702590

April 8, 1986

ESQA

SSRL Prop. #456 "Iodine Dichromography with Monochromatic X-ray Beams for Angiography"

Bill Gough, Director, SSO/ER

ESQA has reviewed the information you forwarded to us on the subject proposal. It is likely that the requirements of 10CFR745 have been met. We believe the necessary safety precautions are being taken. We do offer the two comments below for your consideration.

It is recommended that the existence of an "approved general assurance" on file with the Department of Health and Human Services be verified and that a copy be obtained.

In discussions with Dr. Jim Robertson of the Office of Health and Environmental Research (OHER ER-70), it became clear that the aspect of "informed consent" is extremely important. It is recommended that the informational paper to the patient clearly outline any differences between the synchrotron radiation protocol and the normal procedures, such as the difference in radiation dose. It is also suggested that guidance on informed consent be solicited from OCC and OHER.

/s/

James T. Davis, Director
Environment, Safety and
Quality Assurance Division

| CONCURRENCES | |
|---|---|
| RTG. SYMBOL | ESQA |
| INITIALS/SIG. | KOPENHAVER |
| DATE | 4/8/86 |
| RTG. SYMBOL | ESQA |
| INITIALS/SIG. | WARNER |
| DATE | 4/8/86 |
| RTG. SYMBOL | ESQA |
| INITIALS/SIG. | DAVIS |
| DATE | 4/8/86 |
| RTG. SYMBOL | |
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| INITIALS/SIG. | |
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REPOSITORY DOE-OAK
COLLECTION Environment & ~~Safety~~ Support Div
BOX No. Central Files
FOLDER 1300.3.C Angiography Experiment at SSRL (1986)

0020937

John Cerino
From: E. Rubenstein

A.B
SSRL 284-2

RECEIVED
JAN 17 1986
SSRL

RECEIVED
JAN 23 1986
SSRL

DATE: January 7, 1986

TO: E. Rubenstein, M.D.,
R. Hofstadter, Ph.D. & D.C. Harrison, M.D.
Department of Medicine

FROM: Chairman, Medical Committee for the
Protection of Human Subjects in Research

PROTOCOL TITLE:
K-edge Angiography with Synchrotron X-rays.
(Grant: K-edge Subtraction Angiography with Synchrotron X-rays)

The Committee approved human subjects involvement in your research project on January 7, 1986.

The expiration date of this approval is January 6, 1987. If this project is to continue beyond that date, please submit an updated proposal in advance for the Committee's re-approval. If this proposal is used in conjunction with any other human experimentation or if it is modified in any way, it must be re-approved for these special circumstances. In addition, the Committee requests prompt notification of any complications which may occur during any experimental procedure.

All continuing projects and activities must be reviewed and re-approved at least annually by the Committee. Committee approval of any project is for a maximum period of one year. It is the responsibility of the investigator to resubmit the project to the Committee for annual review.

for Kathy McClelland
Don R. Goffinet, M.D., Chairman

cc: Sponsored Projects
Marshall O'Neill

0020938

Funding Agency: (NIH HL29024; NIH HV33039; DOE DE-AT03-84ER50200) (R)
Period of Time: 01/07/86 through 01/06/87
Investigational New Drugs: N, N/A
Investigational New Device: N, N/A
Cooperating Institution: N

RENEWAL

protocol #

REQUEST FOR INSTITUTIONAL APPROVAL OF PROJECT INVOLVING HUMAN SUBJECTS AT RISK
THE MEDICAL COMMITTEE FOR THE USE OF HUMAN SUBJECTS IN RESEARCH

To: Kathy Callahan, 851 Welch Rd., #115

Date: November 20, 1985

PI for Grant/Project: Robert Hofstadter, Ph.D. MD/PhD Title: Professor
Other Investigators: Edward Rubenstein, M.D. MD/PhD Professor (Clinical
Donald C. Harrison, M.D. MD/PhD Professor

Title of Research Project: K-edge Angiography with Synchrotron X-rays

(AND GRANT, IF DIFFERENT) K-edge Subtraction Angiography with Synchrotron X-rays

Contract/Grant # 1 R01 HL29024-01-A1 NIH Grant 7/1/83-6/30/86
1 HV-38039 Sponsor NIH Contract Period 7/1/83-6/30/86
DE-AT03-84ER60200 DOE Grant 2/1/84-1/31/87

Investigator's Address Rm. TC-129 Dept. Medicine Ext. 7-7188

Sponsored X Unsponsored ___ Investigational Drug ___ Investigational Device ___

Department Chairman [signature]
SIGNATURE

REVIEW PROCESS - Check One: REGULAR REVIEW ___ PLEASE SEND 4 COPIES (DO NOT STAPLE)

EXPEDITED REVIEW ___ PLEASE SEND 2 COPIES (See regulations
(VA Not Eligible) on reverse side of this form)
___ Paragraph number under which expedited review is requested.

APPROVAL OF THE HUMAN SUBJECTS COMMITTEE SHOULD BE OBTAINED PRIOR TO SUBMISSION OF THE RESEARCH PROJECT TO HHS/NIH. THE COMMITTEE MEETS THE FIRST TUESDAY OF EVERY MONTH AND APPLICATIONS SHOULD REACH THE COMMITTEE 30 DAYS PRIOR TO THE MEETING DATE.

PLEASE PROVIDE INFORMATION IN THE FOLLOWING AREAS AND ATTACH TO THIS FORM:

1. Protocols Involving Use of Radioactive Materials.
   A separate form for projects involving radioactive materials should be obtained from the Health Physics Department, Room 67, Encina Hall, X-3201.

2. Number of Subjects Involved to Date.

3. Description of Results to Date.

4. Problems or Complications.

5. Description of Remainder of Project.

6. Describe Any Changes Since Original Approval.

7. Attach the Consent Form(s) You are Using for this Study.
   (Even if it is the same as previously approved.)

OR:

If this project is the same as a previously approved study under a different name, please supply the title, investigator, date approved and consent form approved by Committee:

6/84 0020939

Approval Date

RENEWAL

Request for Institutional Approval of the Protocol Entitled:
"K-Edge Subtraction Angiography with Synchrotron X-rays"

Additional Information:

1. Protocols Involving Use of Radioactive Materials.

   Radioactive materials are not used in this project.

2. Number of Subjects Involved to Date.

   Human subjects have not been studied to date. Experiments have been conducted on anesthetized dogs. The first experiments on human subjects are currently scheduled for April 1986.

3. Description of Results to Date.

   The left anterior descending, the right coronary and the circumflex arteries have been visualized following transvenous injections of contrast agent in anesthetized dogs.

4. Problems or Complications.

   None

5. Description of Remainder of Project.

   As previously described.

6. Describe Any Changes Since Original Approval.

   Results of experiments on anesthetized dogs indicate that some injections of contrast agent may be made into a central vein, such as the superior or inferior vena cava, rather than into a vein in the upper extremity. For the central venous injections, the injection rate will vary from 5-20 ml per second. For the higher injection rates, a power injector will be employed.

7. Consent forms are attached.

INFORMED CONSENT FOR SYNCHROTRON ANGIOGRAPHY BY MEANS OF VENOUS INJECTION OF CONTRAST AGENT

You are invited to participate in a study of angiography. We hope to develop a means of visualizing arteries without the direct injection into the arteries of x-ray contrast agents. You were selected as a possible participant in this study because your physician(s) has recommended that you undergo angiography by the invasive technique, involving arterial catheterization and the direct injection of contrast agents into the arteries.

If you decide to participate, we will perform an angiographic procedure (coronary, cerebral, other,) by means of a venous injection of contrast agent, employing x-rays produced at the Stanford Synchrotron Radiation Laboratory. You will be given injections into a vein of a radiographic contrast agent, as employed in routine clinical practice. The injection may be given directly into a vein in the arm or may be given into a vein in the chest. In the latter instance a flexible, hollow tube, called a catheter, will be inserted into a vein in an extremity (usually the arm), and the catheter is then advanced into the chest so that its tip is in a central vein adjacent to the intake chamber (right atrium) of the heart. The contrast agent will then be administered using a power injector, at a rate up to 20 ml/kg of body weight per injection. Following the injection, scanning digital radiographs will be taken of the arterial structures being studied. The procedure will probably require 1/2 to 1 1/2 hours. The risks of this procedure include the following: severe allergic (anaphylactoid) reaction to the iodine contrast agent; mechanical tear of a vein; impaired kidney function; reaction to local leakage of dye; the radiation exposure inherent in an x-ray examination.

It would be impractical and even misleading to describe in detail all of the possible risks and complications which might result from the procedure. Any questions should be discussed with a member of the angiography team who will be performing the study. This person will review the procedure as is planned for your individual case.

0020941

Potential benefits that may be accrued to you relate to information about the status of the arteries to be studied. Such information might be accumulated without the necessity of performing invasive arterial injections. We can not or do not guarantee or promise that you will receive any benfits from this study. After analyzing the results of this examination, your physician may recommend that you undergo the alternative procedure, that of routine angiography employing arterial catheterization and direct injection of radiocontrast agents into the arteries.

Any data that may be published in scientific journals will not reveal the identify of the subjects. In the interest of public safety, patient imformation will be provided to federal and regulatory agencies as required.

There will be no fee charged for the non-invasive angiogram.

Your decision whether or not to participate will not prejudice you or your medical care. If you decide to participate, you are free to withdraw your consent and to discontinue your participation at any time without prejudice to you or effect on your medical care. If you have any questions, we expect you to ask us. If you have any additional questions later, we will be pleased to try to answer them.

In the event of physical injury that arises solely out of the negligence of the Stanford Univeristy Medical Center or its staff in this study, reimbursement for expenses incurred for necessary medical treatment and hospitalization is available. For further information,

please call 497-5244 or write the Medical Center Committee for the Protection of Human Subjects at 851 Welch Road, Room 115, Palo Alto, California, 94304. In addition, if you are not satisfied with the manner in which this study is being conducted, you may report any complaints to the same telephone number and address.

Persons who participate in a medical experiment are entitled to certain rights. These rights include but are not limited to the subject's right to: be informed of the nature and purpose of the experiment; be given an explanation of the procedures to be followed in the medical experiment, and any drug or device to be utilized; be given a description of any attendant discomforts and risks reasonably to be expected; be given an explanation of any benefits to the subject reasonably to be expected, if applicable; be given a disclosure of any appropriate alternatives, drugs, or devices that might be advantageous to the subject, their relative risks and benefits; be informed of the avenues of medical treatment, if any, available to the subject after the experiment if complications should arise; be given an opportunity to ask any questions concerning the experiment or the procedures involved; be instructed that consent to participate in the medical experiment may be withdrawn at any time and the subject may discontinue participation without prejudice; be given a copy of the signed and dated consent form; and be given the opportunity to decide to consent or not to consent to a medical experiment without the intervention of any element of force, fraud, deceit, duress, coercion or undue influence on the subject's decision.

YOUR SIGNATURE INDICATES THAT YOU HAVE READ AND UNDERSTAND THE ABOVE INFORMATION, THAT YOU HAVE DISCUSSED THIS STUDY WITH THE PRINCIPAL INVESTIGATOR(S) AND HIS OR HER STAFF, AND THAT YOU HAVE DECIDED TO PARTICIPATE BASED ON THE INFORMATION PROVIDED. A COPY OF THIS FORM IS AVAILABLE TO YOU UPON REQUEST.

_____ _____

Signature Date

_____

Signature of Investigator or Witness

11/81

STANFORD UNIVERSITY HOSPITAL
STANFORD MEDICAL CENTER

# CONSENT TO OPERATION, ADMINISTR/ OF ANESTHETICS, AND FOR DIAGNO: OR THERAPEUTIC PROCEDURES

Date _____ / _____ _____
NAME OF PATIENT

Hour _____ _____
NAME OF ATTENDING PHYSICIAN

_____
NAME OF SURGEON OR PHYSICIAN PERFORMING PROCEDURE

1. Your physician(s) has determined that the operation or procedure listed below may be beneficial in the diagnosis or tre of your condition. All surgical operations and diagnostic and therapeutic procedures involve risks of complication, or even death, from both known and unknown causes. No warranty or guarantee has been made as to result or cure.

2. OPERATION/PROCEDURE TO BE PERFORMED: _____

3. Physicians performing professional services, such as anesthesia, radiology, pathology and the like, are not employees Hospital. These physicians are either in private practice in the community or faculty members of the Stanford Uni School of Medicine.

4. Stanford University Hospital and Clinics is an educational institution, and as part of the medical education program re: interns, medical students, postgraduate fellows, and other health care students may, under the supervision of the att physician, participate in the care of teaching patients.

5. As a patient you have a right to receive as much information as you may need in order to give informed consent or tc the recommended course of treatment. Except in emergencies, your physician(s) should describe in language you can stand the proposed treatment or procedure, the medically significant risks involved, and the alternate courses of treatr nontreatment, including the respective risks of each. If you have questions, you should consult your physician(s) p giving your written consent to such operation or procedure.

Having read the above and having received the above information from my physician(s), I hereby authorize the above physician(s) and any associates or assistants of my physician(s) to perform the above-named operation or procedure and to p such additional services as may be deemed medically reasonable and necessary, including, but not limited to, the adminis and maintenance of anesthesia and services involving pathology and radiology. I further authorize the pathology service to discretion in the disposal of any severed tissue or member, except: _____

_____
SIGNATURE OF PATIENT, LEGAL GUARDIAN, CONSERVATOR OR LEGAL REPRESENTATIVE

_____
SIGNATURE OF WITNESS

*(If patient is a minor or unable to sign, complete the following.)*

Patient is a minor _____, or is unable to sign because _____

_____ _____
SIGNATURE OF FATHER SIGNATURE OF MOTHER

_____
LEGAL GUARDIAN, CONSERVATOR, OR LEGAL REPRESENTATIVE

0020945

15 01 (Rev 1/81)

(Vea en el reverso la versión española)

HOSPITAL DE LA UNIVERSIDAD DE STANFORD
CENTRO MEDICO DE STANFORD

PERMISO PARA OPERACION, PARA LA APLICACION DE ANESTESICOS Y PARA PROCEDIMIENTOS DIAGNOSTICOS O TERAPEUTICOS

Fecha _____ / _____
NOMBRE DEL PACIENTE

Hora _____ _____
NOMBRE DEL MÉDICO DE CABECERA

_____
NOMBRE DEL CIRUJANO O MÉDICO A CARGO DEL PROCEDIMIENTO

1. Su Médico (o Médicos) ha determinado que la operación o procedimiento que se consigna más adelante puede ser de beneficio para el diagnóstico o tratamiento de su estado de salud. Todas las operaciones quirúrgicas y procedimientos diagnósticos y terapeuticos inplican riesgos de complicación, lesión o aún muerte, de causas conocidas o desconocidas. Ninguna garantía o seguridad se ha determinado en cuanto al resultado o cura.

2. OPERACION/PROCEDIMIENTO A EJECUTAR: _____

_____

_____

3. Los médicos que prestan servicios profesionales tales como anestesia, radiología, patología y servicios semejantes no son empleados del hospital. Estos médicos se dedican a la práctica privada en la comunidad o son miembros de la Facultad de Medicina de la Universidad de Stanford.

4. El Hospital y la Clínica de la Universidad de Stanford constituyen una institución educacional, y como parte del programa de educación médica, los residentes, los internos, los estudiantes de medicina, los becarios graduados y otros estudiantes del cuidado de la salud pueden, bajo la supervisión del Médico en asistencia, participar en el cuidado de los pacientes que están bajo el plan de estudios.

5. Como paciente, usted tiene derecho a recibir tanta información como usted pueda necesitar a fín de dar el correspondiente permiso, o a rechazar o negar el curso del tratamiento recomendado. Excepto en casos de emergencia su Médico (o Médicos) deben describir, en lenguage que usted pueda entender, el tratamiento o procedimiento propuesto, los significantes riesgos médicos comprendidos y los métodos alternativos de tratamiento o no tratamiento, incluyando los respectivos riesgos de cada uno. Si usted desea saber algo o tiene preguntas que hacer, usted debe consultar a su Médico (o Médicos) antes de otorgar su permiso por escrito para tal operación o procedimiento a seguir.

Habiendo leído lo explicado anteriormente y habiendo recibido la información anterior de mi Médico (o Médicos), por la presente autorizo al Médico (o Médicos) mencionado anteriormente y a cualquiera de sus colaboradores o ayudantes de mi Médico (o Médicos) para llevar a cabo la operación que se detalla anteriormente o procedimiento a seguir y a proveer tales servicios adicionales como fueren razonables y necesarios desde el punto de vista médico, incluyendo, pero no limitados, la aplicación y mantenimiento de anestesia y servicios de patologia y de radiologia. También autorizo al servicio patológico para usar su criterio en la disposición de cualquier tejido o miembro removido, excepto: _____.

_____
FIRMA DEL PACIENTE, TUTOR, ENCARGADO, O REPRESENTATANTE LEGAL

_____
FIRMA DEL TESTIGO

*(Si el Paciente es menor de edad o no puede firmar, complete lo siguiente.)*

El Paciente es menor de edad _____, o no puede firmar porque _____.

_____ _____
FIRMA DEL PADRE FIRMA DE LA MADRE

_____
FIRMA DEL TUTOR, GUARDIAN O REPRESENTANTE LEGAL

002094b

February 7, 1986
JOHN OTIS
ALBERT THOMPSON

# FRAMEWORK OF ANGIOGRAPHY SAFETY PLAN

## Introduction

The use of beamline IV-2 at SSRL for diagnostic medical imaging of coronary arteries is being planned. An initial run is scheduled for April/May of this year. The radiation safety and monitoring of these human patient studies is an important part of our planning. Since this program is quite different from the normal procedures followed at SLAC and SSRL for radiation protection, a detailed safety plan has been prepared.

At the SLAC radiation committee meeting on Feb 13 we will present our safety plan for your study. A general outline of our experiment and the results from previous dog runs will be presented first, then the specific instrumentation relevant to radiation safety will be described, and finally the safety interlock logic and imaging protocol will be covered.

## General Plan

The general principle for using a synchrotron radiation beamline for medical imaging is to use a fan beam of monochromatic x-rays. To take a picture the patient will sit in a chair which will be moved vertically through the beam to acquire two digital x-ray images. One image is taken at an x-ray energy just below the iodine absorption edge at 33 keV and the other is taken with the energy just above this edge. The logarithmic difference of the two images is then taken to produce a difference image. Since the iodine absorption jumps by a factor of 7 at the edge while the absorption of tissue and bone changes only slightly this difference image is very sensitive to iodine. To image coronary arteries a venous injection of an iodine containing contrast agent will be given and after about 10 seconds the iodine bolus will have passed through the heart and lungs and will begin to fill the coronary arteries. Just before this time we will have begun to scan the patient to acquire images of the arterial system.

## Safety Plan Outline

The overall scanning procedure will be controlled as in any radiological laboratory by a responsible physician who will determine the total x-ray exposure permissible. The exposure will be within the limits approved for this study by the Human Subjects Ethics Committee at the Stanford University Hospital.

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A series of radiation shutters are installed on the beamline which are controlled by a safety protection system. The detailed logic of the system will be presented at the meeting but the general features will be described here. During a scan the radiation is turned on and off during the acquiring of different images frames by a computer controlled imaging shutter. In case of a unsafe condition the radiation is rapidly turned off by a pair of fast closing shutters. These shutters close if any unsafe condition is sensed by the protection system. Some of the unsafe conditions are:

a) X-ray beam on with the patient chair not in motion.

b) Scanning procedure going on too long.

c) Physician releasing the deadman switch.

As well as controlling the radiation safety, a calibrated radiation monitoring system will be implemented to record the total radiation dose received by the patient.

The radiation safety interlock system will be installed by SSRL under the direction of Bob Hettel and the radiation safety will be verified by Gary Warren of SLAC.

## SAFETY SYSTEM HARDWARE AND PROTOCOL

The X-ray images will be acquired in line-scan fashion, with the patient moving vertically at constant speed and the X-ray beam sweeping over the field of interest. The experimental protocol, as presently envisaged, calls for the acquisition of several images in rapid time sequence (a "scan sequence") by repeating the scan motion alternately in opposite directions. To prevent X-ray exposure to the patient during the periods of deceleration and acceleration between the constant-velocity scans (as well as before and after the imaging sequence) the X-ray beam will be blocked by a fast-acting imaging shutter (IS).

The monochromator provides two monochromatized X-ray beams, initially separated by approximately 1 mm vertically but converging toward the patient position. The two beams are produced by single Bragg diffraction from separate Si(111) crystals, each of which intercepts half the vertical profile of the incident beam. The upper beam has an energy within 100 eV above the iodine K-edge (33.17 keV), and the lower beam has an energy within 100 eV below this edge. The monochromatized X-ray beams exit from the monochromator at a rising angle of 6.84 degrees to the primary beam, and pass above a beam stop located within the monochromator enclosure. The beam stop protects the patient from any penetrating gamma radiation coming from SPEAR along the primary beam direction. The rotating drum mechanism, located immediately downstream of the monochromator, transmits only one of the monochromatic beams at any instant, switching between them in synchronization with the scan data acquisition.

The monochromator is set to provide the correct beam energies during the initial setup and alignment of the imaging apparatus. Thereafter, inadvertent change in the angle of the monochromator crystals cannot admit to the patient area a beam differing from the intended energy by more than a few keV, since the resulting change in the beam angle will cause it to miss the apertures provided for its passage. That the energy setting is correct for the imaging procedure will be verified by beam tests immediately prior to a patient scan.

To allow thermal equilibration, the monochromator must be illuminated continuously by the primary X-ray beam. The SSRL hutch stoppers (HS1 and HS2) controlling the primary beam cannot be opened unless both safety shutters (SS1 and SS2) are closed, preventing the monochromatized beam from entering the patient examination area. Subsequently, the angiography PPS interlock (see Appendix) prevents the safety shutters from being opened unless the radiation screen is closed and the deadman switch is actuated. Each safety shutter consists of a rotating blade held open against spring tension by two rotary solenoids. When the solenoids are deenergized, the blade rotates rapidly (within 20 ms) by 45 degrees to the closed position. The safety shutters will close if external power is lost. To achieve the desired response time (10-20 ms) during normal scan operation, the imaging shutter is driven by a servo-controlled dc motor; therefore, external power is required for its operation.

Both the imaging shutter and the safety shutters are located downstream of the monochromator enclosure, and are incorporated into the housing of the energy-switching (rotating drum) mechanism associated with the monochromator. In the closed position, the imaging shutter has a thickness of approximately 5/8 inch steel (72 absorption lengths for 33 keV photons), and each safety shutter has a thickness of 0.176 inch steel (21 absorption lengths).

During the scan sequence, the patient will be alone in the shielded examination room that confines direct and scattered radiation. The attending physician will have the responsibility for seeing that the patient is properly positioned and that the examination room is clear of other personnel. However, the attending personnel must be able to enter this room immediately in response to a possible medical emergency, even if a scan is in progress. Therefore, the door on the examination room nearest to the patient must be left open. In its place will be erected an easily opened radiation screen, with a large leaded acrylic transparent window so that the physician and patient will be able to maintain eye contact throughout the procedure. The safety shutters are triggered by the angiography PPS interlock if the screen is opened while a scan is in progress, extinguishing the X-ray beam before personnel can reach the radiation area.

The physician will determine the projection and image field by initial positioning of the patient and scanning chair, and by providing the upper and lower scan limits to the scan control program. Once this setup is complete and all personnel have left the examination room, the radiation screens are closed and the physician stands outside, visible to the patient.

By closing and holding the deadman switch, the physician initiates the programmed scan sequence and allows it to proceed. The safety shutters can then be opened while the imaging shutter is closed. The imaging shutter remains closed until it is opened under computer control as part of the scan sequence. If the patient requires medical attention during a scan, or if the physician observes some malfunction in the scan operation, release of the deadman switch will extinguish the beam and abort the scan.

To prevent unauthorized operation of the system, the deadman switch is inoperative unless it is first enabled by the operation of a momentary-contact key-lock switch located next to it, the key being kept by the physician. Operation of the key-lock switch starts a timed interval of about 20 s during which the deadman switch must be closed. If the deadman switch is not closed within this timed interval, it must again be enabled by use of the key-lock switch.

Release of the deadman switch or opening of the radiation screen while either of the safety shutters is not closed will generate a fault condition (ANGI FAULT) in the angiography PPS interlock, which forces closure of the two safety shutters, the imaging shutter, and the SSRL hutch stoppers. ANGI FAULT is latched, and can be reset only by use of a key carried by the SSRL operator.

The rate of X-ray exposure from the monochromatized 33 keV beam collimated to a height of 0.5 mm is approximately 47 R/s. This assumes SPEAR operating conditions of 3 Gev, 100 mA and an 18 kG wiggler field. Thus, the safety of the patient requires that the imaging shutter be closed unless the scanning chair is in motion at the correct speed. Two independent chair-motion detectors are incorporated into the angiography PPS interlock. The motion detectors will be driven by the chair motion, independent of the motor-drive coupling. If either motion detector fails to give an indication of correct scanning speed when the imaging shutter is not closed, ANGI FAULT will be generated unless both safety shutters are closed. Thus the beam will be extinguished if control malfunction or power failure either cause the scanning chair to stop in the middle of a scan or cause the imaging shutter to remain open while the chair is decellerating at the end of a scan.

Since an upper limit to beam intensity is known, given SPEAR operating conditions, total exposure to the patient can be kept within safe limits by imposing a time limit on the total length of a scan sequence. For each scan sequence, the timed interval begins when the imaging shutter is first opened. If either safety shutter is not closed when the time limit is reached, ANGI FAULT is generated.

Interlocks prevent opening of any beam shutters if that action would create an immediate ANGI FAULT. With two exceptions, ANGI FAULT cannot occur if HS1 and HS2 are both closed, or if SS1 and SS2 are both closed. The exceptions are actuation of the emergency stop switch and withdrawal of the computer OK. The computer OK will be provided by a watchdog timer that verifies the correct operation of the scan-system's control computer.

Table I summarizes the possible range of potential patient exposures as a function of the selectable scanning speed of the patient chair or, equivalently, the acquisition time for each horizontal line element in the image (summed over both X-ray energies). The actual exposures allowed for a particular patient study will depend on the patient thickness and the level of iodine sensitivity required in the image. The exposure level should be in the range 0.4 - 0.8 R per image frame.

TABLE I

MAXIMUM PATIENT EXPOSURES ACHIEVABLE WITH THE ANGIOGRAPHY SYSTEM AT SSRL BEAM LINE IV-2, ASSUMING SPEAR OPERATING CONDITIONS OF 100 MA AT 3 GEV, AND A WIGGLER FIELD OF 18 KG. IT IS ASSUMED THAT THE MONOCHROMATIZED BEAM IS COLLIMATED TO A HEIGHT OF 0.5 MM AT THE PATIENT POSITION, 28 M FROM THE WIGGLER.

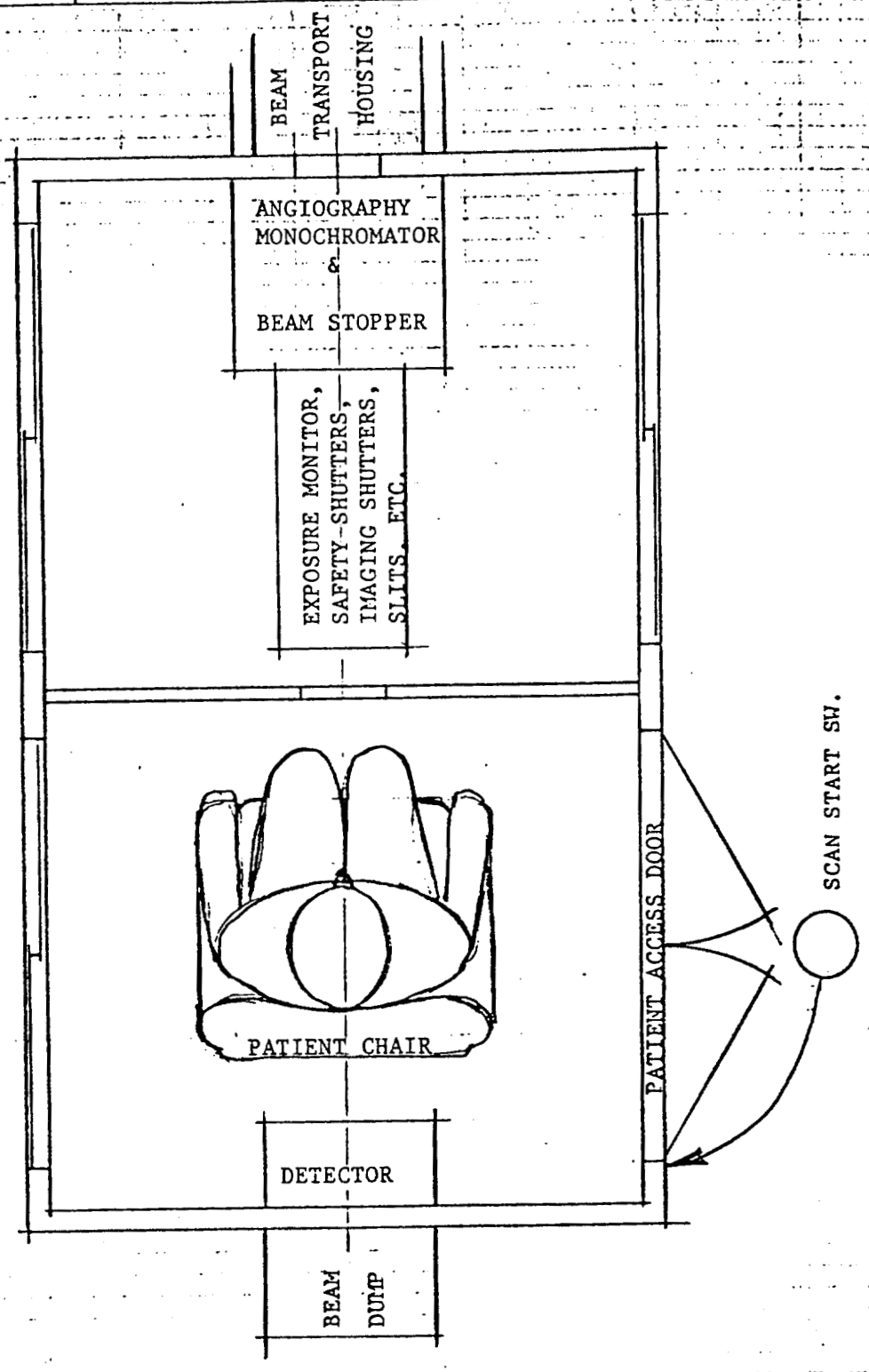
| SCAN SPEED (cm/sec) | TOTAL ACQUISITION TIME PER LINE (msec) | MAXIMUM EXPOSURE PER IMAGE FRAME (mR) |
|---|---|---|
| 24 | 2.1 | 98 |
| 12 | 4.2 | 195 |
| 6 | 8.3 | 391 |
| 3 | 16.7 | 782 |

STANFORD SYNCHROTRON RADIATION LABORATORY

# ENGINEERING NOTE

| CODE | SERIAL | PAGE |
|---|---|---|
| | | OF |

| AUTHOR | DEPARTMENT | LOCATION | DATE |
|---|---|---|---|
| J. CERINO | | | FEBRUARY 5, 1986 |




ANGIOGRAPHY HUTCH SCHEMATIC PLAN

7600-54250

RL-3320 (Rev. 5/75)

0020952

ANGIOGRAPHY PPS INTERLOCK (ANGI) - BL 4-2

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    12.4 HUTCH STOPPER OPEN ENABLE FROM ANGI
13.0 SCAN SWITCH INTERLOCK
    13.1 LOGIC
    13.2 SCAN SWITCH FOLLOWER RELAYS.

STANFORD SYNCHROTRON RADIATION LABORATORY

# ENGINEERING NOTE



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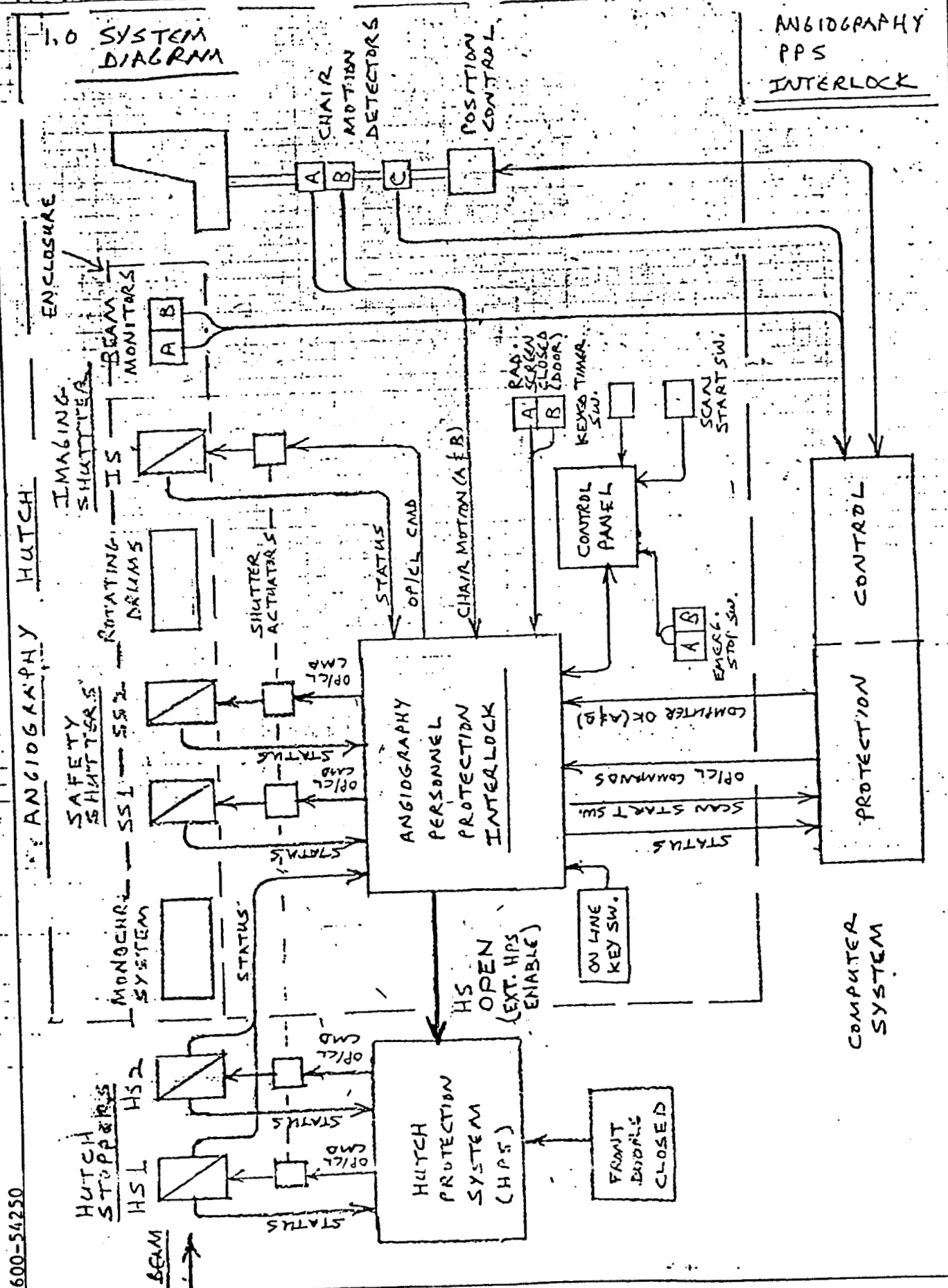
DEPARTMENT: ANGIOGRAPHY HUTCH (BL 4-2) PPS INTERLOCK

LOCATION:

DATE: 1-26-86

## 1.0 SYSTEM DIAGRAM

ANGIOGRAPHY PPS INTERLOCK



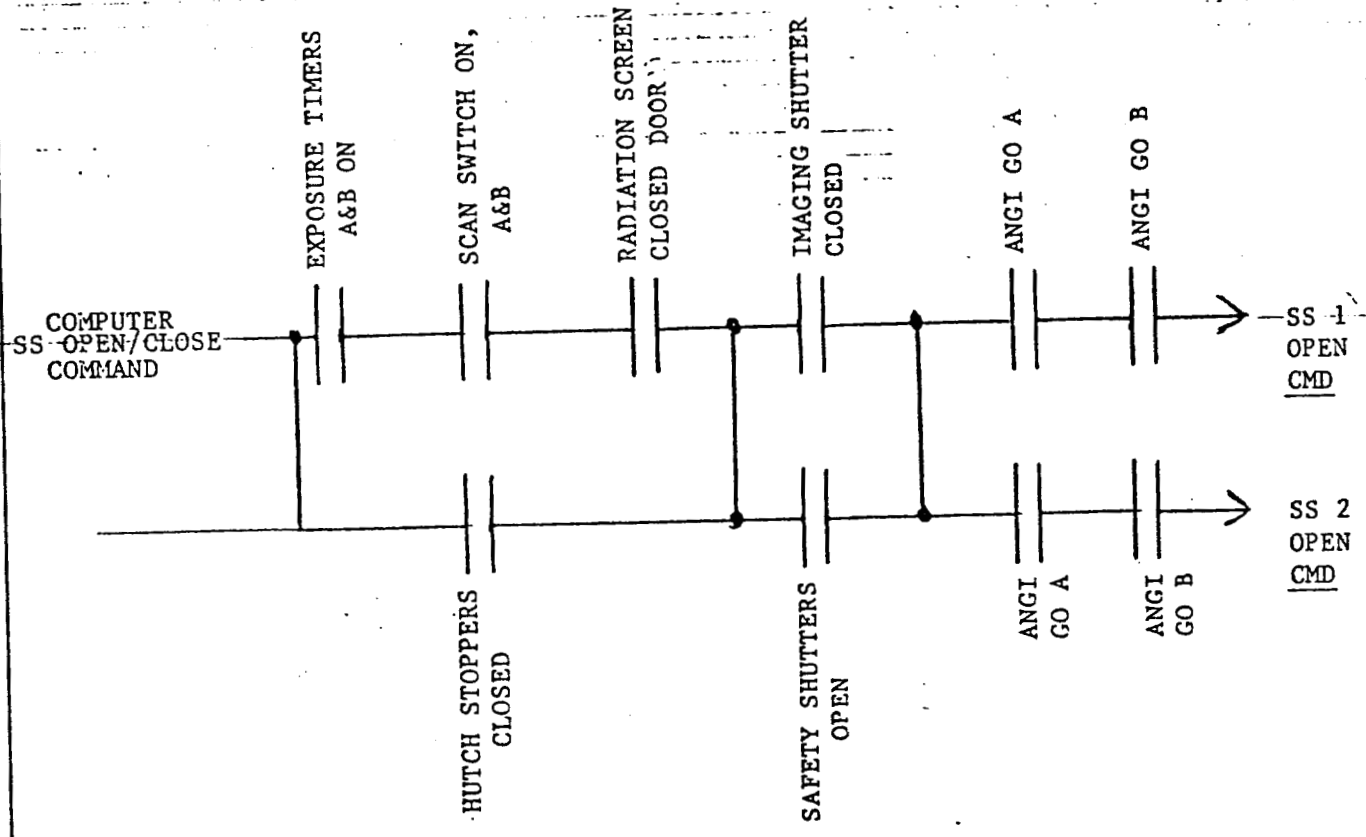

7600-54250

RL-3220 (Rev. 5/75)

0020954

ANGIOGRAPHY PPS INTERLOCK (ANGI) BL IV-2

## 2.0 SAFETY SHUTTER OPEN/CLOSE COMMAND (SS OP/CL CMD)

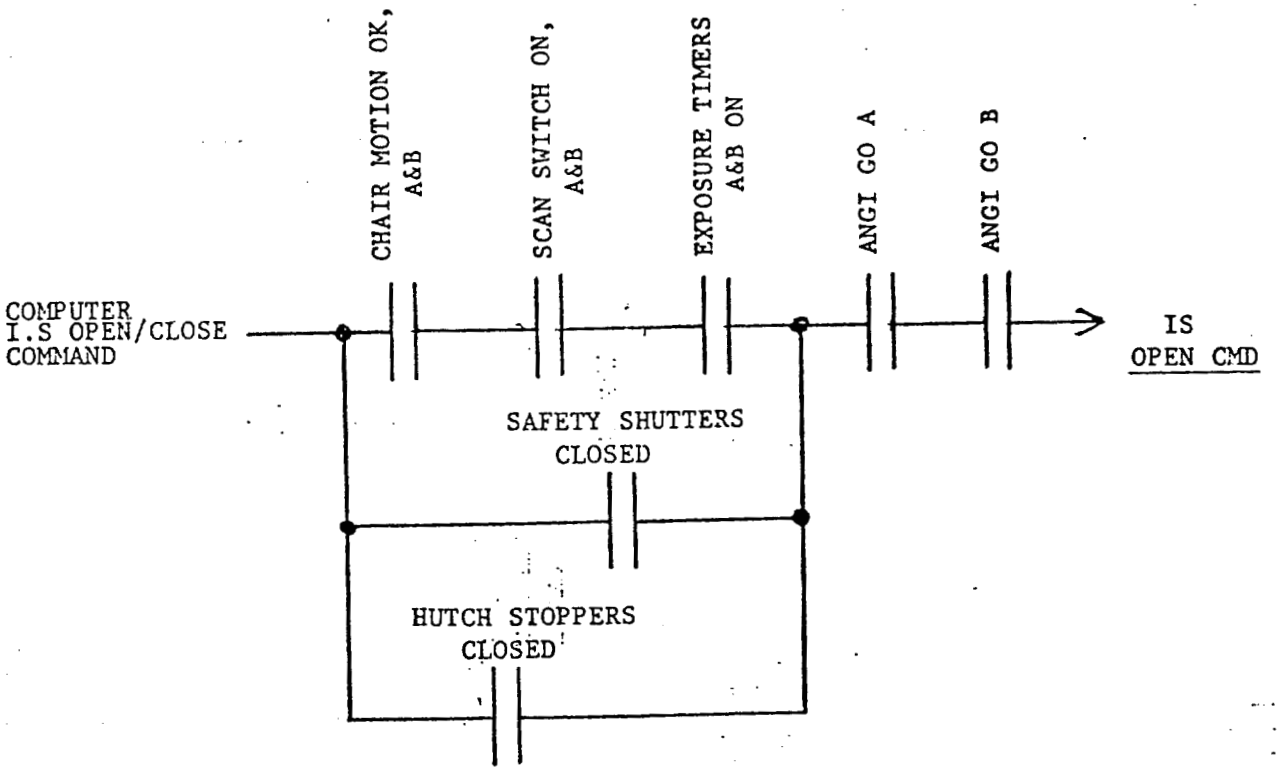



CLOSED CMD = $\overline{\text{OPEN CMD}}$

NOTES:
1. IMAGING SHUTTER MUST BE CLOSED TO OPEN SAFETY SHUTTERS. ONCE SAFETY SHUTTERS ARE OPEN, IMAGING SHUTTER MAY BE OPENED.
2. IF HUTCH STOPPERS ARE CLOSED, SAFETY SHUTTERS MAY BE OPENED WITHOUT STARTING THE KEYED TIMER OR CLOSING THE RADIATION SCREEN DOOR.

ANGIOGRAPHY PPS

3.0 IMAGING SHUTTER (I.S.) OPEN/CLOSED COMMAND

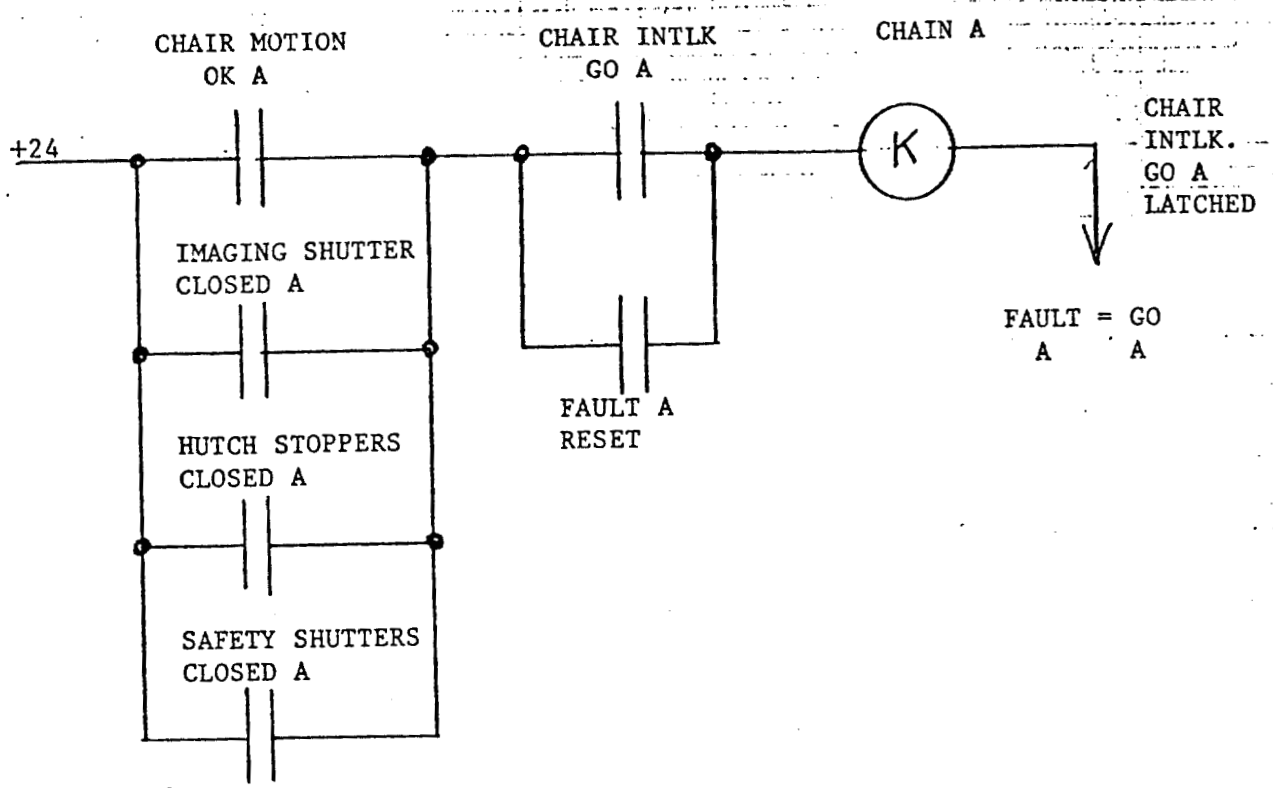



NOTES: 1. IMAGING SHUTTER MAY BE OPENED WITHOUT CHAIR MOTION OK OR THE KEYED TIMER ON IF EITHER THE SAFETY SHUTTERS OR THE HUTCH STOPPERS ARE CLOSED.

ANGIOGRAPHY PPS

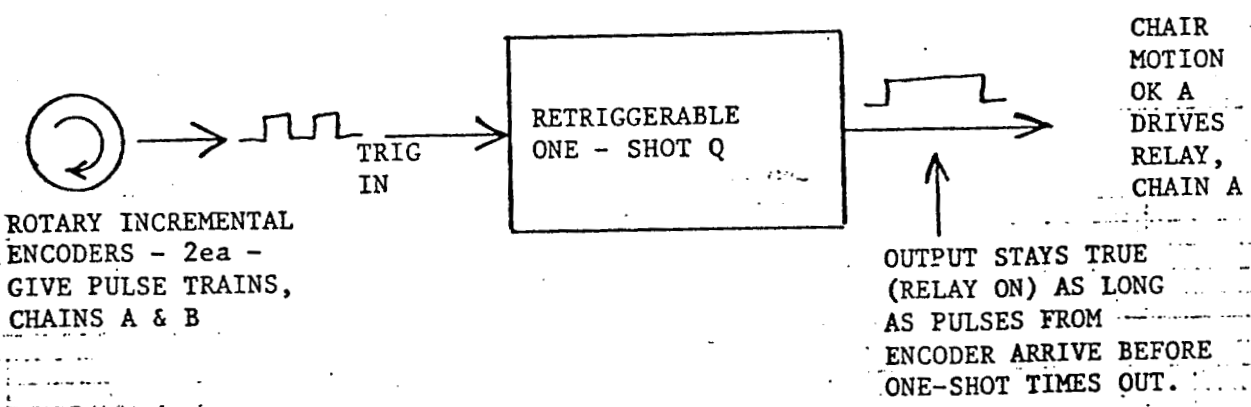
4.0 CHAIR MOTION INTERLOCK - REDUNDANT

4.1 FAULT LOGIC




CHAIN B IS LIKEWISE CONFIGURED.

4.2 CHAIR MOTION OK - REDUNDANT




CHAIN B IS SIMILAR

NOTE: EACH ENCODER CIRCUIT (CHAIN A & CHAIN B) HAS ITS OWN INDEPENDENT POWER SUPPLY.