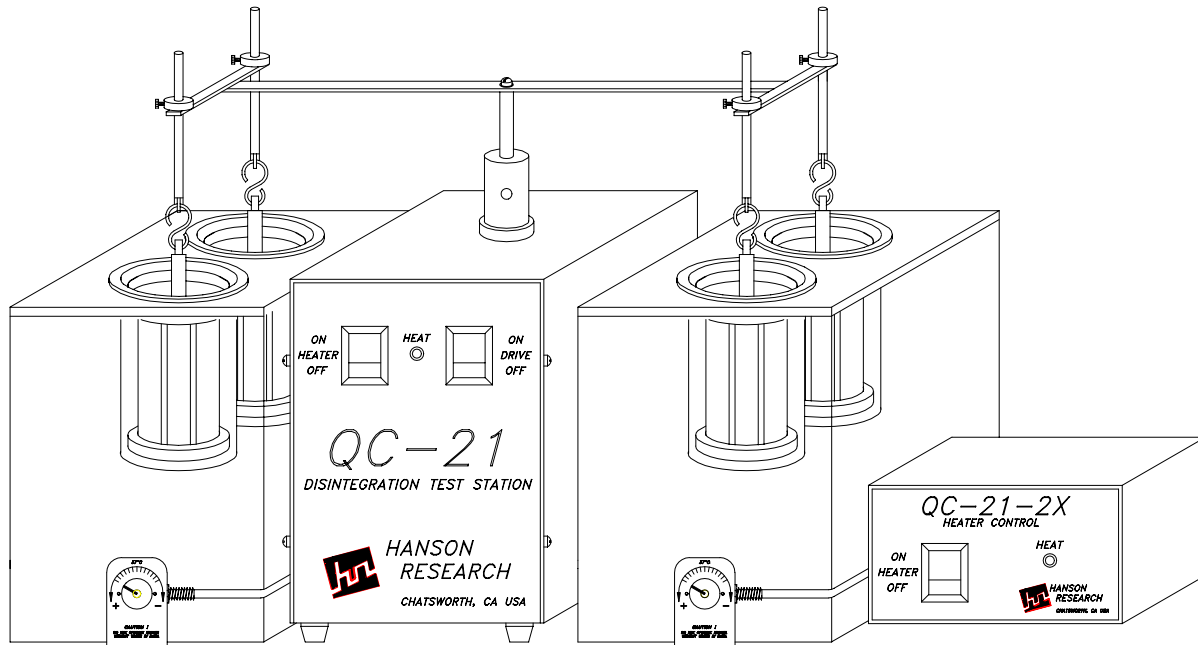


QC-21, QC-21-2X

Operation Manual

39-400-801

REV. A.
DATE: 2002-12



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TABLE OF CONTENTS

I. COMPONENT IDENTIFICATION

II. INSTALLATION

A. SET-UP & OPERATION PROCEDURE

III. QC-21-2X UPGRADE

A. SYSTEM LAYOUT

QC-21 COMPONENT IDENTIFICATION

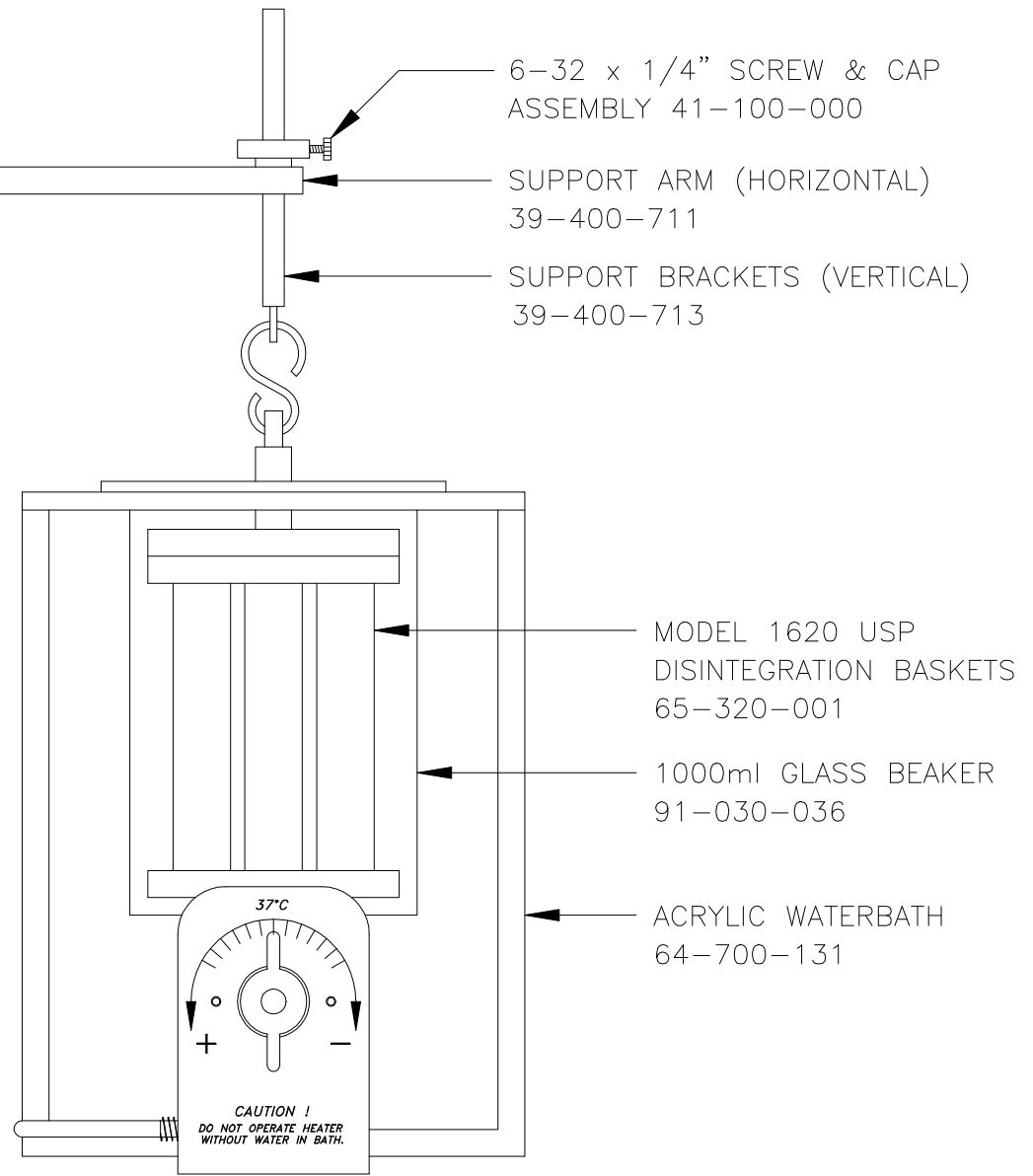
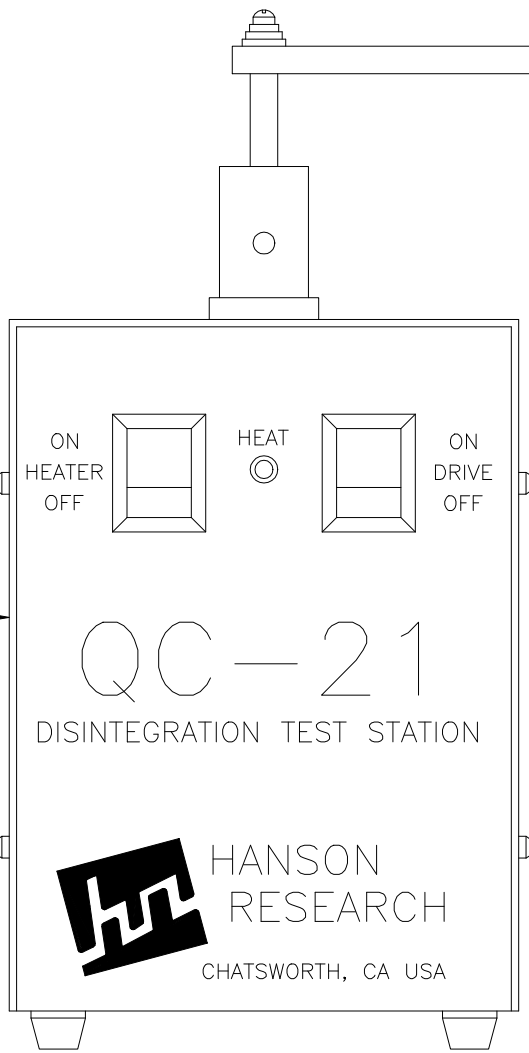
The Model QC-21 DISINTEGRATION TEST SYSTEM will consist of the following components:

- 1 ea. Drive / Heater Control Unit
- 1 ea. Clear Acrylic Waterbath (with heater element & sensor)
- 2 ea. 1000ml Glass Flasks (Beakers)
- 1 ea. Support Arm (horizontal)
- 2 ea. Support Brackets (vertical)
- 2 ea. USP Disintegration Baskets (Model 1620)

Please carefully un-pack and identify all component pieces, see page 2.

If any shipping damage has occurred, NOTIFY CARRIER IMMEDIATELY.

QC-21
DRIVE/HEATER
CONTROL UNIT



6-32 x 1/4" SCREW & CAP
ASSEMBLY 41-100-000

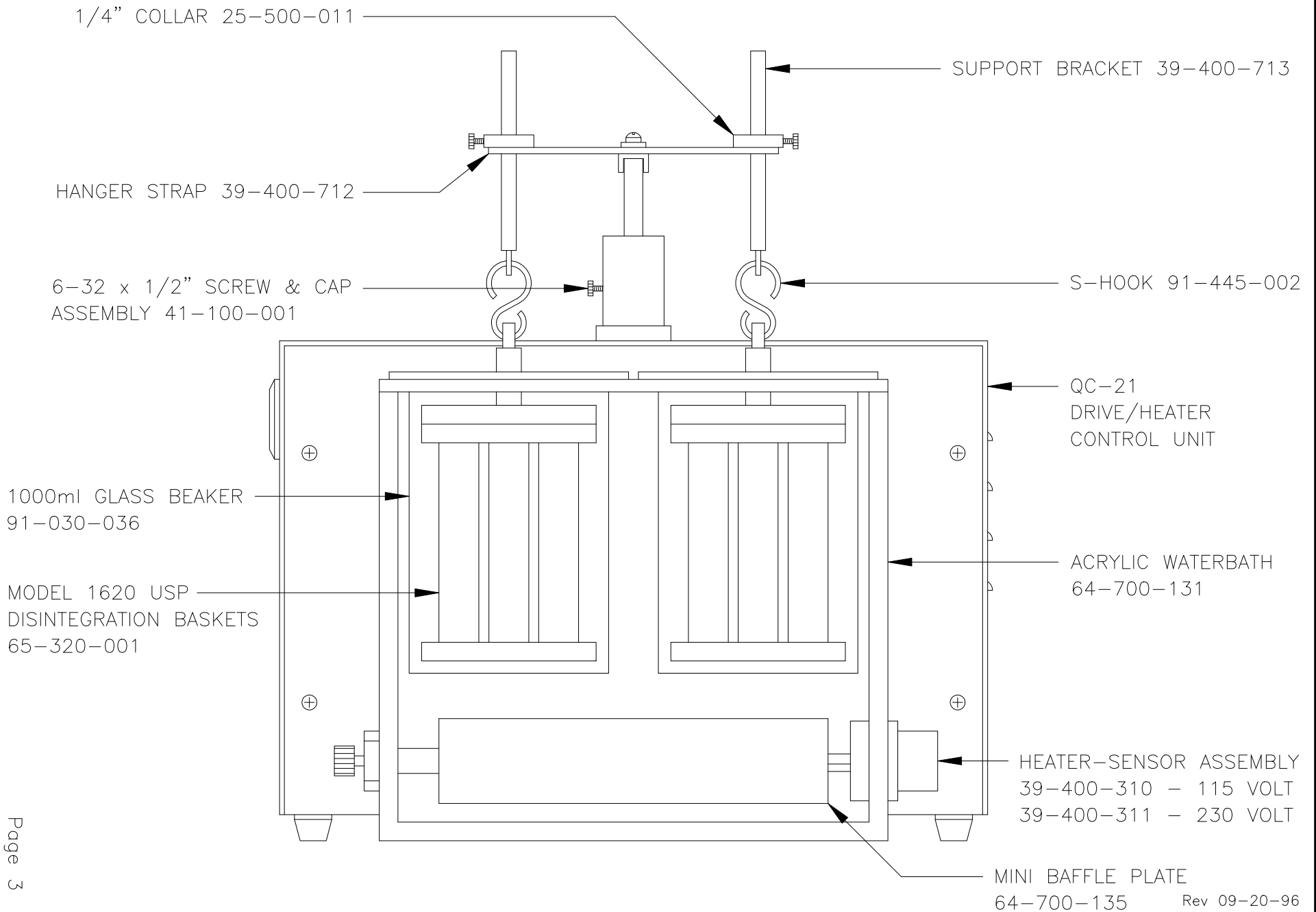
SUPPORT ARM (HORIZONTAL)
39-400-711

SUPPORT BRACKETS (VERTICAL)
39-400-713

MODEL 1620 USP
DISINTEGRATION BASKETS
65-320-001

1000ml GLASS BEAKER
91-030-036

ACRYLIC WATERBATH
64-700-131

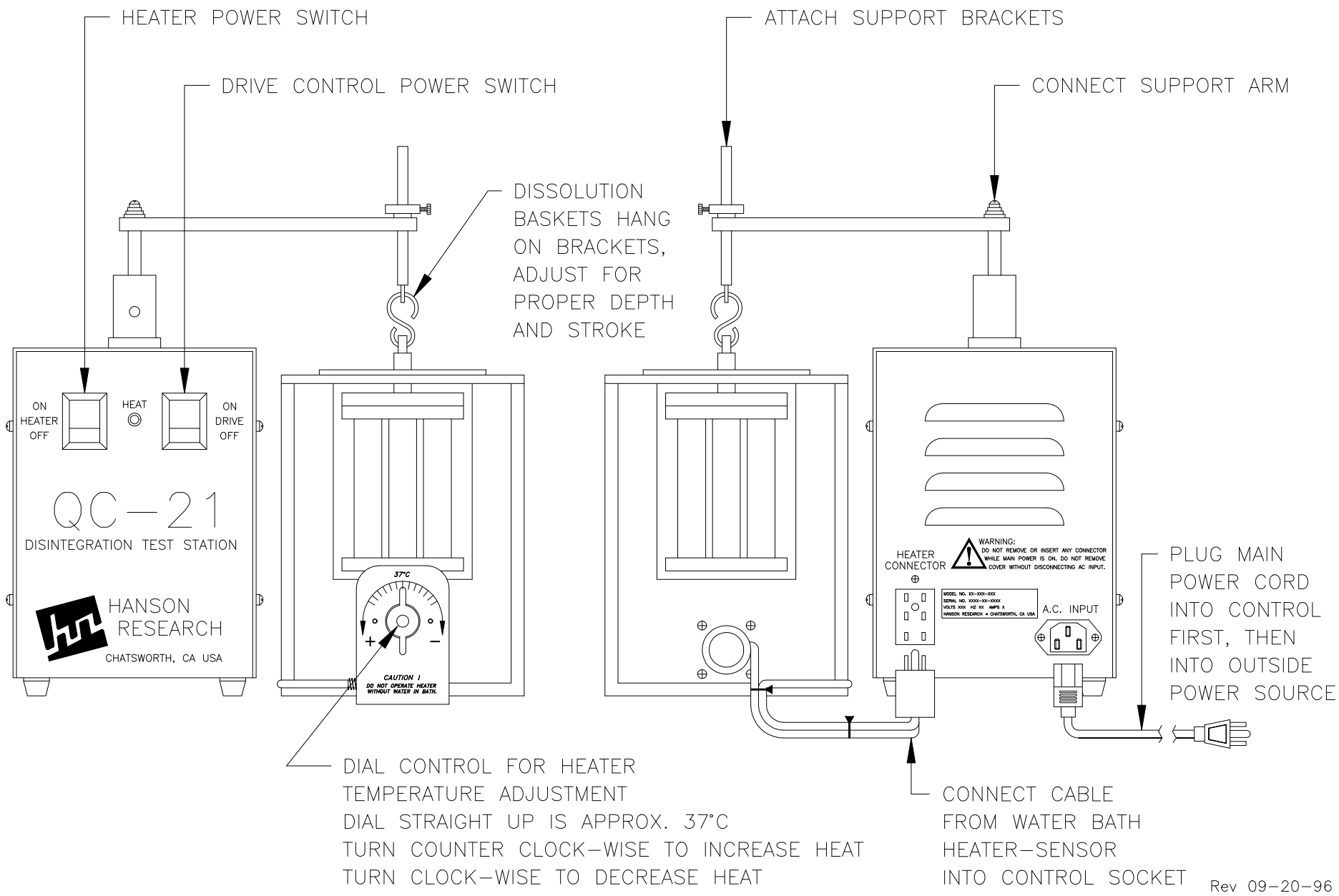


QC-21 COMPONENT IDENTIFICATION



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RESEARCH

39-400-801



SET UP & OPERATION PROCEDURE

1. Prepare clean lab-bench work area for QC-21 Test System.
(Approximately 2 feet by 2 feet minimum bench space required).
2. Set-up Drive/Heater Control Unit and Acrylic Waterbath side by side as shown on pages 3 and 4.
3. Make sure the main power cord is disconnected and both power switches are in the off position.
4. Connect cable from Waterbath heater / sensor into Control Unit socket as shown.
5. Connect Support Arm (horizontal) to drive shaft on top of control Unit. Use screwdriver to secure Arm into position.
6. Attach Support Brackets (vertical) to Support Arm as shown. Slide Brackets up-down to adjust Baskets to proper test position.
7. Fill Waterbath with water, approximately 75% full.
(Water level will rise when flasks are immersed).
8. Fill 1000ml Glass Flasks (Beakers) with prescribed media solution, and set into waterbath.
9. Plug Main Power Cord into outside power source.
10. Turn Heater Power Switch on, Heater Light should turn on.
11. Set the Heater Control Dial to Point straight up. This setting is for approximately 37°C. As temperature rises and stabilizes, a thermometer should be used to monitor precise bath temperature.
12. To INCREASE The temperature setting, turn dial counter clock-wise. To DECREASE the temperature setting, turn Dial clock-wise. The Heater light will begin to flick on and off as bath temperature approaches the set value, this is normal operation of the Heater / Sensor system.

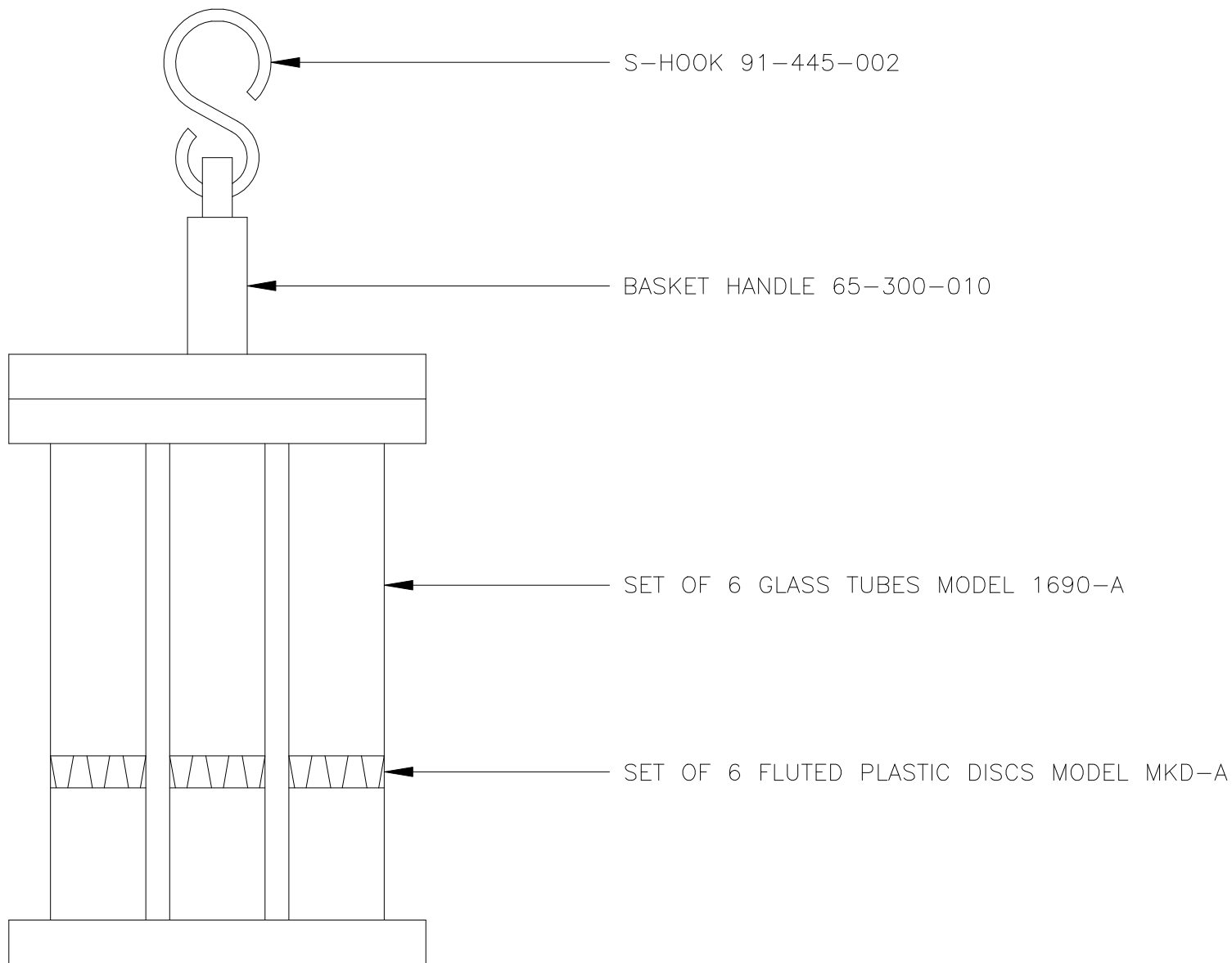
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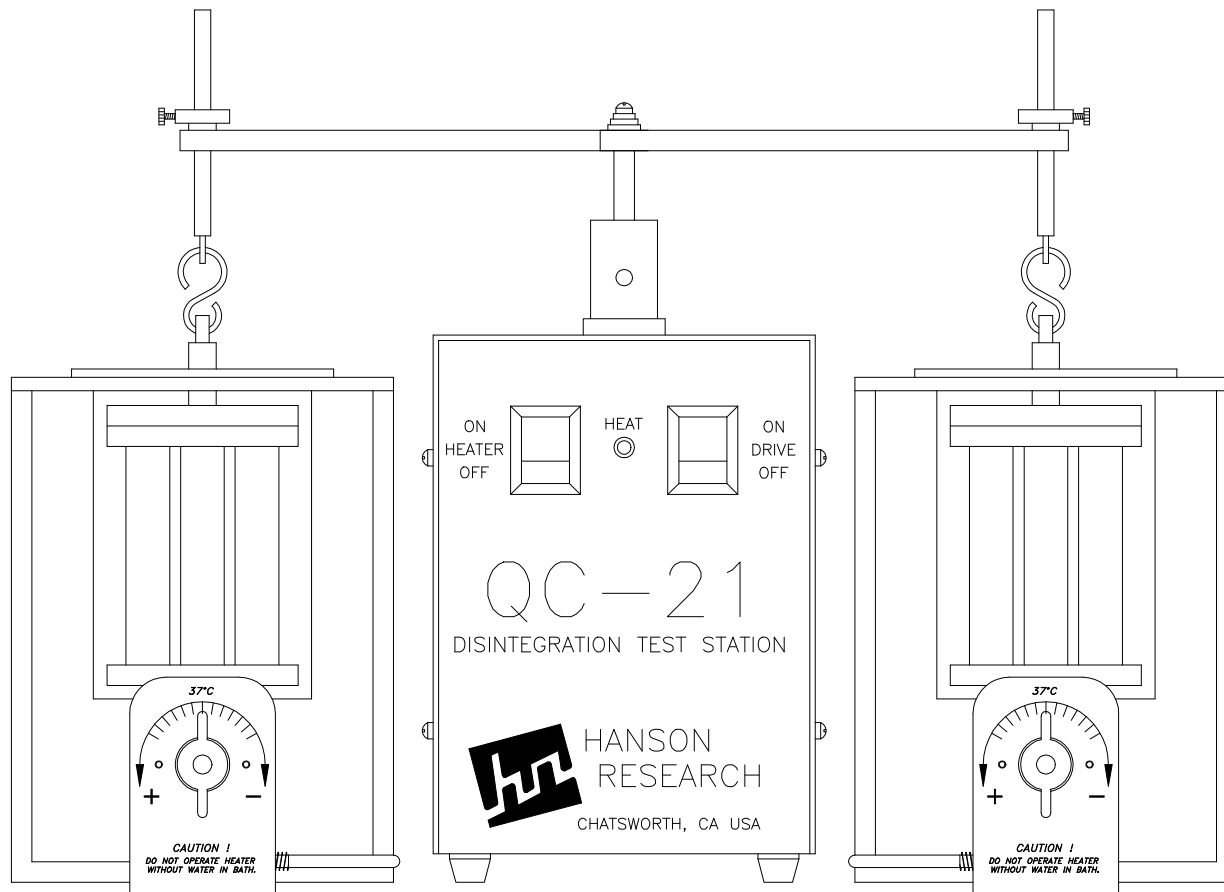
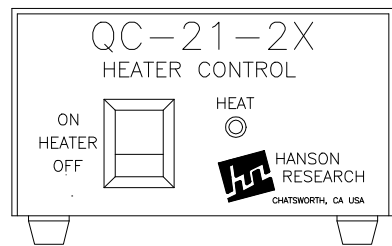
SET-UP AND OPERATION (CONTINUED)

13. Attach the Disintegration Baskets (with test samples inside, per USP disintegration specifications) to the Support Brackets using the “S” hooks as shown.
14. Turn Drive Control Power Switch On. The Drive Unit will begin to automatically raise and lower Baskets. Basket should come close to, but not touch, bottom of flask on down stroke . Adjust Basket position, as needed, by sliding the Support brackets up or down and securing with collar.
15. This system operates on steady, even up / down movement, and is designed to conform to USP Disintegration specification of 29-32 cycles per minute. No speed adjustment is required on the part of the operator.
16. For Disintegration Testing, please refer to the current USP (United States Pharmacopoeia), or the required Pharmacopoeia for different countries , and / or in-house test procedures.
17. Always turn both Drive Control and Heater Control switches OFF at end of test. **NEVER OPERATE HEATER IF BATH IS EMPTY.**

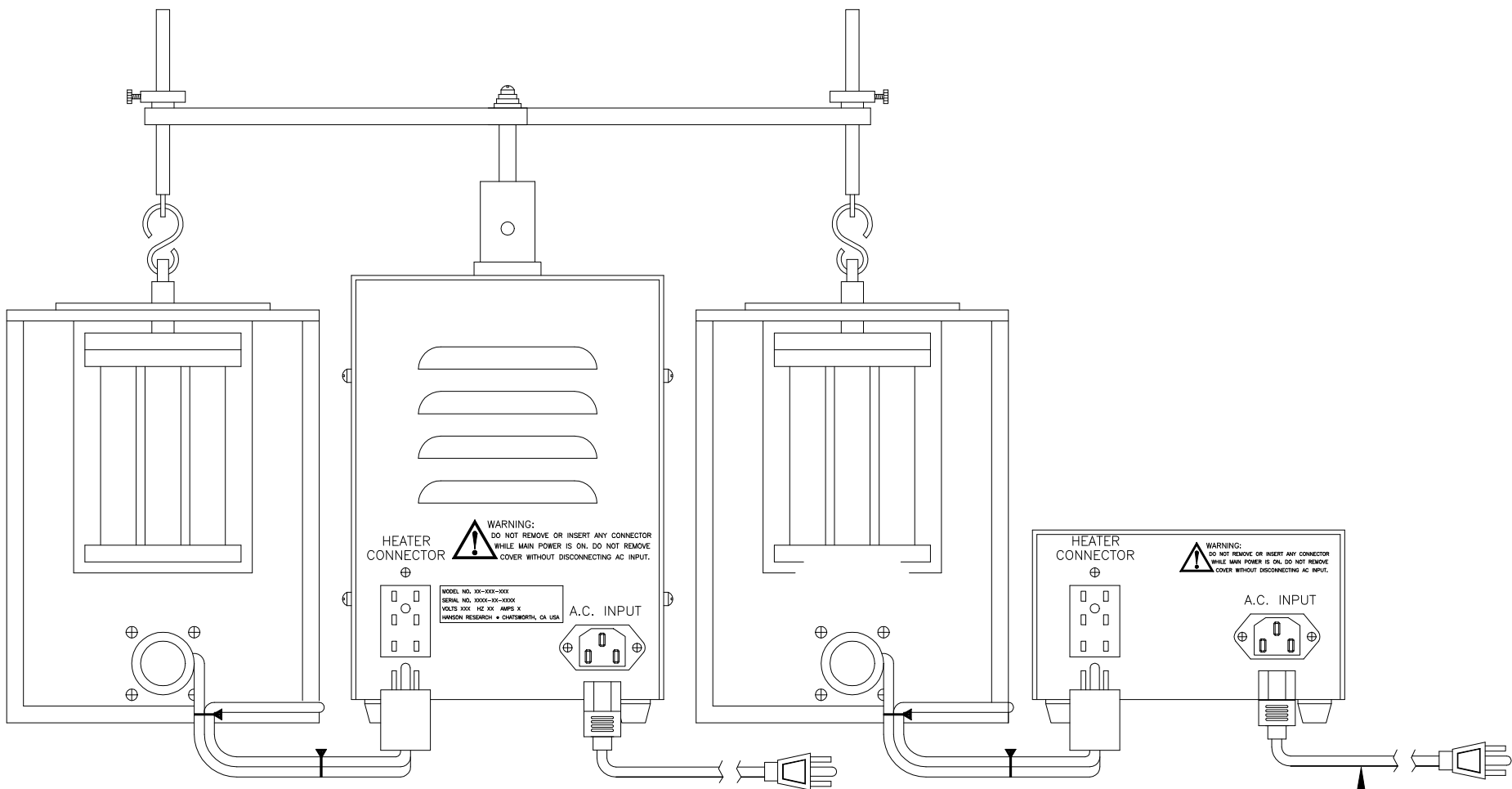
Note: In case the system develops a chatter, manually lift the square drive to its uppermost position and wipe shaft clean. Lubricate the shaft by removing the nylon screw and with the help of a syringe, apply grease through that hole before replacing the screw. Recommended grease is CHEVRON SRI grease, Hanson P/N 91-635-010.

Please refer to Hanson Research Applications Staff or Hanson Representative in your area for any questions regarding operation, service, and / or test applications.





FRONT VIEW



REAR VIEW

PLUG MAIN
POWER CORD
FIRST, THEN
INTO OUTSIDE
POWER SOURCE