

Computer Sports Medicine, Inc., (CSMi)

HUMAC® NORM™ TESTING & REHABILITATION SYSTEM

Assembly and Installation Manual

WARNING

Assembly, Installation and Repair of the NORM System should be performed by qualified service personnel only.

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Adverse Medical Event Reporting is intended to provide the Food and Drug Administration (FDA) with the necessary information to assure product safety without imposing an unreasonable burden on device manufacturers and importers.

In accordance with FDA regulations, original equipment manufacturers (OEM) and importers of medical devices are required to report to the FDA whenever the OEM or importer receives or becomes aware of information suggesting that one of its marketed devices may have caused or contributed to a death or serious injury. Also, the OEM and importer(s) are required to report to the FDA if one of their devices has malfunctioned, and a recurrence of that malfunction would be likely to cause or contribute to a death or serious injury.

An injury is considered “serious” if it is life threatening or results in permanent impairment of a body function or permanent damage to a body structure. A “serious injury” is also defined as an injury requiring medical or surgical intervention to preclude permanent impairment of a body function or permanent damage to a body structure, or to relieve unanticipated temporary impairment of body function or unanticipated temporary damage to a body structure

Please contact the CSMi Quality Assurance Department to report any such stated incidence.

The CSMi NORM™ and TMC Systems are designed to be operated with software that is installed at the time of shipment. Any additional software not authorized by CSMi, that is added to the factory installed program, is done at the user’s risk and may cause service problems not covered by the customer’s warranty.

The software used to operate either system is protected under copyright laws. Any use of the software other than its intended use with the CSMi 6000 or NORM™ Testing and Rehabilitation System is prohibited. Altering or tampering of the software in any manner constitutes an unwarranted use of the NORM system and immediately voids all warranties expressed or implied by CSMi. Additionally, such changes may render the device non-compliant with its’ regulated intended use. CSMi assumes no liability for damaged equipment or harm to any individual as a result of malfunction due to tampered software.

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IMPORTANT INFORMATION

Qualified Personnel Notice

WARNING: The NORM System contains no user serviceable parts. Installation, Assembly and Repair of the NORM Testing & Rehabilitation System should only be performed by qualified service personnel.

Classification Information

- The NORM is Testing and Rehabilitation System is ELT Listed and CE Certified.
- The NORM System has been classified for use in accordance with the following sections of the Standards for Medical Electrical Equipment:
 - IEC 60601-1 (1988), 'Medical Electrical Equipment, Part 1: General Requirements for Safety' + A1(91) + A2(95).
 - EN 60601-1 (1990), 'Medical Electrical Equipment, Part 1: General Requirements for Safety' + A1(93) + A2(95) UL 60601-1 (2003), 'Medical Electrical Equipment, Part 1: General Requirements for Safety'.
 - CAN/CSA C22.2 No 601.1-M90 (1990), 'Medical Electrical Equipment, Part 1: General Requirements for Safety'.
 - IEC 60601-1-1 (2000), 2nd Edition, 'Medical Electrical Equipment Part 1: General Requirements for Safety - Collateral Standard: Safety Requirements for Medical Electrical Systems'.
 - CB Scheme.
- The NORM System is rated as Class I, Type B as indicated by the  icon located on the Transformer box rating label.

Cleaning and Maintenance

CAUTION: Do not use Benzene, thinner, or any volatile substance to clean the unit as they may leave a permanent mark. Never leave the unit in contact with rubber or vinyl for an extended period.

- Mechanical parts which contact the patient that appear rusted or cannot be cleaned should be replaced.
- Clean/Sterilize removable mechanical parts only.

Upholstery: Use a cloth dampened with a mild household cleaner after each use.

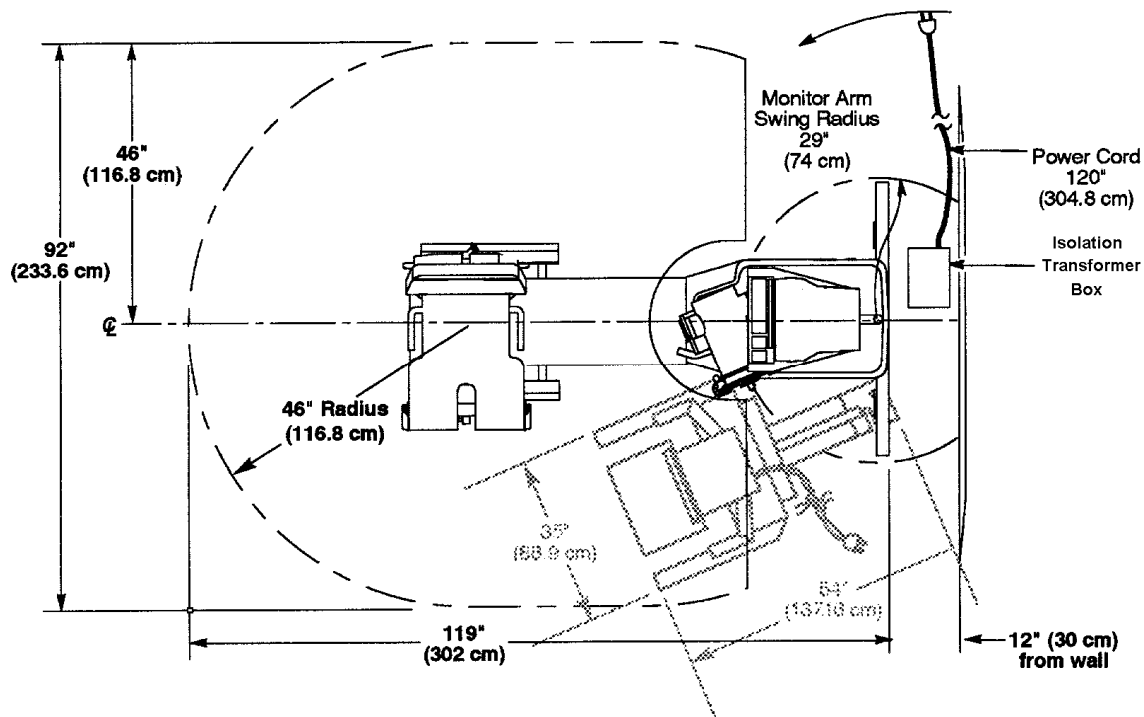
Straps: The belts used on the NORM absorb large and repetitive loads. To ensure patient safety, it is important to check regularly for signs of wear. Any belt with significant wear should be immediately replaced. Keeping extra shin pads and stabilization belts on hand ensures timely replacement and avoids possible injury or downtime.

- The Calibration procedure should be run once per month to assure accurate measurements.

- The user is responsible for disposal of any NORM components per local regulations.

Assembly and Installation Notes

- The NORM System can be installed in any Ordinary Location.
- The system should be installed in such a way that the User is able to carry out the necessary cleaning, and where applicable the sterilization and disinfection measures as specified in this document.
- The system should be installed in such a way that the User is able to disconnect the system from the mains power if required to perform service or other procedures.
- Do not attempt to lift the NORM Electronics Module or Patient Positioning Module. When it is necessary to move either of these sections, use an appropriate leverage tool such as a Johnson Bar or a long (approximately 4 foot) sturdy piece of wood to act as a lever with another block of wood to act as the fulcrum. To move either Module, insert a leverage tool anywhere under the perimeter of its base frame and “walk” the module into position. Exercise extreme caution when lifting the NORM unit in this manner so as not to “drop” the unit, doing so could damage the electronics. Take care NOT to place your feet near the module base frame.



Ratings

- The NORM System is not intended for use in the presence of flammable anesthetics.
- The NORM System is rated for Continuous Operation.
- Operating Temperature 10° Centigrade to 35° Centigrade.
- Storage Temperature -10° Centigrade to 55° Centigrade.

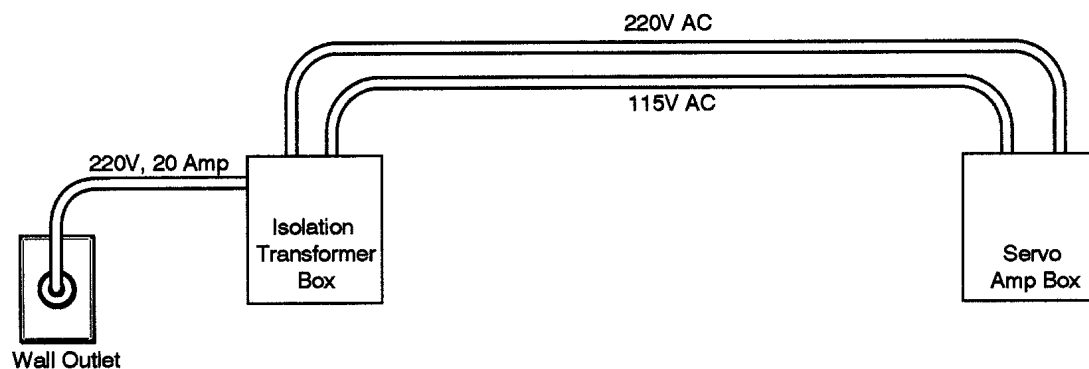
IMPORTANT INFORMATION

- Operating Relative Humidity 20% noncondensing to 80% noncondensing.
- Storage Relative Humidity 20% noncondensing to 80% noncondensing.
- Special cooling is not required for the operation of the TMC.

Note: It is not recommended that the NORM be changed in any way. If any changes are made, adherence to the CE standards becomes the owner's responsibility, if you have any questions, please contact the CSMi Customer Services Department at: (Voice) 781-297-2034 or (FAX) 781-297-2039 or (e-mail) service@csmisolutions.com.

Electrical Connections Notes

- The NORM System is factory wired for 208 VAC.
- The NORM System must be plugged into the Isolation Transformer Box ONLY. After connecting to the Isolation Transformer Box, replace the receptacle cover bracket over the plugs.



- Both NORM system A/C Cables MUST be plugged into the NORM Isolation Transformer ONLY.
- Only the NORM system A/C Cables are to be plugged into the NORM Isolation Transformer.


WARNING: To avoid risk of electric shock, this equipment must only be connected to a supply mains with protective earth"

Additional multiple portable socket outlet or extension cord shall not be connected to the system.


Do not connect items which are not specified as part of the system.



The multiple outlets on the Servo Amplifier Module are connected in parallel. The following ratings apply.

115V 
 1Ø
 50/60 Hz
 5A Max across all outlets

The following ratings apply to the isolation transformer.










200/208/220/230/240 V 
 1Ø
 50/60 HZ
 10A

Only the computer A/C Cables supplied with the NORM at to be plugged into the multiple outlets on the Servo Amplifier Module.


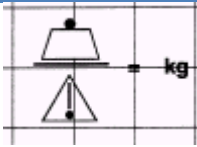







Any changes made to the transformer configuration must be done by a qualified technician.

The switch on the NORM Isolation Transformer Box is a circuit breaker. NORM Systems should be powered On or Off with the switch located on the NORM System’s electronic module housing.

Labels

Symbol	IEC Publication	Description
	417-5032	Alternating Current
	417-5019	Protective earth (ground)
	417-5017	Earth (ground)
	348	Attention, consult accompanying documents
	417-5008	Off (power: disconnection from the mains)
	417 - 5009	Stand-by
	417-5007	On (power: connection of the mains)
	417-5265	“Off” (only for a part of equipment)
	417-5264	“On” (only for a part of equipment)

IMPORTANT INFORMATION

Symbol	IEC Publication	Description
	417-...878-02-02	Type B applied part
	60601-2-38	Weight Limits on support parts
	878-5110	Emergency Switch
	ISO 7000-1641	Operator should optionally refer to the accompany documents for additional advice.
	60878	Operator must refer to the accompany documents for additional advice.
		WEES directive
		Temperature Limits
		Humidity Limits
		Pressure Limits

Additional Notes/Warnings


Symbol	Definition
	The user is responsible for disposal of the system in compliance with local regulations.

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SECTION 1. MEET NORM™

NORM (*Normative Outcomes for Rehabilitation Management*) is a powerful isokinetic testing and rehabilitation system, based on the CSMI tradition of providing reliable, accurate and consistent patient data. NORM utilizes an innovative design to unite a single chair, Patient Positioning Stabilization module with a compact, pre-assembled Electronics module. The result is an extremely user-friendly system that combines the latest in computer technology with over twenty-five years of isokinetic testing and rehabilitation experience.

SECTION 2. INSTALLATION

NORM is extremely simple to install. The modules are pre-assembled at the factory and shipped to the customer in two palletized cartons. The Electronics module (or Computer module) carton also contains the computer, monitor and keyboard. The user manuals and the Dynamometer adapters are packed in the Patient Positioning Stabilization module (or Seat Assembly module) carton. (Note: Microsoft Windows™ and the NORM™ System software have been factory installed.)

Prior to assembling the system, read through this Installation Manual to become familiar with the procedures. Read each procedure completely, and follow the steps in order. All directions given are relative to being positioned in the unit as a patient unless otherwise noted.

If you encounter any difficulty with the installation procedure, or have a problem with the unit, call CSMI Customer Service at 1-781-297-2034.

Examine the Delivered Equipment

Report any obvious damage or missing cartons to CSMI Customer Service at 1-781-297-2034.

The contents of each carton are follows:

Carton #1 Electronics Module

Carton #2 Patient Positioning Stabilization Module

Carton #3 Accessory Cart

Carton #4 Computer System

Carton #5 Computer Monitor

Carton #6 Printer

Tech Note *If a TEF Modular Component unit was purchased along with the NORM System, assemble the NORM System first.*

Refer to the TEF Modular Component Assembly and Installation Manual for instructions on assembling that unit.

Practice safety at all times to prevent personal injury and damage to equipment.

Keep in mind:

- The vicinity of the install area should be kept clear of all packaging material.

- Do not attempt to lift the NORM Electronics Module or Patient Positioning Module. When it is necessary to move either of these sections, use an appropriate leverage tool such as a Johnson Bar or a long (approximately 4 foot) sturdy piece of wood to act as a lever with another block of wood to act as the fulcrum.

CAUTION: *To move either Module, insert a leverage tool anywhere under the perimeter of its base frame and “walk” the module into position. Take care NOT to place your feet near the module base frame.*

Tools and Materials Required for Installation

Note: *Tools are not provided, unless noted below.*

- ✓ 3/4” socket wrench
- ✓ 3/4” open end wrench
- ✓ Regular screwdriver
- ✓ Phillips screwdriver
- ✓ Loctite® 242
- ✓ Stabilizing / leveling block or, if not available use a 6” [~150 mm] long piece of “2x4” lumber (US standard size 1 1/2” x 3 1/2” [~38 mm x ~89 mm] block of wood)
- ✓ 4-25 lb. Calibration weights (provided)
- ✓ 6’ Tape Measure
- ✓ 2’ Carpenter’s Level
- ✓ Johnson (or ~4’ [~1.2 meter] long pry) bar

Examine the Installation Site

- Determine the best position for the NORM System before beginning assembly.
- Review Site Plan with the customer before proceeding. If no Site Plan is available, review the floor plans shown in Figure 1 to determine the best layout. Assemble the unit in the exact location where it will be used.

Note: *The location of the 220 VAC, 20 amp outlet and the position of the TEF Modular Component as shown in Figure 1 are for illustration purposes only. **They can be located on either side of the NORM System.***

The rear support arm must be positioned at least 12” (30cm) from wall. Extended seat assembly in fully reclined position requires approximately 46” (116.8cm) on each side. Dimensions shown in

the Suggested Floor Plan indicate maximum floor space required. Most patterns require less operating area.

CAUTION: Make sure the recommended power source (dedicated 220VAC, 20 amp) is available for the NORM System BEFORE beginning the assembly.

If a TEF Modular Component is being installed at the same time, make sure a regular 115V wall outlet is available in the vicinity of the NORM System.

Suggested Floor Plan

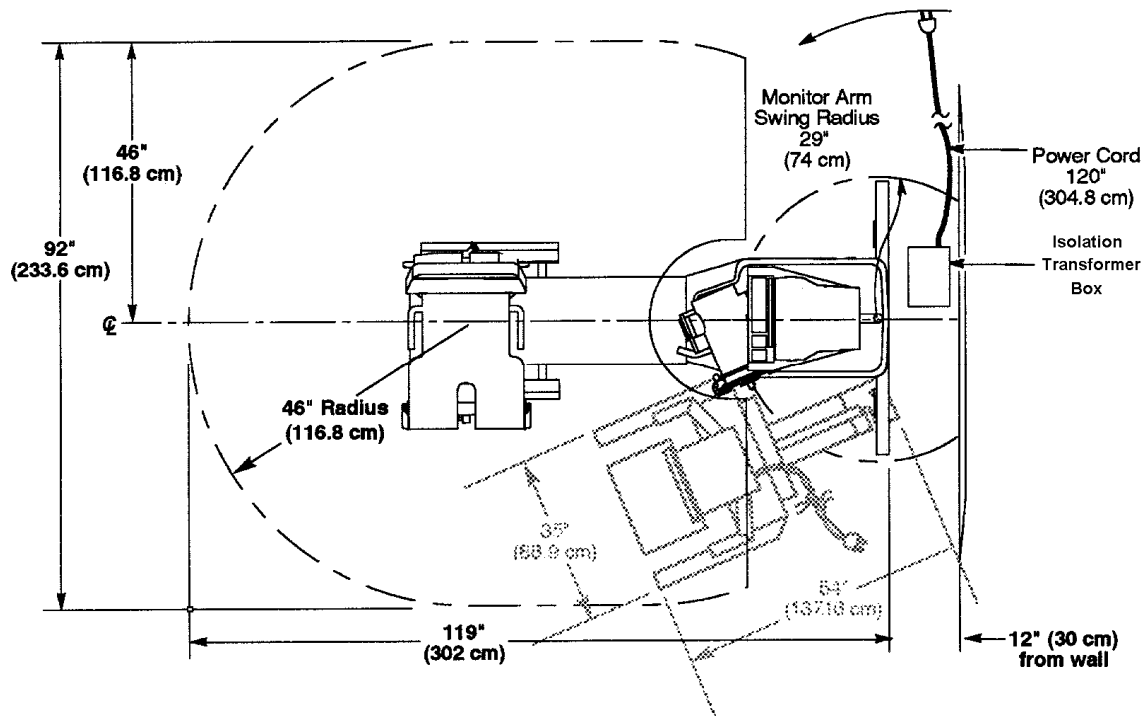


Figure 2-1 Suggested Floor Plan

INPUT VOLTAGE SELECTION

Check the power outlet

1. Verify that there is a dedicated 20 amp outlet for the CYBEX NORM system.
2. Set the DVM to the 250 VAC range. Measure and record the line voltage at the outlet to be used during the typical time of day when the system will be operating. Refer to the instructions *How to Take a Voltage Reading* below.
3. **All units are factory wired for a primary input voltage of 208 VAC.**

Ensure the voltage reading is within the acceptable range for the installation site nominal voltage. If it differs, refer to the diagram and chart in Figure 2 on the next page to select the correct wiring configuration for the transformer.

Note: A dedicated 20 amp line is necessary. Use a DVM to check the wall outlet.

It is recommended to check the reading approximately every 1/2 hour you are on site to obtain an average reading.

How to Take a Voltage Reading

Refer to the Figure 2-2 when taking a voltage reading. Measure at point A then at both points B.

At Point A
Measure the High Voltage.

At Points B
The voltage reading should be approximately equal to and approximately half of the reading taken at point A.

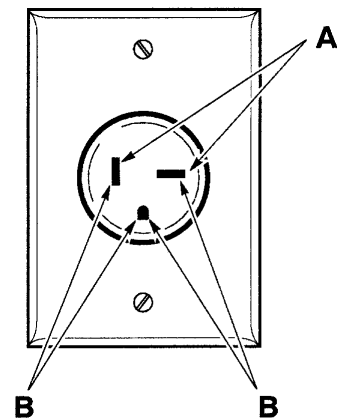


Figure 2-2 Voltage Measurements

For example: If the reading at Point A is approximately 220V then the reading at each Point B should be approximately 110V.

CAUTION: *If the input voltage is not within the acceptable range for the site GRID voltage, consult the local utility.*

WARNING: ELECTRIC SHOCK HAZZARD. UNPLUG THE TRANSFORMER FROM THE WALL OUTLET BEFORE CHANGING THE VOLTAGE TAP.

Isolation Transformer Wiring Configuration

Configuration Selection Wire Chart

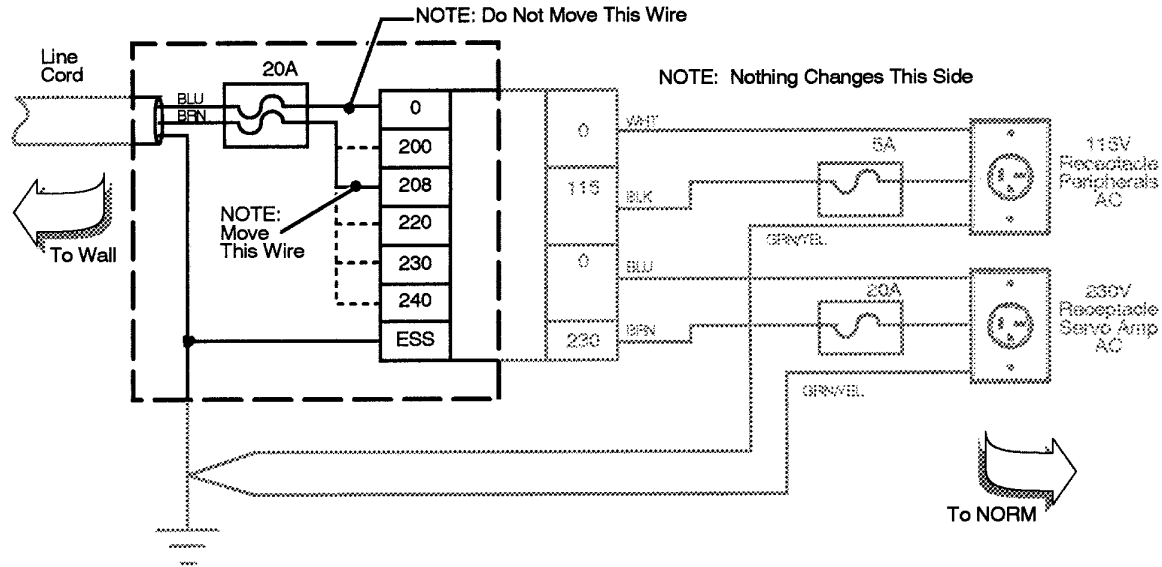


Figure 2-3. Isolation Transformer Wiring Configuration Diagram and Chart.

Note: Select a transformer voltage configuration that falls closest to the middle of the input voltage range. *REMEMBER - Do not move the wire to the zero (0) tap.*

Example: If the voltage range is between 184 and 216 on the DVM, configure the transformer for 200 volts. If it's between 191 and 224 use 208 volts and so on.

Use	If the input voltage range is
200	184 / 216
208	191 / 224
220	202 / 238
230	212 / 248
240	221 / 259

How to Reconfigure the Transformer

1. Make sure isolation transformer is not plugged in to any power source. Remove cover.
2. Along the side of the transformer is a row of terminals. Each terminal is marked with a voltage value: 0, 200, 208, 220, 230, and 240.

3. With a small screwdriver, loosen the terminals needed to reconfigure the isolation transformer for the site input voltage noted.
4. Make the necessary changes as shown in Figure 2 using the chart as a guide.
5. Tighten all terminal connections so the wires are held securely.
6. Replace the transformer cover.

WARNING: *If the NORM Transformer Box has an On/Off switch, this switch is a Master Emergency Switch and should always remain ON. Do not use it to power the NORM System - use the NORM Main Power Switch to turn the machine on or off.*

Additional Notes

- The transformer outputs are non-selectable at 115 VAC and 230 VAC. The secondary (output) side of the transformer should not be changed at any time.
- It is the distributor's responsibility to remove the right angle plug shipped with the system. A new plug end compatible with the customer's facilities is to be installed by the distributor.
- All internal ground wires are green with a yellow trace to meet European standards.

How to Re-orient the Power Cord Plug

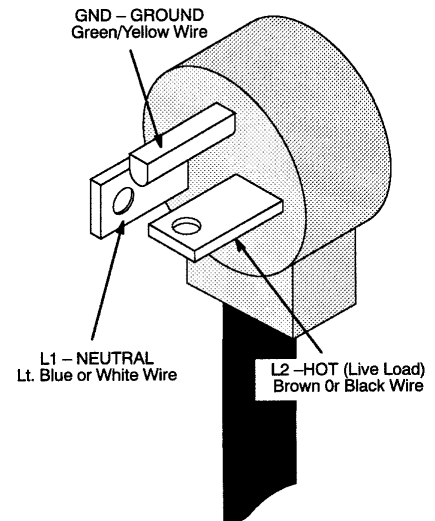
1. With a DVM set to the 250 VAC range, verify that the voltage at the 20 amp isolated dedicated outlet is still within the acceptable range for the grid specified.
2. Plug the line cord into the wall receptacle. If the cord does not hang straight down, reorient the plug.

Tech Note: *Techs are never to open the wall plate or re-orient the wall receptacle.*

Note: *In most instances when the plug needs to be reoriented it will be necessary to rotate it 180°. Please follow the steps listed below to accomplish this.*

- Unplug the line cord from the wall receptacle. Remove the right angle plug from the line cord. DO NOT cut the line cord.
- Strip the jacket back 1-3/4"±1/8". Cut the fillers back to the jacket.
- Cut the green/yellow conductor to 1"±1/8" and the blue (or white) conductor to 1-5/8" ±1/8".

- Strip all conductors to $\frac{1}{2}$ " $\pm 1/16$ ".
- Strip ground insulation down to jacket and separate strands. Separate 20 strands of the drain and cut remainder back down to jacket. Combine what is left of drain with ground strands and twist. Place PVC tubing over drain/ ground combination from jacket to ground terminal.
- Connect the green/yellow conductor to the GND (green screw). Connect the blue (or white) conductor to L1 (gold screw). Connect the brown (or black) to L2 (gold screw). See diagram below. Tighten all screws securely.
- Reassemble plug with $\frac{5}{8}$ " of the jacket protruding into the strain relief area.
- Plug line cord into receptacle.



SECTION 3. NORM™ SYSTEM ASSEMBLY

Install the Electronics (Computer) Module

Note: Do not adjust the levelers until instructed to do so.

1. Position rear support leg and Electronics Module near wall where system is to be permanently installed. Rear Support Leg must be oriented as shown in Figure 3.
2. Using a Phillips screwdriver, remove the 10 sheet metal screws from the two plastic side enclosures, and remove enclosures from the Module.
3. Place the Electronics Module on top of the Rear Support Leg and align the four bolt holes. Apply Loctite 242 to the four-3/4 inch bolt threads. Install screw cap washers and tighten bolts using a 3/4 inch socket wrench. (Rear Support Leg Glides are preset at the factory. Do not adjust.)

Note: Install all four bolts by hand first before tightening with wrench. Make sure bolts are fully tightened.

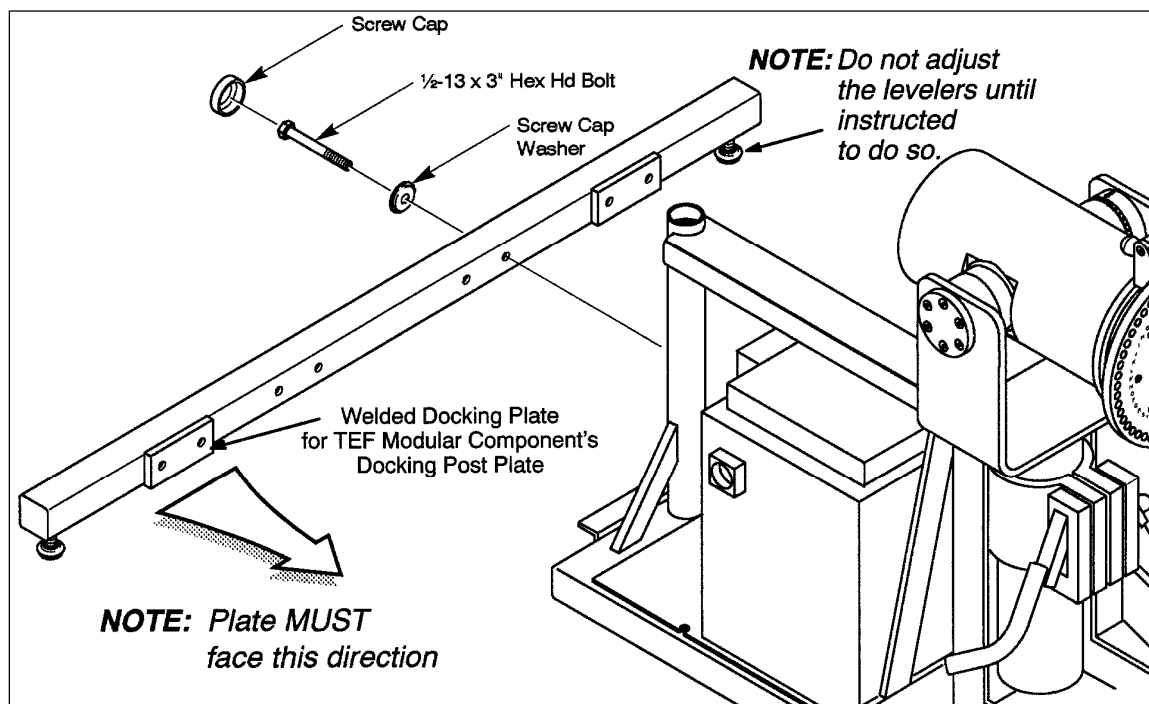


Figure 3-1. Rear Support Leg and Electronics Module.

Install the Seat Assembly Module

1. Position the front edge of the Seat Assembly Module onto the rear lip of the Electronics Module base and align the four bolt holes.
2. Apply Loctite 242 to the four-3/4 inch bolt threads and install lockwashers.
3. Tighten bolts using a 3/4 inch socket wrench. (See Figure 3-2.)

Note: *Install all four bolts by hand first before tightening with wrench. Make sure bolts are fully tightened in a cross-pattern.*

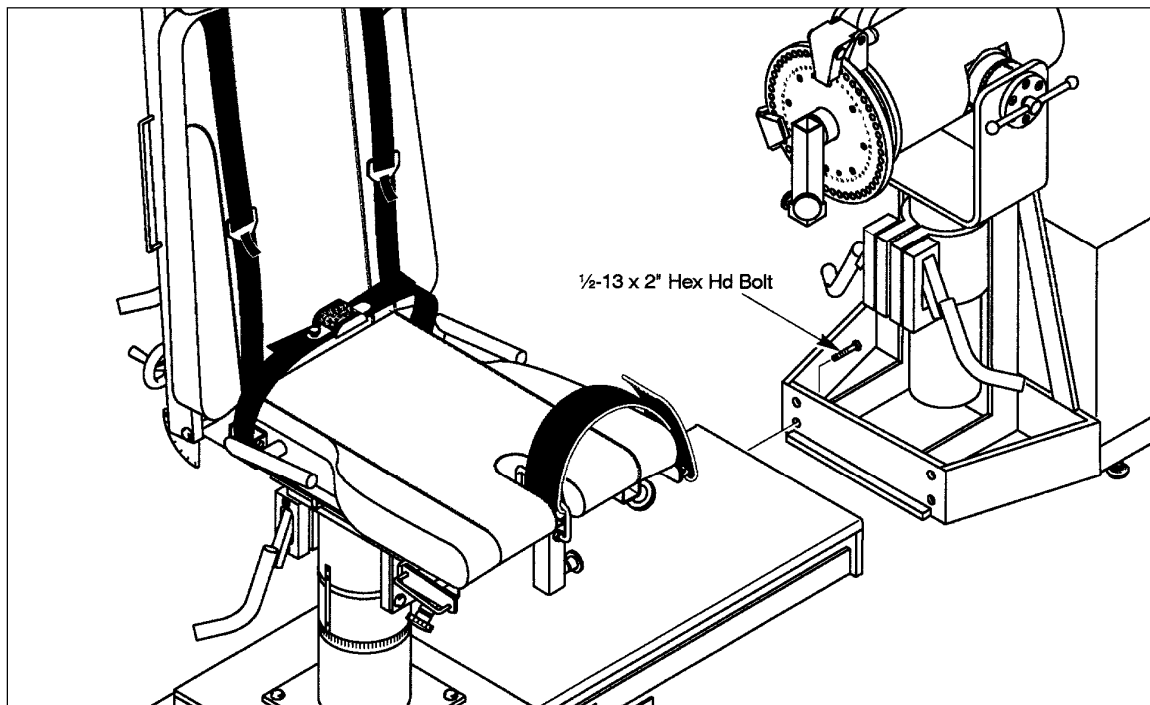


Figure 3-2. Seat Assembly Module attaches to Electronic Module

Stabilizing and Leveling the System

The stabilizing and leveling procedure must be followed exactly as described below to insure system stability and patient safety. (**Note:** Use caution and proper leverage tools when moving unit.)

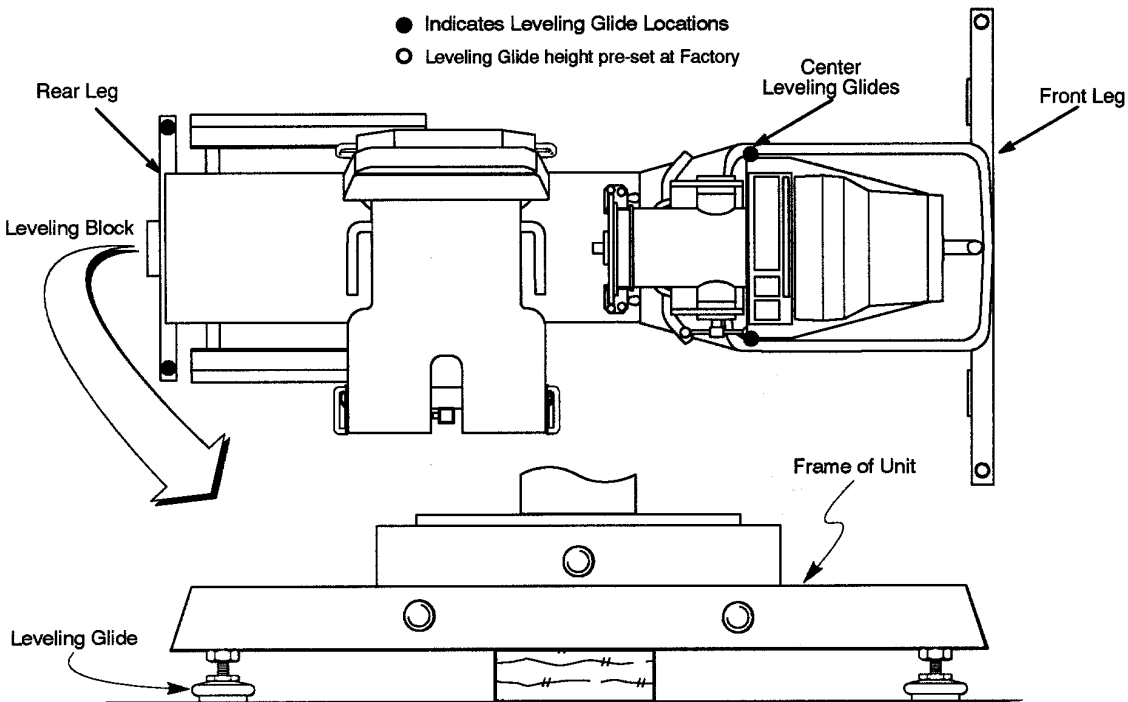


Figure 3-3. System Stabilization.

Seat Assembly Module Rear Leveling Glides

To adjust the leveling glides on the Seat Assembly Module, the leveling block must be placed under the rear of the unit (in the exact center of the module) so the glide screws can be extended equally. (See Figure 3-3.)

Note: If a leveling block is unavailable, use a piece of 2x4 lumber (1½" x 3½" wood).

1. Move seat carriage to its forward most position (toward computer,) and make sure that the seat is in the upright position. Do not let seat hit dynamometer.
2. Check that the center leveling glides are raised.
3. Carefully place a suitable leverage tool under the rear of unit and lift until the leveling block can be put in place. Be careful not to damage module with lifting tool.
4. With unit resting solidly on leveling block, adjust leveling glides on Seat Assembly Module until stops contact floor and the glides cannot be turned by hand.
5. Using a 3/4" open end wrench, extend leveling glides an additional 1 turn. Carefully tighten leveling glide lock nuts up against frame. (See Figure 5.)

6. Carefully place the leverage tool under the rear of unit and lift until the leveling block can be removed. Be careful not to damage module with lifting tool. Keep leveling block for future use.

Level the System

1. Place a 2' carpenter's level along the length of the Seat Assembly Module floor (oriented fore and aft). A slight fore/aft angle could cause the seat to have a tendency to "roll downhill" forcing the clinician to "pull uphill" when adjusting the patient position.

To eliminate any fore/aft angle, adjust the rear leveling glides up or down to level NORM's frame.

2. Place the 2' carpenter's level across the Seat Assembly Module floor width (left to right). Check that NORM is level laterally. A lateral angle will cause the seat assembly to rotate to the low end whenever the pedestal locking clamp is released.

To eliminate any lateral angle, adjust the two leveling glides (one on rear leg, one on front leg) on the same side a matching number of turns.

Seat Assembly Module Center Leveling Glides

1. Return Seat Assembly to the rear carriage position. Adjust center leveling glides until stops contact floor and the glide cannot be turned by hand. (See Figure 5.)
2. Using a 3/4" open end wrench, extend leveling glides an additional 1 turn. Carefully tighten leveling glide lock nuts up against frame.
3. With the chair still in the rear carriage position, test that the system is absolutely stable.

Assemble the Accessory Cart

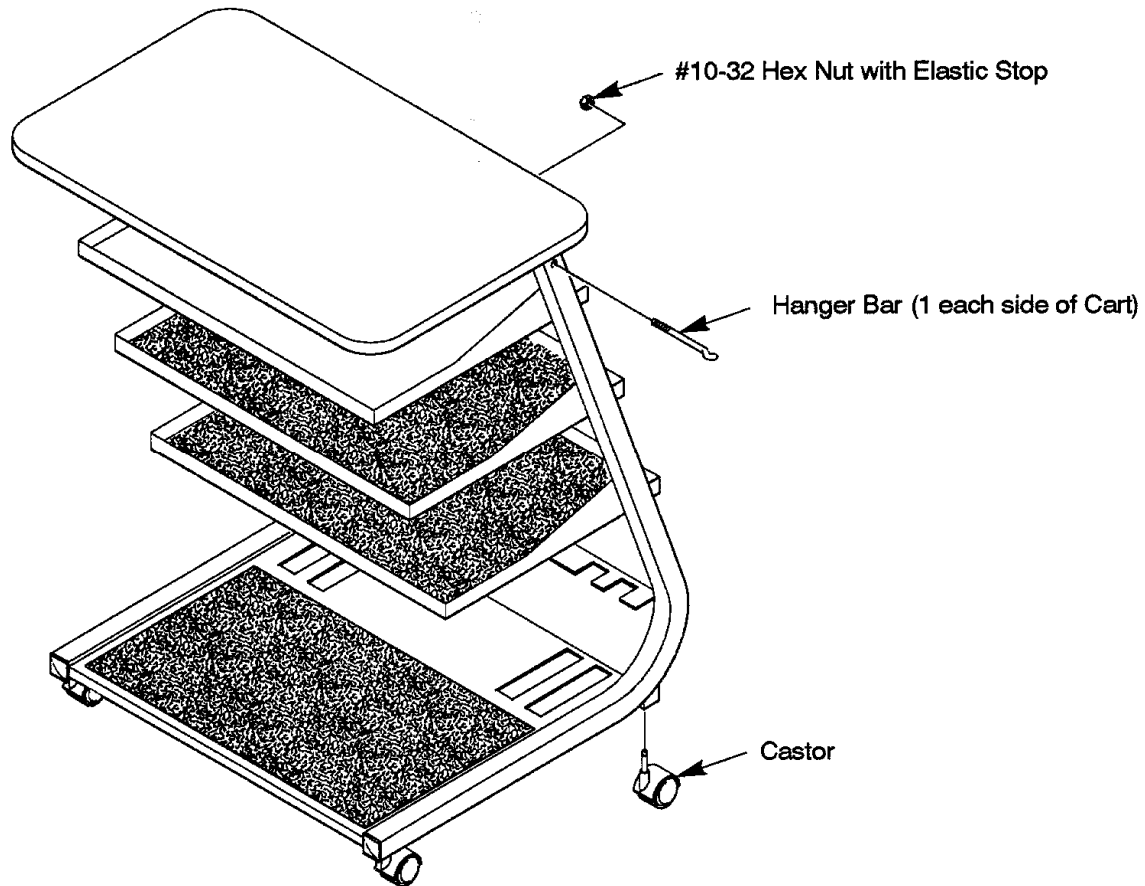


Figure 3-4. The Accessory Cart.

1. Remove cart from box.
2. Thread casters onto bottom of cart.
3. Thread left and right hanger bars from outside cart frame until threads protrude through frame tube. Screw a #10-32 nut onto the exposed threads of each hanger bar, making sure hanger bar hooks face upwards.

Assemble the Printer.

1. Unpack the printer and TEMPORARILY place the printer on the accessory cart.
2. After completing all system checks and replacing the NORM panels, the printer is placed on top of the electronic module.
3. Locate the printer operating manual and follow the manufacturer's instructions for setting up the printer.
4. Set all manufacturer's printer documentation aside. It is to be given to the customer at the completion of the NORM system checks.

Install the Computer

Note: Follow ESD Guidelines for handling electronic components.

1. Slide computer into the open space of the Electronics Module base, with electronic connections facing the left side of the unit. (See Figure 7.)
2. Give computer manufacturer's instruction manual and warranty registration to the customer.

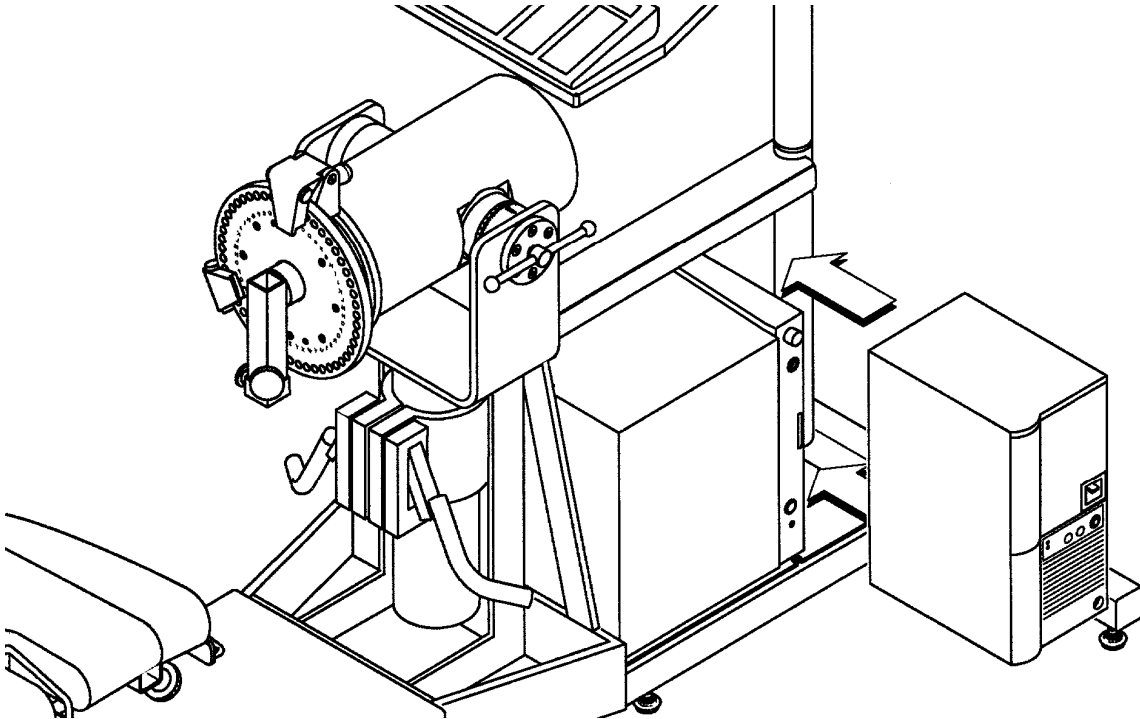


Figure 3-5. Computer Placement.

Install Monitor, Keyboard, and Mouse

1. Screw loose end of ground wire (green/yellow cable) onto underside of monitor shelf. Confirm that ground wire makes contact with metal surface of monitor shelf. See Figure 8.
2. Carefully place monitor, keyboard and mouse on monitor shelf. Use installed Velcro fasteners to hold the keyboard and monitor securely on the shelf.
3. Run keyboard cable over the monitor shelf (hangs off rear of shelf) and connect it to rear of computer. See Figure 8 & 9.
4. Encase cables from monitor, keyboard and the ground wire in the split flexible conduit (provided.) Remember to leave enough slack at the rear of the monitor so the monitor arm can swivel.

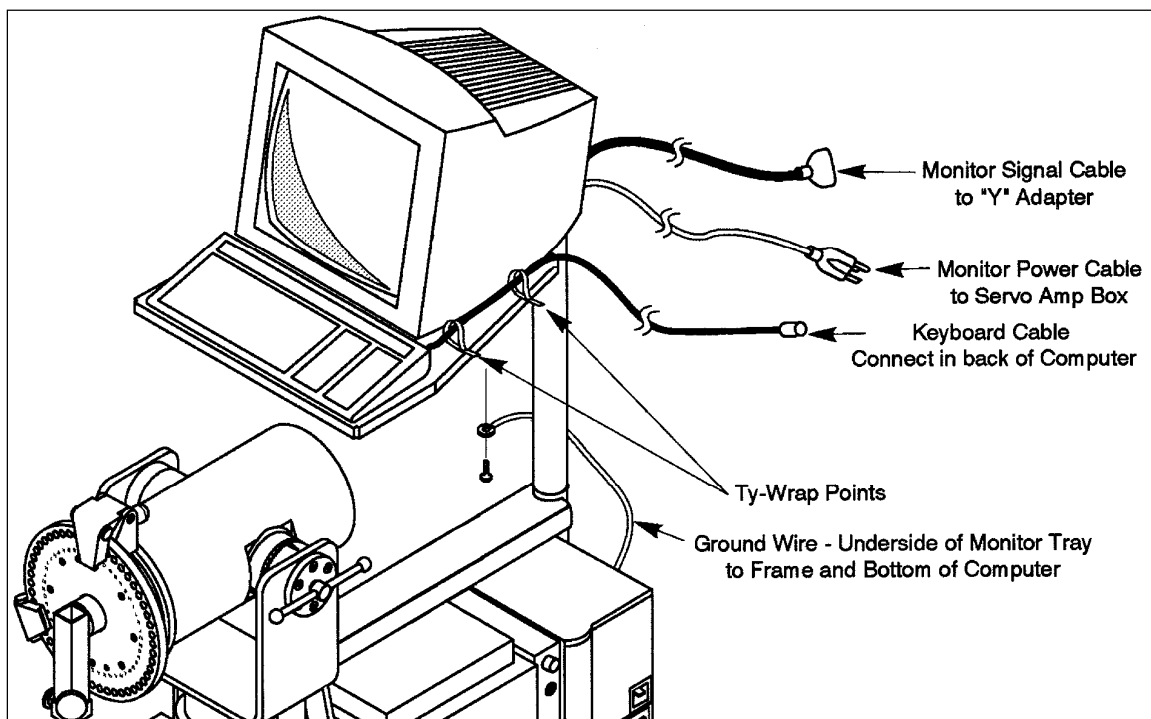


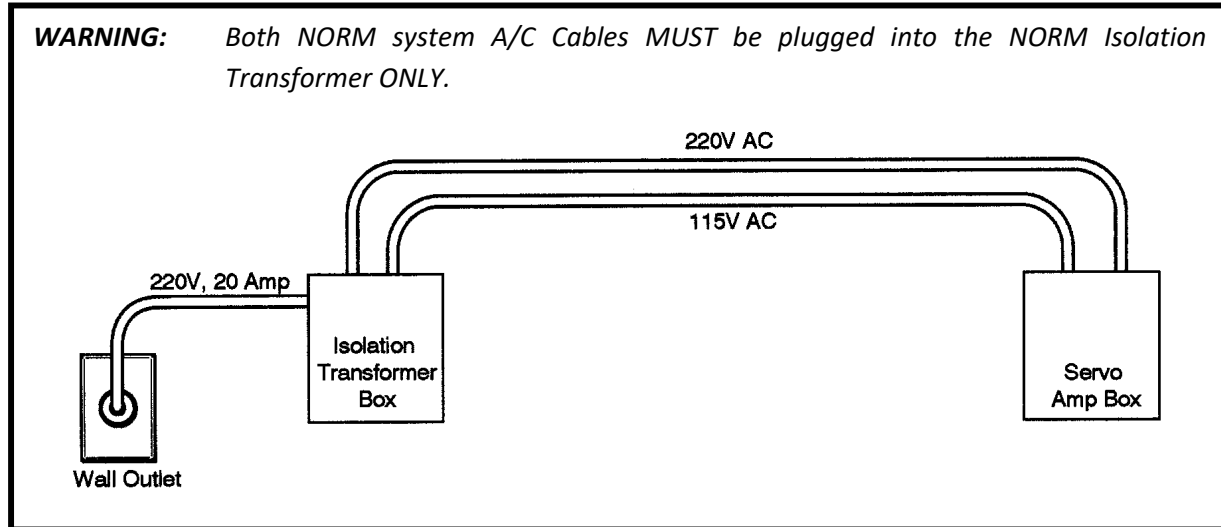
Figure 3-6. Monitor Installation.

Install Computer Data Cables

1. Install the HUMAC USB cable into any USB slot at the rear of the computer.
2. Install printer data cable into any USB slot at the rear of the computer.
3. Install printer A/C power cable into any Servo Amp receptacle.
4. Install the monitor signal cable to the video connector at the back of the computer.
5. Install monitor power cable into any Servo Amp receptacle.
6. Install the speaker signal cable into the speaker connector at the back of the computer.
7. Install the speaker power cable into the any Servo Amp receptacle.
8. Install A/C power cord from computer into any Servo Amp receptacle.

Make Electrical Connections

1. Unscrew the receptacle cover bracket from the transformer box and set it aside.
2. Install the 220V line from the Servo Amp Box into Transformer Box 220V receptacle.



3. Connect the 115V line from the Servo Amp Box into Transformer Box 115V receptacle.
4. Screw the receptacle cover bracket (removed in step a) over the two Servo Amp plugs in the Transformer Box.

WARNING: The receptacle cover bracket *MUST* be reinstalled across the plugged in 220V and 115V receptacles on the Transformer Box. See Figure 9.

5. Install the hand held patient comfort switch into the front of the HUMAC Interface box.
6. Install the HUMAC USB cable into the front of the HUMAC Interface box.
7. Install the line cord from the transformer into the dedicated 220VAC, 20 amp wall outlet. (See Figure 9.)

NORM System Cable Connections

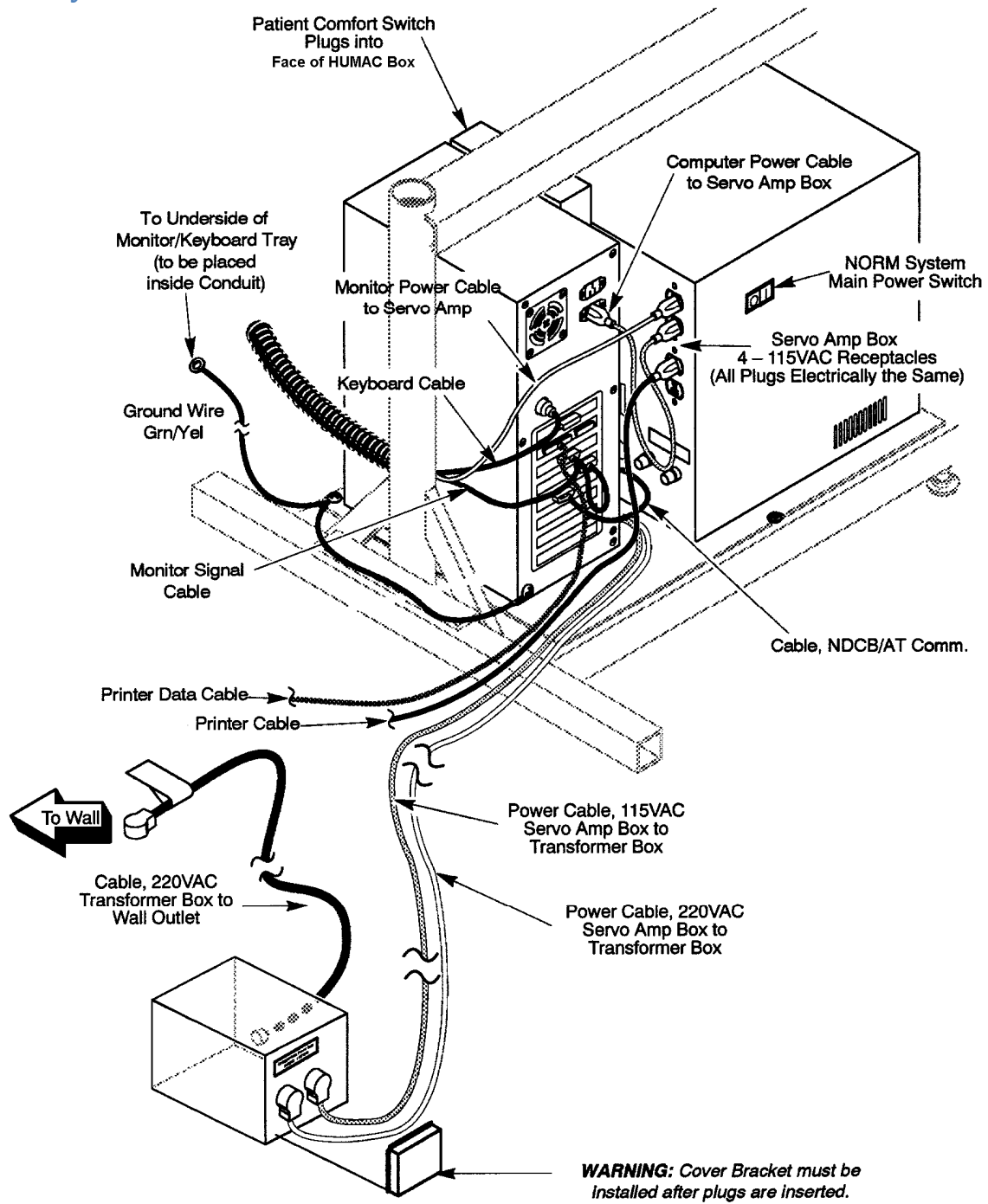


Figure 3-7. Cable Connections.

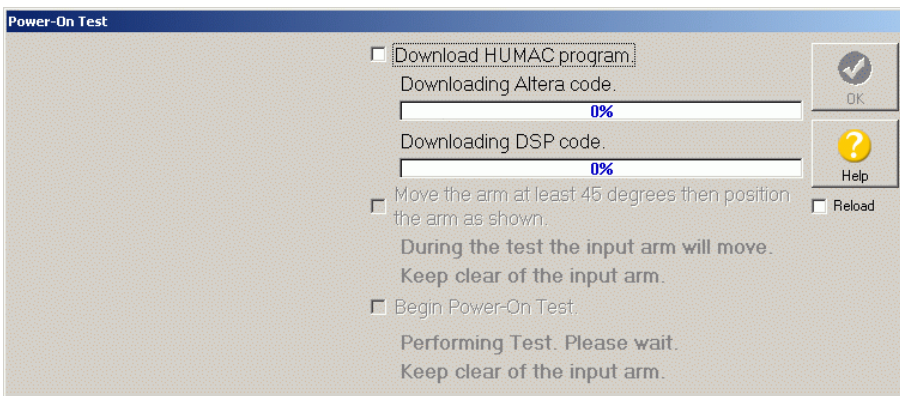
SECTION 4. SYSTEM POWER-UP

1. Turn on system switch.
2. Turn on peripherals (printer, monitor and computer.) The NORM runs through its hardware and software checks; at their completion, the Microsoft Windows™ Desktop with the HUMAC Icon is displayed.

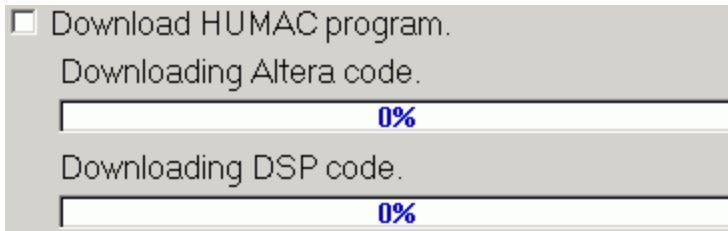


Note: The computer screens shown on this page and the following pages may vary according to the software version loaded on the NORM System.

3. Double-click the HUMAC for Windows icon to start the HUMAC program.
4. If the HUMAC Demo Mode message is displayed:
 - a. Click **OK**.
 - b. From the **File** menu, select **Preferences**.
 - c. Set the **Machine** to “NORM” and the **Interface** to “USB”.
 - d. Click **OK**.
5. The HUMAC Power-on Test screen is displayed.

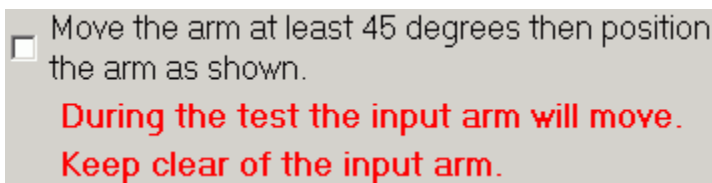


6. Click the Download HUMAC program box. The HUMAC will download the program code to the interface.



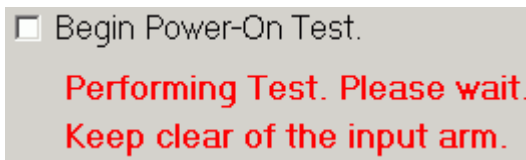
- After the program is downloaded, the HUMAC powers-up the NORM servo amplifier. When the next step is enabled you should move the CYBEX arm at least 45 degrees and then position the arm at 6:00 (pointed straight down).

IMPORTANT: The input adapter must be positioned straight down before you click the next checkbox.



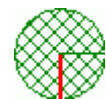
- When you check the next box the HUMAC runs the dynamometer power-on-test.

IMPORTANT: During the Power-On Test the input adapter will move slightly. It is very important that you not touch or be near the input arm during the Power-On Test procedure.



- If the Power-On Test completes successfully, the OK button will be enabled. Click OK to continue. If you receive an error, contact CSMI Technical Support at 781-297-2034.

- Using one finger, apply a slight pressure on the input arm to move it and verify that it “tracks” or follows your finger. You will be able to hear the motor running with the arm’s motion. The marker on the screen’s “clock” or circle diagram moves to correspond to the input arm movement and the torque and position numbers to the right of the diagram changes.



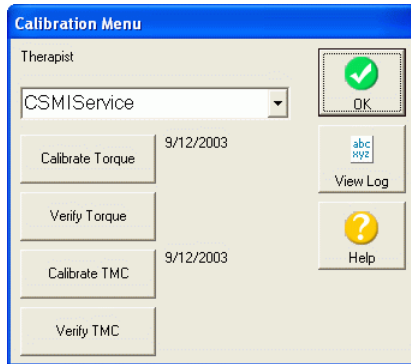
Tech Note: If the system doesn’t track properly call CSMI Technical Support. Before placing the service call, have the packing slip or shipping papers and the customer’s phone number available.

The HUMAC NORM System is now operational.

11. Continue with calibration procedures, patient testing and report print-out procedure.

SECTION 5. PERFORM SYSTEM CALIBRATION

1. On the **Utilities** menu, click **Calibration**.
2. From the **Calibration Menu**, enter **CSMIService** in the **Therapist** field.



Calibrate Torque

1. From the **Calibration Menu**, click **Calibrate Torque**.
2. Setup the dynamometer for the calibration. Only the Knee/Hip Adapter should be installed on the dynamometer input arm. Click the box when the dynamometer is positioned correctly.

Place the arm at 6:00.
Set the arm to number 45. (Pin should click in-place.)
Set ROM stops to gray "D" and gray "U".
Set the tilt to 0 degrees.

3. Raise the input adapter toward 12:00 (straight up) until the arm locks into isometric mode. Click the box after the arm locks at 12:00.

Move the arm to 12:00.

4. Carefully load 100 pounds of weight onto the Knee/Hip adapter. After the weights are loaded, make sure the monitor and keyboard are clear of the falling weight, stand clear of the dynamometer input arm, and check the box. The arm will begin to fall.

Place 100 pounds on the arm.

5. After the arm reaches 6:00 (straight down) the following box will be highlighted. Remove the weights and then check the box.

Remove all weight from the input arm assembly.

Verify Torque

The HUMAC does a two-point verification. You will be asked to perform a weight drop with 100 pounds followed by a weight drop with 25 pounds.

1. On the **Utilities** menu, click **Calibration**.
2. From the **Calibration Menu**, click **Verify Torque**.
3. Setup the dynamometer for the verification. Only the Knee/Hip Adapter should be installed on the dynamometer input arm. Click the box when the dynamometer is positioned correctly.

Place the arm at 6:00.
Set the arm to number 45. (Pin should click in-place.)
Set ROM stops to gray "D" and gray "U".
Set the tilt to 0 degrees.

4. Raise the input adapter toward 12:00 (straight up) until the arm locks into isometric mode. Click the box after the arm locks at 12:00.

Move the arm to 12:00.

5. Carefully load 100 pounds of weight onto the Knee/Hip adapter. After the weights are loaded, make sure the monitor and keyboard are clear of the falling weight, stand clear of the dynamometer input arm, and check the box. The arm will begin to fall.

Place 100 pounds on the arm.

6. After the arm reaches 6:00 (straight down) the following box will be highlighted. Remove the weights and then check the box.

Remove all weight from the input arm assembly.

7. The HUMAC will then repeat the weight drop with 25 pounds. Remove all weights from the dynamometer. Click the box when the dynamometer is positioned correctly.

Place the arm at 6:00.
Set the arm to number 45. (Pin should click in-place.)
Set ROM stops to gray "D" and gray "U".
Set the tilt to 0 degrees.

8. Raise the input adapter toward 12:00 (straight up) until the arm locks into isometric mode. Click the box after the arm locks at 12:00.

Move the arm to 12:00.

PERFORM SYSTEM CALIBRATION

- Carefully load 25 pounds of weight onto the Knee/Hip adapter. After the weights are loaded, make sure the monitor and keyboard are clear of the falling weight, stand clear of the dynamometer input arm, and check the box. The arm will begin to fall.


Place 25 pounds on the arm.

- After the arm reaches 6:00 (straight down) the following box will be highlighted. Remove the weights and then check the box.

Remove all weight from the input arm assembly.

- The HUMAC will display the verification results.

Calibration Results			
Success			
Expected Value:	42.0	154.5	ft-lbs
Measured Value:	41.7	153.7	ft-lbs
Percent Error:	0.7	0.5	%
Percent Full Scale Error:	0.1	0.2	%



Note: If the HUMAC reports Verification Error, you should repeat the calibration and verification procedures. If the HUMAC reports an error a second time, contact CSMI Technical Support.

Print Calibration Report

- From the Calibration Menu, click the **View Log** button.
- From the View Log window, click the **Print** button.
- Click the **X** button to close the View Log.
- Click **OK** to exit the Calibration Menu.

SECTION 6. PERFORM A MOCK TEST

Create a Patient



1. Click the **Patient** button .
2. From the Patient Selection screen, click the **New** button.
3. From the Patient Background Information screen, enter “CSMIService” as the Patient’s Last Name and the system Serial Number as the ID. Click OK to continue.

Select a Pattern



1. Click the **Test** button .
2. From the Pattern Selection screen, single click “Knee Extension/Flexion” and click the **OK** button.

Joint	Motion	Specifier
Ankle	Inversion/Eversion	
Ankle	Plantarflexion/Dorsiflexion	Prone
Ankle	Plantarflexion/Dorsiflexion	Supine
Chest	Extension/Flexion	
Elbow	Extension/Flexion	
Forearm	Pronation/Supination	
Hip	Abduction/Adduction	
Hip	Extension/Flexion	
Hip	Internal Rotation/External Rotation	
▶ Knee	Extension/Flexion	
Knee	Extension/Flexion	Prone
Knee	Internal Rotation/External Rotation	

Select a Protocol

1. Click the **Delete** button to delete all sets in the displayed protocol.
2. Click the **Add** button to add a new set.
3. Program the set as follows:

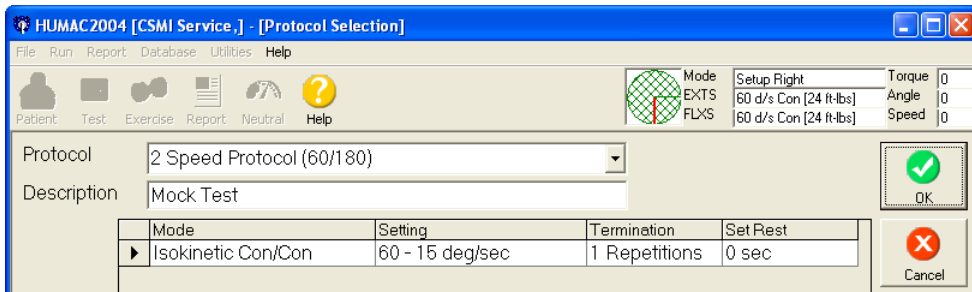
Parameter	Setting
Mode	Isokinetic
Action	Con/Con
Set Termination	1 Rep
Set Rest	0
Trial Reps	0
Trial Rest	0
Speed EXT/FLX	60/15
Cushion	0
Concentric Torque Limit ADBS/ADDS	500/500
Eccentric Torque Limit ADBS/ADDS	0/0
Torque Threshold	0

The screenshot shows a software window titled "Protocol" with the following settings:

- Mode:** Isokinetic (selected), CPM, Isometric, Isotonic.
- Action:** Con (EXTS) / Con (FLXS) (selected), Con (EXTS) / Ecc (EXTS), Con (FLXS) / Ecc (FLXS), Ecc (EXTS) / Ecc (FLXS).
- Set:** Termination: 1 Repetitions; Rest: 0.
- Trial Reps:** Reps: 0; Rest: 0.
- Isokinetic Speed:** EXT=FLX: 60; EXT: 60; FLX: 15; Cushion: 0.
- Torque Limits:**
 - Concentric:** EXTS=FLXS (checked), EXTS: 500, FLXS: 500.
 - Eccentric:** EXTS=FLXS (unchecked), EXTS: 0, FLXS: 0, Torque Threshold: 0.

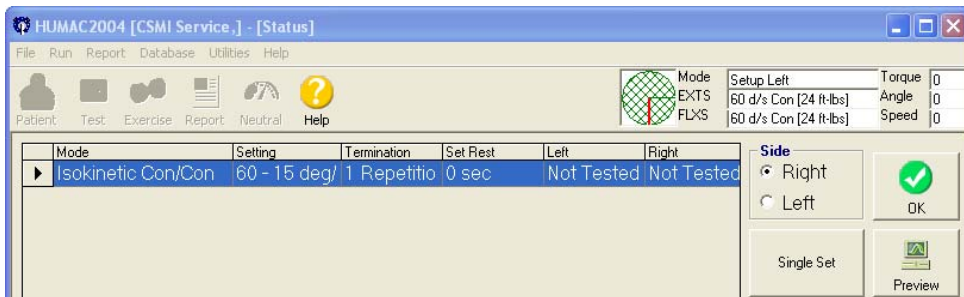
Buttons for OK, Cancel, and Help are visible on the right side of the window.

4. Click **OK** to save the Set.
5. Enter "Mock Test" as the **Description** in the Protocol Selection screen.
6. Click **OK** to save the Protocol.



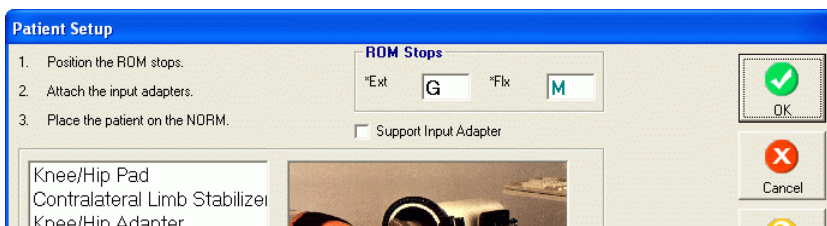
Performing the Test

1. From the Test Status screen, click the **Right** side. Click **Single Set**.



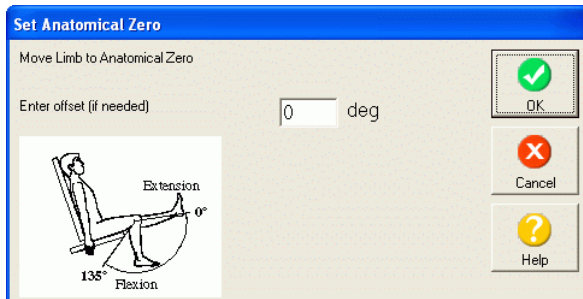
Dynamometer Settings

1. Set the ROM Stops at Teal “V” and White “F”.
2. Install the Hip/Knee adapter at the 37 setting. Remove any pads from the adapter.
3. Click OK to save the settings.



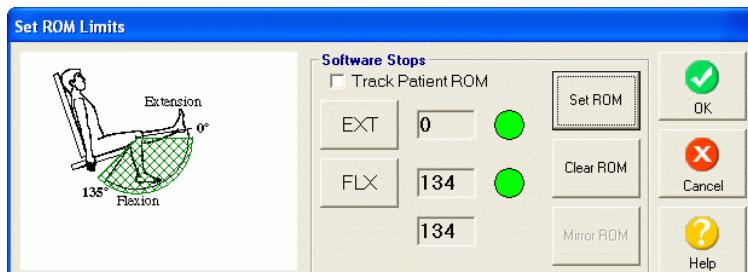
Anatomical Zero

1. Position the arm against the White “F” stop.
2. Click **OK** to set the Anatomical Zero.



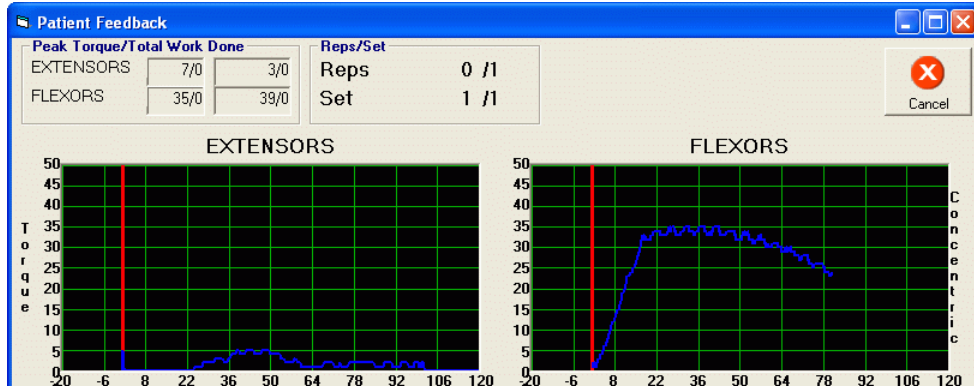
Set ROM Limits

1. Position the arm against the White “F” stop and click the **EXT** button.
2. Position the arm against the Teal “V” stop and click the **FLX** button.
3. Click the **Set ROM** button.
4. Click **OK** to save the settings.



Perform the Test

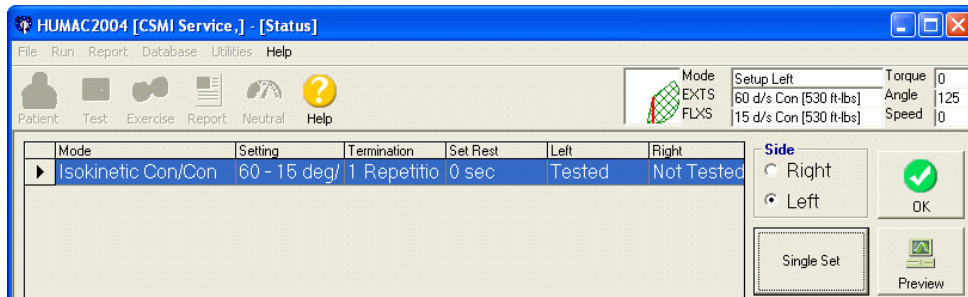
1. The HUMAC will instruct you to place the arm in full Flexion. Position the arm straight down and place the single 25 pound calibration weight on the adapter. Move the arm against the Teal “V” stop. The feedback display will appear.
2. Perform a single repetition by raising the arm to the White “F” stop. After you reach the stop, allow the arm to begin falling smoothly.
3. After the arm moves to straight down, if the feedback display is still showing, gently move the arm against the Teal “V” stop and release the arm.



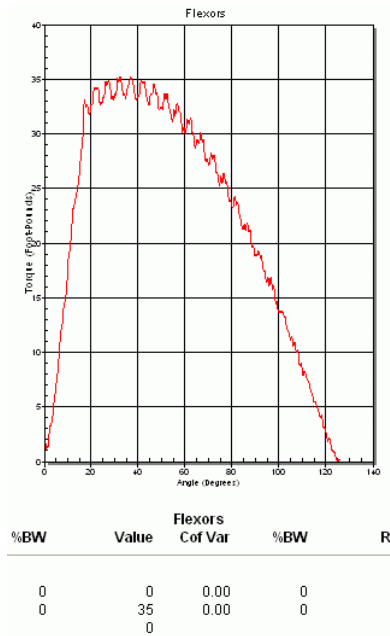
- Repeat the test for the Left side.

Printing the Report

- From the Status screen, click the Preview button.



- The HUMAC will display a short report. Verify the Flexion torque is **35 ± 2 ft-lbs** (45 to 50 nm).



Ending the Mock Test.

1. Click the **Print** button to print the test.
2. Click **OK** to close the Print Preview window.
3. Click **OK** to exit the Test Status screen.
4. Click **Yes** to the *"Not all test were run"* message.
5. Click **OK** to exit the Print Report screen.

SECTION 7. COMPLETING THE INSTALLATION

Test the Patient Comfort Switch

1. With the NORM powered-on, press the patient comfort switch. The HUMAC should report Error 2001, Patient Comfort Switch Pressed. If the HUMAC does not report the error, contact CSMi Technical Support.
2. From the **File** menu, select **Exit**.

Close the System

1. Replace both plastic enclosures on the Electronics Module using the 10 sheet metal screws.
2. Give all product documentation to the customer.
3. At the conclusion of the installation, FAX the mock test report and installation checklist to CSMi.