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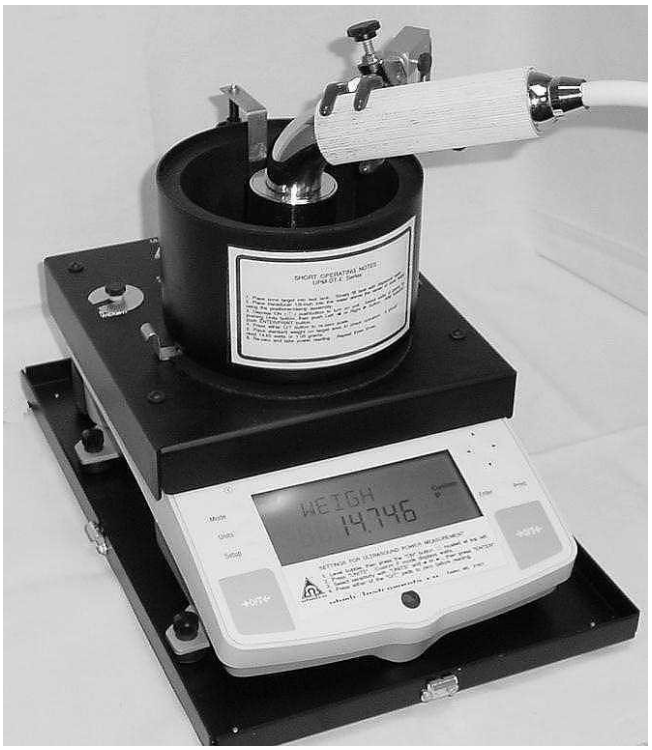
ULTRASOUND POWER METER
Models UPM-DT-1 & 10



OPERATOR'S MANUAL

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INTRODUCTION

Measurement of power output levels of diagnostic and therapeutic ultrasound equipment has become increasingly important to determine exact patient exposure levels in case a potential risk exists to the patient. Since the Radiation Control for Health & Safety Act of 1968 and the 1976 Medical Device Amendments to the FDA Act became effective, all manufacturers of diagnostic Doppler ultrasound equipment are required to submit information regarding their maximum peak and average exposure level, beam patterns, and other pertinent information. Hospitals are responsible for regularly scheduled testing (every six months) of output power and safety to maintain their accreditation.

The Ultrasound Power Meter, Model UPM-DT series, is designed to measure the ultrasound power output of diagnostic or therapeutic transducers up to 30 watts. The principle of measurement is the radiant force method. The UPM-DT-1 and UPM-DT-10 are mechanically identical, each having a positioning clamp to hold the transducer in de-gassed water above a conical target. The ultrasonic energy passes through the water to reflect off the target and is then absorbed by the rubber lining. The radiant power is directly proportional to the total downward force (weight) on the target. This weight is then transferred through the target support assembly to the electro-mechanical load cell inside the scale. The cell is in a computer-controlled feedback loop and produces a digital readout in watts of power (custom units) or grams of force. The choice of units (grams or watts) is selected by front panel pushbuttons. The units are supplied with a plug-in 120 VAC to 24 VAC 50/60Hz adapter. A mechanical shock mounting in the carrying case protects the electronic balance mechanism. Model UPM-DT-1 has a display resolution of ±2 milliwatts and Model UPM-DT-10 has a display resolution of ±10 milliwatts.

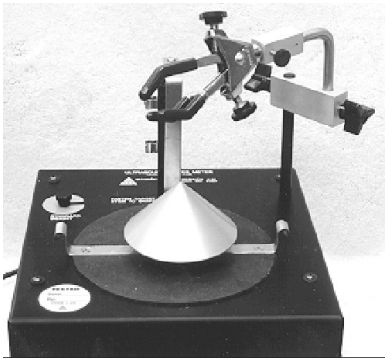
UNPACKING THE UPM-DT POWER METER

The power meter comes complete with all accessories in a sturdy carrying case. To make ultrasonic measurements, the water tank requires only one pint of de-gassed water. If de-gassed water is not available, use distilled water, NOT tap water.

The following replacement parts can be ordered if necessary from Ohmic :

- Test Tank with Rubber
- Positioning Clamp Assembly
- Cone Assembly
- Calibration Weight Standard [specify Ohmic #53001]
- Detachable Line Cord / 120 VAC Adapter
- Instruction Manual [specify “DT1-10_MANUAL.PUB”; available in PDF format]
- Carrying Case

Front view of UPM-DT-1 & 10. Shown is the electronic balance, base assembly, test tank & transducer positioner.



The picture above shows the cone target assembly and transducer positioner (Tank not shown).

The rear panel of the UPM-DT Series provides power and RS-232 computer / printer connections. Adjustments to level the unit are made by rotating the rear stands.

SELECTING A LOCATION FOR OPERATION

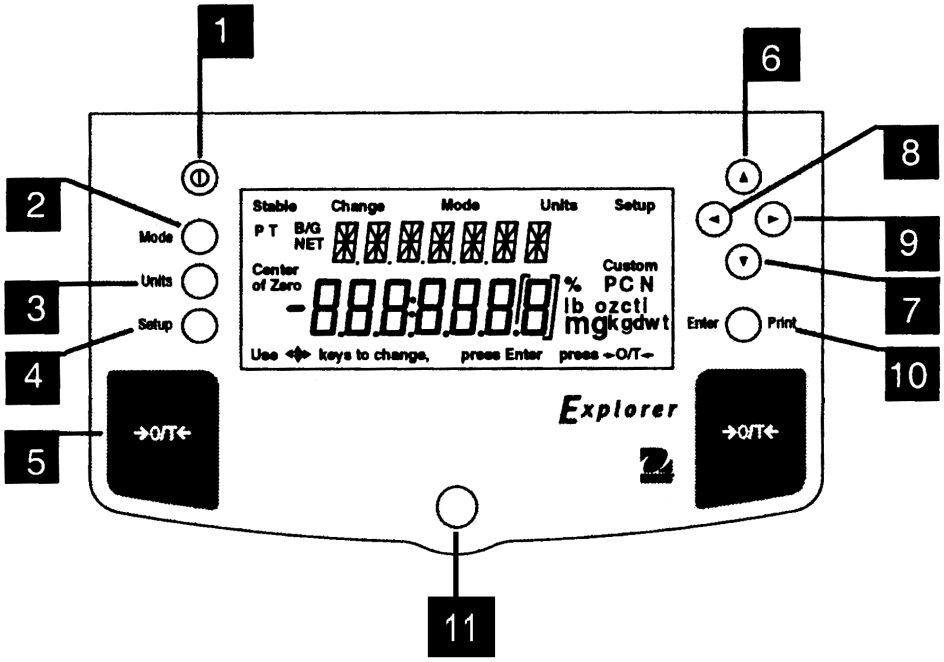
The UPM-DT-1 & 10 Power Meters should always be used in environments free from excessive air currents, corrosives, vibration and temperature or humidity extremes. These factors will affect the displayed readings.

DO NOT operate the Power Meters:

- Next to open windows or doors causing drafts or rapid temperature changes
- Near air conditioning or heat ducts
- Near vibrating, rotating or reciprocating equipment
- Near magnetic fields or equipment that generate magnetic fields
- On an unlevel work surface

Allow sufficient space around the instrument for ease of operation and keep away from radiant heat sources. Never set any material on the Power Meter or place your hands or fingers on it while taking readings.

PANEL CONTROLS & DISPLAY INDICATOR



1. **Power On/Off** button
2. **Mode** button; selects standard weighing and animal weighing modes
3. **Units** button; selects grams-P-C-N-Custom units
4. **Setup** button (service use only)
5. **➔O/T←** button; when pressed, sets the unit to zero
6. ▲ when pressed, travels up through menus
7. ▼ when pressed, travels down through menus
8. ◄ when pressed, travels to the left through menus
9. ► when pressed, travels to the right through menus
10. **Enter/Print** button; when in menus, selects items on display; otherwise prints data
11. **Leveling Indicator**; indicates leveling position of the balance

Not shown:

- **Leveling feet**; used to level the balance (located at rear)
- **Hold-Down Clip**; located under tank; secures tank to unit (for transportation only)

OVERVIEW OF DISPLAY INDICATORS

- **Use ► or ◄ key to change:** Used to prompt the user while navigating through the menu system.
- **Stable:** Indicates that the measured value has become stable.
- **Change:** Is displayed together with **Mode**, **Units** or **Setup**, signifying that a change to balance settings is being performed.
- **Mode:** Is displayed when the Mode button is pressed. Allows the user to know what area of the balance menu is being addressed.
- **Units:** Is displayed when the Units button is pressed. Allows the user to know what area of the balance menu is being addressed.
- **Setup:** Is displayed when the Setup button is pressed.
- **Custom:** Displays total power output in watts.
- Symbols for weighing units include:

	DT-1	DT-10
g = grams	x.xxx	x.xx
p = custom watt units	x.xxx	x.xx
c = custom watt units	x.xx	x.x
n = custom watt units	x.x	x.

OPERATING PROCEDURE

1. Remove the top of the carrying case by unlatching the clamps located on each side. The Ultrasound Power Meter is mounted on the base of the carrying case. **For all applications, the unit must be removed from the carrying case base, by removing the 4 thumbscrews at the sides of the unit.**

2. Place the UPM-DT on a stable and level surface (use the Leveling feet and indicator on the unit). Avoid air currents and mechanical vibrations. Level unit as much as possible.

3. Loosen the positioning clamp and remove target from the test tank where it is normally stored.

4. Place the back of the tank against the target sleeve. Lower the target rod into the concentric test sleeve located behind the test tank, which simultaneously place the cone target into the tank. If the cone can swing in an arc, it is not down far enough. Tip the rod back slightly to fully engage the rod.

5. Fill the test tank to ¼ inch below the top of the rubber liner with recently de-gassed water at room temperature. *(To obtain de-gassed water, boil distilled water for 20 minutes, fill a jar completely, cover surface with saran wrap, and allow to cool)*

6. By means of the positioning clamp, attach the transducer head and place its radiating face 1/8" to 1/4" inch below the water level, parallel to the water surface, and directly above the center of the cone. Check transducer surface for uniform wetting (no air pocket or bubbles should be on its surface).

7. Plug the line cord/adapter into a 120 VAC, 50/60Hz power outlet and depress the ON/OFF button.

8. Allow 5 minutes for the scale to stabilize. With no ultrasonic power applied to the transducer, press either of the two **➔O/T←** buttons to zero the unit.

9. Check response using the 1 gram weight. 1 gram is equal to 14.65 watts.

10. Apply power to the Transducer Under Test (TUT). Re-zero before each measurement and take your power reading when the display has stabilized. Determine the maximum peak power with the maximum duty cycle and pulsed output settings with the equation:

PAVE = Pp ÷ Rtpa

PAVE = calculated average power
Pp = Peak Pulsed Power Setting on unit under test
Rtpa = Ratio of Temporal Peak to Average Power (from each manufacturer)

11. To calculate the watts/cm^2 output, take the total watts reading from the unit and divide by the area. The area is **$\pi d^2 \div 4$ (d is the diameter of the transducer)** if the transducer is smaller than the cone. Otherwise, use cone area.

12. After tests are completed, unplug the meter, empty the tank, and place the dry target cone in the tank for protection.

TRANSPORTING THE UPM-DT

Lift off the target cone assembly from the sleeve, empty water into a sealable container, dry the tank and cone, place cone in the tank and clamp the target rod into the storage clips on the side of the target sleeve. Rotate the transducer clamp arm over the top of the tank and stretch the large rubber band between the two hooks of the hold-down clip, over the clamp arm and tank. Place unit on base of carrying case and secure it on posts using knobs provided (for shipping instructions see Page 11).

GENERAL OPERATING NOTES

Line Power / Voltage: UPM-DT Series meters are set to operate on 12 VAC 50/60Hz. The unit is supplied with a 120 VAC adapter. Check for correct line voltage before use. For voltages 220/240 VAC, an optional power adapter and line cord are required.

Measurement Range, Watts & Grams: Model UPM-DT-10 has four ranges. When **Custom P** is showing, the UPM-DT-10 displays watts with a resolution of ± 20 milliwatts or ± 0.02 watts. When the grams indicator **g** is on, the resolution is 10 milligrams (± 0.01 gram). Each gram equals 14.65 watts and 10 milligrams is equivalent to 146.5 milliwatts (rounded to 0.14 watt). Use **Custom C** mode for most therapy equipment testing. If measurement conditions are not stable, use **Unit N** or **Grams** mode (when using the grams mode multiply the readings by 14.65 to obtain watts).

Model UPM-DT-1 also has four ranges. When watts or milliwatts are being measured, a **Unit** indicator below the display will illuminate. **Unit P** appears for ±2 milliwatt resolution; **Unit C** gives ±10 milliwatts, and **Unit N** displays to the nearest ±0.1 watt. Use **Unit C** and **N** for all measurements except the lowest range requiring **Unit P** mode. When the gram **g** sign appears, the display gives readings to the nearest ±1 milligram. Each milligram corresponds to 14.65 milliwatts. Depressing the **Units** button, then ▶ or ◀ buttons will select the desired range.

Re-Zero / Tare: By depressing the **➔O/T←** button, the meter will zero at the present balance condition. During re-zeroing, the display will be blank until the microprocessor senses a stable condition. If no ultrasound force is applied, then the display will simply indicate true zero reference; otherwise the applied ultrasound will become the offset zero reference. This feature is convenient for automatic zero setting before taking a reading, but also to balance out a fixed ultrasonic power setting and to measure incremental ± deviation from this mean setting.

Set Up: If you accidentally get into the **Setup** menu, push the ▶ button until **exit** is displayed, then push **Enter**. The UPM-DT Series Ultrasound Power Meters are custom programmed balances with additional hardware (cone target, tank, etc.) designed to provide ultrasound power readings. Entry into the Setup menu enables a user to modify certain setup parameters with respect to custom units, calibration stability and linearity. Ohmic Instruments Company assumes no responsibility for the performance of these units if user changes to the internal setup parameters or program are made. Any change to the internal program parameters voids the warranty and calibration certification. Should reprogramming to the original parameters be required, the unit must be returned to Ohmic's facility in Easton, Maryland. An hourly labor rate of $75 will be charged and recalibration fees will be assessed.

CALIBRATION

A 1-gram calibration weight is suplied. With the transducer under test turned off, zero the unit by pressing the **➔O/T←** button. Place the weight on the arm of the cone target. Within 10 seconds the unit should read 14.65 watts (± 1%). A set of precision weights and a scale pan assembly is needed to recalibrate the unit. Send the unit to our service department for calibration. A calibration kit is also available. If you accidentally get into **CAL** mode, push the ▶ button until **exit** is displayed, then push **Enter**. It is recommended that these units be returned to Ohmic Instruments Company on a yearly basis for recalibration and recertification.

PROGRAMMING PRINT CONTROL

The Print menu provides a number of options which can be turned on or off. It contains eight submenus: **Auto Print**, which includes selection of Off, Continuous, Interval and Stability; **Inter**, which specifies the time interval for automatic output of displayed data; **Stable**, a data-only feature, **Numeric** only or full display data for output; **PrtDate, PrtTime, Reference**, which prints reference weight value, and **Lock**, which enables you to program balance parameters and to lock the settings.

Procedure:

1. Press the **Setup** button; CAL is displayed.
2. Press ▶ or ◀ button until PRINT is displayed.
3. Press **Enter** button to save setting.
4. Press ▶ or ◀ button until either AUTOPRT, INTER, STABLE, NUMERIC, PRTDATE, PRTTIME, REFEREN, LOCK, or EXIT is displayed.
5. Press **Enter** button to save setting.
6. Press ▲ or ▼ button and select either menu setting or On or Off.
7. Press **Enter** button to save setting.
8. Press ▶ or ◀ button to continue to LOCK or EXIT.
9. Press **Enter** button to save setting.

Auto Print Feature: When enabled, the Auto Print feature causes the balance to automatically output display data in one of three ways: continuously, at user-specified time intervals, or upon stability. Default settings are shown **bold:**

- **OFF**—when set on, turns off the Auto Print feature
- **Cont**—when set on, outputs printed data continuously
- **Inter**—provides a user specified printing interval
- **On Stb**—provides printed data only when a stable reading is achieved

Interval: Can be set to provide a specified printing interval between 1 and 3600 seconds.

Print Stable Data Only: When set On, this feature permits only stable display data to be output. **OFF** is the default setting.

Print Numeric Data Only: When Numeric Data Only function is turned ON, this allows the balance to output only numeric data for the RS-232 output (see page 10). **OFF** is the default setting.

Print Time: When the Time function is set ON, allows the balance to output the current time to the printer. **OFF** is the default setting. See Setting Date and Time below.

Print Date: When the Date function is set ON, allows the balance to output the current date to the printer. **OFF** is the default setting.

Reference: When the Reference function is ON, prints the value of weight used as a reference in either Percent or Parts Counting modes. **OFF** is the default setting.

Lock: **Lock ON/OFF can be changed only when the Hardware Lock switch is set OFF/disabled.** A menu is locked when the menu lock is set ON and the Lock switch is ON. Lock, when selected and turned on, locks all of the entries made under the Print menu. In the locked condition, items may be looked at but not changed in the menu. When set off, entries may be changed. **OFF** is the default setting.

SETTING DATE AND TIME

The UPM-DT Series provides date and time data which can be viewed on a computer or printed out on an external printer. When you put your new instrument into operation for the first time, you should enter the current date and time. These settings are retained as long as the balance remains connected to a power source.

Date is a feature which enables the balance to be set to a U.S. date standard or European. U.S. standard has the month, day and year each separated by a / in the printout. The European date standard has the day, month and year each separated by a period. The default setting is U.S. standard.

Procedure:

1. Press the **Setup** button; CAL is displayed.
2. Press ▶ or ◀ button and select Date from the menu.
3. Press **Enter** button; TYPE is displayed.
4. Press **Enter** button; SET M d y, d M y, y M d, M y d, y d M, or d y M is displayed.
5. Press ▲ or ▼ button and select type of date.
6. Press **Enter** button; SAVED is displayed, then SET is displayed.
7. Press **Enter** button; first digit of date will flash.
8. Using ▲ or ▼ buttons, enter the correct date.
9. When the correct date is entered, press **Enter** button.
10. SAVED is displayed momentarily, and EXIT appears.
11. Press **Enter** button; balance returns to weighing mode.

Time is a feature which enables the balance to be set to the current time in either U.S. standards (12 hour periods) or European/military standards (24 hour periods). The default setting is U.S. standards.

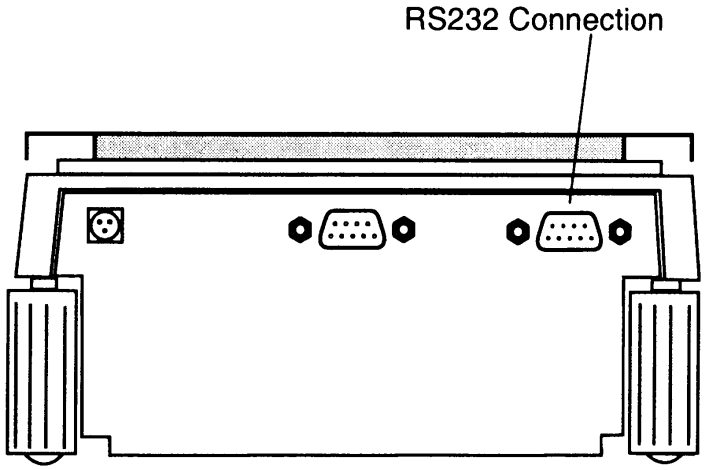
Procedure:

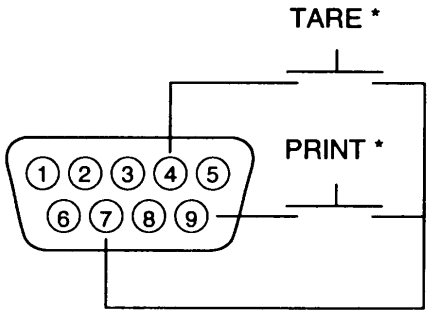
1. Press the **Setup** button; CAL is displayed.
2. Press ▶ or ◀ button and select Time from the menu.
3. Press **Enter** button; TYPE is displayed.
4. Press **Enter** button; TYPE 12 hr is displayed.
5. Press ▲ or ▼ button and select 12 hr or 24 hr.
6. Press **Enter** button; SAVED is displayed, then SET is displayed.
7. Press **Enter** button; SET with time will flash.
8. Using ▲ or ▼ buttons, enter the correct time.
9. When the correct time is entered, press **Enter** button.
10. SAVED is displayed momentarily, and EXIT appears.
11. Press **Enter** button; balance returns to weighing mode.

Adjustments up to ± 60 seconds a month can be made to the balance's internal clock. Repeat the first seven steps, ADJUST is displayed. Using the arrow buttons, enter time correction and press **Enter** button.

SERIAL COMPUTER/PRINTER INTERFACE

IMPORTANT!
An Ohaus RS-232 cable is required to enable the balance to communicate with a computer or printer; a standard RS-232 cable will not work. The cable can be ordered from Ohmic or directly from Ohaus (www.ohaus.com). Cable part numbers are as follows:
25-pin: #AS017-02;
9-pin: #AS017-09.





1. N/C
2. Data Out (TXD)
3. Data In (RXD)
4. Tare (External Signal)*
5. Clear to Send (CTS)
6. Data Terminal Ready (DTR)
7. Ground
8. Request to Send (RTS)
9. Print (External Signal)*

** External PRINT and/or TARE switches may be installed as shown. Momentary contact switches must be used.*

RS-232 INTERFACE: The UPM-DT-1 and UPM-DT-10 Ultrasound Power Meters are equipped with a bi-directional RS-232 compatible interface for communication with printers and computers. When the balance is connected directly to a printer, displayed data can be output at any time by simply pressing **PRINT** or by using the Auto Print feature. Connecting the balance to a computer enables you to operate the balance from the computer, as well as receive data such as displayed weight, weighing mode, stability status, etc.

Hardware: On the rear of the balance, the right hand 9-pin male subminiature "D" connector is provided for interfacing to other devices. The balance will not output any data unless pin 5 (CTS) is held in an ON state (+3 to +15 VDC). Interfaces not utilizing the CTS handshake may tie pin 5 to pin 6 to defeat it.

Output Formats: Data output can be initiated in one of three ways: 1) by pressing PRINT; 2) using the Auto Print feature or 3) sending a print command ("P") from a computer.

Default Settings: Baud-2400; Data bits-7; Parity-None; Stop bits-2; Lock-Off.

RS-232 Commands: All communication is accomplished by standard ASCII format. Characters shown in the following table are acknowledged by the balance. Invalid command response "ES" error indicates the balance has not recognized the command. Commands sent to the power meter must be terminated with a carriage return-line feed (CRFL).

Command Character	Description
?	Prints current mode: Mode, Stability, CR, LF
nnnA	Set Auto Print Feature: nnn = 0 Turns feature OFF nnn = S Output on Stability nnn = C Output is continuous nnnn = 1-3600 Sets Auto Print interval in seconds
P	Print Display Data
xD	Set 1 second print delay: x = 0 for OFF x = 1 for ON
T	Tare (Same effect as pressing ➔**O/T**← button)
ON	Turns balance on
OFF	Turns balance off
TIME	Prints current time
Mm/dd/yy SETDATE	Set date
hh:mm:ss SETTIME	Set time

The UPM-DT Series Ultrasound Power Meters are custom programmed balances with additional hardware (cone target, tank, etc.) designed to provide ultrasound power readings. When utilizing the RS-232 interface certain setup commands may be entered that enable changes to the internal programming with respect to custom units, calibration stability and linearity. ONLY THE COMMANDS ABOVE SHOULD BE USED.

Ohmic Instruments Company assumes no responsibility for the performance of these units if user changes to the internal setup parameters or program are made. Any change to the internal program parameters voids the warranty and calibration certification. Should reprogramming to the original parameters be required, the unit must be returned to Ohmic's facility in Easton, Maryland. An hourly labor rate of $75 will be charged and recalibration fees will be assessed.

SHIPPING INSTRUCTIONS FOR UPM-DT SERIES POWER METERS

To make certain that your Ultrasound Power Meter arrives at our repair department unharmed during shipment, please follow these instructions:

1. Empty water from tank and lock scale.

2. Wrap the target cone in a protective covering and place in tank, **do not put target support bracket in the tabletop tube nor in the clips** (if tank should move during shipment, the bracket will be damaged).

3. Place the weight under the screw provided. Make sure the transducer clamp asembly is screwed in place tightly over the tank and pull the large rubber band over the tank and clamp.

4. Secure unit in case using wing brackets and knobs.

5. Fasten the case lid onto the base, after making certain there is nothing loose inside.

6. The package used for shipping should be strong and large enough to allow for adequate packing material on all sides of unit.

7. Ship to:
   Ohmic Instruments Company
   508 August Street
   Easton, Maryland USA 21601

8. Enclose paperwork (packing slip, purchase order form, letterhead) which includes your return address, contact name and telephone number. A description of the work that needs to be done would be helpful.

By using the above instructions you will avoid additional charges which can be incurred if the unit is not packaged well enough to withstand rough handling during shipment.

SPECIFICATIONS

	UPM-DT-1	UPM-DT-10
Power Range	0 to 30 Watts	0 to 30 Watts
Resolution	±2mW	±10mW
Minimum Detectable Power	1mW	10mW
Display Sensitivity	0.001 / 0.01 / 0.1 Watt	0.01 / 0.1 / 1 Watt
Accuracy	±3% + One Digit	±3% + One Digit
Zeroing Method	Automatic	Automatic
Averaging of Measured Values	100	100
Stabilization	2.5 Second Integration	2.5 Second Integration
Maximum Weight Capacity	210 Grams	600 Grams
Maximum Transducer Size	3" Diameter	3" Diameter
Transducer Operating Frequency	0.5 to 10MHz	0.5 to 10MHz
Test Media	Degassed Water	Degassed Water
Computer Interface	RS-232, 300-9600 Baud	RS-232, 300-9600 Baud
Default Baud Rate	2400	2400
Power	12 VAC, 1 Amp	12 VAC, 1 Amp
120 VAC Adapter Supplied (Adapters for 240 VAC Available on Special Order)	120 VAC to 12 VAC w/ 3-Prong Male Plug and 6-Ft. Cord	120 VAC to 12 VAC w/ 3-Prong Male Plug and 6-Ft. Cord
EMI Rating	Conforms to CE & FCC	Conforms to CE & FCC
Electrical Safety	Conforms to UL & CSA	Conforms to UL & CSA
Size	11" x 15" x 10" (H x L x W)	11" x 15" x 10" (H x L x W)
Weight	22 Lbs. Net	22 Lbs. Net
Carrying Case	Black Anodized Aluminum	Black Anodized Aluminum

MAINTENANCE

Verification of Proper Scale Functioning: Small variations of water surface motion, air currents or mechanical movements may cause uncertainties in power measurements. To test scale accuracy at low levels, set up the scale as in the Operating Procedure (Page 7). Place the 14.65 watt weight on the flat surface of the target arm. Read meter three times; readings should be within ± 1% (for example, 14.504 to 14.796 for UPM-DT-1 and 14.52 to 14.80 for UPM-DT-10). In case of doubt about lower power resolution, repeat the same procedure using light objects such as thin paper slices to produce readings of 5 to 10 counts; repeat readings. Average uncertainty should be within ± 2 counts on the grams as well as on the watts scale. Avoid mechanical and air movement or variations in magnetic fields while making tests.

Out of Measurement Range Warnings: Model UPM-DT-1 accommodates weight differential of ± 200 grams while UPM-DT-10 accommodates ± 600 grams. When the scale exceeds this range, "Error 8.3" will be displayed. Something may be pressing hard on the target or support. "Error 8.4" indicates underweight condition. This will occur if the target is out of place on the UPM-DT-1.

No Display: 1) Check power and line cord; 2) Verify that the line voltage is set correctly.

If you need further assistance, please call our service department.

WATER, TANK SIZE, TRANSDUCER PLACEMENT & TEMPERATURE CONSIDERATIONS

Water as a Measurement Medium: The measurements are to be performed in de-gassed water because ultrasound propagation in water closely approximates that in tissues (see UL-1-1981, AIUM/NEMA Standard Publication). The ultrasonic attenuation in water can be taken as a lower limit on the attenuation which will be encountered in the body. Large areas in the body can consist of low attenuating material such as urine and amniotic fluid. The use of water prevents measurements in a more highly attenuating material such as liver equivalent gels from representing the highest possible intensities which might be encountered in the body. A measurement temperature of 24°C ± 3°C (75°F ± 5°) is chosen for convenience.

De-Gassed Water: Ultrasound power measurement accuracy is affected (by lowering the power reading) if the water contains more than five parts per million of air. To de-gas, boil distilled water for one half-hour, then pour into a suitable container, seal tightly and place in refrigerator. This process will give the required quality. The container should be heat resistant glass; or thick plastic may be used **after** the water has been cooled. Before testing, pour water into tilted test tank to minimize turbulence. The test tank water surface will absorb oxygen and a change of de-gassed water is recommended before each test. An alternative method of de-gassing water is to heat the water to the boiling point, then put a vacuum to it for five minutes.

Water temperature affects accuracy; use a testing temperature of 21 to 27°C ambient. Sonic energy agitates the water surface through heating and scattering. Testing time should be limited to a few minutes; prolonged testing, particularly at higher power levels, will drive out dissolved air and air bubbles will be visible on surfaces in the tank. These bubbles can be gently brushed off.

Transducer Wetting and Placement: After tilting the transducer into the water at a 45° angle, verify that the surface is uniformly wetted; if not, wipe the surface clean. The transducer should be positioned above the cone target. Small variations will occur due to placement. Try various positions above target to obtain a maximum power reading.

ULTRASOUND RADIATION LEVELS

There are no maximum limits in the U.S. for therapy power, only the verification of the displayed setting accuracy to ± 20% of actual output is required. Exposure levels for physical therapy applicator heads range from 100mW/cm^2 to 3W/cm^2. Total power requires multiplication by the radiated cross sectional area in cm^2.

The power limits shown in the following table for diagnostic ultrasound have been extracted from FDA Section 510(k) guidance to manufacturers on submissions and clearance as of February 1993. Refer to the AIUM and FDA publications for complete and up to date testing standards and interpretations. Measurements are done in all standard modes of operation. Power intensity is rated as Spatial Peak Temporal Average (I_{SPTA}) and Spatial Peak Pulse Average (I_{SPPA}). The values in mW/cm^2 are derated for tissue and in parenthesis for the water medium (use the chart below):

PRE-AMENDMENT ACOUSTIC OUTPUT LIMITS

Use	I_{SPTA} Tissue	(mW/cm^2) Water	I_{SPPA} Tissue	(mW/cm^2) Water
Peripheral Vessel	720	1500	190	350
Fetal Imaging & Other *	430	730	190	350
Cardiac	94	180	190	350
Opthalmic	17	68	28	110

* Abdominal, intra-operative, pediatric, small organ (breast, thyroid, testes, etc.), neonatal cephalic, adult cephalic

THEORY OF MEASURING ULTRASOUND POWER WITH THE RADIATION FORCE METHOD

Sound is a form of energy that sets the particles in the isonated medium into vibrational motion. The particles then possess a kinetic energy. If $\mathbf{dP_m}$ is the rate of the flow of this energy about an area **dA**, then the mean acoustic energy is:

Eq. 1 $\mathbf{I = dP_m/dA}$ **I** = Acoustic intensity at a point in that area, Watts/cm^2

When a plane sound wave propagates through a uniform non-absorbent medium, the intensity must be the same for all points in the wave. Let **E** represent the energy density, i.e., the energy per unit volume. When the sound energy passes through a unit cross-sectional area with a speed **c**, the intensity is:

Eq. 2 $\mathbf{I = cE}$ **E** = Energy density per unit volume, ergs/cm^3
c = Ultrasound wave velocity, cm/sec

The radiation pressure effect can be explained by analogy to the application of an alternating electric voltage to a non-linear load. With the non-linear load it appears that both AC and DC components are present. In ultrasonics the non-linear element is the density of the fluid and hence acoustic impedance (load) varies in the same periodical manner as the density. Therefore in ultrasound the two components of pressure, one alternating and the other direct are present. The average AC pressure per cycle is zero, but the DC pressure of radiation is:

Eq. 3 $\mathbf{P\tau = I/C}$ $\mathbf{P\tau}$ = Pressure of Radiation, ergs/cm^3

Therefore, from the above two equations, the pressure of radiation ($\mathbf{P\tau}$) is equal to the energy density (**E**).

Eq. 4 $\mathbf{P\tau = E}$

It is this DC pressure of radiation that can be measured. At low frequencies, below 100KHz, a standard high frequency hydrophone can be used. For higher frequencies, generally used in medical applications, 1-15 MHz, hydrophones are not available. At these frequencies the force can be measured using a precision balance and a radiation force target that is perfectly absorptive. The conversion from force to power can be accomplished using the equation:

Eq. 5 $\mathbf{p = Wgc}$ **W** = measured force, grams
g = acceleration, dynes
c = velocity of ultrasound, cm/sec
p = power, ergs/sec

By combining all constants together and converting from ergs/sec to watts, we obtain a simplified equation that is used to calculate the ultrasonic power once the force is measured:

$\mathbf{P = w(14.65)}$ **P** = Ultrasonic power in watts
w = Ultrasonic force in grams

To determine the ultrasonic watt density (watts/cm^2 or watts/in^2) of a given transducer the P is divided by the cross sectional area of the transducer.

ULTRASONIC THERAPY UNIT INSPECTION RECORD	ACTION						WORK ORDER NO.
		NOT NEEDED		NEEDED		TAKEN	

LOCATION	MANUFACTURER	DATE OF INSPECTION	CARD COLUMNS	WORK ORDER TRANSACTION
UNIT MODEL	TRANSDUCER MODEL	NEXT INSPECTION DUE	1-15	STOCK NO.
UNIT SERIAL NO.	TRANSDUCER SERIAL NO.	TECHNICIAN	18	DETACHMENT
1. PREVENTIVE MAINTENANCE INSPECTION		SAT. / UNSAT.	20-24	INDEX NO.
REMARKS			26-29	PM MANHOURS
			30	PM MINUTES
2. FUNCTIONAL/OPERATIONAL CHECKOUT		SAT. / UNSAT.	32-35	REPAIR HOURS
REMARKS			36	REPAIR MINUTES
3. LEAKAGE CURRENT - CHASSIS - 100µA TRANSDUCER - 50µA		SAT. / UNSAT.	38-43	CONTRACT COSTS

TEST CONDITION	POWER	CHASSIS	TRANSDUCER	45	REPAIRMAN'S CODE
GROUNDED NORMAL POLARITY	ON			47-50	DATE COMPLETED
	OFF			51-52	ACTION CODE
GROUND LIFTED NORMAL POLARITY	ON			53-60	WORK ORDER NO.
	OFF			61-66	RC/CC
GROUND LIFTED REVERSE POLARITY	ON			67-69	DOWN DAYS
	OFF			70-75	QUANTITY INSPECTED
4. GROUND WIRE RESISTANCE (150 milliohms max.)			_____m ohms	78-80	TRANSACTION CODE

5. TIMER	TOL.	SELECTED	TIMED		
< 8 MIN.	± 0.8 MIN.			6. ANNUAL INSPECTION REQUIREMENTS COMPLETED	DATE
8 M. - 10 MIN.	± 10%			7. IS UNIT SUBJECT TO 21CFR1050 REQUIREMENTS?	YES NO
> 10 MIN.	± 1.0 MIN.			8. COMBINED MUSCLE STIMULATOR INSPECTED?	YES NO

REMARKS

WORK PERFORMED BY	LABEL AFFIXED:
	USER MAINTENANCE:

9. CONTINUOUS WAVE MODE CERTIFICATION (Average Power)

WATTS SELECT		POWER ON	POWER OFF	DIFF.	WATTS	ALLOWABLE RANGE	
5	1					3.7 - 6.3	
	2						
	3					SAT.	UNSAT.
	Average of 3 Readings						

WATTS SELECT		POWER ON	POWER OFF	DIFF.	WATTS	ALLOWABLE RANGE	
10	1					7.4 - 12.6	
	2						
	3					SAT.	UNSAT.
	Average of 3 Readings						

WATTS SELECT		POWER ON	POWER OFF	DIFF.	WATTS	ALLOWABLE RANGE	
15	1					11.1 - 18.9	
	2						
	3					SAT.	UNSAT.
	Average of 3 Readings						

WATTS SELECT		POWER ON	POWER OFF	DIFF.	WATTS	ALLOWABLE RANGE	
20	1					14.8 - 25.2	
	2						
	3					SAT.	UNSAT.
	Average of 3 Readings						

WATTS SELECT		POWER ON	POWER OFF	DIFF.	WATTS	ALLOWABLE RANGE	
	1						
	2						
	3					SAT.	UNSAT.
	Average of 3 Readings						

WATTS SELECT		POWER ON	POWER OFF	DIFF.	WATTS	ALLOWABLE RANGE	
	1						
	2						
	3					SAT.	UNSAT.
	Average of 3 Readings						

10. PULSED MODE CERTIFICATION (Amplitude Modulated Waveform)

MAX. PULSE MODE SETTING	POWER ON	POWER OFF	DIFF.	WATTS	CALCULATIONS
(Pp)					
	Average of 3 Readings				= Measured Average Power (Av)

Pp	R_{TPA}	CALC. AVERAGE POWER (Pp / R_{TPA})	Difference Between Measured AV And Calculated AV	Is Difference < ± 0.6% Of (Pp / R_{TPA}) YES NO	REMARKS

11. SHORT TERM LIFE TEST COMPLETE? YES NO

12. ADDITIONAL TEST (Describe in Detail):

WARRANTY

Not withstanding any provision of any agreement the following warranty is exclusive.

Ohmic Instruments Company warrants each instrument it manufactures to be free from defects in material and workmanship under normal use and service for the period of 1-year from date of purchase. This warranty extends only to the original purchaser. This warranty shall not apply to fuses or any product or parts which have been subjected to misuse, neglect, accident, or abnormal conditions of operation.

In the event of failure of a product covered by this warranty, Ohmic Instruments Co. will repair and recalibrate an instrument returned within 1 year of the original purchase: provided the warrantor's examination discloses to its satisfaction that the product was defective. The warrantor may, at its option, replace the product in lieu of repair. With regard to any instrument returned within 1 year of the original purchase, said repairs or replacement will be made without charge. If the failure has been caused by misuse, neglect, accident, or abnormal conditions of operations, repairs will be billed at a nominal cost. In such case, an estimate will be submitted before work is started, if requested.

THE FOREGOING WARRANTY IS IN LIEU OF ALL OTHER WARRANTIES, EXPRESSED OR IMPLIED, INCLUDING BUT NOT LIMITED TO ANY IMPLIED WARRANTY OF MERCHANTABILITY, FITNESS, OR ADEQUACY FOR ANY PARTICULAR PURPOSE OR USE. OHMIC INSTRUMENTS COMPANY SHALL NOT BE LIABLE FOR ANY SPECIAL, INCIDENTAL, OR CONSEQUENTIAL DAMAGES, WHETHER IN CONTRACT, TORT, OR OTHERWISE.

If any failure occurs, the following steps should be taken:

1. Notify Ohmic Instruments Co. giving full details of the difficulty, and include the model, type, and serial numbers (where applicable). On receipt of this information, service data, or shipping instructions will be forwarded to you.

2. On receipt of shipping instructions, forward the instrument, transportation prepaid. Repairs will be made and the instrument returned, transportation prepaid.

SHIPPING TO MANUFACTURER FOR REPAIR OR ADJUSTMENT

All shipments of Ohmic Instruments Co. instruments should be made via United Parcel Service or "Best Way" prepaid. The instrument should be shipped in the original packing carton, or if it is not available, use any suitable container that is rigid and of adequate size. If a substitute container is used, the instrument should be wrapped in paper and surrounded with at least four inches of excelsior or similar shock absorbing material.

CLAIM FOR DAMAGE IN SHIPMENT TO ORIGINAL PURCHASER

The instrument should be thoroughly inspected immediately upon delivery to purchaser. All material in the shipping container should be checked against the enclosed packing list. The manufacturer will not be responsible for shortages against the packing sheet unless notified immediately. If the instrument is damaged in any way, a claim should be filed with the carrier immediately. (To obtain a quotation to repair shipment damage, contact Ohmic Instruments.) Final claim and negotiations with the carrier must be completed by the customer.

Ohmic Instruments Company will be pleased to answer all application or use questions, which will enhance your use of this instrument. Please address your requests or correspondence to: Ohmic Instruments Company, 508 August St., Easton, Maryland 21601, ATTN: Technical Support. Or call Ohmic Technical Support at 410-820-5111.

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