INTRA-ORAL CONTROL SYSTEMS

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Summary

This paper describes the development work being done at Rancho Los Amigos Hospital on intra-oral telemetry control systems. The design of a tongue actuated intra-oral telemetry control system to control the "Rancho Electric Arm" (a seven degree of freedom electrically powered arm brace), is described in detail. Results of patient tests with this system are discussed. Also described are techniques for measuring a patient's performance with various intra-oral configurations (to optimize the design of the intra-oral control unit).

The present system consists of 15 specially designed solid state strain gauge pressure transducers and an eight-channel PAM/FM telemetry system mounted in a metal dental appliance. The dental appliance fits the lingual area of the mandible in such a way that pressure can be exerted on the various pressure transducers by the tongue. The control signals which are generated are telemetered to an FM receiver mounted on the wheelchair and are used to control the velocity of the respective arm joints.

Introduction

In the past two decades improved medical care has resulted in the survival of an ever-increasing group of patients with severe neuromuscular disabilities who otherwise would have succumbed to their disease or remained bedridden. This has created a large population of severely paralyzed persons dependent upon society for care.

During the past eight years, considerable emphasis has been placed upon the development of externally-powered arm ortheses, resulting in the design of some highly sophisticated systems such as the "Case Research Arm Aid" [1] and the "Rancho Electric Arm" [2]. It is only in recent years, however, that patients with disorders causing severe paralysis of the upper and lower extremities have been able to look forward to a life of increased activity. This change is the result of almost routine fitting of electrically powered arm braces and motorized wheelchairs to these patients.

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Although considerable progress has been made in the development of control systems for externally powered orthotic devices, they continue to be the major limiting factor in the degree of function which can be attained. Extra-oral tongue-operated switch controls which provide sequential off-on control of the orthesis are now used routinely (Fig. 1). Although they are easily fitted, inexpensive and reliable, they do not provide the degree of control that is desirable.

Fig. 1. Patient using "Rancho Electric Arm" with extra-oral tongue switch control.

Past experience with these types of controls clearly showed the tremendous potential of the tongue as a control site for externally powered orthotic devices and led to the concept of the intra-oral system now under investigation at Rancho Los Amigos Hospital. Anticipated advantages of the intra-oral control system are:

A) Ease of control — the control system will allow the tongue to function entirely inside the mouth, thereby taking advantage of the tongue's high degree of dexterity. Close placement of the transducers will make possible for the patient to simultaneously control a number of degrees of freedom of an arm brace.

B) Direct attachment to the patient — Attaching the transducer directly to the patient (rather than to an exteral fixture) will provide a more positive control, especially for driving an electric vheelchair. No obstruction will exist in front of the mouth to restrict arm motions in that area.

C) Cosmesis and hygiene — Placing the transducers intra-orally will make the control much more cosmetically acceptable and more sanitary than extra-oral tongue actuated control systems.

D) Velocity control — The use of analog transducers will make it possible to provide velocity proportional control to arm braces.

This paper is a progress report of what has been achieved to date toward the development of a functional intra-oral tongue actuated control system at Rancho Los Amigos Hospital. Although a patient has been fitted with an intra-oral control unit, it must be clearly understood that the system has not been perfected to the point that it is a functional control system for patient use. The system is currently in the prototype stage, and a great deal of work is still required to perfect it.

Research Accomplishments

Although it has application to other externally powered systems the intra-oral control system is designed specifically to control the "Rancho Electric Arm" (an electrically powered arm brace with seven degrees of freedom), and a motorized wheelchair. Since wires running out of the mouth would be unacceptable to patients, it was necessary to develop a multi-channel intra-oral transmitter to telemeter the control information out of the mouth. Fourteen pressure transducers are necessary to provide bidirectional control of the seven degree of freedom electrically powered arm brace. This large number of transducers necessitated the design of miniature, sensitive pressure transducers that would conveniently fit inside the mouth. It was necessary to design special dental appliances to house the electronics and provide a rigid attachment of the transducers to the patient. In addition an instrument was designed to study the effectiveness of various control configurations.

The following five major divisions of this project will be discussed in detail below:

A) Dental appliance development.
B) Pressure transducer design.
C) Development of intra-oral telemetry system*.
D) Patient fitting.
E) Instrumentation for determining effectiveness of an intra-oral control.

* Designed and developed at the Dental Research Laboratory, University of Michigan Dental School, Ann Arbor, Michigan.

Dental Appliance Development

The lingual surface of the gingivae and teeth of the mandible were chosen as the most ideal area for placement of the transducers. This area is readily accessible to the tongue, yet is an area which interferes least with the normal operation of the tongue during mastication and speech.

The dental appliance provides a structure on which to mount the pressure transducers, transmitter, and batteries. In order to provide a strong structure, it was decided to construct the dental appliance out of metal, using retention clasps which would rigidly hold it in place in the mouth and still permit easy removal. A chromium-cobalt alloy (trade name of Vitallium) was chosen since it is used routinely in the construction of various types of metal dental appliances.

Early in this project, four subjects were fitted with dental appliances. These appliances were worn for extended periods of time to determine patient tolerance, and were found to be well tolerated following an initial period of adjustment. The original design of the dental appliance subsequently was modified to reduce the amount of metal used and to increase the area available for

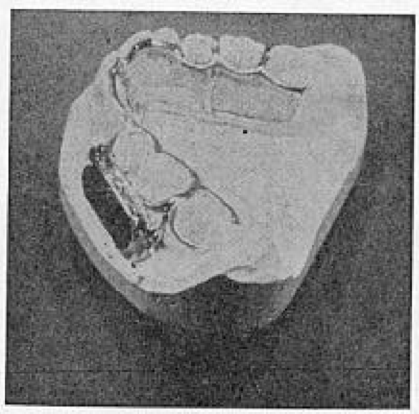

Fig. 2. Chromium-cobalt dental appliance for mounting of pressure transducers and transmitter.

mounting the electronics. It was found that it is possible to extend the lower border of the dental appliance deeper into the floor of the mouth than is normally the case for mandibular dental appliances. A photograph of one of the dental appliances is shown in Figure 2. Battery cases to house the batteries are on the buccal side of the mandibular teeth, allowing more room in the lingual area for the pressure transducers and transmitter.

Pressure Transducer Design

Fourteen pressure transducers are required to provide control of the Rancho Electric Arm and a fifteenth is required as a control mode selector switch. Each of these 15 transducers consists of a

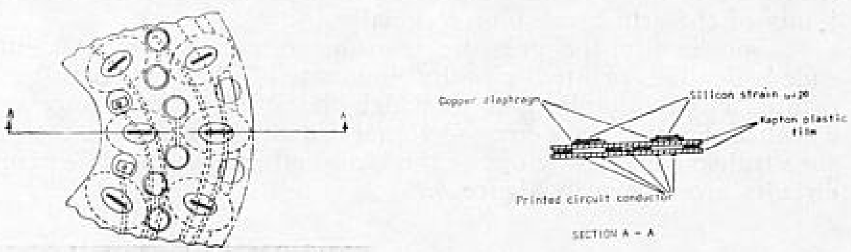

Fig. 3. Cross-sectional drawing of a pair of pressure transducers.

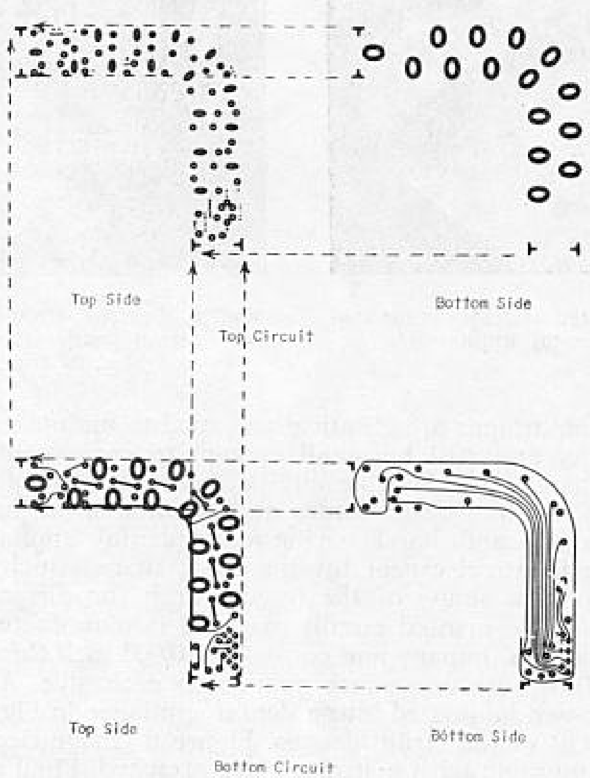

Fig. 4. Drawings of the two double sided flexible printed circuits for use with the PAM/FM telemetry system.

silicon strain gauge mounted in the dental appliance so that it will be stressed when a force is transmitted to it from the tongue. The stress on the strain gauge results in a change in its electrical resistance thereby providing an electrical signal proportional to the tongue pressure. This signal then controls the velocity of the respective arm joint in one direction. The 14 arm control pressure transducers make it possible to control the velocity of the seven joints of the arm brace bidirectionally.

Specifically, the pressure transducers consist of two double-sided flexible printed circuits laminated together, creating 15 printed circuit diaphragms to which the silicon strain gauges are attached. Figure 3 is a cross-sectional drawing of a pair of the pressure transducers. Drawings of the two double-sided flexible printed circuits are shown in Figure 4.

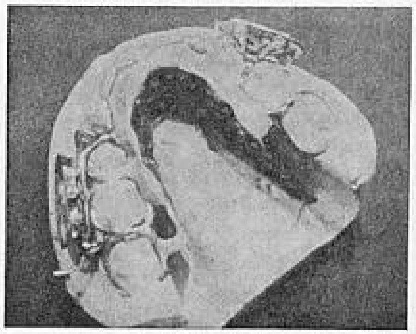

Fig. 5. Printed circuit laminated into dental appliance.

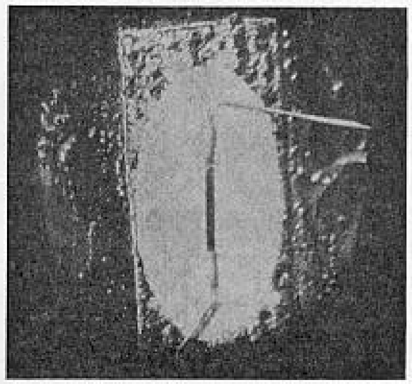

Fig. 6. Printed circuit diaphragm with strain gauge attached (magnified 20 times).

The diaphragms are elliptically shaped to maintain the required sensitivity and still be small enough to conveniently fit in a dental appliance. The flexible circuit makes it possible to design the circuits in three basic shapes and eliminates the necessity for custom making and hand wiring each dental appliance. These circuits are identical except for the basic shape which allows for the variations in shape of the lingual arch for different people.

The flexible printed circuit material is manufactured by the G. T. Schjeldahl Company and consists of 0.003 inch thick polymide (Kapton) film with one ounce copper on each side. A completed circuit is shown laminated into a dental appliance in Figure 5, prior to attachment of the strain gauges. Figure 6 (magnified 20 times) shows a diaphragm with a strain gauge attached. Final preparation of the circuit consists of moisture-proofing with nitrile rubber (Gagekote #2 manufactured by W. T. Bean, Inc.) and coating with

Dow Corning's 891 Medical Adhesive. A 1/8-inch diameter nylon ball is embedded in the Medical Adhesive over the center of each diaphragm to concentrate the tongue's force on the diaphragm. An appliance with transmitter installed is shown in Figure 7. This photograph was taken prior to encapsulation of the transmitter in dental acrylic.

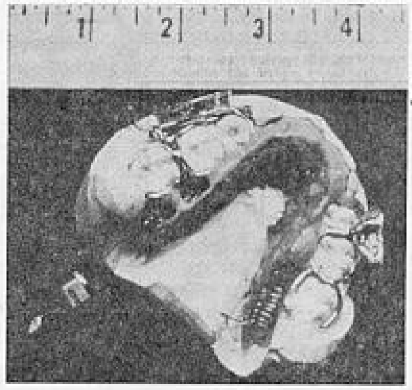

Fig. 7. Telemetry control unit with 15 pressure transducers and 8 channel PAM/FM transmitter.

The resistance change of the pressure transducers is linear from zero to about 200 grams of force. This range appears quite adequate for intra-oral tongue activation.

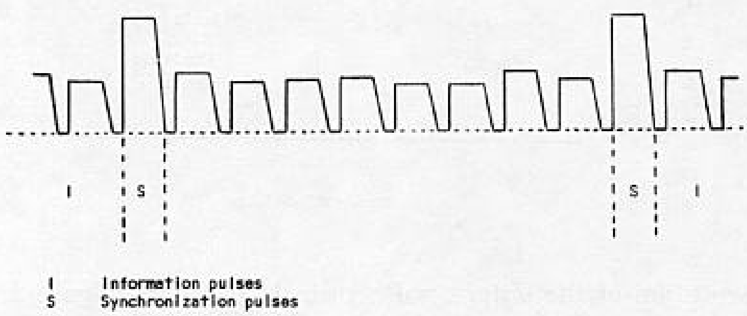

Fig. 8. Representation of transmitter output pulse train (85% duty cycle PAM).

The manufacturer (Whittaker Corporation Instrument Systems Division), now provides inexpensive silicon strain gauges for the pressure transducers. These are uncalibrated gauges with a nominal resistance of approximately 500 ohms and a gauge factor of about 140. Both "P" and "N" type gauges are used.

Development of Intra-Oral Telemetry System

The telemetry system is a pulse amplitude modulated/FM (PAM/FM) system. A number of systems were reviewed prior to the selection of this system. Design breadbords were fabricated of both the PAM/FM and a pulse duration modulated/FM (PDM/FM) system. The PDM/FM system was rejected due to the inability to maintain sufficient sensitivity and still keep the package small enough to meet the size requirements.

Because the PAM/FM system does meet the size and sensitivity requirements, it was selected. This system consists of a 9-stage commutator and an FM transmitter. The commutator samples the inputs from the pressure transducers in sequence, and presents an output pulse train representing the amplitudes of all inputs in a periodic time sequence. The duty cycle of the output wave form is approximately 85%. One channel is used for synchronization, with the remaining eight used as information channels (Table 1). A

Table 1. Function of nine telemetry channels.

<table>
<tr><th rowspan="2">Channel</th><th colspan="2">Function</th></tr>
<tr><th>Mode I</th><th>Mode II</th></tr>
<tr><td>1</td><td rowspan="7">Rancho Electric Arm Control</td><td rowspan="2">Electric Wheelchair Control</td></tr>
<tr><td>2</td></tr>
<tr><td>3</td><td rowspan="5">Auxiliary Controls</td></tr>
<tr><td>4</td></tr>
<tr><td>5</td></tr>
<tr><td>6</td></tr>
<tr><td>7</td></tr>
<tr><td>8</td><td colspan="2">Mode Selector Switch</td></tr>
<tr><td>9</td><td colspan="2">Synchronization Pulse</td></tr>
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representation of the output pulse train is shown in Figure 8. The circuit diagram of this system is shown in Figure 9.

Figure 10 is a block diagram of the receiving and decoding system. The telemetry receiver is of a conventional FM superheterodyne design. The receiver output is processed through the sync. separator, the clock generator, and the signal clamping circuitry resulting in three separate signals, the first two of which control and drive the counter. The third (clamped) signal contains the data pulses which are extracted in the detectors. The signal out of the

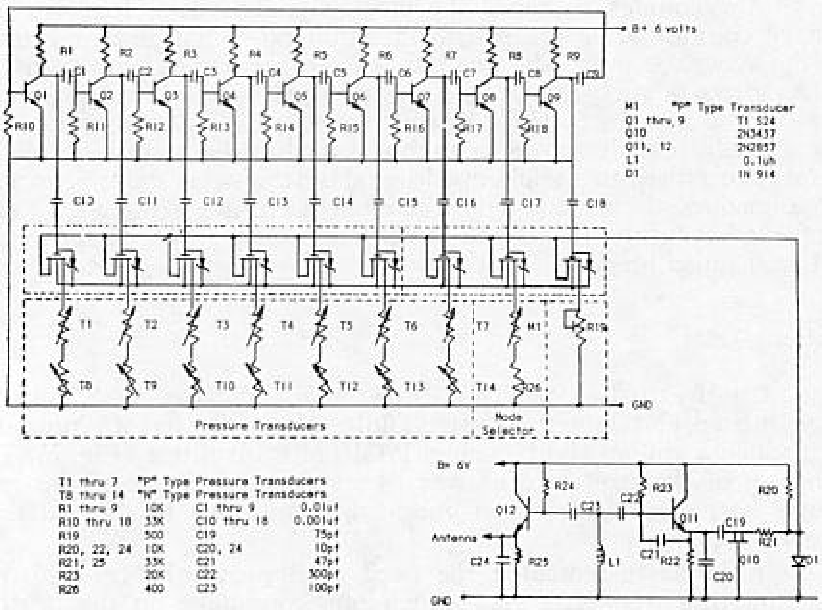

Fig. 9. Circuit diagram of transmitter.

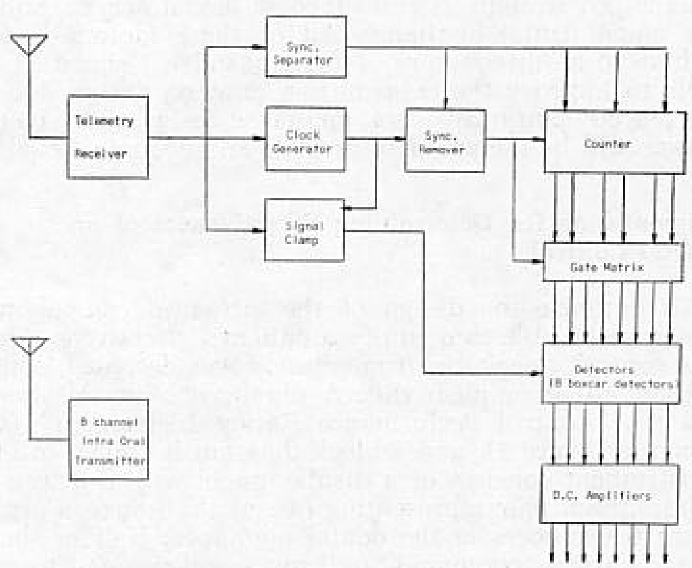

Fig. 10. Block diagram of receiving and decoding system.

sync. separator contains only the synchronization pulse and is used to set the counter to zero. The clock signal is used to drive the binary counter after the synchronization pulse has been removed in the sync. remover. The counter waveforms are combined in the gate matrix in such a manner as to produce gate control pulses in the desired sequence. The control pulses are then used to control the eight boxcar detectors in such a way that the amplitude of the respective pulses in the clamped signal is detected at the appropriate time. Each of the signals from the eight detectors is integrated and amplified resulting in a signal with magnitude proportional to the original pulse height.

Patient Trial

A patient using Rancho Electric Arm was fitted with a prototype intra-oral telemetry control unit. This unit has 15 pressure transducers and an eight-channel PAM/FM transmitter (Fig. 7). The purpose of the control unit was to test the operation of the telemetry system under normal operating conditions in the patient's mouth.

Initial tests indicated the need to improve the transmitting antenna which consists of a 4-inch-long conductor on the printed circuit. It was found that with an external antenna a few inches in length, it was possible to transmit a distance 50 to 100 feet. With the printed circuit antenna, the transmitting distance decreased to less than one foot. It should be noted that the printed circuit antenna is not straight, is embedded in dental acrylic, and is close to the metal dental appliance. All of these factors undoubtedly contribute to an attenuation of the transmitted signal. If it is not possible to improve the transmitting antenna design due to constraints placed upon it by dental appliance design, then the transmitter power will be increased to provide an adequate signal.

Instrumentation for Determining Effectiveness of an Intra-Oral Control

To optimize the design of the intra-oral control unit, it is necessary to be able to quantify a patient's effectiveness in operating the control. Special instrumentation was designed, constructed, and tested to accomplish this. A photograph of this instrument, named the "Control Performance Rating Instrument" (C.P.R.I.), is shown in Figure 11, and a block diagram is shown in Figure 12. The instrument consists of a display panel with fourteen pairs of indicators, each pair representing one of the fourteen arm control pressure transducers in the dental appliance. Half of these indicators are termed "command" indicators and respond to an automatic programming device. The remaining indicators are called "feedback" indicators and are triggered by Schmitt Trigger circuits which respond to the intra-oral pressure transducers. The triggering level of the Schmitt Triggers is adjustable so that the tongue pressure required to activate them can be changed. The outputs of the Schmitt Triggers are gated through an "or" gate and operate

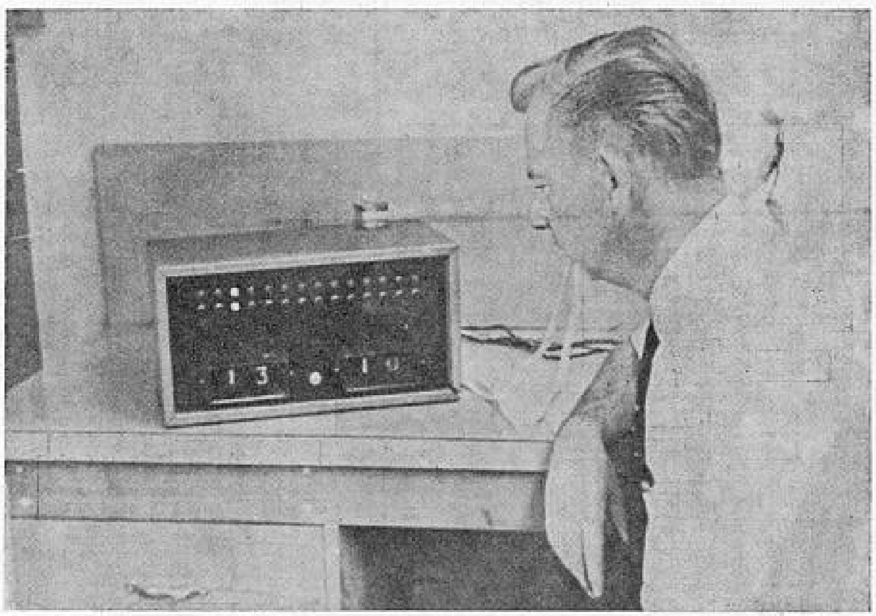

Fig. 11. Photograph showing operation of the "Control Performance Rating Instrument".

a decade counter termed the "total response counter". The "total response counter" registers each time the pressure threshold is exceeded on one or more of the pressure transducers. The feedback signals from the Schmitt Triggers are also compared with the command signals from the programming device in the digital comparator, the outputs of which are gated through an "and" gate. The output of the "and" gate is processed, delayed in time (variable time delay), and used to activate a decade counter termed the "correct response counter". The "correct response counter" counts each time the pressure threshold is exceeded and maintained for a pre-set length of time on only the desired pressure transducer or transducers. The program can be made to advance either at prescribed intervals of time or each time a correct response is obtained. In using the C.P.R.I., a patient is fitted with an intra-oral control unit and the pressure threshold is set to the desired level. The programmer is started, and the patient responds with the control unit in such a way as to attempt to match the feedback and command indicators. Following the completion of a program, the correct response and total response counts are recorded. The program is then repeated for various pressures. The ratio of the correct response count (CRC) to the total response count (TRC) is termed the performance number $\left(PN = \frac{CRC}{TRC}\right)$ and is a measure of the patient's ability to operate the control. The performance number is then plotted vs. pressure. The entire process is repeated

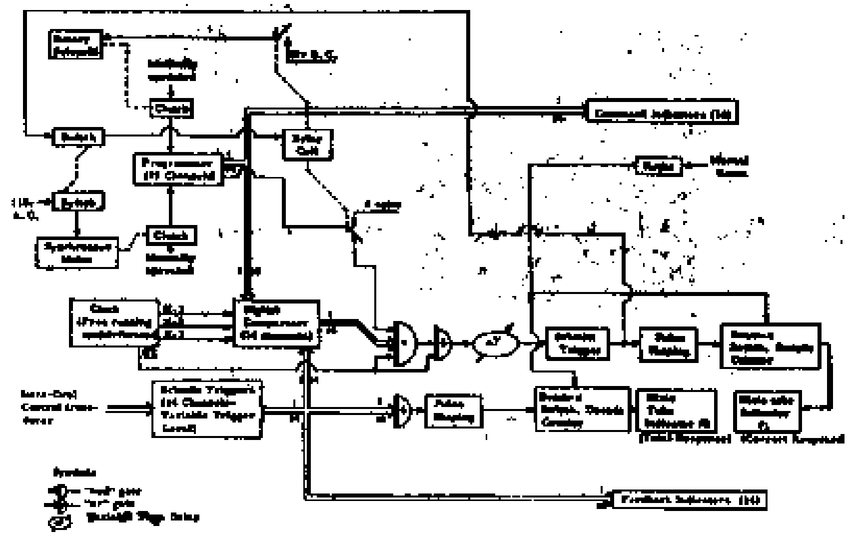

Fig. 12. Block diagram of "Control Performance Rating Instrument".

for various control configurations. The resulting data will be graphed and used to select an optimum design for the intra-oral control.

Dental impressions have been taken and dental appliances are being constructed for six subjects from which data will be collected to optimize the design of the intra-oral control unit. These subjects will test various pressure transducer configurations with their performance being monitored and rated with the C.P.R.I.

Conclusions

In the two and one-half years since the inception of this research project, considerable progress has been made toward developing an intra-oral tongue-actuated control system. Small sensitive pressure transducers have been developed; an instrument has been designed and constructed to measure a patient's performance with a particular control unit; and a telemetry system has been designed and constructed. Patient tests with a prototype system demonstrates the need to improve the transmitting antenna design, or to increase the transmitter power. The work to date establishes the feasibility of an intra-oral tongue-actuated control system. However, additional research is needed to develop this control system into a functional and reliable system.

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