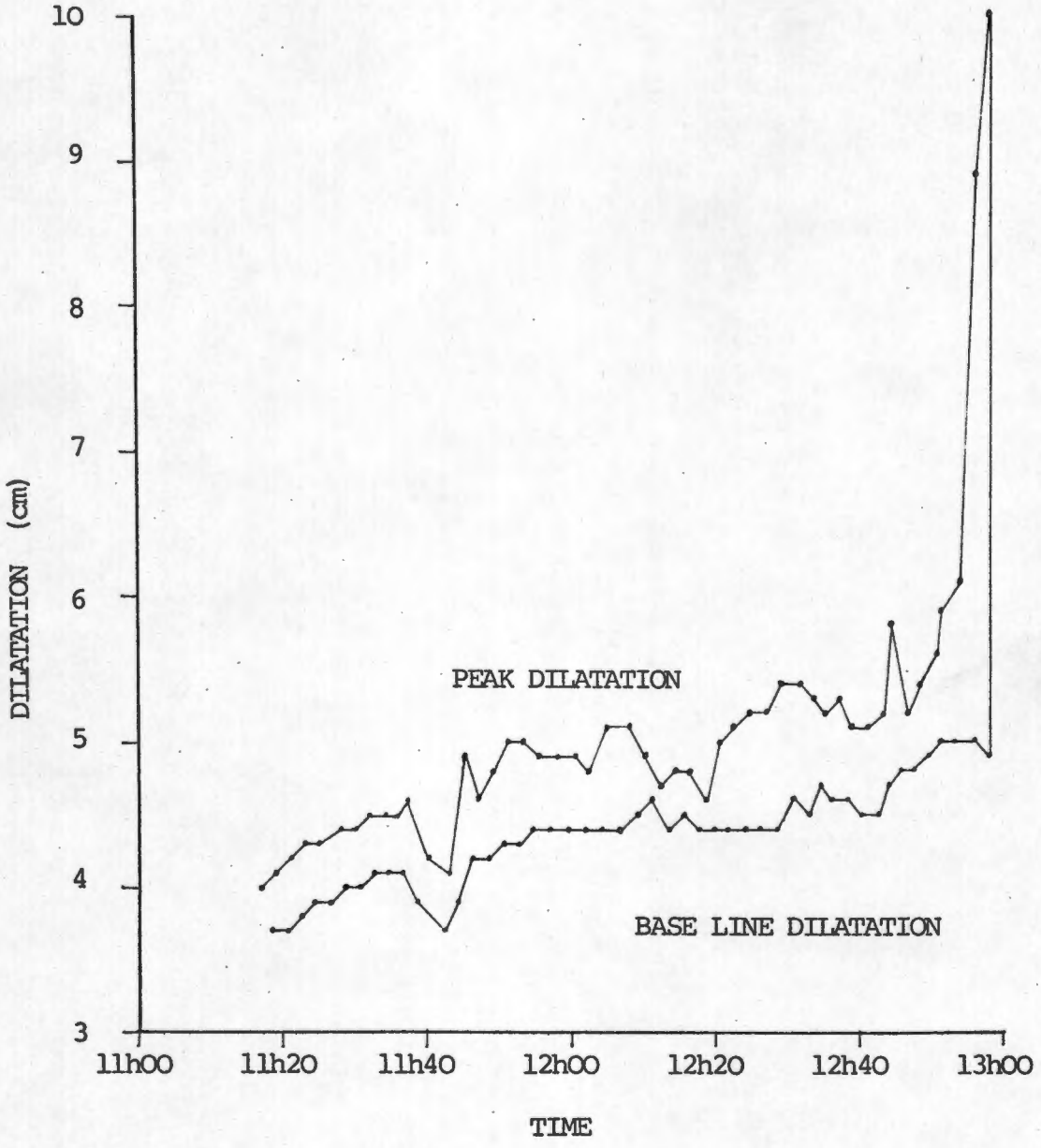

Figure 9 : Graphic representation of dilatation vs time over entire monitoring period

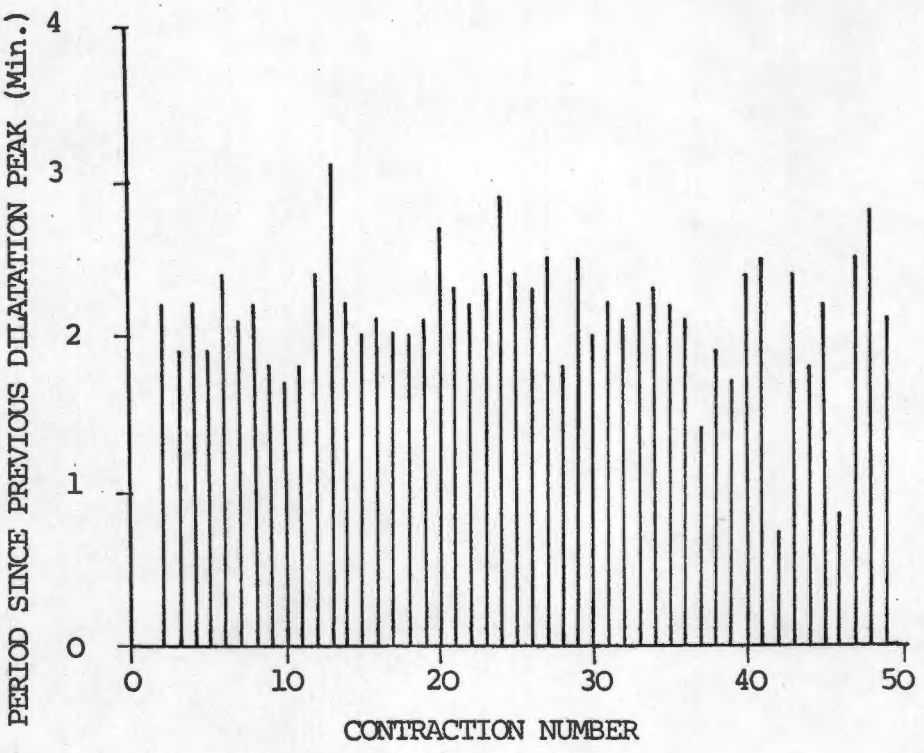

Figure 10 : Graphic representation showing period between dilatation peaks vs contraction number

6. DISCUSSION OF RESULTS

The first stage of normal labour can generally be divided into two phases, a latent and an active phase. The latent phase is from the time when contractions become regular until there is a marked increase in the rate of progress of cervical dilatation. The active phase ends at full dilatation of the cervix and is subdivided into a further three phases : the middle phase is that portion of the 'dilatation curve' undergoing the most rapid change, the

phase of maximum slope; the acceleration and deceleration phases precede and follow the latter respectively.

Figures 6 to 10 show the progress of the labour. From Figure 9 it appears that the monitor was switched on at about the beginning of the acceleration phase. This phase lasted until 12h50, followed by an extremely rapid phase of maximum slope and deceleration phase. This labour can be referred to as abnormal due to the fact that these last two phases were so rapid.

From Figure 10, it can be seen that the period between consecutive dilatation peaks tended to decrease as labour progressed, the average intercontraction time being in the order of 2 minutes.

Figure 6 shows a sample of the initial stages of the recording. Although the dilatation peaks are not very large, there is still an increase in the 'base line' value.

Figure 7 gives an example of how the dilatation peaks can get progressively larger to ultimately cause a change in 'base line' dilatation. The final part of this recording, shown in Figure 8, is rather interesting. From 12h43 onwards, the dilatation peaks became a little erratic, and ultimately larger. What is unusual here is the rate with which dilatation progressed from 5 cm to 10 cm. After

peak no. 48, which reached nearly 9 cm, the dilatation fell right back to ± 5 cm, being its base line value before that peak. This indicates that the cervix has predominantly elastic, rather than viscous, properties.

As the patient tended to groan before each increase in dilatation, it can be concluded that the cervix does not begin to dilate immediately at the onset of a contraction. The fluctuations appearing on the peaks of the tracing resulted from the patient's deep breathing during the contractions.

Because no-one expected the first stage of labour to progress as quickly as it did, the usefulness of the monitor was proved as it alerted hospital staff of the imminent birth.

7. ADVANTAGES OF THIS METHOD OF CERVICAL DILATATION MEASUREMENT

This mutual inductance method does not suffer from coil misalignment problems as discussed earlier.

With the other methods of dilatation measurement using rigid arms, e.g. the caliper method, the vaginal walls pushed on the arms tending to restrict their movement as

dilatation increased. Although the system described in this paper employs a linkage, this should not suffer the same problem with increasing dilatation as the chain is extremely flexible and tends to bend and position itself in such a way as not to interfere with the movement of the coils.

Once the device had been fitted to the cervix, it did not cause the patient any discomfort.

A further advantage is the ease of removal of the Internal Device. In the case of the test patient, where dilatation had exceeded 10 cm, the press stud was visible, just protruding a few millimetres from the vagina. This coupling was popped open, the two chains turned anti-clockwise through 270°, allowing them to be removed very easily from the patient.

8. POSSIBLE IMPROVEMENTS OF THIS CERVICAL DILATATION MONITOR

The major problem with this system is the manner in which the coils are attached to the cervix.

As the cervix is highly vascularized during labour, difficulty in attaching a coil could result in bad haemorrhaging. During the attachment of a prototype

Internal Device which required two stitches to hold it in place, bleeding caused by the needle resulted in the loss of visibility of the cervix. Although the present device is attached purely by feel, cervical haemorrhaging could be detrimental to the patient.

Therefore a non-traumatic method of attachment would greatly improve the system and would help this type of equipment to be accepted more readily within hospitals.

Vacuum cups were used for cervical attachment by Rice in his experiments in 1974, but were easily dislodged. A clamp type system, as used in some caliper methods, might be the solution to the problem.

An improvement which would benefit the system is a reduction in the size of the coils and the thickness of the chain as this would, firstly, make vaginal examinations easier without really disturbing the system and would, secondly, reduce any resistance to movement that the Internal Device might experience.

The cervical dilatation monitor needs an isolating unit at the output to the pen plotter for safety purposes. This was not incorporated into the design as it was not known what pen plotter will ultimately be used with the system.

9. SUMMARY AND CONCLUSIONS

A method of measuring dilatation of the uterine cervix during labour has been described. The technique, being that of mutual inductance, utilises two coils, one on the posterior lip of the cervix and the other on the anterior, the axes of these coils being kept parallel by a flexible linkage.

The coils are attached to the cervix in a manner similar to that in which a fetal scalp ECG electrode is attached to the scalp of a fetus, i.e. twisted in. Although this method of attachment facilitates easy removal of the device in cases of emergency, a different method of attachment should be developed which does not penetrate the cervix and cause haemorrhaging.

Continuous measurement of cervical dilatation can give much information about the properties, functions and drug response of the cervix for research purposes as well as provide hospital staff with valuable data about the progress of a patient's labour and thereby assist with the management thereof.

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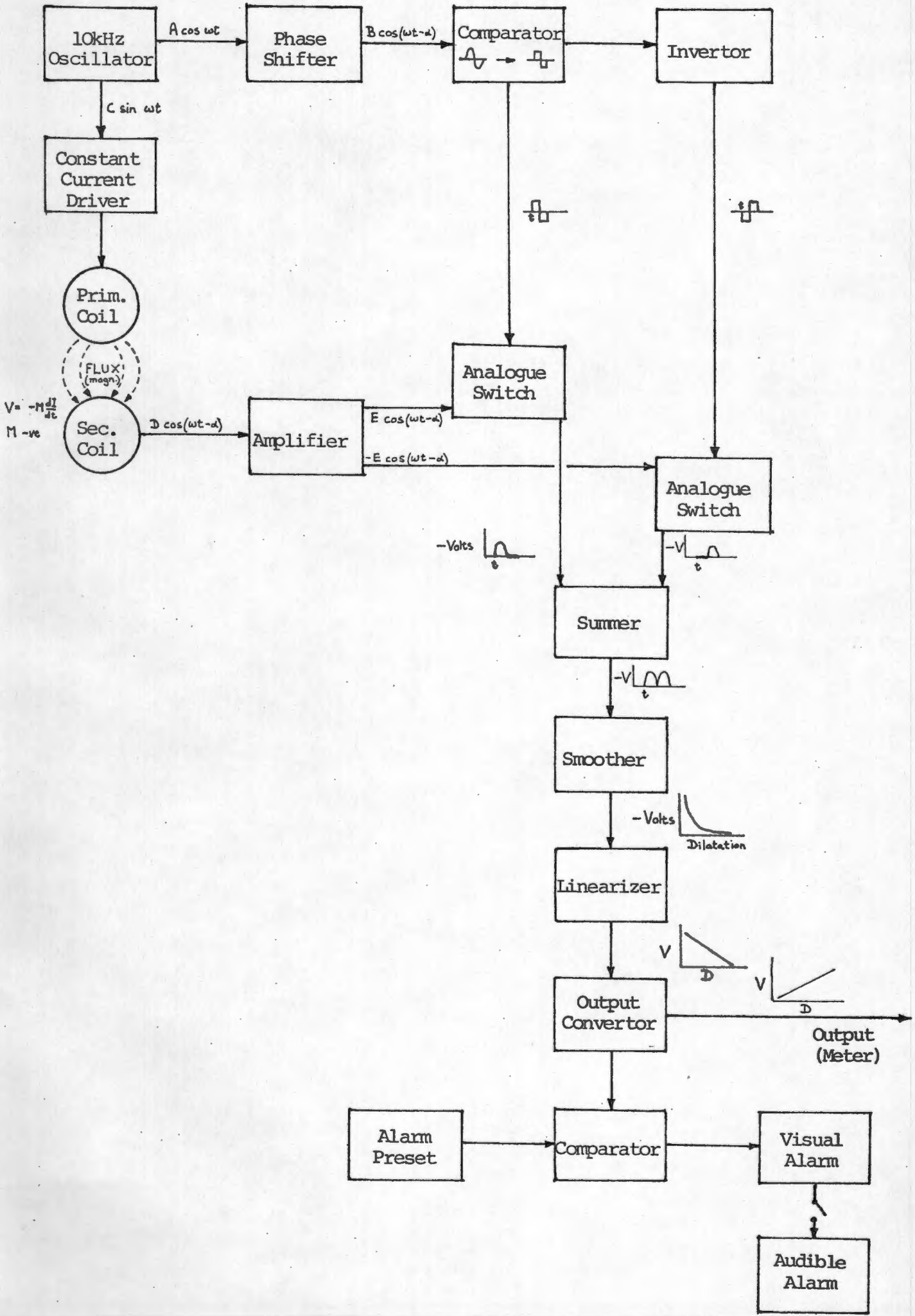
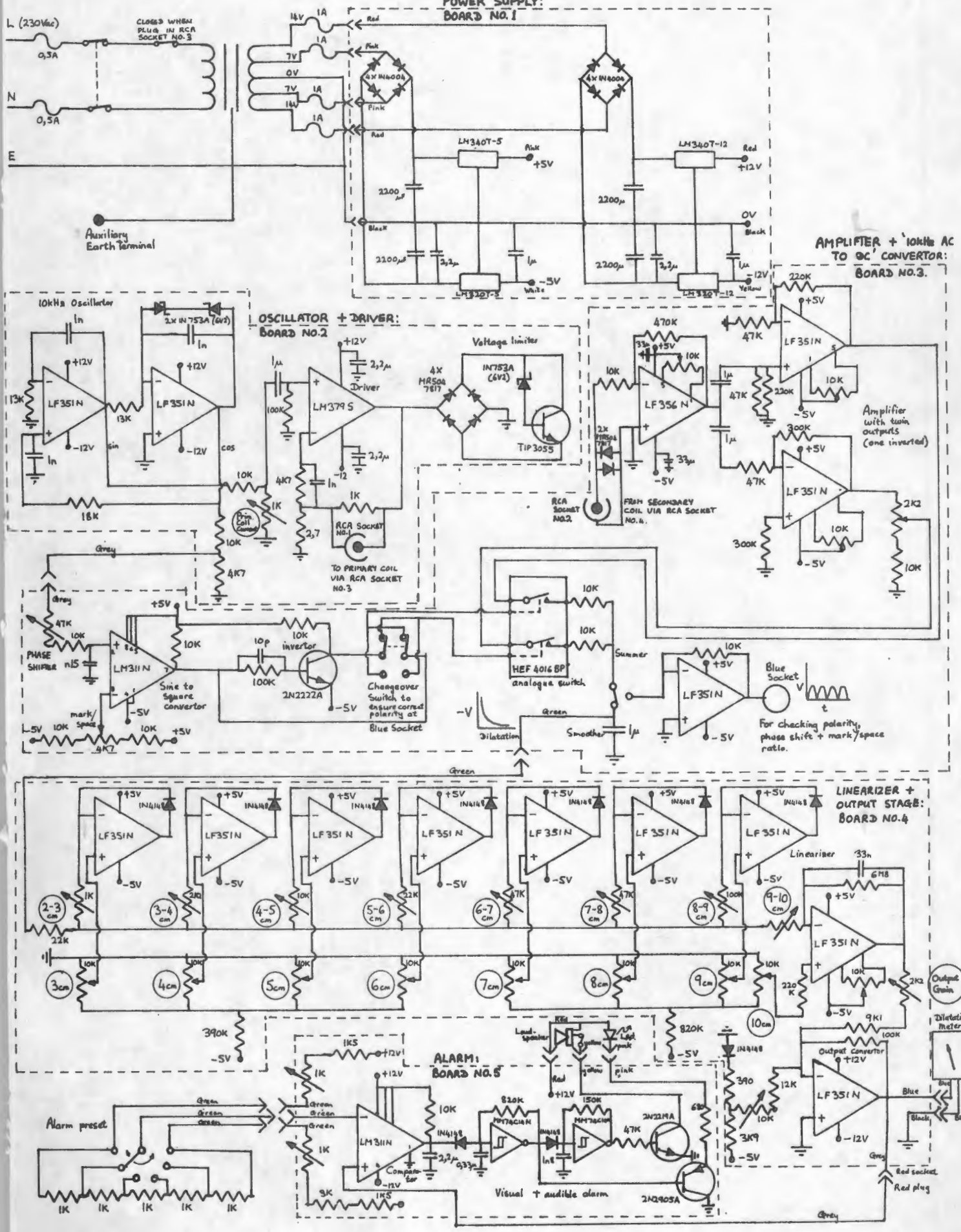
APPENDIX A : DETAILED SYSTEMS DIAGRAM OF THE CERVICAL DILATATION MONITOR



APPENDIX B : CIRCUIT DIAGRAM OF THE CERVICAL DILATATION MONITOR



APPENDIX C

CALIBRATION OF THE CERVICAL DILATATION MONITOR

Due to the fact that the Internal Device requires almost a week to degas after sterilizing with ethylene oxide, there may be a need to manufacture a second or a third device. As it is virtually impossible to produce these Internal Devices all with exactly the same electrical characteristics, calibration of the monitor is essential if one requires the measurement of cervical dilatation to be accurate.

Refering to the circuit diagram (Appendix B), the calibration is carried out as follows :

(1) Breakpoint potentiometers labelled "3 cm", "4 cm" . . . "9 cm" should be turned fully clockwise.

(2) Arrange the Internal Device so that coil axes are 10 cm apart.

(3) Adjust potentiometer labelled "10 cm" such that meter reads 10 cm.

(4) Move coils until axes are 9 cm apart.

(5) Adjust potentiometer labelled "9-10 cm" such that meter reads 9 cm.

(6) Adjust potentiometer labelled "9 cm" such that meter reading is just on the point of increasing.

(7) Move coils until axes are 8 cm apart.

(8) Adjust potentiometer labelled "8-9 cm" such that meter reads 8 cm.

(9) Adjust potentiometer labelled "8 cm" such that meter reading is just on the point of increasing.

ETC.

The range of calibration can be extended by adjustment of the potentiometers labelled "Primary Coil Current" and "Output Gain".