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.

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 monocchromatized 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.

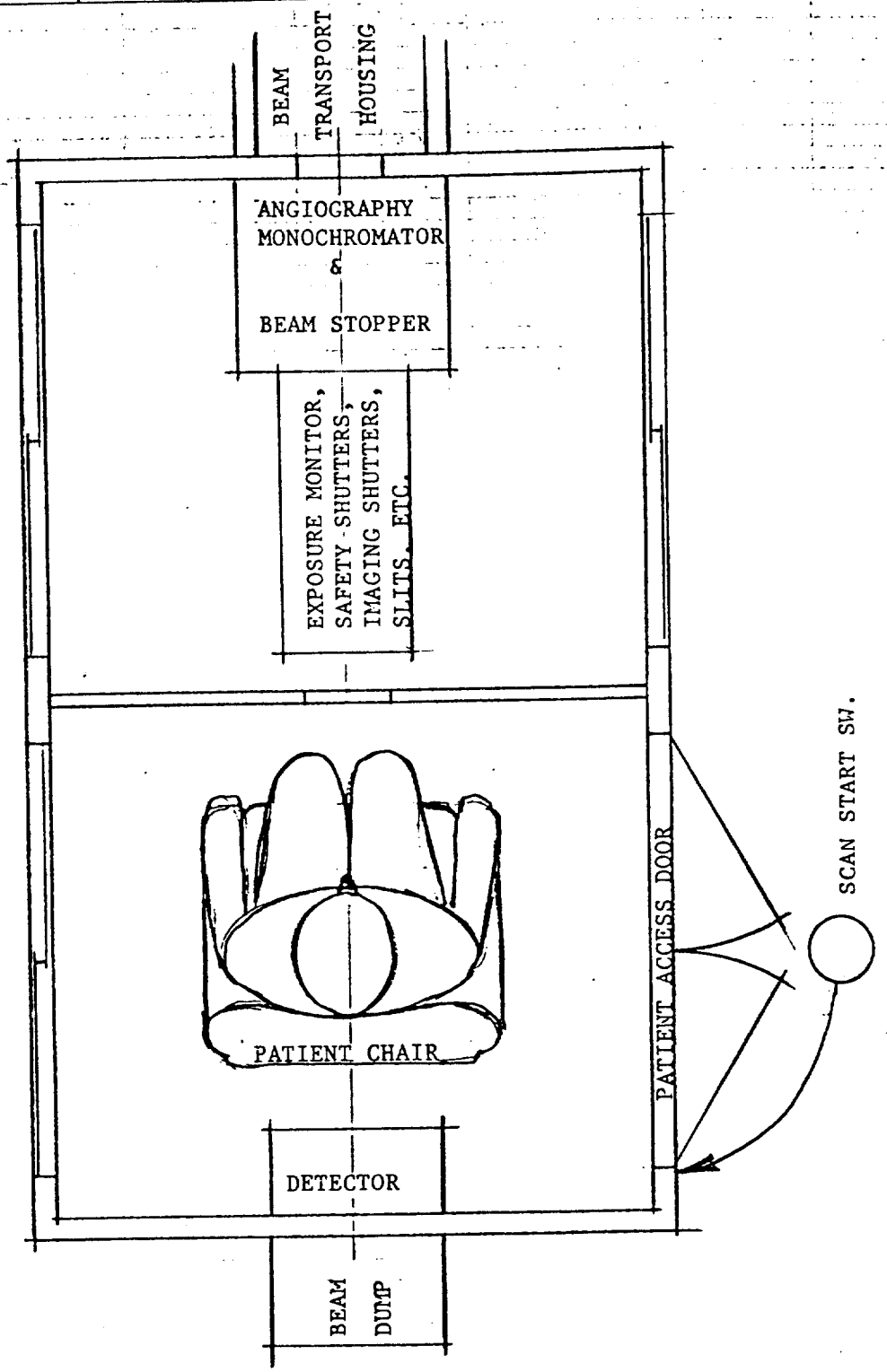
SCAN SPEED (cm/sec)	TOTAL ACQUISITION TIME PER LINE (msec)	MAXIMUM EXPOSURE PER IMAGE FRAME (mR)
24	2.1	98
12	4.2	195
6	8.3	391
3	16.7	782

STANFORD SYNCHROTRON RADIATION LABORATORY

ENGINEERING NOTE

CODE	SERIAL	PAGE
		OF

AUTHOR	DEPARTMENT	LOCATION	DATE
J. CERINO			FEBRUARY 5, 1986



ANGIOGRAPHY HUTCH SCHEMATIC PLAN

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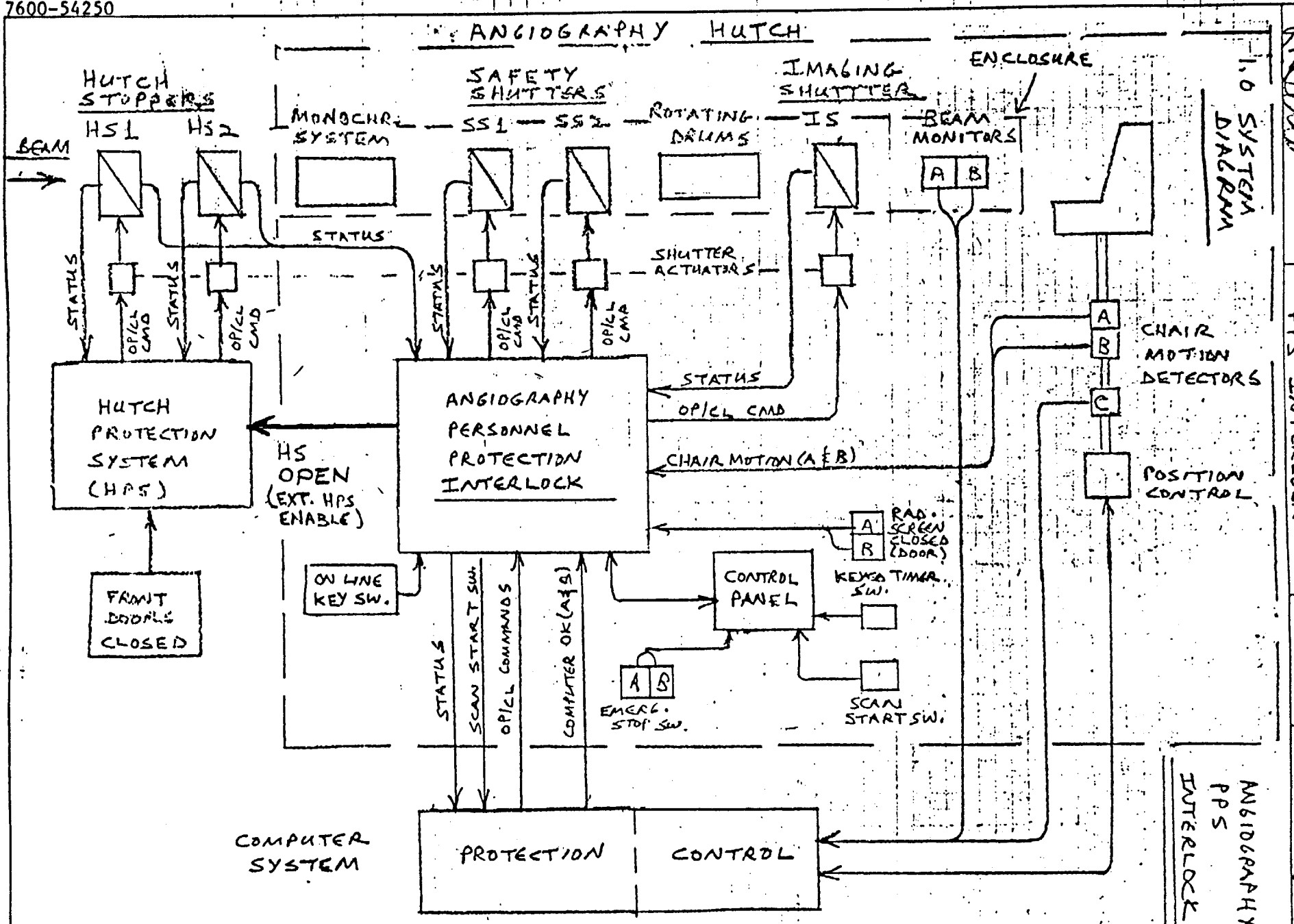
ANGIOGRAPHY PPS INTERLOCK (ANGI) - BL 4-2

TABLE OF CONTENTS

7600-54250



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ENGINEERING NOTE
AUTHOR R. Hubbard
DEPARTMENT ANGIOGRAPHY HUTCH (BL 4-2) PPS INTERLOCK
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PAGE 1 OF 13

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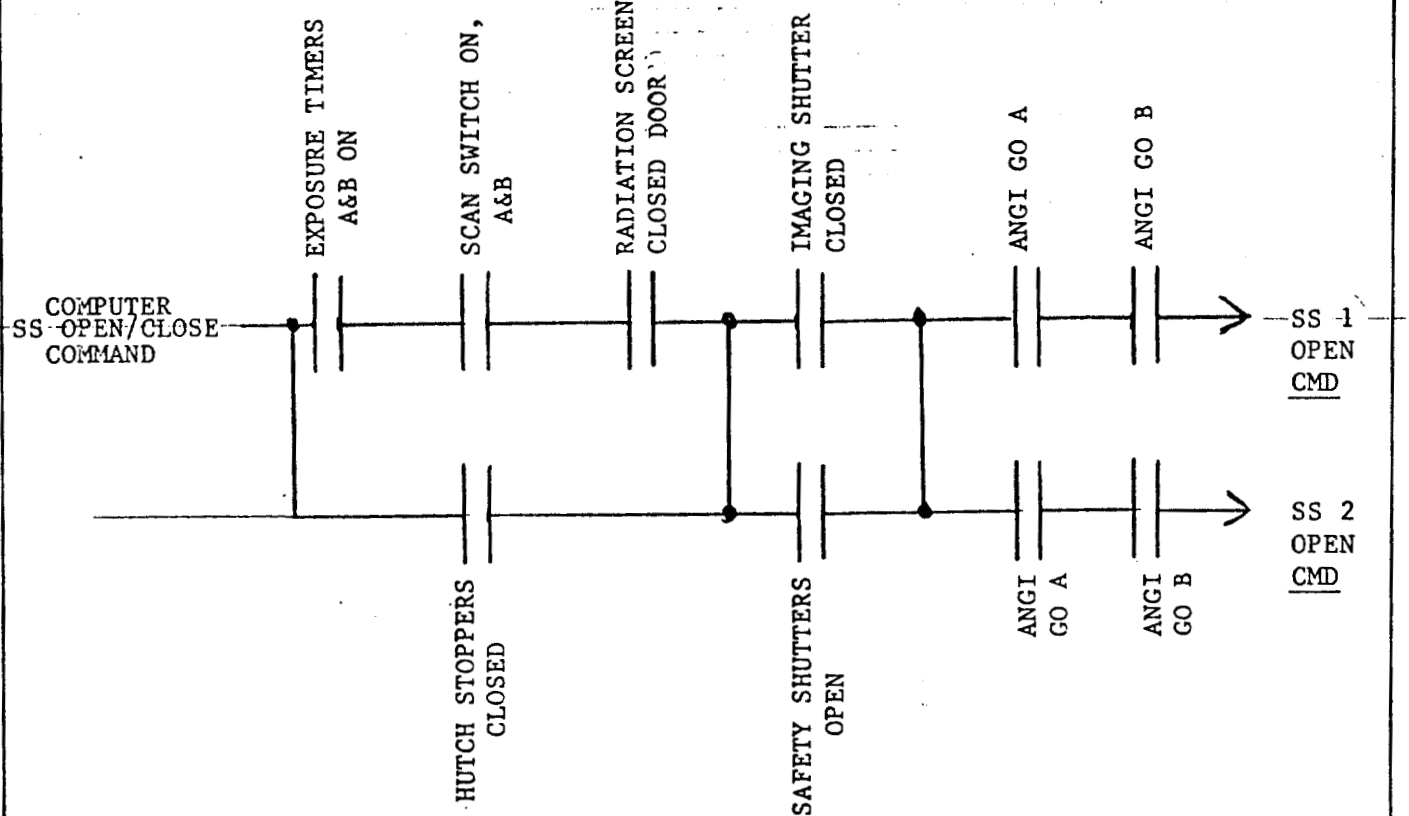
ANGIOGRAPHY PPS INTERLOCK (ANGI) BL IV-2

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

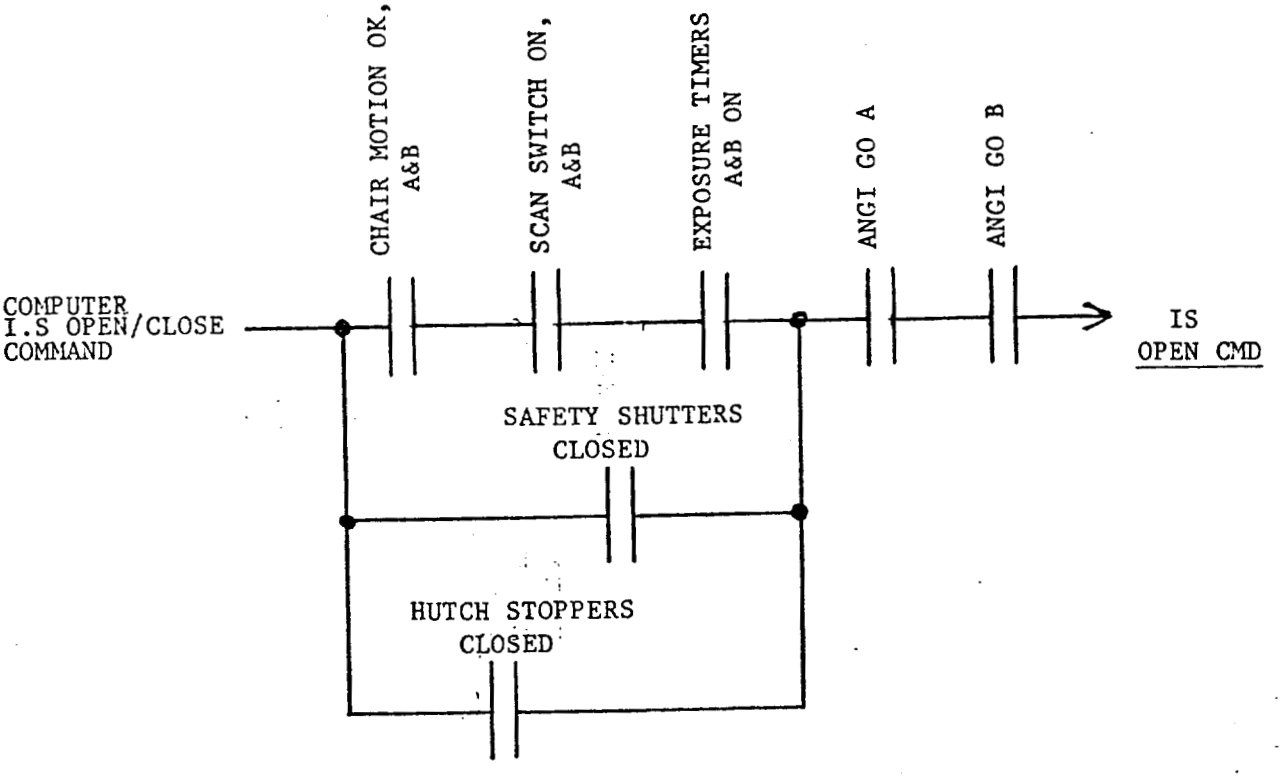


CLOSED CMD = $\overline{\text{OPEN CMD}}$

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

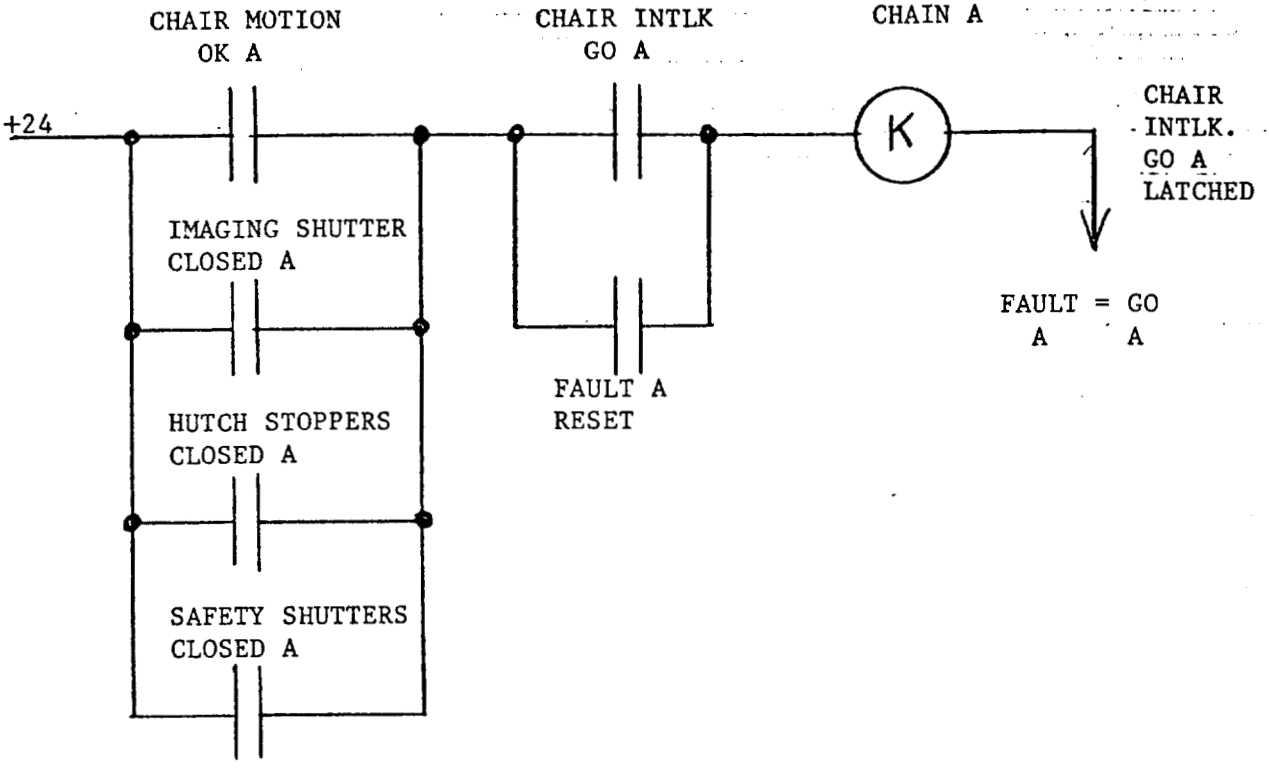


NOTES: 1. IMAGING SHUTTER MAY BE OPENED WITHOUT CHAIR MOTION OK OR THE KEYED TIMER ON IF EITHER THE SAFETY SHUTTERS OR THE HUTCH STOPPERS ARE CLOSED.

ANGIOGRAPHY PPS

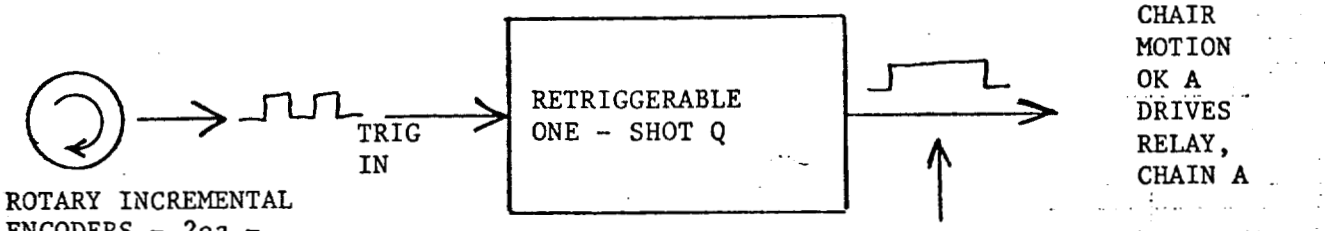
4.0 CHAIR MOTION INTERLOCK - REDUNDANT

4.1 FAULT LOGIC



CHAIN B IS LIKEWISE CONFIGURED.

4.2 CHAIR MOTION OK - REDUNDANT

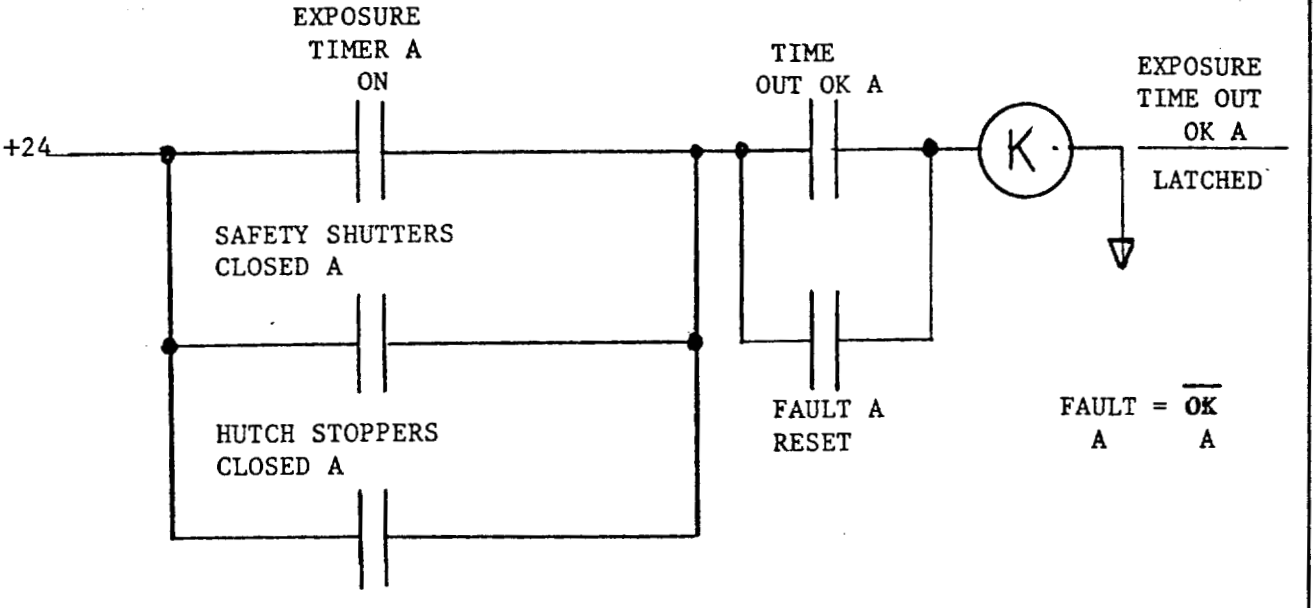


CHAIN B IS SIMILAR

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

ANGIOGRAPHY PPS

5.0 EXPOSURE TIME OUT INTERLOCK – REDUNDANT

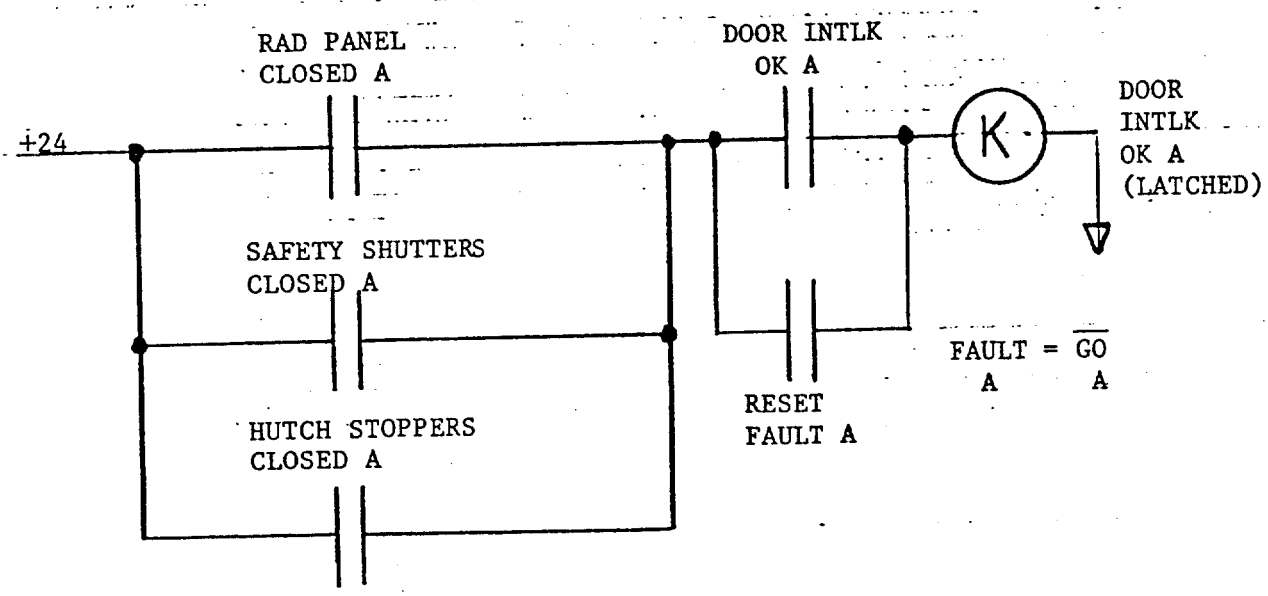


CHAIN B IS LIKEWISE CONFIGURED

NOTE: 1. TIME OUT INTERLOCK FAULTS IF A TIMER (CHAIN A & B) TIMES OUT WITH A SAFETY SHUTTER NOT CLOSED, UNLESS HUTCH STOPPERS ARE CLOSED.

ANGIOGRAPHY PPS

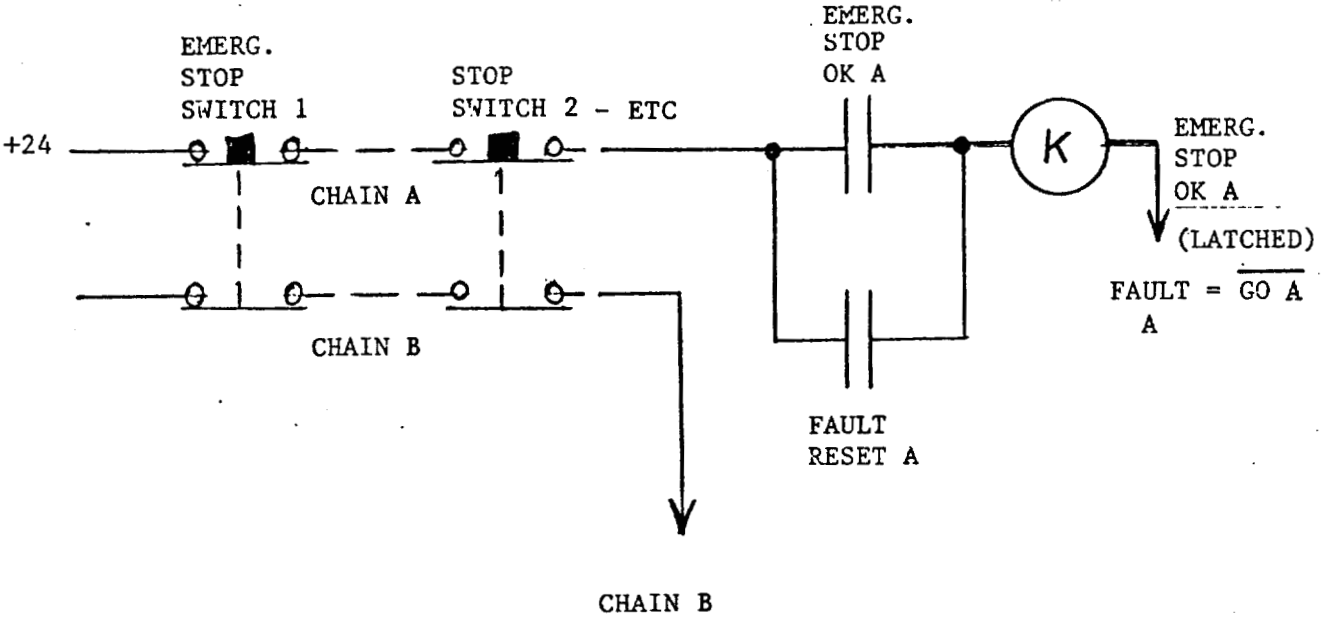
6.0 RADIATION PANEL DOOR INTERLOCK - REDUNDANT



CHAIN B IS LIKEWISE CONFUGURED

ANGIOGRAPHY PPS

7.0 EMERGENCY STOP INTERLOCK - REDUNDANT

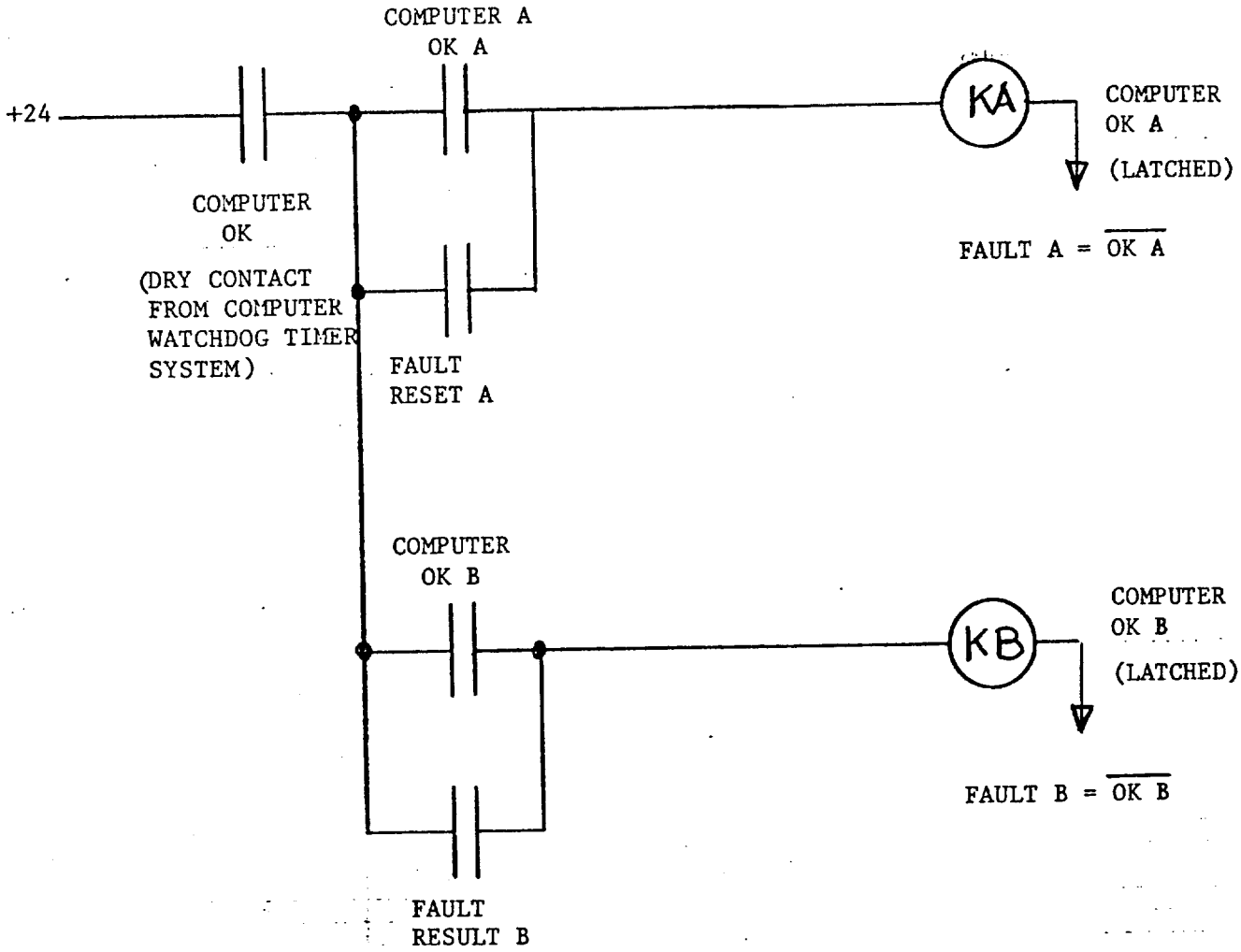


CHAIN B IS IS LIKEWISE CONFIGURED

NOTE: THIS LATCHED FAULT MAY ALSO BE USED TO STOP CHAIR MOTION.

ANGIOGRAPHY PPS

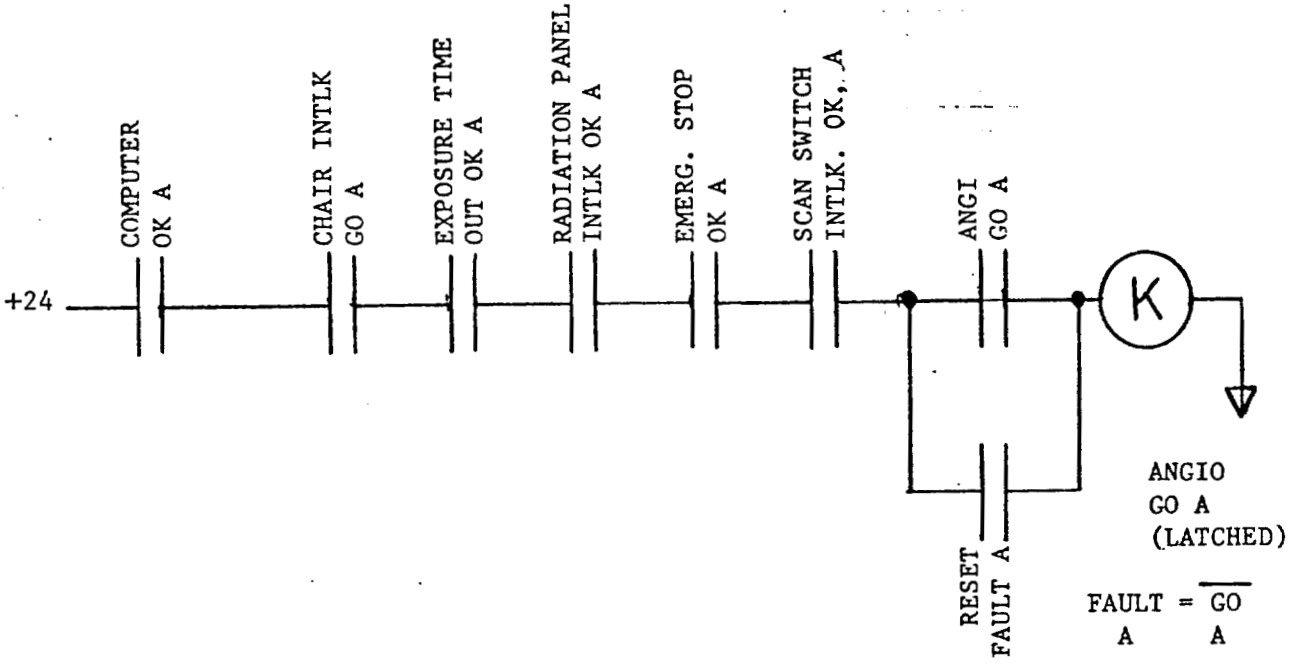
8.0 COMPUTER OK INTERLOCK - WATCHDOG TIMER, ETC



ANGIOGRAPHY PPS

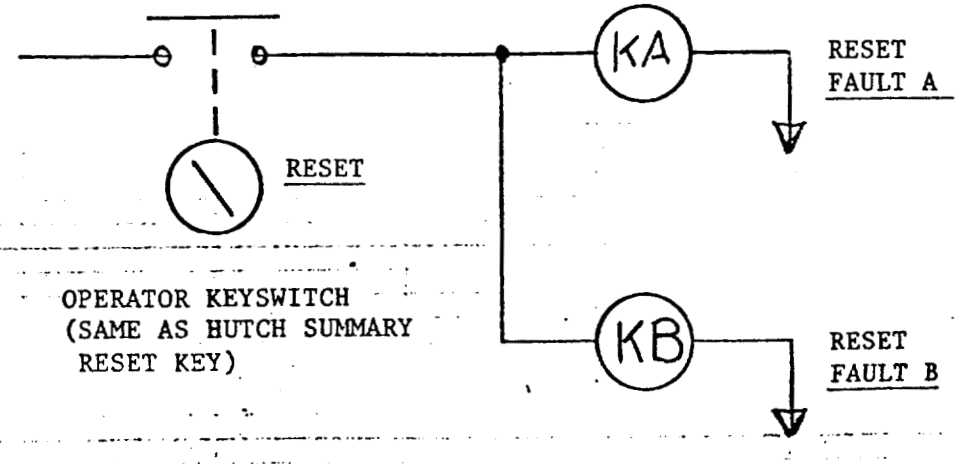
9.0 ANGI GO $\overline{\text{(FAULT)}}$ - REDUNDANT

9.1 GO/FAULT LOGIC



CHAIN B IS LIKEWISE CONFUGURED

9.2 KEYED FAULT RESET

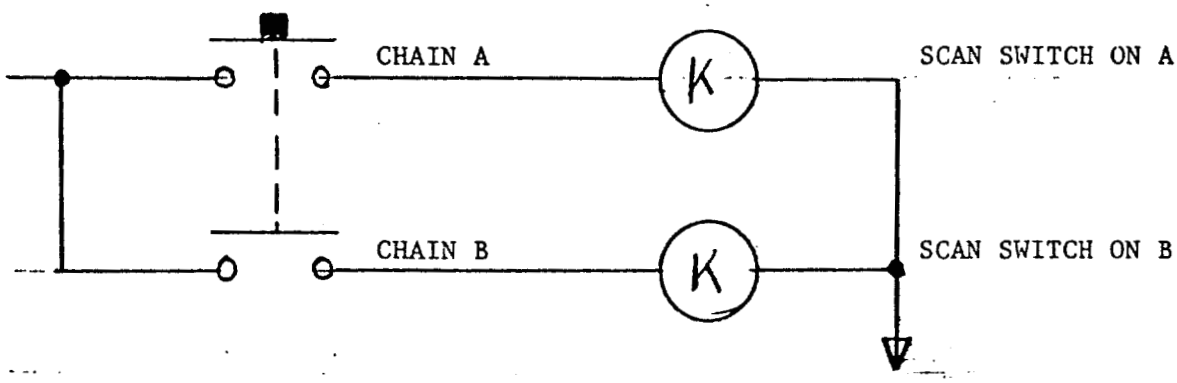


ANGIOGRAPHY PPS

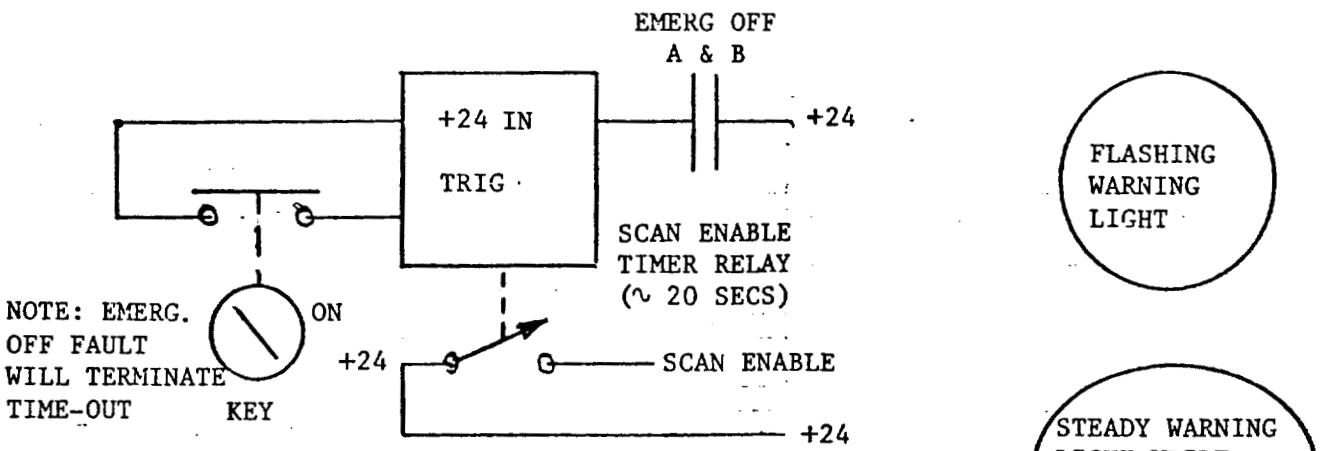
10.0 KEYED TIME CIRCUIT - & SCAN SWITCH

A KEYSWITCH IS ENERGIZED BY A CERTIFIED USER WITH KEY TO INITIATE A START SCAN TIME-OUT PERIOD (~ 20 SECS). A SCAN SWITCH MUST BE PUSHED WITHIN THIS INTERVAL TO BEGIN A SCAN (SAFETY SHUTTERS WILL BE OPENED, ETC.) THE SCAN SWITCH ON ENABLES REDUNDANT EXPOSURE TIMERS TO BE TRIGGERED WHEN THE IMAGING SHUTTER FIRST OPENS. THE SCAN SWITCH MUST BE HELD ON FOR THE SAFETY & IMAGING SHUTTERS TO BE OPENABLE. SEE Pg.13 FOR SCAN SWITCH INTERLOCK. RELEASING SCAN SWITCH WILL NOT CAUSE A FAULT IF SAFETY SHUTTERS OR HUTCH STOPPERS ARE CLOSED.

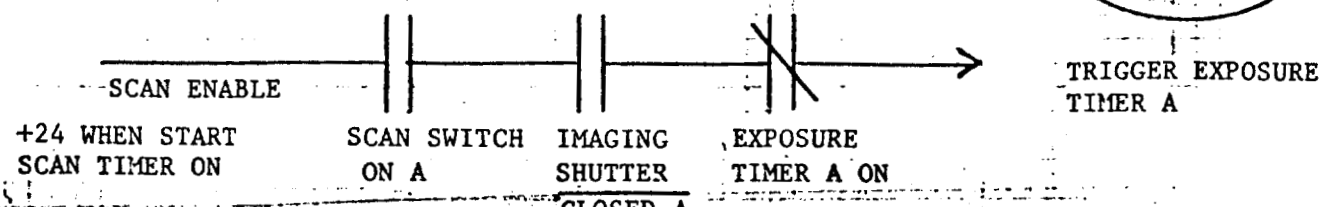
10.1 SCAN SWITCH RELAY FOLLOWERS - REDUNDANT



10.2 START SCAN ENABLE KEYSWITCH & TIMER



10.3 EXPOSURE TIMER - REDUNDANT

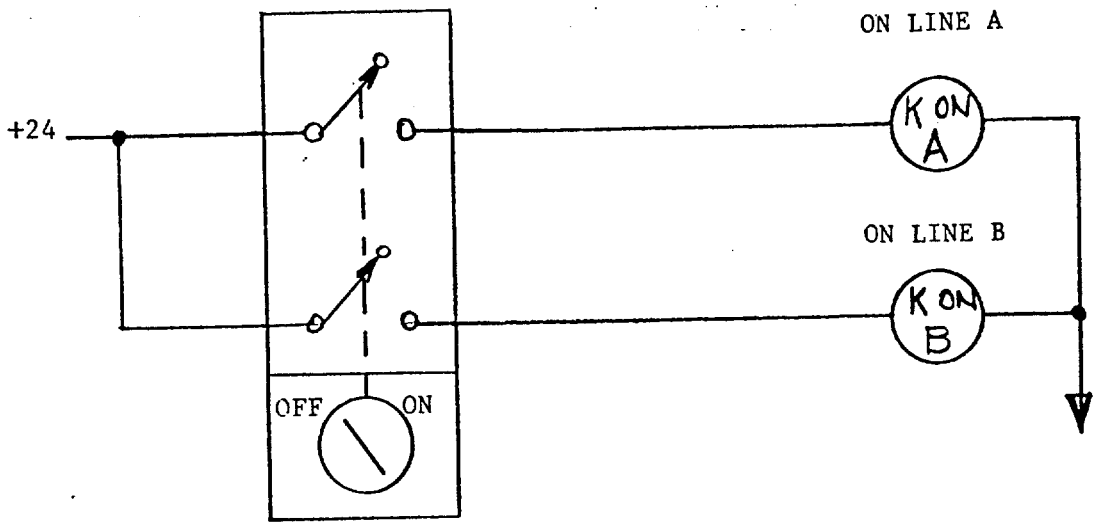


CHAIN B IS LIKEWISE CONFIGURED

ANGIOGRAPHY PPS

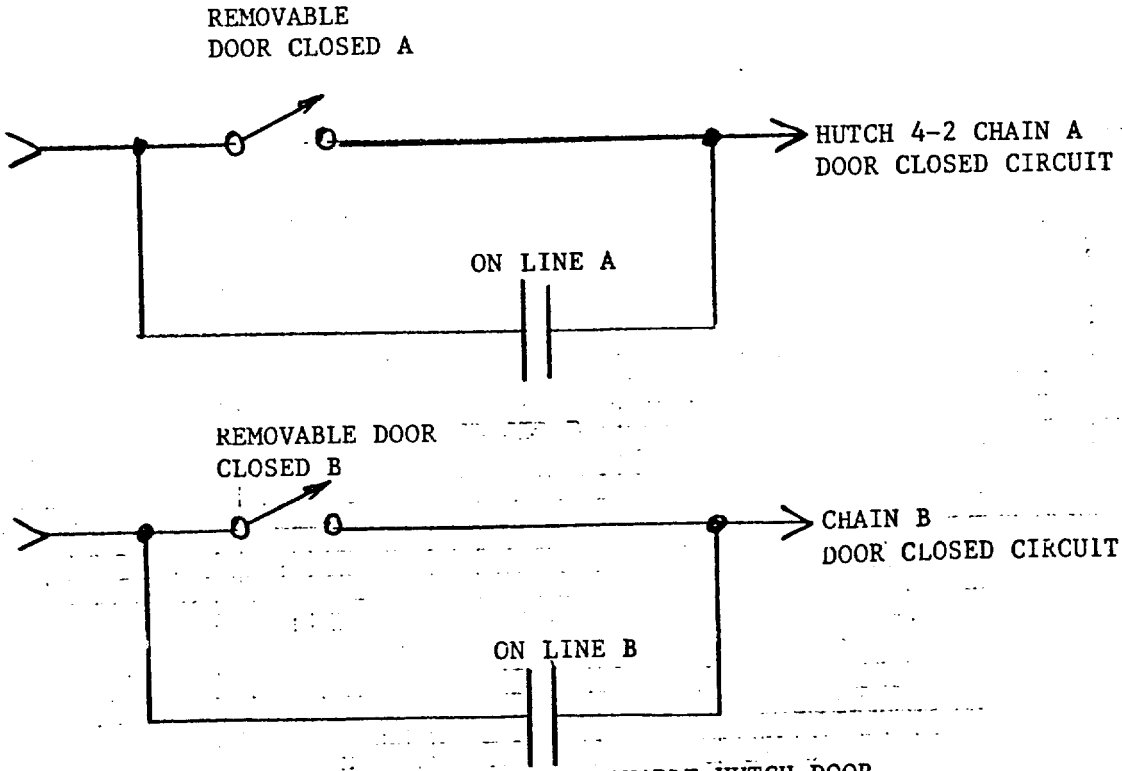
11.0 ANGI ON/OFF LINE CIRCUIT - REDUNDANT

11.1 ON LINE FOLLOWER RELAYS



ON/OFF LINE
KIRK LOCK SWITCH

11.2 HUTCH DOOR BYPASS



NOTES: 1. ANGI ON LINE SWITCH BYPASSES THE REMOVABLE HUTCH DOOR (REDUNDANT CHAINS A & B)

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RL-3220 (Rev. 5/75)

12

ANGIOGRAPHY PPS

12.0 INTERACTION WITH HUTCH PROTECTION SYSTEM (HPS)

12.1 HUTCH STOPPER STATUS

ANGI RECEIVES HUTCH STOPPERS HS1 AND HS2 OPEN AND REDUNDANT (CHAINS A & B) CLOSED STATUS

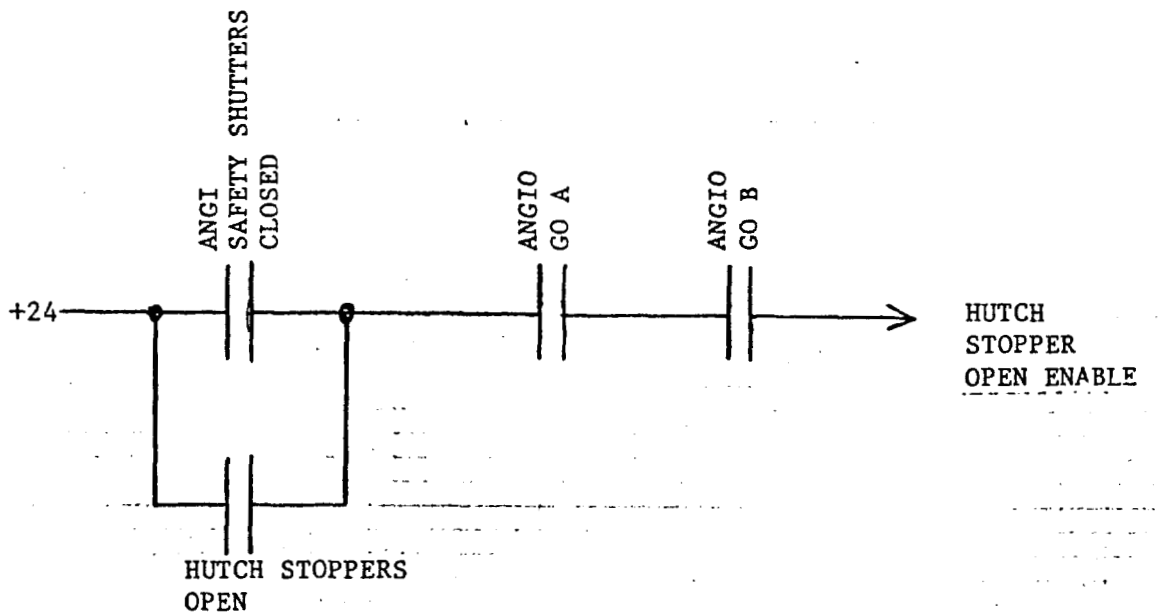
12.2 HUTCH DOOR ADDITIONS

ANGIOGRAPHY MONOCHROMATOR, ROTATING DRUMS, SAFETY SHUTTERS, AND IMAGING SHUTTER ARE ALL ENCLOSED IN A SHIELDED ENCLOSURE INTERLOCKED WITH REDUNDANT SWITCHES AND LOCKED WITH AN OPERATORS PADLOCK (SSRL OPERATOR CARRIES KEY). THE SWITCHES ARE CONNECTED INTO THE HUTCH DOOR CIRCUITS, AND WILL CAUSE AN HPS FAULT (HUTCH SUMMARY FAULT-DUMP SPEAR) IF NOT CLOSED WHILE HUTCH STOPPERS ARE NOT CLOSED.

12.3 HUTCH DOOR REMOVAL

THE REAR DOOR OF THE BL IV-2 HUTCH IS REMOVED FROM THE HPS DOOR CIRCUIT WHEN THE ANGI INTERLOCK IS "ON LINE" - SEE Pg.11

12.4 HUTCH STOPPER OPEN ENABLE FROM ANGI



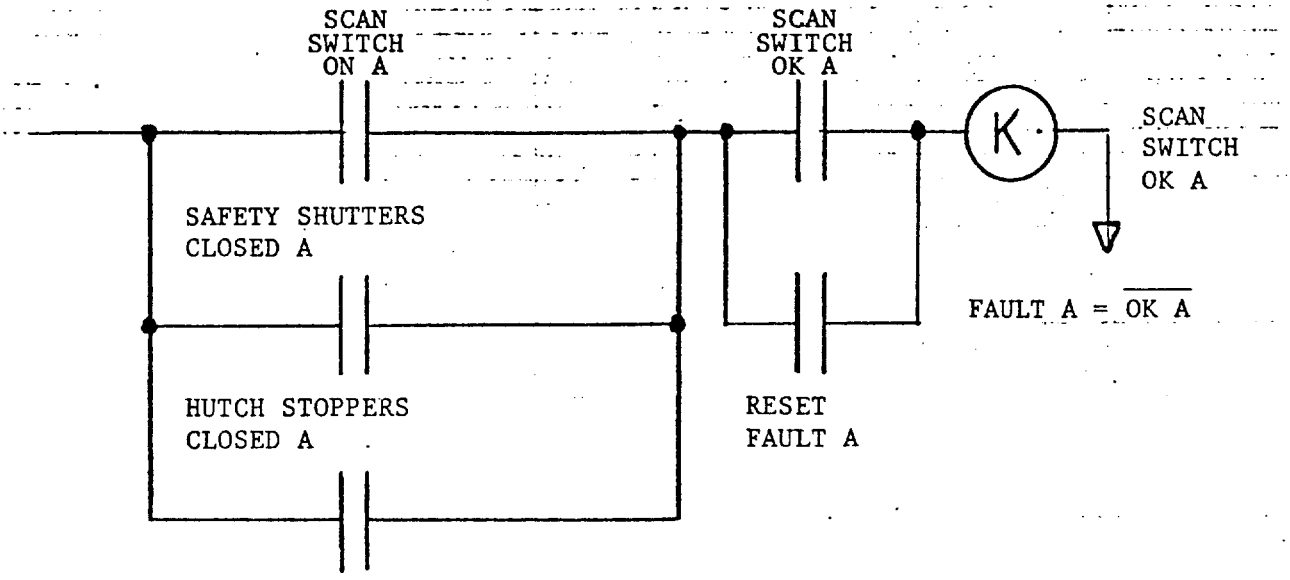
NOTES: 1. ANGI SAFETY SHUTTERS MUST BE CLOSED TO OPEN HUTCH STOPPERS. ONCE HUTCH STOPPERS ARE OPEN, SAFETY SHUTTERS MAY BE OPENED.

43

ANGIOGRAPHY PPS

13.0 SCAN SWITCH INTERLOCK (DEAD MAN SWITCH)-REDUNDANT

13.1 LOGIC



CHAIN B IS LIKEWISE CONFIGURED

NOTE: 1. SCAN SWITCH MUST BE HELD CLOSED DURING ENTIRE EXPOSURE TIME AS DEFINED BY THE SAFETY SHUTTERS BEING OPEN. RELEASING BUTTON WHILE SAFETY SHUTTERS CLOSED, OR WHILE HUTCH STIPPERS CLOSED, WILL NOT CAUSE A FAULT.

13.2 SCAN SWITCH FOLLOWER RELAYS