

Ultimate Contour by Ideal Curves

Two Technologies - One Amazing Result!



Owner's Manual

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1 - INTRODUCTION

This manual describes the set up, use, and functions of the Ultimate Contour. Reading this manual is mandatory to ensure that you have a proper and complete understanding of what the device is used for, how it works, and how to use it safely. Failure to read these instructions may result in damage to the device, or risk of injury to you or to the patient. It is advisable to keep this document with the device and refer to it often when questions arise regarding its use and care.

If at any point you have any questions about the use or application of the Ultimate Contour, feel free to contact a customer service representative at 1-888-861-7211, or visit our website at: www.ultimate-contour.com

2 - USE AND SAFETY



PLEASE READ THIS SECTION CAREFULLY BEFORE ATTEMPTING TO HANDLE OR USE THE ULTIMATE CONTOUR SYSTEM. IMPROPER USE CAN CAUSE INJURY

2.1 Indications for Use

The Ultimate Contour is intended for

1. Application of non-thermal radio frequency for relief of minor muscle aches and pains, relief of muscle spasm, temporary improvement of local blood circulation, and temporary reduction in the appearance of cellulite.
2. Application of ultrasound for non-invasive reduction in abdominal circumference.



2.2 Contra-Indications



WARNING: The ultrasound handpiece may be audible or create a ringing or buzzing sensation in the ears that may be very uncomfortable to the patient. Inform the patient of this prior to treatment and for the patient to immediately indicate if this occurs. Reduce the intensity setting or discontinue use.



CAUTION: Applicator heads may become warm during treatment. To avoid thermal injury to the tissue, keep skin wetted with treatment solutions, always keep the handpiece moving along the tissue, and use the minimum intensity setting necessary to achieve the desired results.

- **DO NOT** use on persons under the age of 18.
- **DO NOT** use ultrasound on persons with a Body Mass Index (BMI) under 25.
- **DO NOT** use radio therapy on or near the face or neck.
- **DO NOT** use on pregnant or nursing women, on those who have given birth in the last 12 months, or on those planning to become pregnant.
- **DO NOT** use near plastic or metal parts within the body (example: implants, stents, ports). Do not allow the transducers to contact hard surfaces when activated.
- **DO NOT** use on patients exhibiting any of the following medical conditions: high blood pressure, heart disease or failure, hypertension, hyperlipidemia, diabetes or blood-glucose sensitivity, hepatitis, liver disease, abnormal liver or kidney functions, unstable weight changes ($> \pm 3\%$ in the last 6 months), HIV positive, blood disorders such as coagulopathy or anemia, aortic aneurysm, connective tissue disorders, thyroid disorders, epilepsy, abdominal wall diastasis, hernia, current or previous history of cancer or premalignant tissues.
- **DO NOT** use on patients who have undergone previous body contouring regimens in the last 3 months, or liposuction in the last 6 months.
- **DO NOT** use on skin lesions, open wounds, abrasions, acne, rosacea, tattoos, or on patients with a tendency to form keloids, have generally poor skin quality, or have had botox or similar filler injections near the treatment area within the last month.
- **DO NOT** use on skin with visible or underlying implanted or foreign bodies (body jewelry, replacement

- joints, mesh, clips, orthopedic hardware).
- **DO NOT** use if patients are taking medications such as anti-aggregation medications (NSAIDs), Isotretinoin (Roaccutane), or rosuvastatin (Crestor).
 - **DO NOT** use the device at all on, near, or around implanted electrical medical devices (examples: pacemakers, insulin pumps).
 - **DO NOT** use treatment gels, oils or solutions that have alcohol or a highly flammable substance as the base carrier. Ignition may occur. Avoid letting these materials pool or collect in depressions or body cavities, such as the navel. If alcohol is used for cleaning purposes, allow thorough drying before device use.
 - **WARNING:** Device contains high-voltage components. Changes or modifications to the equipment not expressly approved by Ideal Curves or described in this manual could void the user's authority to operate the equipment. Unauthorized alterations may result in electric shock or damage to patient tissues.
 - **WARNING:** To avoid the risk of electric shock, this equipment must only be connected to a wall outlet or surge protector with a third ground pin socket. Failure of the equipment may result in an unintended increase in output power.
 - **WARNING:** Use of the Ultimate Contour adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, the Ultimate Contour and the other equipment should be observed to verify that they are operating normally.
 - **WARNING:** Use of accessories and cables other than those specified for the Ultimate Contour or provided by Ideal Curves could result in increased electromagnetic emissions or decreased electromagnetic immunity of the Ultimate Contour and result in improper operation.
 - **WARNING:** Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the Ultimate Contour, including cables specified by Ideal Curves. Otherwise, degradation of the performance of this equipment could result.
 - **CAUTION:** Use of ultrasound on body parts other than the waist, or on tissue that has a low adipose or fatty content may result in rapid heating, tissue damage, and/or the formation of fistulas.
 - **CAUTION:** DO NOT store liquids on the unit.
 - **CAUTION:** Use of controls or adjustments or performance of procedures other than those specified herein may result in hazardous exposure to radio frequency or ultrasound energy.
 - **CAUTION:** Always stop the treatment before removing the handpiece from contacting the patient. Removing the handpiece while the energy is emitting may result in electric shock or damage to the tissue.
 - **CAUTION:** Federal law restricts this device to sale by or on the order of a physician.
 - Device is only to be used in a professional medical office environment, where environmental controls are in place. Specifically, the device should not be used in a dry or arid environment where the relative humidity in the room is < 35%. See Section 9.1.
 - When using the ultrasound handpiece, gas bubbles may form at the surface of the handpiece. Ensure that treatment oils are used that are suitable for ultrasound use to maintain contact between the handpiece and the skin (see page 9).
 - Locate the device on a table, counter, or cart when in use. DO NOT place the device on the floor when using.
 - Ensure all other radio frequency emitting devices (example: cell phones, computers and wireless computer devices, routers, wireless phones) or devices that may generate a strong electromagnetic field (example: MRI, electrosurge) are kept more than 3 meters (10 feet) away from this device, the treatment table, the operator, or the patient.
 - Avoid use of the device if liquids are spilled on the unit. Wipe up spills immediately and ensure the unit

- is dry before using.
- Discontinue use if any portion of the system becomes broken, if cracks or deformations develop, or discoloration occurs.
- This product contains no user serviceable parts beyond what is described in this manual.
- Failure of the Ultimate Contour to function as designed may result in an unintended increase in power output.
- Power surges, or loss of power, may cause this device to momentarily lose power or to behave in an unexpected manner. If this occurs or is observed, immediately halt handpiece emissions, then power off and restart the device. Carefully observe device behavior when first resuming use. If any changes are noted, discontinue use immediately.
- Use of the Ultimate Contour contrary to these instructions could constitute misuse or abuse of the product.
-
- **Patient Considerations:**
- Patient should not eat any food at least 2 hours prior to treatment, and at least 1 hour after treatment.
- Patient must not consume any alcoholic beverages at least 48 hours prior and after treatment.
- Ultrasound should only be applied to the waist area. DO NOT apply ultrasound to any other part of the body.
- Risk of neuromuscular stimulation may occur with Radio Frequency usage, particularly on dry skin where an electric arc may occur.
- Reports of “fatty” or cloudy urine, and constipation, have been reported following application of the ultrasound.
- Patient should not participate in a hot shower (warm is OK), hot bath, or sauna immediately after treatment.
- Avoid use of water-based treatment gels as the water may react to the ultrasound energy.
- Avoid use on patients who are connected to an oxygen supply. **DO NOT** use in the presence of flammable gases.
- All treatments performed with this system must be subjected to the same clinical assessment as with traditional techniques. The patient risk and medical history must be considered and understood before treatment. Caution must be exercised regarding general medical conditions not already mentioned which might contraindicate a localized procedure. Medical clearance from the patient’s general physician is advisable when doubt exists regarding the treatment.

2.3 Training

Use of this device is limited to a licensed and trained medical practitioner. Review with your governing medical board and/or licensing agency regarding the licensing and training requirements for using this device. Training for use of this device is available through Ideal Curves. When you purchased this product, arrangement should have already been made for a qualified Ideal Curves staff member to come to your office to conduct on-site training and to observe proper unpacking and setup of the system. If these arrangements have not been made, please contact Ideal Curves to arrange this. Additionally, instructional videos are available at our website: www.ultimate-contour.com.

2.4 Device Safety & Compliance

Carefully review and understand the Indications for Use in Section 2.1, and the Contra-Indications listed in Section 2.2. This device has been designed and certified compliant to applicable national and international safety standards for medical electrical devices of this type. These standards include IEC 60601-1, IEC 60601-1-2, IEC 60601-1-6, EN60601-1, and CAN/CSA C22.2 No.60601-1. This product is also design and constructed in compliance with U.S. FDA regulations regarding electronic products (21 CFR 1010), as well

as IEC 62304, IEC 62366, ISO 13485, ISO14971, and ISO 10993.

The labels on the device and on the packaging serve as evidence of conformity to these requirements. Labeling provided on the unit and the handpieces are important for safety and regulatory purposes and should not be removed, obscured, or altered. The label on the main unit can be found on the back panel adjacent to the power cord inlet. Labeling on the handpieces are on the body of each handpiece. Access to and use of the Ultimate Contour should be limited to clinicians and technicians who are properly licensed and trained to use this device, consistent with national and state regulations. When not in use, the unit should be secured to prevent unauthorized access.

2.5 Performance and Expectations

To demonstrate the stated performance of the ultrasound portion of this device, a clinical study was conducted to identify the effectiveness of this device to reduce the waist circumference of patients using the ultrasound portion. This study evaluated a total of 42 individuals who were treated for 30 minutes at an intensity level of 4 during each treatment session. There were a total of 3 treatment sessions with 5-7 days interval between sessions. The results show that on average a total waist reduction for the entire regimen was 2.0 inches. The study included a 4-week follow-up where the overall waist reduction was still holding at 2.0 inches on average.

This information is provided as a guide to the clinician when discussing expectations and potential results with the patient.

3 - DEVICE DESCRIPTION

3.1 Kit Contents

When first opening the package, please review the contents to ensure you have received everything needed to utilize the Ultimate Contour system:

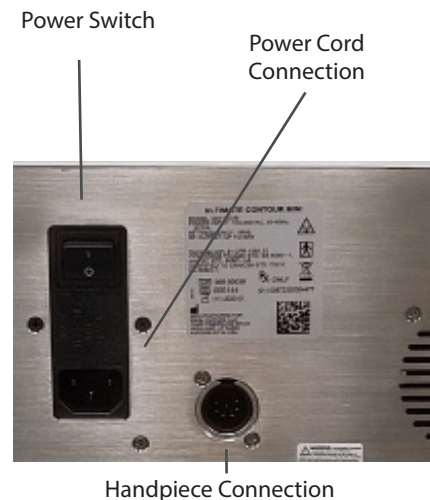
- Ultimate Contour Unit
- 1) Radio Frequency Handpiece
- 1) Ultrasound Handpiece
- Power Cord

3.2 Device Features

Take a moment to familiarize yourself with the design and features of the Ultimate Contour System.



Ultimate Contour
Model: 005-00036



Rear Connection Panel

3.3 Explanation of Symbols

Symbols used on the Ultimate Contour device and within this manual indicate important safety information. These items are now explained:



Non-Ionizing Radiation Hazard



Type BF Applied Part



Dispose of waste electronics responsibly



Date of Manufacture



Manufacturer information



Consult the Owner's Manual



Fuse Rating



CAUTION: Surface may be hot



CAUTION: Risk of Electric Shock

Rx ONLY

Federal law restricts this device to sale by or on the order of a physician.

CAUTION: Make sure the unit is positioned so you can get easy access to the back panel of the unit in case you need to quickly turn the unit off or unplug it.

4 - INSTALLATION AND SET UP

4.1 Office Conditions

The Ultimate Contour should be used in a controlled medical office environment. The Ultimate Contour should be plugged directly into a grounded wall outlet. It may also be plugged into a surge protector provided the surge protector features a ground connection (third pin) and is attached to a grounded wall

outlet. Use of the Ultimate Contour in abnormally hot or cold temperatures should be avoided. Refer to Section 9.1 for the preferred operating temperature. If the unit has been stored or transported in extreme conditions, allow time for the unit to acclimate to room temperature before turning it on and using it. Ensure that the treatment table the patient will be on has no exposed metal surfaces that the patient may come in contact with during the treatment.

4.2 Device Unpacking and Setup

When removing the Ultimate Contour unit and accessories, take care to avoid scratching or damaging any of the components.

- Remove the Ultimate Contour unit from its packaging, and stand the unit upright on a sturdy table or countertop surface.
- Remove the handpieces from the packaging and place these in proximity to the unit. Take care not to twist the transducer cable or bend it in a tight loop.
- Remove the power cord from the packaging. Plug the power cord into the back of the unit. Make sure the power switch on the back of the unit is turned OFF (press on the "O" symbol). Locate a suitable power outlet as described in Section 4.1 above and plug in the power cord. Make sure the unit is positioned so that the power cord may be easily disconnected if needed.
- If needed, clean the unit and handpieces as described in Section 6.

4.3 Registration

Before beginning use of the Ultimate Contour, it is highly recommended that you take a moment to register at www.ultimate-contour.com. Registration facilitates customer service, provides additional information regarding the use of the Ultimate Contour, managing patient expectations, and other useful information.

4.4 Handpiece Attachment

Prior to use on a patient, ensure the desired handpiece has been cleaned consistent with the instructions in Section 6.1. When attaching the handpiece connector to the transducer cable, pay careful attention to the alignment of the connectors. The connectors are designed to only attach in a particular "clock position". If you find the handpiece connector does not attach, DO NOT force it. Slightly rotate the connector and try again until the indexing feature aligns and the connector clicks into place. To detach, squeeze the silver tab on the connector while gently pulling the connector out.

Make sure you attach the handpiece you intend to use. The Ultimate Contour is designed to detect which handpiece is attached (ultrasound or RF) and limit access to controls accordingly. This system is designed for Bipolar RF emissions. A neutral electrode is not necessary.



From Handpiece

Alignment and locking feature



Handpiece connector attaches here, with the locking feature up

5 - DEVICE OPERATION

5.1 Patient Preparation

When scheduling patients for treatment, make sure to advise them of the restrictions and contraindications identified in Section 2, in particular that the patient should avoid alcohol consumption 48 hours prior to the treatment, and to avoid food and beverage consumption 2 hours prior to the treatment. Recommend to the patient to drink at least 1 liter (3 - 12oz bottles) of water per day beginning the day before the treatment and during the course of the entire treatment regimen. Also review with the patient any pertinent restrictions and contraindications listed in Section 2, along with general discussion with the patient regarding their general health and habits, and other existing medical conditions. Advise the patient that during the course of ultrasound treatment, the patient may hear or experience a soft, high-pitched sound. It is recommended that any dense body hair present in the treatment area be shaved or at the very least trimmed to a short length during the course of the treatment regimen. Advise the patient to bathe prior to the visit, and to avoid use of make-up, lotions, or other topical materials so the skin is nice and clean.

It is advisable to conduct an initial consult with the patient to discuss patient motivation for these treatments, and particularly to instruct the patient regarding how the procedure works, what sort of outcomes can be expected, and potential risks that are involved - in particular risks of thermal damage to tissue. This consult may be arranged in connection with the initial treatment.

It is recommended to use a marker to layout on the patient tissues the treatment area, as well as indicate individual spot sizes consistent with the diameter of the handpiece. This will help ensure that all of the treatment area is addressed, and to help avoid overlapping treatment spots - applying excessive energy to a section of tissue - which could cause thermal damage. Make sure to use a marker that will not get wiped away by the treatment oils, but will easily clean off after the treatment.

Use a tape measure and/or skinfold calipers as appropriate to document the circumference of body parts and extent of adipose tissue in the treatment areas. Take measurements prior to the first treatment, and following each treatment. To help the patient visualize the effect of the treatments, take photos before the initial treatment and at various periods during the treatment regimen. Try and be consistent when taking the photos, such as having the patient stand in the same location and using the same camera settings for all photos.

When the patient is ready to begin treatment, have them lie down on the treatment table. The operator should wear protective examination gloves at this point. Make sure clothing is clear from the treatment area a distance of at least 1 inch. Apply a generous amount of the treatment oil to the area, making sure the oil evenly coats the entire treatment area and extends beyond the treatment area. If folds or creases of skin are present, work the oil into these surfaces. Suitable treatment oils are ones with a base content of oils of grapeseed, canola, palm, rosehip seed, flax, and olive.

5.2 Screens and Settings

Make sure the Ultimate Contour unit is fully set up, and the desired handpiece is attached. Turn on the power switch on the back of the unit (press the "I" symbol). After a few moments of starting the programming, the display will show the Home Screen.

NOTE: If at any time the treatment needs to be interrupted or the power to the handpiece stopped for any reason, several methods exist for quick shutdown of the unit:

- Press the Stop button on the screen.
- Press the Safety Stop button on top of the unit (the button will glow red when this is activated).
- Press the power switch on the back of the unit to Off (press the “O” symbol).
- Detach the power cord from the back of the unit.

Home Screen

This is the main menu for the unit. From here, you can select which type of energy you will use (radio frequency or ultrasound), select from tutorial videos in the Media section, or access some basic information and device settings in the Utilities section. To make a selection on this or any of the screens, simply touch the “button” on the screen to make your selection.



Settings Screen

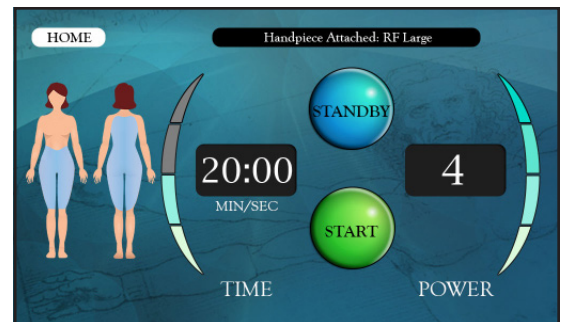
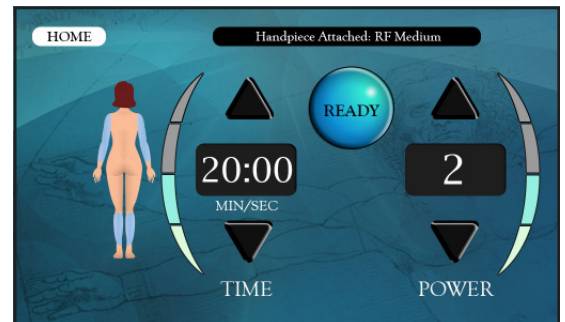
When either the Radio Frequency or Ultrasound energy type is selected, the display shows the control panel for the respective treatment. Functions and features common to both screens are now discussed. Details about specific differences will be discussed in Sections 5.3 and 5.4. The Settings Screen shows:

- The recommended body area that should be treated consistent with the handpiece that is attached (highlighted in blue on the body outline)
- The length of the treatment time that is currently selected
- The relative power level of the energy
- The handpiece that is connected to the unit

Details about specific differences will be discussed in Sections 5.3. To change the treatment time or the power, press the Up arrow to increase the value or the Down arrow to decrease the value. Minutes are selected in quantities of 10 minute increments from 10 to 40 minutes. Intensity is selected at levels of 1, 2, 3, or 4, with 1 being the lowest intensity level and 4 being the highest. **NOTE:** Some time durations and intensity levels may not be available for some handpieces selected. This helps to ensure safe and effective application of the treatment. The table below indicates the recommended device settings for the indicated body parts.

Once the settings are selected, press the Ready Button to prepare the system to activate the handpiece. The Ready button will transition to say “Standby”, and the Start button will appear. At any of these screens, pressing the Home button will return you to the Home Screen. At this point, you may not make adjustments to the treatment Time and Power. If you need to change either of these, press the Standby button to return to the Standby screen.

From this screen, you can also select from tutorial videos in the Media section, or access some basic information and device settings in the Utilities section.





CAUTION: Make sure to select the minimum power level that will achieve the intended results. The maximum power setting presents increased risk of thermal damage relative to the lower settings.

Position the handpiece onto the patient at the first point of exposure. Make sure the skin is still coated with the treatment oil.



CAUTION: Ensure that the handpiece is in direct contact with the skin prior to starting the treatment. Air gaps between the handpiece and the tissue may result in an electric shock.



Remind the patient that they may experience a warming sensation during the treatment, and advise them to indicate if the handpiece feels unbearably hot during the treatment. With everything prepared, press the Start button on the screen to begin the treatment.

During treatment, the Stop button will be present on the screen. The Time indicator will start counting down. The device will emit a beep every 10 seconds during countdown. If you need to interrupt treatment for any reason, or need to lift the handpiece to treat a different area, press the Stop button. Reposition the handpiece as needed, then once the handpiece is in contact with skin again press the Start button to resume the treatment. The unit will continue counting down time where you left off. If you stop the treatment early, and then press the Standby button to return to the Standby screen, the time will reset to the full amount of time you had selected.

CAUTION: Do not lift up the handpiece during treatment. Stop the procedure first before lifting up the handpiece. Do not touch the patient with your hands while the handpiece is active.

When 15 seconds remains in the treatment time, the unit will start to beep once a second indicating the treatment is almost over. Once the timer reaches 0, the unit will automatically deactivate the handpiece and the system will show the Ready screen. The time will reset to the total that you had originally selected. Once the treatment is ended, you can lift up the handpiece.

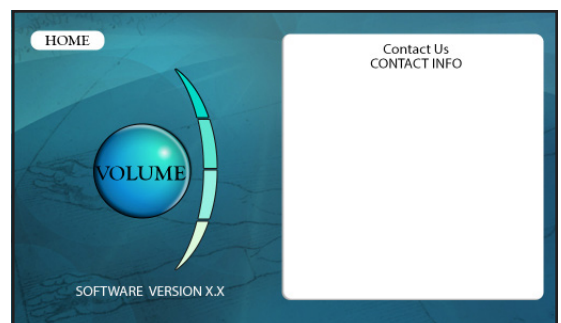
Media Screen

From this screen you can access a number of tutorial videos that demonstrate use of the Ultimate Contour and address some frequently asked questions. You can also find an electronic version of this Owner's Manual for the Ultimate Contour. Press on any of the buttons to launch the video, or view the manual. When done viewing the video or manual, press the Back button at upper left to return to the Media Screen.



Utilities Screen

Here you can adjust the volume of the sounds made by the Ultimate Contour unit. Simply press the Volume button to cycle through the available volume levels. This screen also provides contact information for Ideal Curves in case of questions, as well as the software revision information for the Ultimate Contour.



5.3 Radio Frequency Treatment

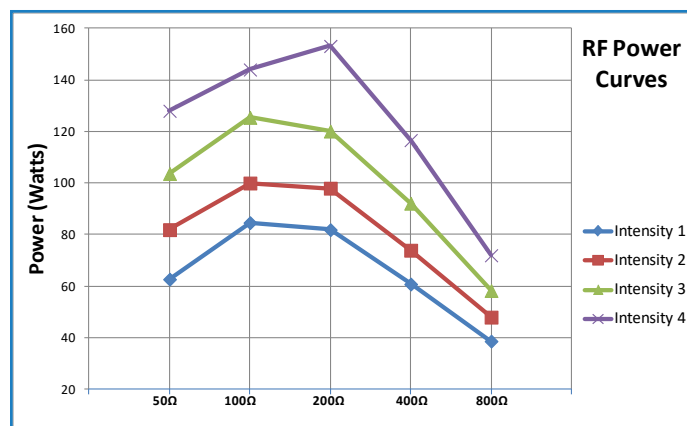
The Radio Frequency treatment is intended to temporarily improve local blood circulation and provide temporary reduction in the appearance of cellulite. This device does not perform surgical or coagulation functions.

- **WARNING** - Do not use on or near the face or neck.
- Large - Recommended for the thighs, hips, buttocks, back, arms, waist, and chest.

BODY PART	HANDPIECE	POWER SETTING	TIME (minutes)
Abdomen	Large	3-4	10-20
Thigh	Large	3-4	10-20

The settings in the table above have been demonstrated to result in the ideal treatment conditions. Failure to follow the device settings and treatment times as indicated in the table could result in excessive heating of the tissue, resulting in tissue damage, or could result in ineffective treatments and minimal results.

ALWAYS keep the handpiece in motion. Never allow the handpiece to sit stationary on the tissue for more than a second or two. Traverse the treatment area using a circular, figure 8, or methodical back-and-forth sweeping motion. A good analogy to think of is mowing a lawn - consistent sweeping patterns that just barely overlap, slowly working from one side of the area to the other. Apply slight pressure into the skin so the handpiece has a sort of kneading effect on the tissue. Most effective results is achieved when folds of skin press up in between the nodes on the handpiece surface. Once the entire area has been covered, you can go back to the starting point and begin the pattern over again.



The Ultimate Contour is designed to have the RF signal travel between two of the three nodes on the handpiece. The system alternates which two nodes are active, changing the active nodes in a circular pattern about once per second. Between the two active nodes, the RF energy travels from one node to the other. The purpose of these rounded nodes is to create a sort of kneading effect when the handpiece is worked along the tissue. The tissue will momentarily fold up in between the nodes, allowing the RF energy to more effectively travel through the skin and achieve its effect.



5.4 Ultrasound Treatment



Some patients may “hear” the ultrasound or experience a ringing sensation in their ears. Inform them ahead of time that this may occur, and to indicate if it becomes uncomfortable.

Some patients may experience vertigo if they get up too quickly after the ultrasound treatment. Be thorough when cleaning off the treatment oil after the treatment, as this will provide time for the patient’s middle ear to reach equilibrium.

The Ultrasound process is indicated only for the waist or central torso area of the body. DO NOT use ultrasound anywhere else.

ALWAYS keep the handpiece in motion and in contact with the tissue. Never allow the handpiece to sit stationary on the tissue for more than a second or two. Traverse the treatment area using a methodical back-and-forth sweeping motion. A good analogy to think of is mowing a lawn - consistent sweeping patterns that just barely overlap, slowly working from one side of the area to the other. Once the entire area has been covered, you can go back to the starting point and begin the pattern over again.

When treating areas with a thinner layer of fatty tissue, consider using lower power levels to avoid thermal damage to the skin. The image to the right shows the ultrasound intensity profile. The focal point is at 6mm from the surface of the handpiece. The profile shows up to 20mm from the surface.



5.5 Concluding the Treatment

Once the treatment is concluded and the unit has stopped delivering energy, lift the handpiece away from the patient tissue. Set the handpiece aside. Use clean towels to wipe away excess treatment oil from the skin. Assess the treated area. There may be some redness or slight swelling of the treatment area. Capture post-treatment photos of the treated area using the same camera settings as were used for the pre-treatment assessment. If skin fold calipers or other measurement methods were used for pre-treatment, repeat these as well. To help the patient visualize the results, you can demonstrate the change using these images and measurements.



As part of the post-treatment discussion with the patient, several recommendations should be provided regarding this treatment, and methods to best maintain the results that were just achieved:

- The patient should not eat for at least an hour after the treatment.
- The patient should continue to focus on drinking at least 1 liter of water each day.
- The patient must not consume alcohol for the next 48 hours after treatment.
- Advise the patient to keep the treatment area moisturized.
- Patient should avoid intense sun exposure immediately after treatment. During the overall treatment regimen, the patient should use sunscreen with a high SPF if prolonged sun exposure is anticipated.
- Avoid taking a hot shower or bath immediately. A warm shower is permitted. Otherwise wait several hours. Similarly the patient should avoid a sauna or hot tub immediately after the treatment.
- The patient should engage in a medium-impact cardio workout within 4 hours of the treatment. This helps to stimulate metabolism and lymphatic activity.

- Advise the patient to follow a diet regimen that is low in fat, low in complex carbohydrates (starches), and low in processed or added sugars.
- Advise the patient on an appropriate, weight-loss reduction exercise program.
- Schedule the next treatment appointment with the patient.
- Allow for a minimum of 1 week between single treatments visits, 3 months between treatment regimens.

Several methods are available to stop the treatment for any reason. Any of these methods will interrupt energy output by the handpiece:

- Press the Stop button on the screen.
- Press the red Safety Stop button on the back corner of the unit.
- Disconnect the handpiece from the delivery cable.
- Turn off the power switch on the back of the unit.
- Detach the power cord from the back of the unit.

6. CLEANING AND MAINTENANCE

6.1 Handpiece Cleaning and Inspection

You should ensure the handpiece is clean prior to use on a patient. Ideally, the handpiece should be cleaned immediately after use, and then stored in such a manner that the handpiece is not likely to get dirty until needed again. Clean all plastic and metal surfaces of the handpiece.

To clean the handpiece, moisten a towel or cloth with a solution of warm water mixed with soap or a mild, non-abrasive detergent. Thoroughly wipe all surfaces of the handpiece. For the RF handpieces in particular, ensure that you wipe around the contact nodes. After cleaning with soap, the handpieces should be treated with a disinfection solution, such as a 1-3% glutaraldehyde solution or 0.2% peracetic acid solution. The handpiece should be visibly wet and remain so for at least 5 minutes. You may need to reapply the disinfection solution to achieve this. After the five minutes, use a new dry towel or cloth to pat-dry the handpiece. Ensure the handpiece is fully dry before next use.

After each use, look over the handpiece and check for any flaws that might appear, such as cracks or build up on the handpiece contact surface, exposed or worn wiring, or unusual discoloration of the handpiece. If any of these are observed, contact Ideal Curves or your distributor to arrange for a replacement.



WARNING: DO NOT immerse the handpiece. Avoid getting the connector wet that is on the end of the handpiece.

WARNING: DO NOT use the handpiece if it is damaged, cracked, or shows signs of flaws.

Prior to use, it may be helpful to briefly wipe down the handpiece with a cloth moistened with an isopropyl alcohol solution. **CAUTION:** Ensure the alcohol has fully evaporated before using.

6.2 Unit Cleaning

The surfaces of the Ultimate Contour unit and cords may be cleaned using a towel or cloth moistened with a solution of warm water mixed with soap or a mild, non-abrasive detergent. Before cleaning the unit, make sure to unplug the power supply cord from the wall outlet. Wipe the surfaces down as needed. We recommend that a dry towel be used to dry off the unit after cleaning. Avoid letting pooled moisture collect on the unit.



WARNING: DO NOT immerse or spray water onto the unit. Avoid forcing excess liquid into the fan vents on the unit.

6.3 Fuse Replacement

The Ultimate Contour unit contains electrical fuses that can be replaced by the operator. **FOLLOW THESE INSTRUCTIONS EXACTLY TO AVOID ELECTRICAL SHOCK.**

1. Unplug the power cord from the wall outlet, and detach the power cord from the back of the unit.
2. Make sure the power switch is set to Off (press on the “O” symbol).
3. Use a small blade screwdriver to dislodge the fuse compartment that is between the power switch and the power cord connection.
4. Remove the fuse compartment.
5. Inside the compartment cover, remove the two fuses.
6. Install the two new fuses. **WARNING:** Make sure you install Type T2A250V fuses. Replacement fuses may be obtained from Ideal Curves (see Section 9.2). Failure to use the correct fuses may prevent the equipment from functioning properly, may damage the equipment, or may increase the risk of electric shock.
7. Return the fuse compartment to the back of the unit. Make sure the wording on the compartment is right-side up. Be sure to press the compartment completely into place.
8. Reconnect the power cord to the back of the unit. Plug the power cord into the wall outlet.
9. Turn on the power switch (press the “I” symbol). If the fan turns on and the screen lights up, then the fuse replacement has been successful.



DANGER: Failure to follow these instructions may result in electric shock.



7 - LIMITED WARRANTY

7.1 Limited Warranty Statement

The Ultimate Contour device along with its accessories, excluding the handpieces (collectively defined as Product), is warranted against defective materials and workmanship for a period of one (1) years from the date of purchase. If the Product is leased from Ideal Curves or from any of its authorized distributors, consult your lease agreement for the terms and conditions of Product repair and/or replacement. Repair and/or replacement shall occur as directed by Ideal Curves or the authorized distributor. This warranty does not cover damage to the Product caused by accident, misuse or alteration/tampering of the Product. Warranty does not include labor or postage/freight charges. Warranty does not apply to the external finish of the Product. Ideal Curves reserves the right to make changes in design or to modify previously manufactured Product.

The handpieces are separately warranted against defective materials and workmanship for a period of one (1) year from the date of purchase. If the handpiece(s) is/are provided in association with a lease agreement with Ideal Curves or any of its authorized distributors, consult your lease agreement for the terms and conditions of handpiece repair and/or replacement.

7.2 Servicing

Replacement of the fuses is described in Section 6.3. No other portion or aspect of the Ultimate Contour system is serviceable by the end-user. Attempting to perform any other repair or service to the system may void the warranty. Ideal Curves will make available diagrams, parts lists, and schematics to authorized service personnel for servicing of this product. Although the Ultimate Contour is designed to provide con-

sistent reliable operation, it is recommended that once a year you contact Ideal Curves and arrange for a maintenance inspection of the unit to ensure continued operation within design parameters. If you are having trouble with the Ultimate Contour system, have questions regarding its use, or need to order replacement parts, feel free to contact a customer service representative at Ideal Curves (1-888-861-7211) or at the distributor from whom you obtained the system. You may find it quick and helpful to review the Troubleshooting section of this manual (Section 8).

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8 - TROUBLESHOOTING

A number of commonly encountered issues are addressed in this section. It is recommended that you review these suggestions and follow directions to correct an issue before contacting customer service.

PROBLEM	SOLUTION
The screen is dark - nothing is showing.	Make sure the power cord is attached and plugged in. Make sure the power switch on the back of the unit is turned on (press the "I" symbol on the switch). Check and replace the fuses (see Section 6.3).
A warning screen is showing on the display.	Follow the directions and information provided on the screen before pressing the Clear button.
The red Safety Switch is glowing.	The button has been pressed. Press the button again - the light should turn off.
The volume on the unit is too loud or too soft.	Go to the Utilities screen and adjust the volume as desired.
A warning screen says no handpiece, or the wrong handpiece, is attached but I know the correct handpiece is connected.	Check the handpiece connector and make sure it is fully connected and secured. Try attaching another handpiece and operating that handpiece. If the other handpiece works, then there may be a problem with the intended handpiece and should not be used.
The handpiece feels hot and/or the patient complains of a burning sensation.	Some warmth is normal as this indicates the procedure is working. If the heat is intolerable, use a lower power setting. Also ensure an ample amount of treatment oil is applied to the treatment area. Tissues with less adipose tissue may get hotter relative to highly fatty tissue. Adjust the power intensity accordingly.
Treated tissue is red or appears swollen.	Slight redness is a natural outcome of the treatment. In case of extreme redness, reduce the power intensity.
There doesn't appear to be any change in the treated tissue.	Increase the power intensity. Leaner tissue will not change as much since there is less fat to remove.
The unit is saying the temperature is too high.	Check and make sure the handpiece is not extraordinarily hot. Make sure the unit is being used at ambient temperatures as described in Section 9.1.
WARNING MESSAGES	
High Temperature - The unit and/or handpiece has reached excessive temperatures.	Make sure the unit is being used in a place with ambient temperature (see Section 9.1). Stop the treatment and allow the unit to sit for 5 minutes.
Timer Error - The unit's internal clock is not working properly.	Turn the unit off, wait 10 seconds, then turn the unit back on. If this issue persists, contact Customer Service.
Current Fault - Excessive electrical power has occurred within the unit.	Turn the unit off, wait 10 seconds, then turn the unit back on. If this issue persists, contact Customer Service.

9 - SPECIFICATIONS

9.1 Unit Technical Specifications

Ultimate Contour (Model: 005-00036)	
Weight • Ultimate Contour 5.0 lbs	Dimensions • Ultimate Contour 13.75" x 14.5" x 14"
Power Input Requirements 100-240 VAC @ 50-60Hz, 1.8A	Audible and Visual Notification Yes
Medical Electrical Equipment Classification Class I	Power Supply Cord Length (total) 8 ft.
Energy Frequency • Radio 1.0±0.05MHz • Ultrasound 37±2kHz	Maximum Handpiece Output Voltage • Radio Frequency (All sizes) 250 Volts • Ultrasound 470 Volts
Maximum Output Power Radio Frequency • Level 1 - 85W • Level 2 - 100W • Level 3 - 130W • Level 4 - 160W	Ultrasound Output Intensity Handpiece Surface (Entry Intensity) At the Focal Point • Level 1 - 0.25 W/cm ² 0.50 W/cm ² • Level 2 - 0.50 W/cm ² 1.00 W/cm ² • Level 3 - 0.75 W/cm ² 1.50 W/cm ² • Level 4 - 1.05 W/cm ² 2.00 W/cm ²
Ultrasound Focal Distance 6mm	Ultrasound Focal Distance 6mm
Ultrasound Focal Volume 2.12cm ³	Ultrasound Entry Power 30.2W
Ultrasound Spatial Peak to Temporal-Average Intensity 2.01W/cm ²	Ultrasound Pre-Focal Temporal-Average Intensity 1.32W/cm ²
Ultrasound Ratio Peak to Temporal-Average Intensity 2.0	Ultrasound Peak Rarefaction Pressure 117µPa
Ultrasound -6dB Beam Area 7.07 cm ²	Handpiece Voltage Rating • Radio Frequency (All sizes) 300 Volts • Ultrasound 1000 Volts
Operating Temperature 10 – 30°C (50 – 86°F)	Storage Temperature -20 – 45°C (4 – 113°F)
Operating Humidity 35 – 60% Relative Humidity	Storage Humidity 5 – 95% Relative Humidity
Warranty • Handpiece • Unit and all other parts of the system	1 year 1 year

9.2 Accessories and Replacements

Handpiece - Large RF	005-00040
Handpiece - Ultrasound	005-00037
Fuses (Pack of 2)	005-00041

10 - ELECTROMAGNETIC COMPATIBILITY

Guidance and manufacturer's declaration – electromagnetic emissions		
The Ultimate Contour is intended for use in the electromagnetic environment specified below. The customer or the user of the Ultimate Contour should assure that it is used in such an environment.		
Emissions Test	Compliance	
RF emissions CISPR 11	Group 1	The Ultimate Contour uses RF energy to achieve its intended function. This energy exceeds the limits identified in this standard. This product is designed to comply with this standard only when switched on and in an idle state (not intentionally generating RF). RF emissions are allowed to exceed limits only in the stated RF frequency range for this device.
RF emissions CISPR 11	Class A	NOTE: The emissions characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.
Harmonic emissions IEC 61000-3-2	Not available	
Voltage Fluctuations/ Flicker emissions	Not available	
The Ultimate Contour is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes		

Guidance and manufacturer's declaration – electromagnetic emissions			
The Ultimate Contour is intended for use in the electromagnetic environment specified below. The customer or the user of the Ultimate Contour should assure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient/ burst	±2 kV common mode	±2 kV for power supply	Mains power quality should be that of a typical commercial or hospital environment.
IEC 61000-4-4	±1 kV for input/ output lines	Lines Not Applicable	
Surge IEC 61000-4-5	±1 kV differential mode ±2 kV common mode	±1 kV differential mode ±2 kV common mode	

Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5 % UT (>95 % dip in UT) for 0,5 cycle 40 % UT (60 % dip in UT) for 5 cycles 70 % UT (30 % dip in UT) for 25 cycles <5 % UT (>95 % dip in UT) for 5 sec	<5 % UT (>95 % dip in UT) for 5 sec	
(50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	

Guidance and manufacturer's declaration – electromagnetic immunity

The Ultimate Contour is intended for use in the electromagnetic environment specified below.
The customer or the user of the Ultimate Contour should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
Conducted RF IEC 61000 4-6	6 Vrms 150 kHz to 80 MHz	8 Vrms	Portable and mobile RF communications equipment should be used no closer than 30cm (12 inches) to any part of the Ultimate Contour, including cables. Otherwise, degradation of the performance of this equipment could result. Recommended separation distance $d = [3.5/V1] \sqrt{P}$
Radiated RF IEC 61000-4-3	7 V/m 80 MHz to 2,5 GHz	3 V/m	$d = [3.5/E1] \sqrt{P}$ 80 MHz to 800MHz $d = [7/E1] \sqrt{P}$ 800 MHz to 2.5 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey a, should be less than the compliance level in each frequency range b Interference may occur in the vicinity of equipment marked with the following symbol:



NOTE 1: At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

^aField strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Ultimate Contour is used exceeds the applicable RF compliance level above, the Ultimate Contour should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the Ultimate Contour.

Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Recommended separation distances between
portable and mobile RF communications equipment and the Ultimate Contour

The Ultimate Contour is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Ultimate Contour can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Ultimate Contour as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter W	Separation distance according to frequency of transmitter m		
	150 kHz to 80 MHz	80 MHz to 800 MHz	800 MHz to 2.5 GHz $d = [7/E1] \sqrt{P}$
	$d = [3.5/V1] \sqrt{P}$	$d = [3.5/E1] \sqrt{P}$	
0.01	0.12	0.12	0.23
0.1	0.37	0.37	0.74
1	1.17	1.17	2.33
10	3.69	3.69	7.39
100	11.67	11.67	23.33

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

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Ultimate Contour

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