ARTAS™

ROBOTIC HAIR RESTORATION

9x ARTAS™ System User Guide

RESTORATION ROBOTICS

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1 Introduction

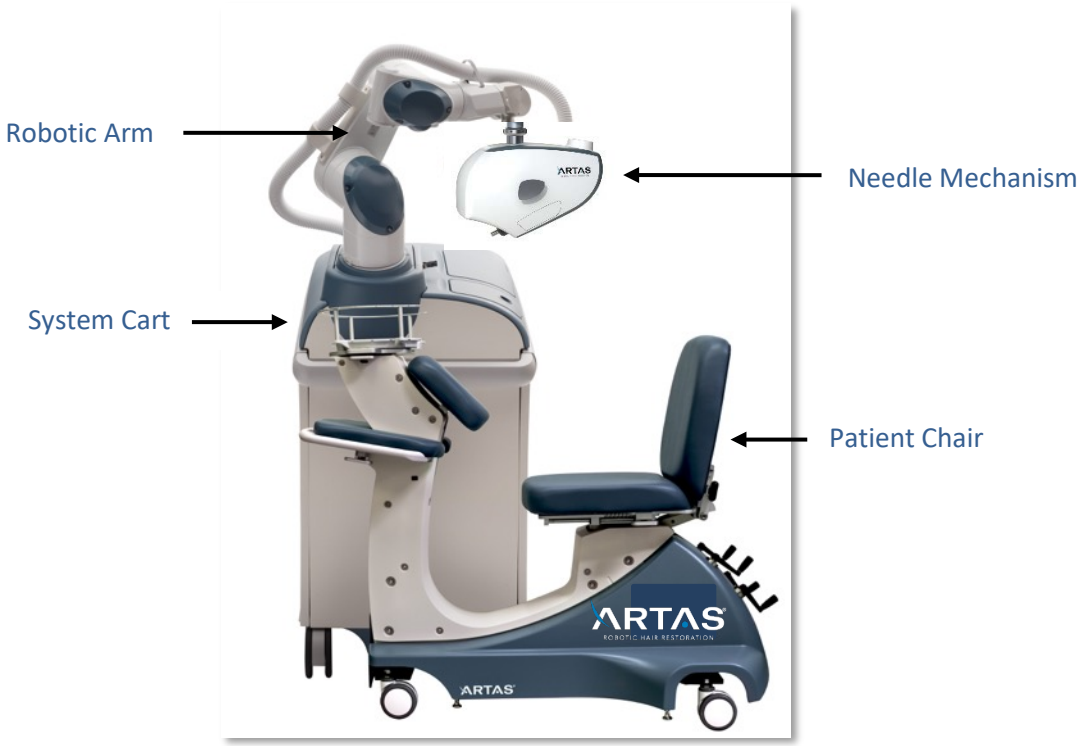
The ARTAS™ System dissects follicular units to prepare them for extraction and assists in the creation of recipient sites as part of a hair transplantation procedure. This manual provides instructions for using the Restoration Robotics ARTAS™ System.

1.1 ARTAS™ System Hardware Overview

The ARTAS™ System Hardware (Figure 1) includes:

- ARTAS™ System Cart, including Robotic Arm and Needle Mechanism (Section 3)
- ARTAS™ Clinical Accessories Kits: Harvesting (Section 3.3.1) and Site Making (Section 3.3.2)
- ARTAS™ Patient Chair (see ARTAS™ Patient Chair User Guide, LB-24500)
- ARTAS™ Hair Pendant (see ARTAS™ Hair Pendant User Guide, LB-102479)
- ARTAS™ Workflow Remote (see ARTAS™ Workflow Remote User Guide, LB-102241)

Figure 1: The ARTAS™ System



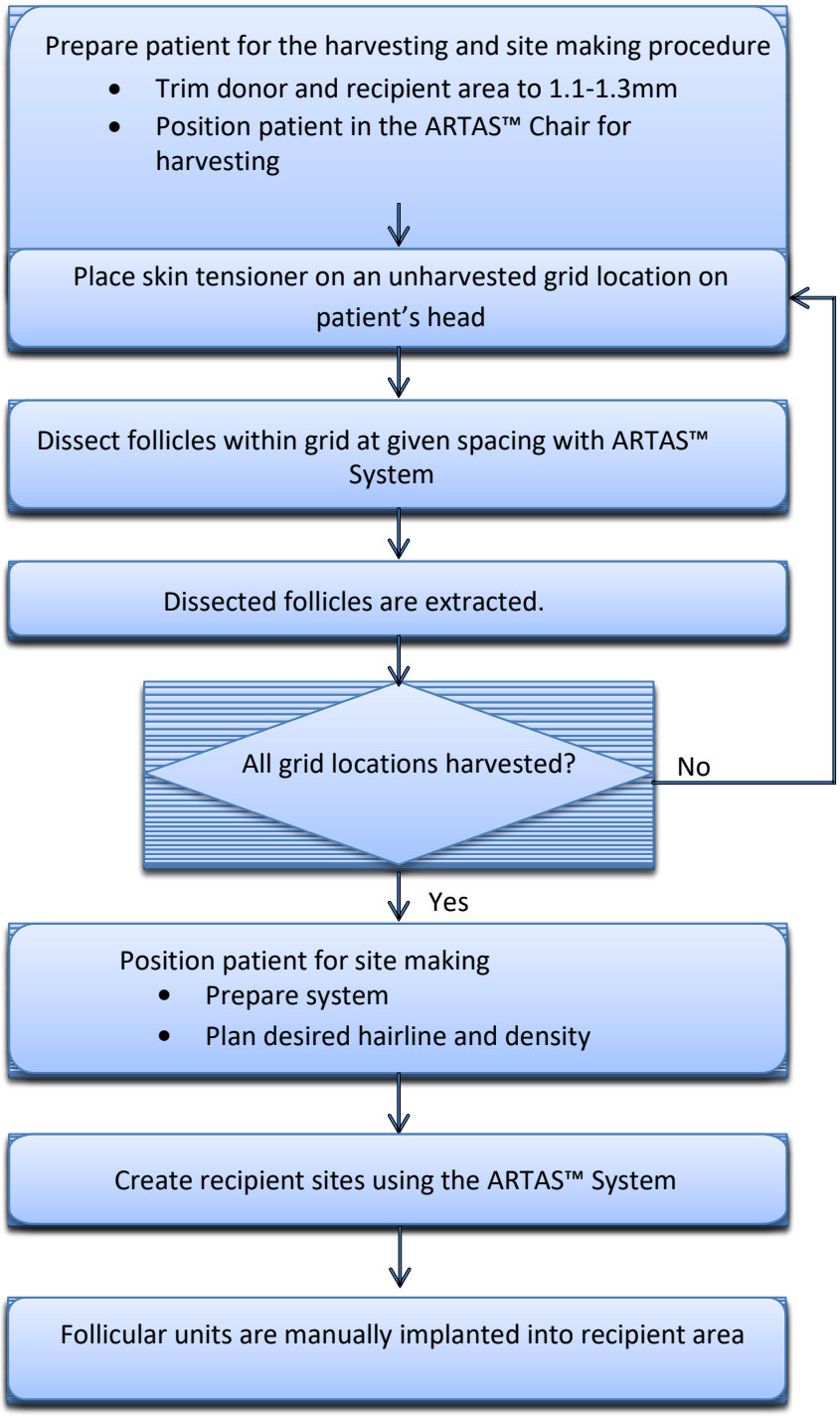
1.2 ARTAS™ Procedure Overview

In patients with male pattern hair loss, there is typically an area on the back and sides of the head that is densely packed with terminal hair. The follicular unit extraction (FUE) procedure harvests a small percentage of this hair so it can be transplanted to the area of the head where hair loss has occurred to produce a natural hairline of lifelong hair.

The ARTAS™ harvesting procedure uses a Robotic Arm with a specialized Needle Mechanism to automate FUE. Hair in the donor area on the back of the head is trimmed to a 1.1-1.3mm length. The trimmed donor area is harvested in a grid pattern by placing a proprietary skin tensioner over one region at a time, harvesting a fraction of the hairs in that region and moving the skin tensioner to succeeding regions until the desired proportion of the hair is removed from the entire donor area. The ARTAS™ System focuses on the important dissection step in the transplant procedure, as described in Figure 2.

The ARTAS™ site making procedure uses a Robotic Arm to automate the recipient site making portion of FUE. A customized surgical plan is created by the physician using the ARTAS HAIR STUDIO™ software. The robot locates and avoids creating incisions over existing terminal hairs, preventing damage to existing hair.

Figure 2: The ARTAS Procedure



1.3 How to Get Help

For any questions regarding the use of the Restoration Robotics ARTAS™ System, please contact:

Restoration Robotics, Inc.
128 Baytech Drive
San Jose, CA 95134
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Phone: 855.88.ARTAS (855.882.7827) or Outside the United States +1.650.587.3537
Fax: 408-883-6889
Email: contactus@restorationrobotics.com

1.4 Reference Documents

Please contact Restoration Robotics for documentation on the ARTAS™ Patient Chair (LB-24500), ARTAS™ System Training, and ARTAS™ System Installation.

1.5 Conventions Used in this Document

The conventions used in this document are shown in Table 1.

Table 1: Conventions Used in this Document

Conventions	Use
Bold	User Interface selections. Headings and Titles.
Italics	Text emphasis. Description of user interface or hardware selection.
`Courier`	Text that is typed into a field.
Lists	Numbered lists for procedures. Bulleted lists for everything else.

2 Safety

2.1 Indications for Use

The ARTAS™ System from Restoration Robotics is indicated for harvesting hair follicles from the scalp in men diagnosed with androgenic alopecia (male-pattern hair loss) who have black or brown straight hair. The ARTAS™ System from Restoration Robotics is intended to assist physicians in identifying and extracting hair FUs (follicular units) from the scalp during hair transplantation. The ARTAS™ System is also indicated for creating recipient sites of subsequent manual implantation of the harvested follicles.

2.2 Warnings, Cautions, and Notes

Several types of special alert notations are used in this manual. In descending order of importance, they are:

Warning  ***This indicates a potentially hazardous situation which, if not avoided, could result in injury or major damage to the equipment.*** **Warning** 

Caution  ***This indicates a situation which, if not avoided, could result in damage to the equipment.*** **Caution** 

NOTE: ***Notes provide supplementary information, emphasize a point or procedure, or give a tip for easier operation.***

2.3 Precautions

The Restoration Robotics ARTAS™ System was developed with patient and user safety as a primary concern at all times.

The physician and technician users are the final and critical link in the safety system and should always be attentive and ready to act in the event of an unplanned or adverse event involving the ARTAS™ System.

Caution  ***The ARTAS™ System from Restoration Robotics is intended for use by physicians and technicians trained and proficient in hair transplantation and the use of the ARTAS™ System. Failure to obtain training may result in damage to equipment, and/or injury to personnel or patients.*** **Caution** 

Only authorized Restoration Robotics service personnel should install, service, repair, or modify components of the ARTAS™ System.

Warning  ***Improper installation, service, repair, or modifications performed by unauthorized personnel may pose a hazard and void the warranty. If this equipment is modified, appropriate inspection and testing must be completed by Restoration Robotics to ensure continued safe use of the equipment.*** **Warning** 

The ARTAS™ System should only be used on the scalp, as it has not been tested to be used on any other areas of the body.

Warning  ***Do NOT use the ARTAS™ System in an oxygen-enriched environment or near a flammable anesthetic mixture with air, oxygen or nitrous oxide. System is not categorized as AP (anesthetic-proof) or APG (anesthetic-proof category G – gas) type of equipment.*** **Warning** 

Warning  ***The filters, liners, needles, punches, and tensioners should only be disposed of in accordance with the hospital or clinic's procedures for the disposal of bio-hazardous waste and in accordance with all local codes.*** **Warning** 

Warning  ***When servicing the subsystems requiring periodic replacement of oil, be sure the oil is disposed of in accordance with all local codes for petroleum products. The oil should only be replaced by trained service technicians.*** **Warning** 

Warning  ***This product contains lead-acid and lithium coin-cell batteries. The batteries should only be replaced by authorized service personnel using ones with the same type and ratings. Do not incinerate the batteries. Dispose of the batteries only in accordance with all local codes for the disposal of hazardous waste. Contact your local waste or environmental control agency for additional details.*** **Warning** 

NOTE: ***At the end of the useful life of the ARTAS™ System, contact Restoration Robotics for proper disposal of the system.***

2.4 The ARTAS™ System Safety Subsystem

Safety-related hardware throughout the ARTAS™ System is designed to ensure patient and operator safety during the computer-assisted ARTAS™ procedure.

2.4.1 Safety-Related Hardware

Safety-related hardware in the ARTAS™ System is described in Table 2 below.

Table 2: Safety Related Hardware

Device	Description
E-Stop Button	The portable red *Emergency Stop* buttons are positioned near the operator. These are located on the desk and User Interface. Pressing an E-Stop causes the Needle Mechanism to retract and motor power to be turned off to the Robotic Arm.
EPO Button	A red *Emergency Power Off* button is attached to the surface of the ARTAS™ System Cart. Pressing the EPO button shuts off power to all subsystems except the computer.
Uninterruptible Power Supply (UPS)	The UPS protects the ARTAS™ System from loss of power to the building by alerting the operator of a power outage and providing power for several minutes afterwards in order to properly shutdown the system.
Power Distribution Unit (PDU)	Contains hardware logic that prevents the system from sending power to the Robotic Arm or Needle Mechanism if an E-Stop or other safety condition is indicated.
Six-Axis Force Sensor	Monitors force levels exerted in all directions by the Needle Mechanism and triggers an E-Stop if limits are exceeded.
Axial Force Limiter	Monitors forces along the punch axis. The axial force limiter triggers an E-Stop if a preset force limit is exceeded by the punch.
Robotic Arm Brake Release	Push-Button on Robotic Arm used to move the Robotic Arm away from the patient in instances that the ARTAS™ System is not responding to the software.

2.4.2 Safeguards

The ARTAS™ System provides safeguards so operations are only allowed to proceed if the system is in the proper state, as described in Table 3.

Table 3: Safeguards

Condition	Safeguard
A subsystem fault is detected by the PDU	Power is removed from the Robotic Arm and Needle Mechanism. The Needle and Dissection Punch are retracted.
Imaging system loses sight of a hair follicle	The Robotic Arm stops tracking that specific hair follicle. In automation mode, the system attempts to identify and track another hair follicle. If no new follicle is identified in automatic mode, the Robotic Arm motion stops.
A communication timeout occurs between the robot controller and the ARTAS™ System software	A subsystem fault is declared on the Robotic Arm and in the ARTAS™ software, shutting down power to the Robotic Arm and retracting the Needle and Punch.
The Needle or Punch penetrates too deeply in the skin and contacts firm tissue	The resulting force is detected by the force sensor as well as the axial force sensor integrated into the Needle Mechanism, triggering an E-stop that automatically retracts the Needle and Punch.
An E-Stop button is pressed	The Needle Mechanism retracts and the motor power is turned off to the Robotic Arm. The operator must clear the E-Stop condition before power can be restored to the Robotic Arm.
Facility power to the ARTAS™ System is lost	An audible warning is sounded by the UPS. The operator is expected to move to a safe position and shut down the system during the interval in which the battery backup allows continued operation. The procedure can be continued after power is restored.

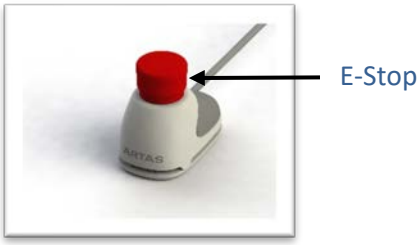
2.4.3 Emergency Stop

After any Emergency Stop, or E-Stop, the Needle Mechanism retracts the Needle and Punch and motor power is turned off to the Robotic Arm.

2.4.3.1 Emergency Stop Button – System Hardware

The *Emergency Stop,* or *E-Stop Button* (Figure 3) is provided to site near the User Interface on the workstation desk. The Robot Teach Pendant (Appendix B Robot Teach Pendant) can be placed on the workstation desk. The Robot Teach Pendant only applies to system serial numbers 1001-1041.

Figure 3: Workstation E-Stop Button



2.4.3.2 *Emergency Stop Icon – System Software*

There is also an E-Stop in the ARTAS™ System Application main control panel (Figure 4).

Figure 4: E-Stop Icon on User Interface

2.4.3.3 *Emergency Stop Recovery*

To recover the ARTAS™ System after an E-Stop:

1. If the hardware e-stop was activated, reset the button by twisting to release it.
   - This step is skipped if the e-stop was activated by the software.
2. Select the blinking warning icon (Figure 5) in the ARTAS™ application to re-enable power to the Robotic Arm and continue operation within a few moments.

Figure 5: E-Stop Warning

2.4.4 Emergency Power Off (EPO) Button

The Emergency Power Off, or EPO, button is the red button (Figure 6) located on the top of the ARTAS™ System Cart.

Pressing the EPO button shuts off power to all subsystems except the computer, including power to the:

- Robotic Arm
- Vacuum and air pumps
- Needle Mechanism

Figure 6: Emergency Power Off (EPO) Button

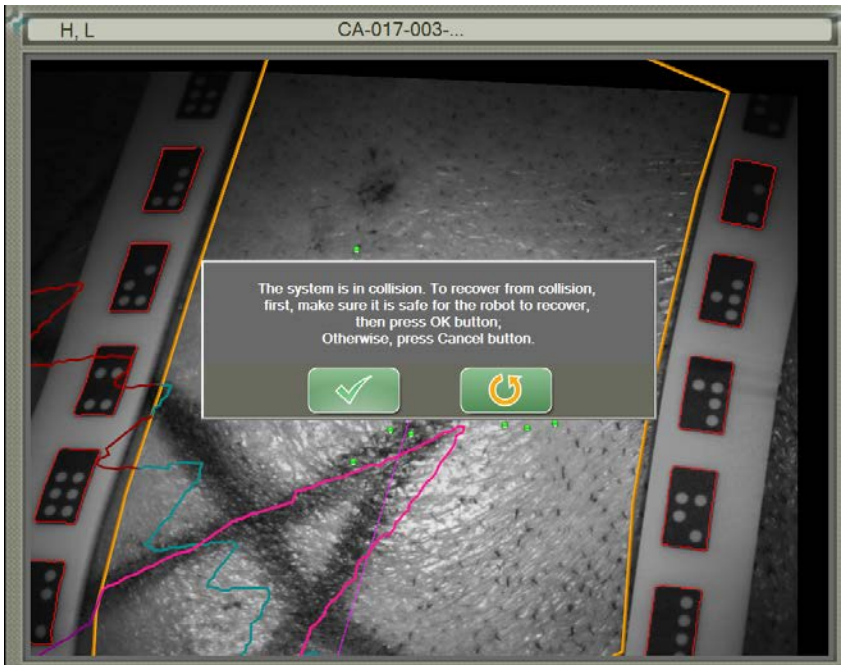
2.4.4.1 EPO Recovery

Recovery from an EPO state requires resetting the EPO button by twisting and releasing it. Next, press the **ON** button on the Cart Control Panel. EPO recovery takes approximately five minutes.

2.4.5 Auto Collision Detection & Recovery

If the ARTAS™ System detects a collision, the system will display a dialog box with the option to automatically recover from the collision (Figure 7). To recover, select the ✓. An audible beep will sound, and the system will move to a safe location. To resume the procedure, follow the work flow steps in Sections 7.3 & 8.4.

Figure 7: Auto Collision Detection & Recovery



2.4.6 Robotic Arm Brake Release

A Push Button on Robotic Arm used to move the Robotic Arm away from the patient in instances that the ARTAS™ System is not responding to the software. The Robotic Arm Brake Release (Figure 8) will move joints number 1 & 6 of the Robotic Arm.

Figure 8: Arm Brake Release Button

2.4.6.1 Using the Robotic Arm Brake Release

If the Robotic Arm is not responding to the ARTAS™ Software, use the Robotic Arm Brake Release to move the Needle Mechanism and Robotic Arm to a safe position away from the patient.

Warning ***When the Arm Brake Release is activated, downward movement on the operator's hand should be anticipated due to gravity.*** **Warning**

1. To activate, use the palm of your hand to press and hold the Robotic Arm Brake Release button at the top of the Needle Mechanism until a beeping sound is repeated with flashing LED lights (Figure 9).

Figure 9: Using the Arm Brake Release

2. Once the beeping sound increases in speed, continue to push the Robotic Arm Brake Release and move the Robotic Arm toward the System Cart away from the patient.
3. Once the Needle Mechanism and Robotic Arm are in a safe position, release the Robotic Arm Brake Release to deactivate.
4. Select **Resume** on the User Interface to clear the *Lost Robot Power* error.
5. Put the Needle Mechanism into Safe Position.
6. Select **Restore Frame** from the User Interface to continue with the current grid.

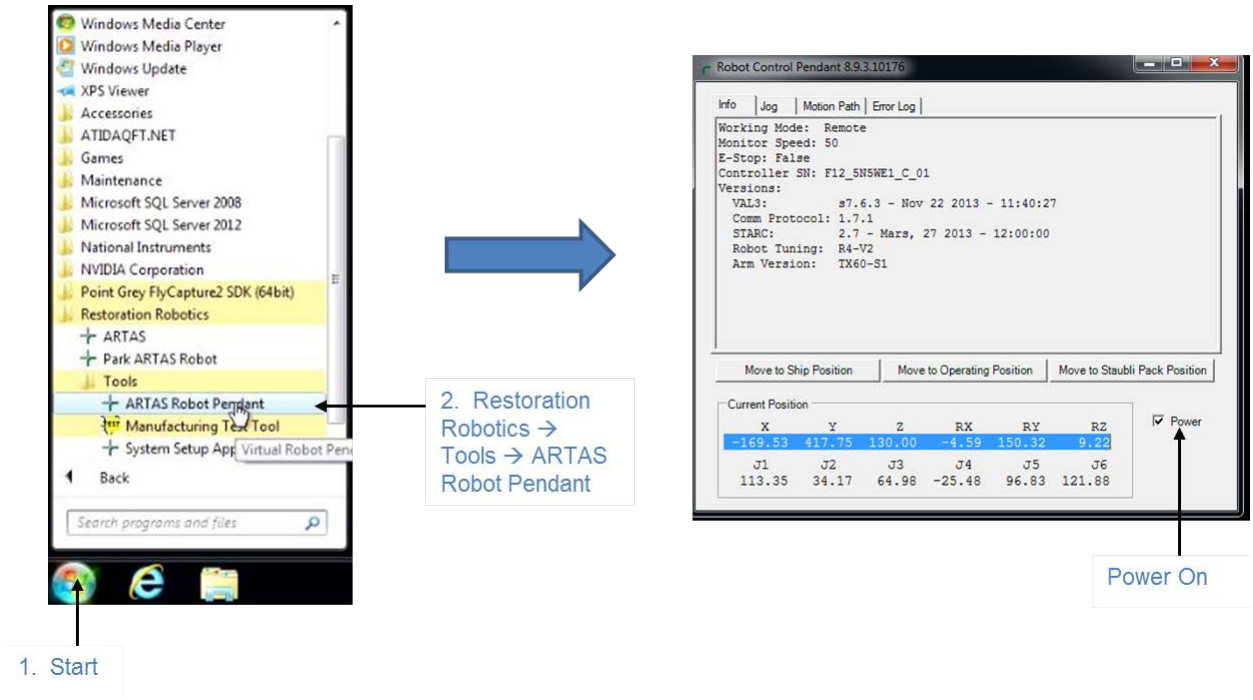
2.4.7 ARTAS™ Robot Pendant

The ARTAS™ Robot Pendant is software used to control the movement of the Robotic Arm in a situation that the Robotic Arm is not responding to the ARTAS™ Software and the Arm Brake Release is not able to move the Robotic.

To use:

1. In the Start menu of Windows, select *All Programs* → *Restoration Robotics* → *Tools* → *ARTAS™ Robot Pendant.*
2. Power on the system by checking the **Power** box (Figure 10).

Figure 10: Launching and Powering On the ARTAS™ Robot Pendant



3. There are predetermined positions. *Move to Operating Position* will move the Robotic Arm and Needle Mechanism to Center Position (Sections 7.3.2.1 & 8.4.1). Select and hold the Move icon until the system fully completes the motion.
4. Close the program when complete.

Warning	***Do NOT move between ship and operating positions. A large sweeping movement may occur. The Needle Mechanism should be removed between these positions.***	Warning

Warning	***The tool umbilical cable should be watched during movement to ensure it does not bind.***	Warning

2.4.8 Handling Unexpected Situations

Unexpected situations that might occur during operation and their resolutions are shown in Table 4.

Table 4: Handling Unexpected Situations

Critical Situation and Potential Causes	Resolution
Patient Movement (preventing the system from finding stable hairs to harvest)	There are several reasons for patient movement including nervousness, discomfort, etc.: • Proper chair adjustment should help to remedy many discomfort problems • Taking a break from the procedure might relax a nervous patient
Needle Mechanism Failure	If the Needle Mechanism does not pass verification at startup, properly perform a harvest during the procedure or successfully create recipient sites, it might be necessary to abort the procedure. Call Restoration Robotics customer support for assistance.
Robotic Arm Failure	If the ARTAS™ software repeatedly indicates that power to Robotic Arm cannot be enabled, then the ARTAS™ System cannot be used in this state. Call Restoration Robotics customer support for assistance.
ARTAS™ Software Failure	If the ARTAS™ software cannot be operated due to computer or software failure, the procedure must be paused, and the Robotic Arm moved to a safe position with the Robotic Arm Brake Release or in some circumstances, the ARTAS™ Robot Pendant. For system serial number 1001 -1041, the Teach Pendant (Appendix B) will be used in place of the Arm Brake Release and ARTAS™ Robot Pendant.
Power Outage	In the event of an unexpected power outage that occurs during a procedure, move the Robotic Arm to Safe Position and exit ARTAS™ software promptly. There is an Uninterruptable Power Supply (UPS) within the ARTAS™ System that will provide backup power for a limited time. However, it should not be relied on to continue a patient's treatment.

3 The ARTAS™ System Hardware

The ARTAS™ Computer-Assisted System hardware includes the ARTAS™ System Cart (Section 3.1), ARTAS KEY™ USB device (Section 3.3), and the clinical accessory kits (Section 3.3).

3.1 The ARTAS™ System Cart

The ARTAS™ System Cart includes the following:

- Robotic Arm (Section 3.1.1)
- Needle Mechanism (Section 3.1.2)
- Imaging Subsystem (Section 3.1.3)
- Power Subsystem: Main Power Connection, Uninterruptible Power Supply (UPS), and Power Distribution Unit (PDU) (Section 3.1.4)
- System control computer
- Camera calibration and Needle Mechanism control displays
- Saline Dispenser
- Pressurized air and vacuum pumps

3.1.1 Robotic Arm

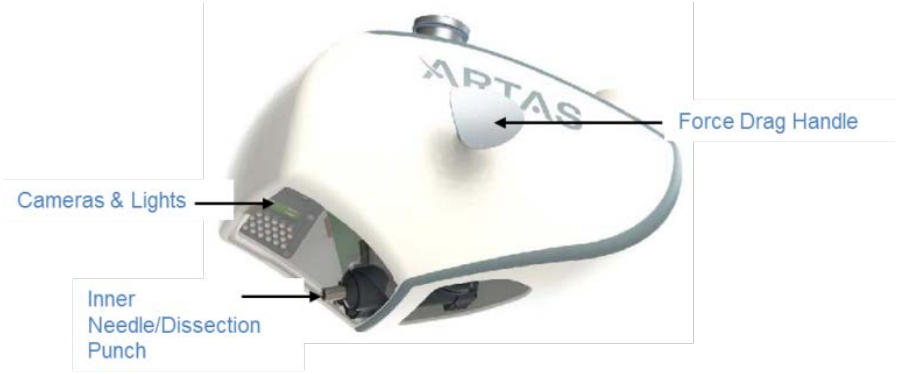
The Robotic Arm is mounted to the System Cart and holds the Needle Mechanism that performs the follicular unit dissections and recipient site making. The Robotic Arm has six degrees of freedom, meaning that it can freely move and rotate around all three axes (X, Y, and Z). The Robotic Arm controller is built into the cart and turned on automatically at system startup.

3.1.2 Needle Mechanism

The Needle Mechanism (Figure 11) is mounted on the end of the Robotic Arm.

- The Needle Mechanism includes the motors and pneumatics that actuate the Inner Needle and Dissection Punch
- The Needle Mechanism is also used as the mounting point for the stereo cameras

Figure 11: Needle Mechanism



3.1.3 Imaging Subsystem

The imaging subsystem consists of one pair of stereo cameras. The stereo cameras provide the position and orientation information that allow the ARTAS™ System to identify and track hairs for dissection and avoid terminal hair during recipient site creation.

The stereo cameras provide a left and right view of the scalp area providing three-dimensional position and orientation of the hairs.

- Low and high magnification images are achieved through one pair of stereo cameras
- Low magnification imaging provides an overview of the harvest/recipient area that is used for planning spacing and direction
- High magnification imaging provides a detailed view of the hairs for dissection

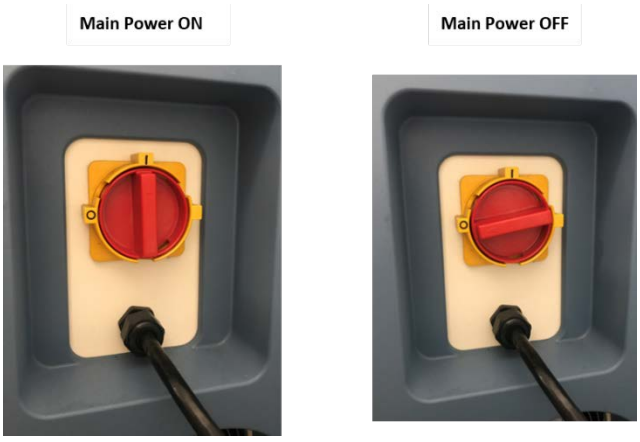
3.1.4 Power Subsystem

The power subsystem is composed of the main power connection, an Uninterruptible Power Supply (UPS) and a Power Distribution Unit (PDU) within the ARTAS™ System Cart.

The main power connection (Figure 12) is located at the back side of the System Cart, just below the cart rating label. With the main power switch in the off ‘O’ position, the cord should be

plugged into a 208VAC single-phase outlet. The main switch needs to be in the on '|' position to operate the ARTAS™ System.

Figure 12: Main Power Connection



3.1.4.1 Uninterruptable Power Supply (UPS)

The UPS (control panel shown in Figure 13) ensures that power is maintained to all critical systems for several minutes after a power outage. Systems 1001 – 2041 have version 1 of the UPS. While systems 2042 and higher have version 2 of the UPS.

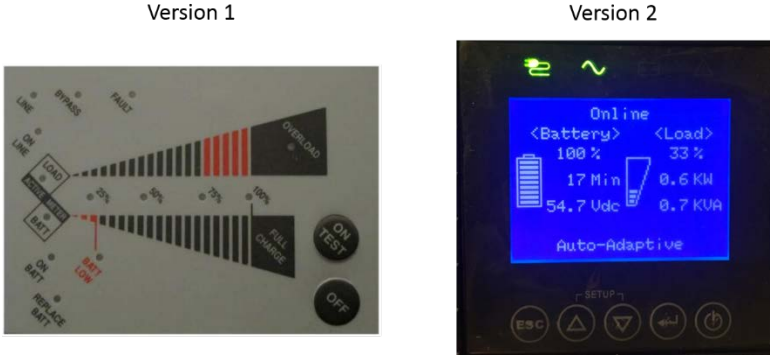
Caution

The UPS provides short-term internal power to the ARTAS™ System using a battery. The System is only intended to be operated from internal power in case of power failure in order to put the system back into a safe state before shutdown. Power to the system is not fully removed until the UPS is turned off.

Caution

The buttons on the UPS, located inside the System Cart, are used during system startup and shutdown (Sections 4.3 & 11).

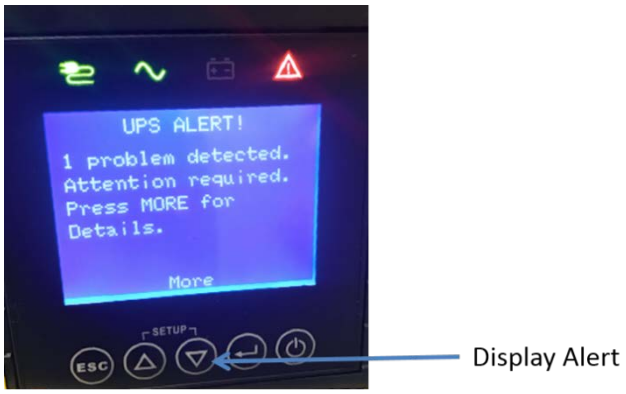
Figure 13: UPS Control Panel



3.1.4.1.1 Version 2 UPS Errors

If the UPS detects an error it will enter Alert Mode. The UPS will display a red triangle and alert notification. To display the UPS alert details, press the button below **More** (Figure 14).

Figure 14: UPS Version 2 Alert Mode with Notification



The most common error is a Power Load Error (Figure 15). This can be cleared by restarting the UPS and ARTAS™ System Cart as described in sections 4.3 & 11.

Figure 15: Common UPS Version 2 Error

3.1.4.2 Power Distribution Unit (PDU)

The PDU, inside the System Cart, provides a central point that ensures power is sent to all critical subsystems and should only be accessed by authorized Restoration Robotics personnel.

3.2 ARTAS KEY™ USB Device

The ARTAS KEY™ USB device contains information indicating how many more harvests, harvest procedures or site making procedures are licensed to be performed.

For harvesting, there is a minimum harvest requirement. For example, if the minimum requirement is 750, when a procedure is started 750 harvests will be deducted after the first harvest. Once the procedure reaches 751 harvests, each time a harvest is performed, a counter within the device is decremented. Once the number of licensed harvests is exhausted, more harvests may be ordered online. A harvest occurs any time a hair is selected, and the needle and punch are activated. Operating the ARTAS™ System in Simulation mode (Section 5.4.4) does not constitute a harvest.

For site making, one procedure is deducted after the first incision is created in the procedure. Once the number of licensed site making procedures is exhausted, additional site making procedures may be ordered online.

The ARTAS KEY™ USB device (Figure 16) is typically plugged into the USB hub built into the computer monitor, or it may be plugged into the USB port of the ARTAS™ System control computer.

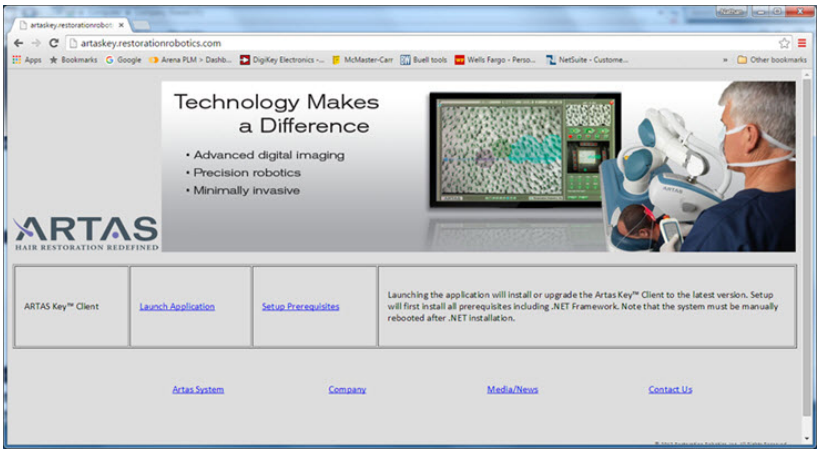
Figure 16: ARTAS KEY™ USB Device

3.2.1 ARTAS KEY™ Client

To recharge the ARTAS KEY™ USB device online with additional harvests and/or harvest/site making procedures, follow these steps:

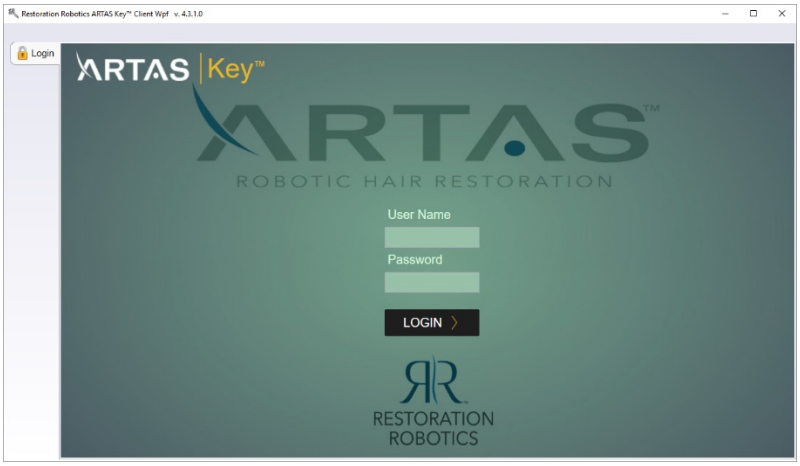
1. Unplug the ARTAS KEY™ USB device from the system. Plug it into the USB port of a computer connected to the Internet, to which the user has administrative privileges to install applications.
2. Using Internet Explorer, navigate to http://artaskey.restorationrobotics.com/.
3. Select **Launch Application** to download ARTAS KEY™ Client (Figure 17).

Figure 17: Launch ARTAS KEY™ Client



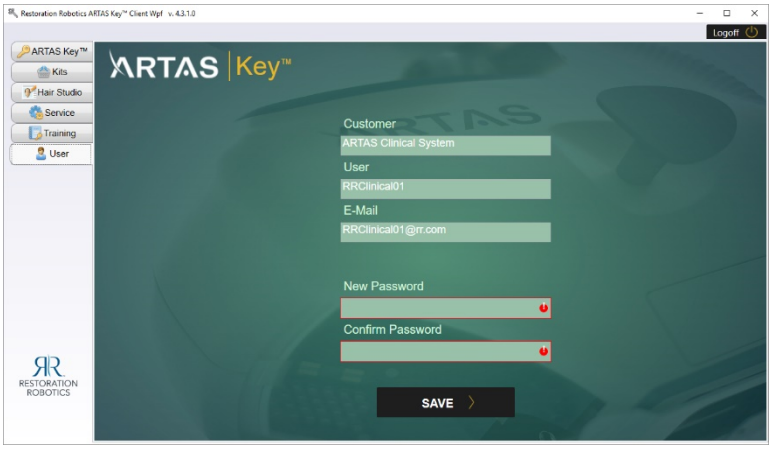
4. Enter the username and password that was issued with the ARTAS™ System (Figure 18).

Figure 18: ARTAS KEY™ Client Login



5. If this is the first time the ARTAS KEY™ USB device program is being run, change the given password on the *User* tab to a new password known only to you (Figure 19).

Figure 19: ARTAS KEY™ Cient Update Password



3.2.1.1 For ARTAS Procedure Kit Customers Purchasing with PayPal

1. Select the **QR Kits** tab. The user can add procedure kits for harvesting and site making. The user also has the ability to order accessory kits that include an Inner Needle and Dissection Punch.
2. Select the desired quantities of kits.
    a. Harvesting Kits are available in quantities of 3, 5, 10, and 20 kits.
        a) Harvesting Small Kits – For procedures up to 800 harvests.
        b) The Standard Harvesting Kit – For procedures of 801 or more harvests.
    b. Site Making Kits are available to order individually.
    c. Accessory Kits – Includes 5 pouches of an Inner Needle & Dissection Punch set.

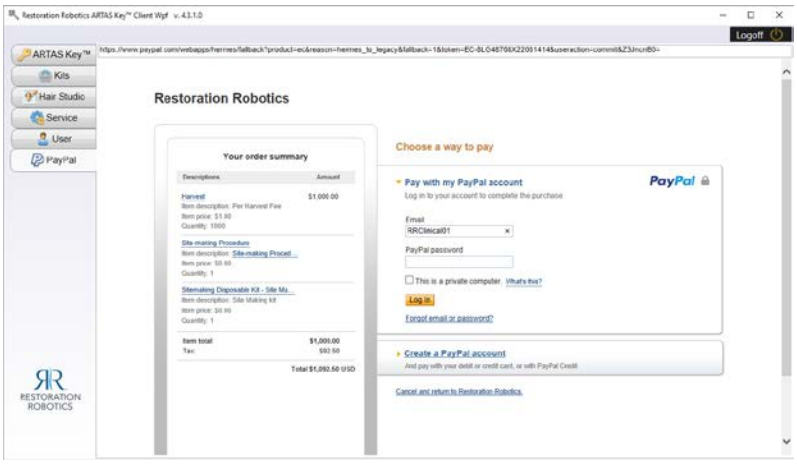
Figure 20: Ordering ARTAS Procedure Kits

3. Select desired shipping method.
    a. G – Ground Shipping
    b. 2 – 2 Day Shipping
    c. 1 – Standard Overnight
    d. 11 am – Priority Overnight, Delivery by 11 am
    e. 8 am – First Overnight, Delivery by 8 am

f. Select desired shipping method.

4. After all desired numbers of harvests and site making procedures and kits have been selected; check out using PayPal (Figure 21).
    a. Select the Checkout icon
    b. An order summary screen will appear
    c. Login to your existing PayPal account
    d. Review the order and complete the checkout process

Figure 21: ARTAS KEY™ Client Check Out with PayPal



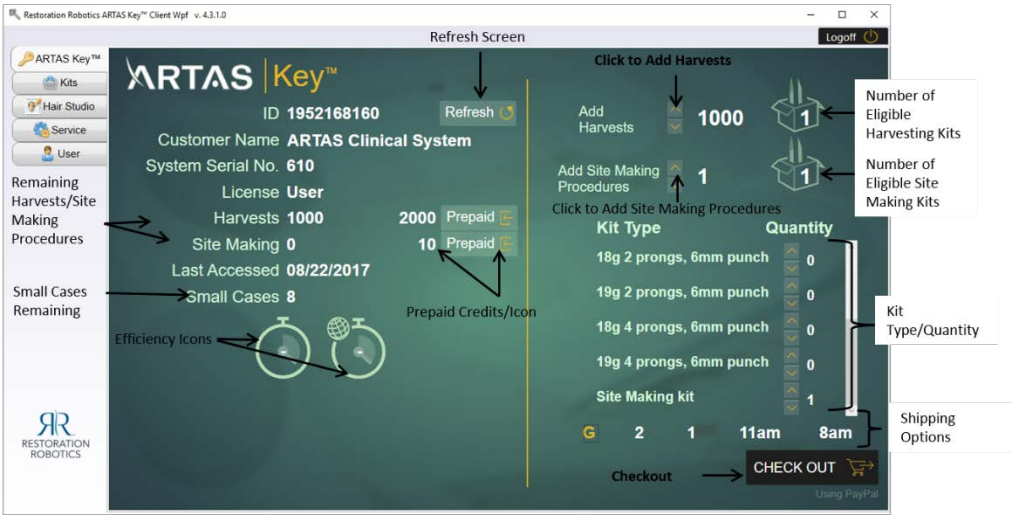
5. After completing the checkout process, an order confirmation dialog will be presented. Select **Confirm** to charge the credit card. Select **Cancel** to abort without charging the credit card.

3.2.1.2 For Per Harvest Customers Purchasing with PayPal

1. Select the **ARTAS KEY™** tab. The user can add harvests and site making procedures by two methods (Figure 21)
    a. Load Prepaid: Use pre-paid harvest/site making credit to load harvests
        a) The number of available prepaid credits will show in the right column next to *harvests* and *site making*
        b) Select the Prepaid icon to add these harvests/site making procedures to the ARTAS KEY™ USB Device
            1. Harvests will be added in increments of 1000
            2. Site making procedures will be added individually
    b. Purchase with PayPal: The workflow for purchasing through PayPal is described here (This method requires a valid PayPal account)
            3. Insert ARTAS KEY™ USB device into the USB port
            4. Start the ARTAS KEY™ Client application
            5. Log into the software
            6. For harvesting, use the arrows next to *Add Harvests* to add the desired number of harvests
                a. Harvests can be purchased in increments of 1000

7. Under *Kit Type* and *Quantity,* select the desired number of disposable kits
    a. The number of eligible kits will be displayed in the box next to *Add Harvests*
    b. Select the quantity of the desired kit type
8. For site making, use the arrows next to *Add Site Making Procedures* to add the desired number of site making procedures
    a. The number of eligible kits will be displayed in the box next to *Add Site Making Procedures*
    b. Select the quantity of kits desired
9. Select desired shipping method
    a. G – Ground Shipping
    b. 2 – 2 Day Shipping
    c. 1 – Standard Overnight
    d. 11 am – Priority Overnight, Delivery by 11 am
    e. 8 am – First Overnight, Delivery by 8 am

Figure 22: ARTAS KEY™ Client Main Screen



6. After all desired numbers of harvests and site making procedures and kits have been selected; check out using PayPal (Figure 20).
    e. Select the Checkout icon
    f. An order summary screen will appear
    g. Login to your existing PayPal account
    h. Review the order and complete the checkout process
7. After completing the checkout process, an order confirmation dialog will be presented. Select **Confirm** to charge the credit card and add harvests and site making procedures to the ARTAS KEY™ USB device. Select **Cancel** to abort without charging the credit card.

8. Once completed, select the **ARTAS KEY™** tab. Select **Refresh** (Figure 21) and verify that the harvests and site making procedures purchased are included in the number available.

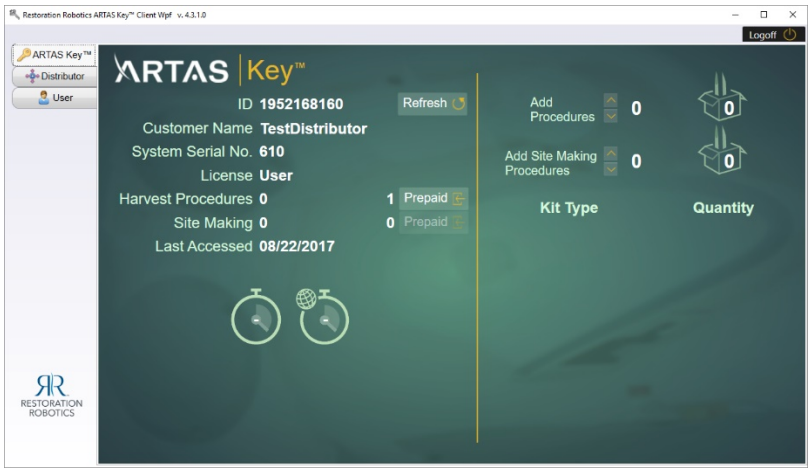
Additional features of ARTAS KEY™ Client include:

1. Efficiency Icons
    a. The first icon represents the clinics efficiency when using the ARTAS™ System percentage over the last 3 months. For example, if the percentage is 50%, this means that the robot is working 50% of the time. The other half of the procedure time is being used for non-robotic activities
    b. The second icon compares the efficiency of the clinic when using the ARTAS™ System to the top ranked systems over the past 3 months. For example, if the clinics efficiency percentage is 50% and the top ranked efficiency is 80%, the percentage here would be 50%/80% = 62%

3.2.1.3 For Customers Purchasing Through a Distributor

1. Select the **ARTAS KEY™** tab (Figure 22). The user can add harvest and site making procedures using the following method.
    a. Load Prepaid: Use pre-paid harvest/site making credit to load procedures
        i. The number of available prepaid credits will show in the right column next to *Harvest Procedures* and *Site Making*

Figure 23: ARTAS KEY™ Client for Customers Purchaising Through a Distributor



2. Once completed, select the **ARTAS KEY™** tab. Select Refresh and verify that the harvesting and site making procedures purchased are included in the number available.
3. Efficiency Icons
    a. The first icon represents the clinics efficiency when using the ARTAS™ System percentage over the last 3 months. For example, if the percentage is 50%, this means that the robot is working 50% of the time. The other half of the procedure time is being used for non-robotic activities

b. The second icon compares the efficiency of the clinic when using the ARTAS™ System to the top ranked systems over the past 3 months. For example, if the clinics efficiency percentage is 50% and the top ranked efficiency is 80%, the percentage here would be 50%/80% = 62%

3.3 Clinical Accessories and Supplies

There are clinical kits provided for each harvesting and site making procedure using the ARTAS™ System.

- Reusable Clinical Kit for Harvesting (Section 3.3.1.1)
- Sterile Disposable Clinical Kit for Harvesting (Section 3.3.1.2)
- Non-Sterile Disposable Clinical Kit for Harvesting (Section 3.3.1.3)
- Sterile Disposable Clinical Kit for Site Making (Section 3.3.2.3)
- Reusable Clinical Kit for Site Making (Section 3.3.2.1)
- Reusable Blade Holder for Site Making (Section 3.3.2.2)

3.3.1 Harvesting Procedure Kits

There are three clinical kits provided for a harvesting procedure using the ARTAS™ System:

- Reusable Clinical Kit (Section 3.3.1.1)
- Sterile Disposable Clinical Kit (Section 3.3.1.2)
- Non-sterile Disposable Clinical Kit (Section 3.3.1.3)

Both the reusable clinical kit and the disposable clinical kits include Instructions for Use (IFU) documentation with information and directions for use. Section 7.1.4 reviews how to properly install the harvesting clinical kits.

3.3.1.1 Reusable Clinical Kit for Harvesting

The reusable clinical kit for harvesting includes:

- Tensioner Tray (Figure 23)
- Punch Wrench (Figure 24)
- Needle Stylet (Figure 25)
- Tensioner Tool (Figure 27)
- Face Cushion (Figure 28)

The Tensioner Tray, Punch Wrench, Needle Stylet, and Tensioner Tool must be cleaned and sterilized per the instructions for use after each procedure to allow for reuse. The Face Cushion should be properly wrapped with a waterproof barrier prior to each procedure.

Warning	***The reusable clinical kit is non-sterile and must be sterilized prior to coming into contact with the patient. See the IFU included in the reusable clinical kit for information on sterilization.***	Warning

3.3.1.1.1 Tensioner Tray

The Tensioner Tray is used to store the Skin Tensioner when not applied to the scalp to prevent damage to the pins of the Skin Tensioner.

- Between grids, gently place the Skin Tensioner in the Tensioner Tray
- The corners of the Skin Tensioner fit into the molded corners of the Skin Tensioner Tray

Figure 24: Tensioner Tray

3.3.1.1.2 Punch Wrench

The Punch Wrench is used to tighten the Dissection Punch onto the spindle during installation and loosen the Dissection Punch during removal.

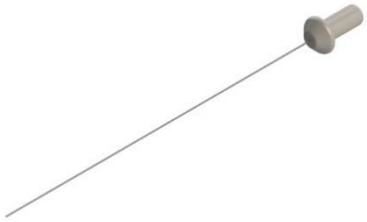
- Follow the instructions in Section 7.1.4 and 7.8 for installation and removal

Figure 25: Punch Wrench

3.3.1.1.3 Needle Stylet

The Needle Stylet is used to remove obstructions within the inner needle.

Figure 26: Needle Stylet



- Select **Change Needle** from the **Utilities** menu on the User Interface
- On the Control Panel of the System Cart, press the **Manual** button
- Holding the white end of the Needle Stylet, gently guide the distal end of the Needle Stylet through the distal end of the Dissection Punch
- Gently slide the Stylet into the Needle/Punch until resistance is felt
- Pull the Stylet out of the Needle/Punch gently
- Resume software control by pressing the **Manual** button on the Control Panel of the System Cart
- Select **Resume** from the User Interface
- Flush the tubing of the Inner Needle by selecting the **Saline Flush** icon in the **Utilities** Menu

Figure 27: Using the Needle Stylet

3.3.1.1.4 Tensioner Tool

The Tensioner Tool is used to apply the Skin Tensioner to the scalp. The Tensioner Tool is used to compress and pick up the Skin Tensioner, and then to transfer it between a chosen grid location on the area to be harvested and the Tensioner Tray.

Figure 28: Tensioner Tool

3.3.1.1.5 Face Cushion

The Face Cushion is used throughout the ARTAS™ procedure. The cushion is layered with memory foam for improved patient comfort. The cushion should be wrapped with a waterproof covering before each procedure.

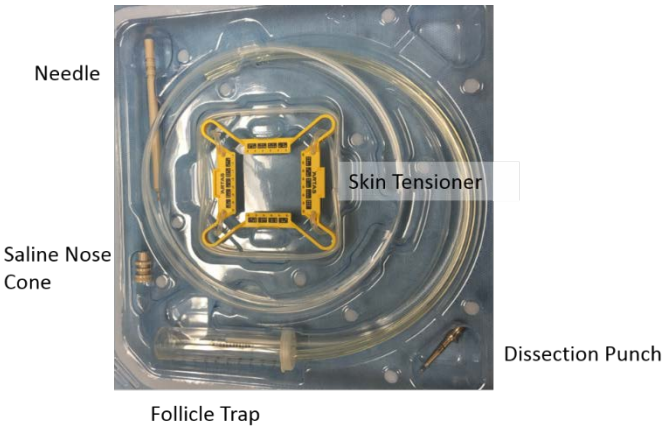
Figure 29: Reusable Face Cushion

3.3.1.2 Sterile Disposable Clinical Kit for Harvesting

Disposable clinical accessories are provided sterile. The sterile disposable clinical kit (Figure 30) includes:

- Inner Needle (Section 3.3.1.2.1)
- Dissection Punch (Section 3.3.1.2.2)
- Skin Tensioner (Section 3.3.1.2.3)
- Saline Nose Cone (Section 3.3.1.2.4)
- Follicle Trap (Section 3.3.1.2.5)

Figure 30: Sterile Disposable Clinical Kit for Harvesting



3.3.1.2.1 Inner Needle

The ARTAS™ System uses a 2-step dissection technique designed to split the roles of puncture and dissection. The sharp Inner Needle (Figure 31 & Figure 32) is used to puncture or score a 0.8mm (20g), 0.9mm (19g) or 1-mm (18g) diameter incision around the follicle in the first step of the 2-step dissection.

Available in sizes:

- 18g – 2 prong or 4 prong
- 19g – 2 prong or 4 prong
- 20g – 2 prong only

Figure 31: Inner Needle with Needle Cover

Figure 32: Inner Needle without Cover

Figure 33: 2 Prong vs 4 Prong Inner Needle

3.3.1.2.2 Dissection Punch

The ARTAS™ System uses a 2-step dissection technique to split the roles of puncture and dissection. A dull Dissection Punch (Figure 34) dissects the follicle from the surrounding tissue after the sharp Inner Needle scores the epidermis in the 2nd step of the 2-step dissection. The distance from the tip of the Dissection Punch to the shoulder is 6mm. The Dissection Punch is available in 18g, 19g & 20g in coordination with the Inner Needle.

Figure 34: Dissection Punch

Warning		Warning
	***The Dissection Punch is a one-time use item and must be disposed of into a Sharps container after a single use.***	

Warning		Warning
	The Inner Needle and Dissection Punch mush be used in the same gauge.	

3.3.1.2.3 Skin Tensioner

The Skin Tensioner (Figure 35) ensures that the skin maintains sufficient tension in the current area of harvesting.

After being applied to the scalp, the flexures at the corners pull the skin toward the sides of the Skin Tensioner. The elastic tubing of the tensioner reminds the patient to refrain from excessive motion and holds the tensioner against the patient's scalp.

There are also fiducial markings on the Skin Tensioner that are used to track dissection locations during the dissection procedure.

Warning		Warning
	The Skin Tensioner is a one-time use item and must be disposed of into a Sharps container after a single use.	

When not affixed to the patient's scalp, the Skin Tensioner is stored in the Tensioner Tray. The Locking Tensioner Tool may also be stored with the Skin Tensioner using the Tensioner Tray in between grids (Figure 36).

Figure 35: Skin Tensioner

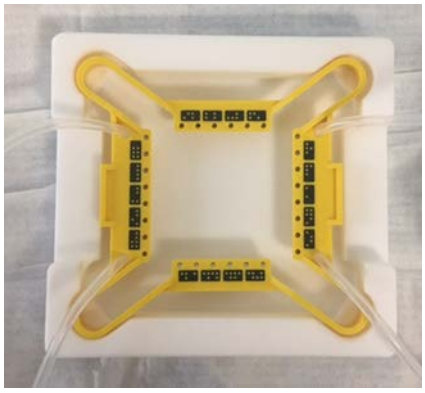


Figure 36: Locking Tensioner Tool with Skin Tensioner in Tray

3.3.1.2.4 Saline Nose Cone

The Saline Nose Cone (Figure 37) attaches to a 10cc Luer Lock syringe (not provided) to allow the ARTAS™ System to flush the Inner Needle and tubing after each grid. See Section 5.4.4.

Figure 37: Saline Nose Cone

Warning		Warning
	***The Saline Nose Cone is a one-time use item and must be disposed of into the proper container after a single use.***	

3.3.1.2.5 Follicle Trap

The Follicle Trap attaches to the vacuum and the tubing of the Inner Needle providing a receptacle for saline that has been flushed through the Inner Needle and tubing after each grid.

Figure 38: Follicle Trap

Warning *The Follicle Trap is a one-time use item and must be disposed of into the proper container after a single use.* **Warning**

3.3.1.3 Non-Sterile Disposable Clinical Kit

The non-sterile disposable clinical kit contains non-sterile, single-use disposable items:

- Needle Clip - Holds the Inner Needle to the Needle Mechanism (Figure 39)

Figure 39: Harvesting Needle Clip

- Vacuum Canister Liner - Contains any overflow from the Follicle Trap (Figure 40)

Figure 40: Vacuum Canister Liner

- Face Cushion Overlay and Cover - To be used in conjunction with the reusable Face Cushion (Figure 41).

Figure 41: Face Cushion Overlay & Cover

Warning *The Harvesting Needle Clip, Vacuum Canister Liner and Face Cushion Overlay are one-time use items and must be disposed of into the proper container after a single use.* **Warning**

3.3.2 Site Making Procedure Kits

Each site making procedure requires one reusable and one disposable kit described in Sections 3.3.2.1 & 3.3.2.3. Refer to Sections 8.2.6 & 8.2.7 for proper assembly instructions.

- Reusable Clinical Kit (Section 3.3.2.1)
- Reusable ARTAS™ Blade Holder (Section 3.3.2.2)
- Sterile Disposable Clinical Kit (Section 3.3.2.3)

Both the reusable clinical kits and the disposable clinical kits include Instructions for Use (IFU) documentation with information and directions for use.

3.3.2.1 Site Making Reusable Clinical Kit

The site making reusable clinical kit contains the components listed below and should be sterilized per the IFU prior to the Site Making procedure.

- Site Making Wrench (Section 3.3.2.1.1)
- Needle Protector (Section 3.3.2.1.2)
- Site Making Needle Clip (Section 3.3.2.1.3)
- Site Making Guide (Section 3.3.2.1.4)
- Dampening Spring (Section 3.3.2.1.5)
- Probe (Section 3.3.2.1.6)
- Site Making Headrest (Section 3.3.2.1.7)

Warning		Warning
	***The reusable clinical kit is non-sterile and must be sterilized prior to coming into contact with the patient. See the IFU included in the reusable clinical kit for information on sterilization.***	

3.3.2.1.1 Site Making Wrench

The Site Making Wrench (Figure 42) is used to tighten the Site Making Guide onto the spindle during installation and loosen the Site Making Guide during removal.

- The Punch Wrench for harvesting and the Site Making Wrench are interchangeable

Figure 42: Site Making Wrench

3.3.2.1.2 Needle Protector

The Needle Protector (Figure 43) is placed over the needle or blade once installed into the Site Making Guide to protect the user from the tip of the needle or blade.

Figure 43: Needle Protector

3.3.2.1.3 Site Making Needle Clip

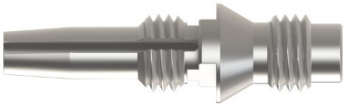
The Needle Clip (Figure 44) for site making is reusable and does not have a cushioned side. This holds the base of the site making needle or Blade Holder to the Needle Mechanism.

Figure 44: Site Making Needle Clip

3.3.2.1.4 Site Making Guide

The Site Making Guide (Figure 45) is installed with the needle or blade and provides a guide for the system to create incisions.

Figure 45: Site Making Guide



3.3.2.1.5 Dampening Spring

The Dampening Spring (Figure 46) is installed over the base of the needle or Blade Holder.

Figure 46: Dampening Spring

3.3.2.1.6 Probe

The Probe (Figure 47) is an instrument used to measure the length of harvested grafts and the depth of the incisions created in order to achieve desired depth. The bands on the probe are 2mm each.

Figure 47: Probe for Site Making

3.3.2.1.7 Site Making Headrest

The Site Making Headrest (Figure 48) is placed on the existing headrest of the Patient Chair to elevate the patient's head so the recipient area is easily accessible to the Needle Mechanism.

Figure 48: Site Making Headrest

3.3.2.2 ARTAS™ Reusable Blade Holder

For the site making procedure, we recommend using the needles from the ARTAS™ System Site Making Disposable Kit (Section 3.3.2.3). Alternatively, we also provide a Blade Holder to be used with commercially available blades at the user's convenience. These include square, 45°, spear point and chisel blades. The Blade Holder is designed to be used with the ARTAS™ System Needle Mechanism only.

Restoration Robotics, Inc. is not responsible and will not be held responsible for any potential or actual claims or causes of action arising out of, or damages in connection with, or resulting from the use of commercially available blades other than the recommended blades, or any modifications to those blades.

A blade cutter may be required for some types of blades. See Section 8.2.7 for instructions for proper installation. The Blade Holder components are:

- Blade Holder Wrench (Section 3.3.2.2.1)
- Blade Release Tool – Thumb Screw (Section 3.3.2.2.2)
- Blade Collet - 0.10mm, 0.25mm & 0.65mm (Section 3.3.2.2.3)
- Collet Sleeve (Section 3.3.2.2.4)
- Blade Protector (Section 3.3.2.2.5)
- Back Extension (Section 3.3.2.2.6)

Warning	***The ARTAS™ Blade Holder is non-sterile and must be sterilized prior to coming into contact with the patient. See the IFU included in the reusable clinical kit for information on sterilization.***	Warning

Figure 49: ARTAS Site Making Blade Holder with Square Blade

3.3.2.2.1 Blade Holder Wrench

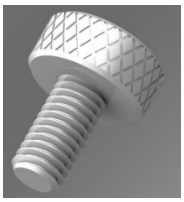
The Blade Holder Wrench (Figure 50) is used to tighten the Back Extension to the Collet and Collet Sleeve.

Figure 50: Blade Holder Wrench

3.3.2.2.2 Blade Release Tool – Thumb Screw

The Blade Release Tool, or Thumb Screw, (Figure 51) is used to release blade and Blade Collet from the Blade Holder at the end of the site making procedure.

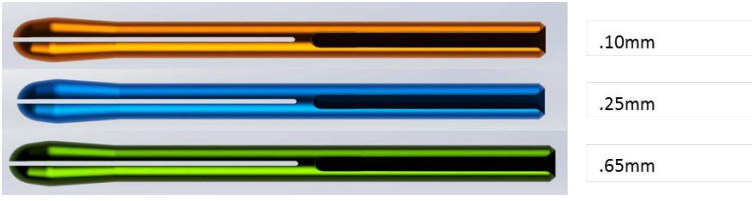
Figure 51: Blade Release Tool - Thumb Screw



3.3.2.2.3 Blade Collet

The Blade Collet comes in 3 sizes - 0.10mm (yellow), 0.25mm (blue), and 0.65mm (green). The Blade Collet (Figure 52) holds the blade in place.

Figure 52: Blade Collets



3.3.2.2.4 Collet Sleeve

The Collet Sleeve (Figure 53) is tightened onto the Blade Collet and the Back Extension of the Blade Holder.

Figure 53: Collet Sleeve

3.3.2.2.5 Blade Protector

The Blade Protector (Figure 54) is placed over the tip of the blade while tightening the Back Extension during assembly of the Blade Holder and loosening the Back Extension from the Collet Sleeve during disassembly. The Blade Protector is also used with the Blade Release Tool at the end of a procedure to release the Collet and Blade from the Collet Sleeve.

Figure 54: Blade Protector

3.3.2.2.6 Back Extension

The Back Extension (Figure 55) is tightened onto the Collet Sleeve.

Figure 55: Back Extension

3.3.2.3 Site Making Sterile Disposable Kit

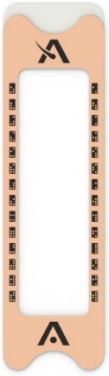
Disposable clinical accessories for the ARTAS™ site making procedure are provided sterile. The sterile disposable clinical kit includes:

- 2 Self-Adhesive Fiducial Platforms (Section 3.3.2.3.1)
- 2 Solid Core Needles – 18g & 19g (Section 3.3.2.3.2)

3.3.2.3.1 Self-Adhesive Fiducial Platform

The Fiducial Platform (Figure 56) is self-adhesive and applied to the recipient area during the site making procedure. There are fiducial markings on the Fiducial Platform that are used to track incision locations during the recipient site making procedure.

Figure 56: Self-Adhesive Fiducial Platform



Warning		Warning
	The Self-Adhesive Fiducial Platform is a one-time use item and must be disposed of into the proper container after a single use.	

3.3.2.3.2 Solid Core Needles

Two sizes of solid core needles (Figure 57) are included in the sterile disposable kit for site making – 18g and 19g.

Figure 57: Solid Core Needles

Warning		Warning
	The Solid Core Needles are one-time use items and must be disposed of into a Sharps container after a single use.	

4 ARTAS™ System Setup

This Section will go over how to set up the ARTAS™ System for the procedure.

4.1 ARTAS™ Patient Chair Positioning

Position the System Cart and Patient Chair in a stable, level location.

4.1.1 Patient Chair Positioning for the Harvesting Procedure

For harvesting, the chair should be positioned in front of the cart. The center of the Patient Chair headrest should be directly in front of the Robotic Arm, and the seat of the Patient Chair should be to the right. Position the Patient Chair approximately 1 foot away from the System Cart.

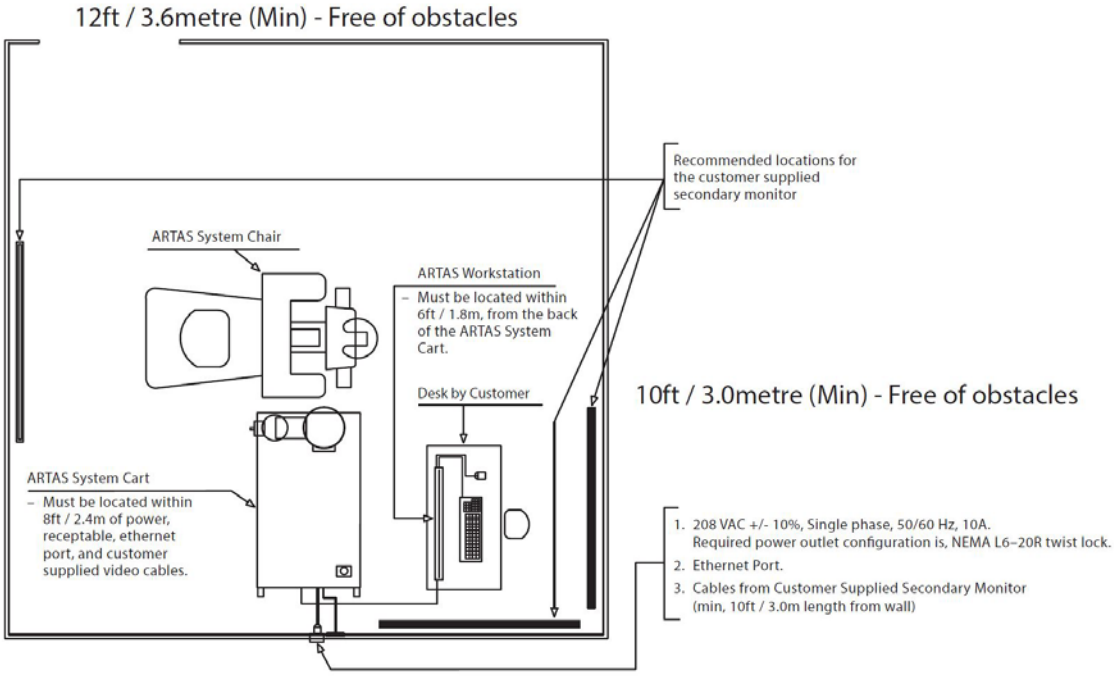
Allow sufficient space for the patient to be able to access the chair, the technician to be able to access either side of the cart, and the physician to be able to work next to the patient. Figure 58 shows the proper Patient Chair position for the Harvesting Procedure, and Figure 59 shows the space that should be allotted for the equipment itself in the harvesting procedure.

Place the pillow into the headrest and adjust the chair to the patient's comfort in order to minimize movement during the procedure.

Once the Patient Chair is positioned, lower the chair to its feet by turning the bottom right lever to the left.

Figure 58: Chair Position for Harvesting Procedure

Figure 59: Room Layout Example for Harvesting Procedure



4.1.2 Patient Chair Positioning for the Site Making Procedure

For site making, the Patient Chair will be rotated 180° from the harvesting procedure position. The Patient Chair should be placed as close to the System Cart as possible with the headrest aligned to the Robotic Arm. Remove the harvesting halo from the headrest by removing the 4 pins. Save the 4 pins for future use. Tilt the headrest upward and place the Site Making Headrest and pillow on the existing headrest on the Patient Chair. Figure 60 shows the proper Patient Chair positioning for the Site Making Procedure. Figure 61 shows the space that should be allotted for the equipment itself in the site making procedure.

Figure 60: Chair Positioning for the Site Making Procedure

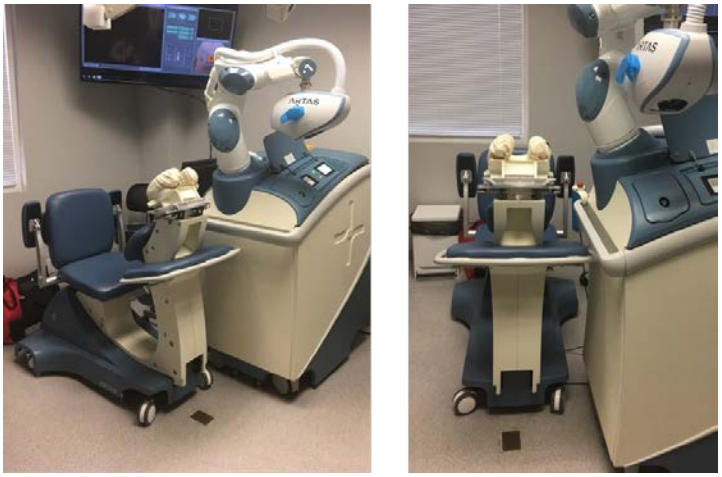
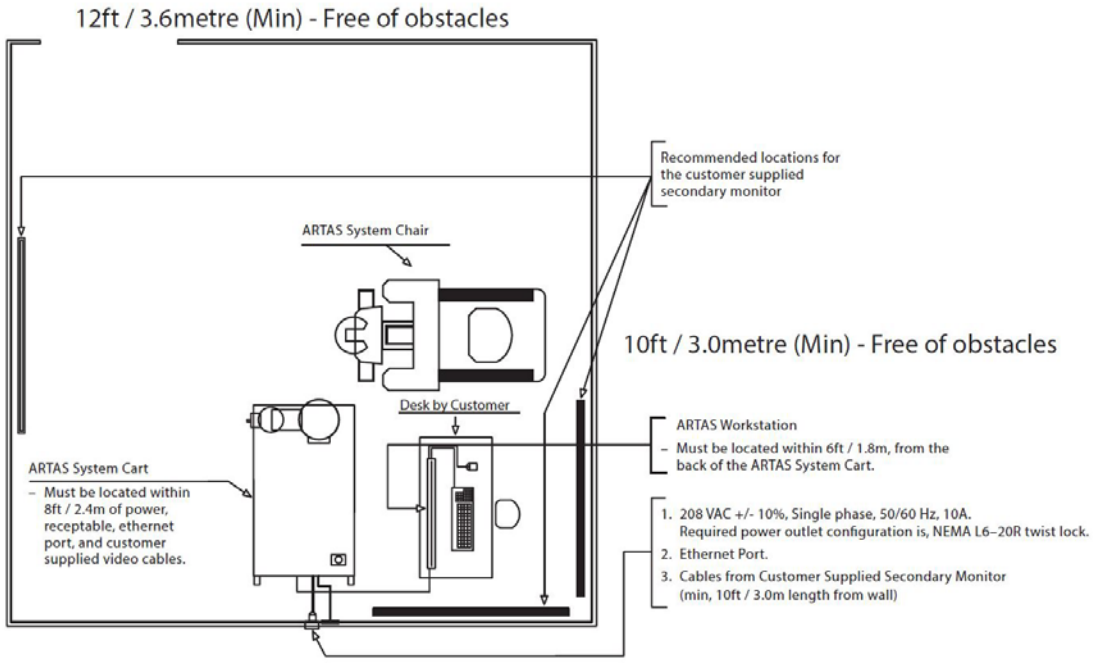


Figure 61: Room Layout Example for the Site Making Procedure



Using the face down pillow from the harvesting procedure, place it into the Site Making Headrest so that the opening of the pillow is facing upward. Adjust to their comfort in order to minimize movement during the procedure (Figure 62).

Once the Patient Chair is positioned, lower the chair to its feet by turning the bottom right lever counter clockwise.

Figure 62: Site Making Patient Positioning

4.2 ARTAS™ System Cart and User Interface Setup

- Position the computer workstation (User Interface) to the side of the cart with the AC Power cord for the computer, USB Cables, Teach Pendant (if applicable) and the long DVI video cables (PRT-22983 should be used in place of the short cables provided with the monitor) plugged into the electrical panel for the System Cart, as shown in Figure 63.
    - Plug the operator keyboard and mouse into the USB ports on the monitor
    - Plug the desk e-stop into the electrical panel connection named E-STOP #1, as shown in Figure 63 and position it as shown in Figure 64.

Figure 63: System Cart Interconnect Panel

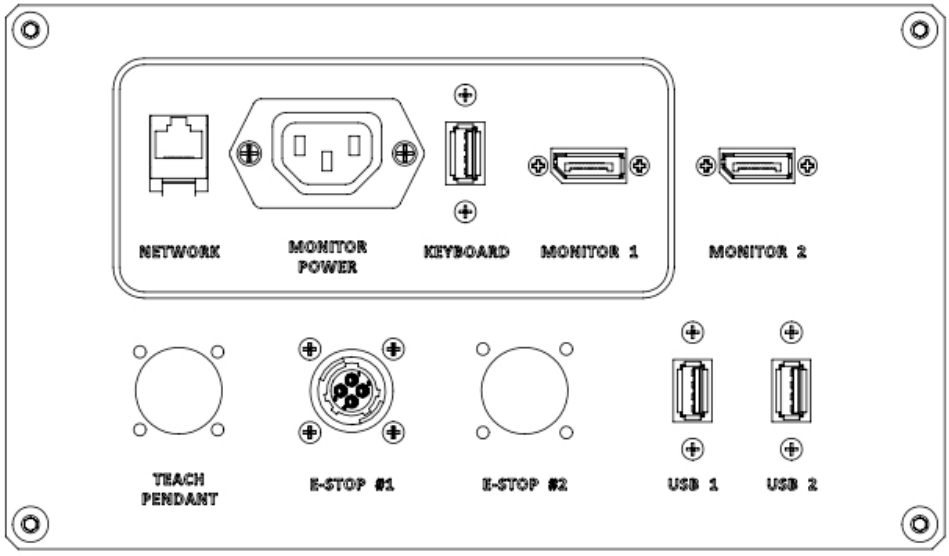
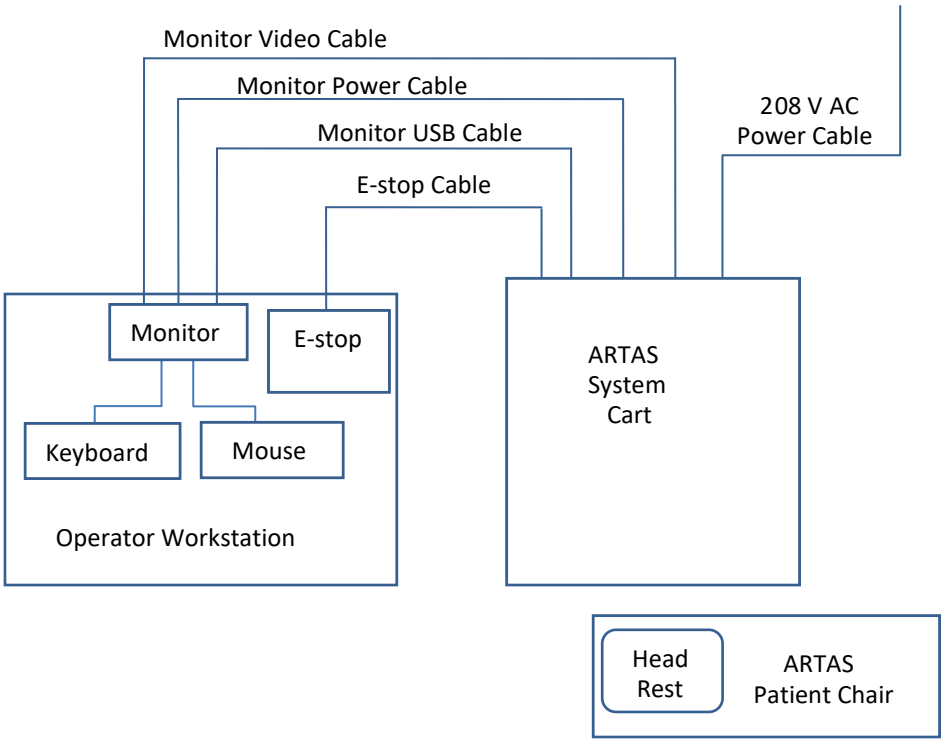


Figure 64: System Connections



- Plug the power cord from the System Cart into a 208V +/- 10%, single-phase AC outlet rated minimum current of 10A

4.3 Powering On the ARTAS™ System

During the initial power on of the ARTAS™ System, the system will go through a series of tests. Please refer to the ARTAS™ System Quick Setup Guide, LB-102084.

4.3.1 Powering On Systems 1001-2041

1. Turn on the main AC switch on the back of the System Cart next to the power cord. This provides input power to the UPS, but does not provide power to any other components of the System Cart until the UPS powers on.
2. Open the System Cart door.
    a. Press and hold **ON/TEST** on the UPS until a beep sounds, indicating that output power is enabled (Figure 13)
    b. Release **ON/TEST**
        - The computer will now power on
3. Press the green **ON** button on the top of the System Cart (Figure 65) to turn on power to the remaining cart subsystems.

Figure 65: Cart Control Panel

1. System Power ON/OFF button.
2. Enable manual control of Needle Mechanism.

Remaining buttons visible in needle mechanism Manual mode:

3. Extend Dissection Punch.
4. Demo Harvest.
5. Activate suction.
6. Next screen (Version Information, Light control)

4.3.2 Powering On Systems 2042 and Higher

1. Turn on the main AC switch on the back of the System Cart next to the power cord. Upon initial startup, the UPS does not require pressing the **Power On** button. The UPS will power up once incoming power is detected. Open the System Cart door to confirm the UPS powered on properly.
2. Press the green **ON** button on the top of the System Cart (Figure 65) to turn on power to the remaining cart subsystems.

4.4 Starting the ARTAS™ Software Application

1. Log into the Window® Operating System using the username and password given to you by Restoration Robotics.
2. Double-tap on the ARTAS™ System software icon  on the desktop. A splash screen is displayed briefly (Figure 66).

Figure 66: ARTAS™ System Software Splash Screen

4.5 Start-up Screen and Patient Data Entry

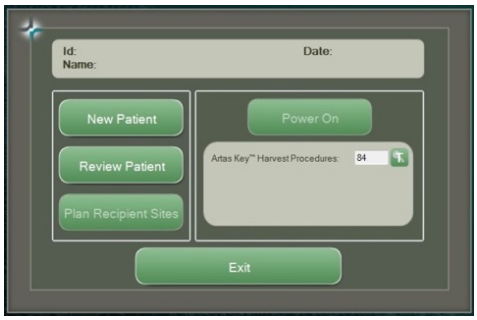
The ARTAS™ application maintains an internal database that tracks patient information and procedure data. That information is made available for use by the physician in the treatment report for each patient case.

To ensure the patient's data entry is properly initialized, the ARTAS™ application presents the patient data entry form at start-up.

Before starting the procedure by selecting **Power On**, the operator must choose between:

- Creating a new patient entry
- Selecting an existing patient

Figure 67: Startup Screen



If selecting an existing patient, the user has the option to continue a case already in progress on the same day or start a new case for an existing patient that was previously entered into the ARTAS™ System. Cases are automatically closed at the end of the day the case was started on.

Note that when continuing a case from earlier in the same day, the **Autoload Configuration** checkbox becomes visible. If selected, this will restore the system parameters to the state they were in before the software was shut down. If not selected, parameters will be restored to their default values. This checkbox is selected by default.

In addition, the display shows how many harvests or harvest procedures remain in the ARTAS™ KEY™® USB device. If there are an insufficient number of harvests that remain for the procedure, replenish the number of harvests on the USB Authenticator using the ARTAS KEY™ Client (Section 3.2.1).

4.5.1 New Patient Form

For a new patient, select **New Patient** on the startup screen (Figure 67) to open the new patient data form (Figure 68).

Figure 68: New Patient Data Form

- At a minimum, the user must enter a *Subject ID, Date of Birth, Gender, Ethnicity, Hair Caliber, Texture, Norwood Scale Progression, Dyed Hair* and *Previous Transplantation*
  - The required entries are indicated by a red exclamation point
  - The Subject ID may be used by the physician to create a unique identifier for a particular case and patient: for example, use a DATE-INITIALS format such as 20170217-JMS
- The Norwood Scale is a hair loss measurement scale
  - The values range from I to VII (in roman numerals)
  - Further classifications, using the letters 'a' and 'v', describe the direction of the hair loss
    - 'a' stands for anterior, meaning a general front to back progression of hair loss
    - 'v' stands for vertex, describes a back to front hair loss progression
  - Choose the value that most closely matches the hair loss pattern of the patient
- The *Grids* field refers to how many placements of the Skin Tensioner are expected to be performed during the harvesting procedure
- The ARTAS KEY™ USB device icon indicates how many Harvests or Harvest Procedures are remaining
  - Select the icon to view the number of Site Making Procedures remaining on the ARTAS KEY™ USB device

Once all patient data is entered, select the **Ok** icon. The User Interface will display the start-up screen.

4.5.2 Review Patient Form

When the patient has already been entered into the system, select **Review Patient (**Figure 67). A list of patients already in the system database is shown (Figure 69).

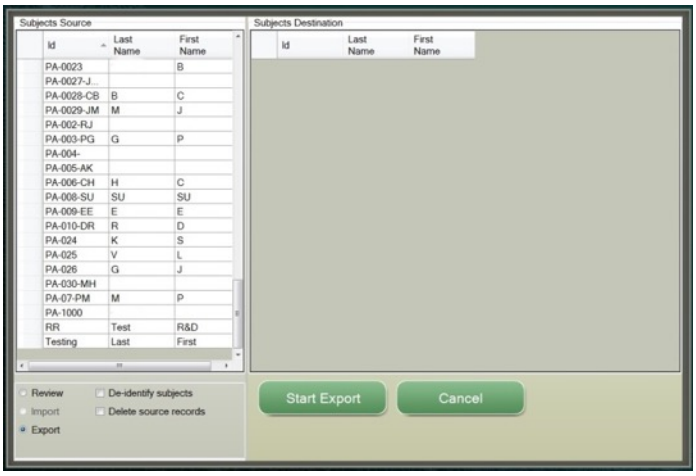
Figure 69: Review Patient Data Form

The list can be sorted by ID, Last Name or First Name. Select the column title to sort by the desired item. Select the patient from the list, and then choose **Continue Case** to continue a procedure that is already underway, or **New Case** to start a follow-up procedure on a patient. If a New Case is selected, the user will be required to indicate if the hair was dyed for the follow-up procedure.

Special elements on the *Patient Data Review Form* include:

- Post Process - Used to add information to the patient's data records following the procedure (Section 7.7.2)
- Basic Report - Select to create a one-page report for the procedure date selected (Section 10).
- Research Report – Select to create a multi-page detailed report for the procedure date selected
- Import and Export - Used to transfer single patient data to another system. These features are useful after a database upgrade, in order to migrate an older database into the newer format, or to copy data from one system to another for the physician's convenience
    - When **Export** is selected, an export file name is requested followed by the export data form (Figure 70). If it is necessary to mask any individually-identifiable information, select **De-identify Subjects**

Figure 70: Patient Export Data Form



From the Patient Data Review Form, select **Continue Case** to return to the Startup Screen. Next, select **Power On** (Figure 67) to enable power to the Robotic Arm and begin system operation.

4.6 System Verification

Caution

The following commands result in Robotic Arm movement.

Caution

After **Power On** is selected, the user is prompted to perform System Verification. System Verification ensures that all subsystems are working properly. All disposables should be removed prior to beginning System Verification.

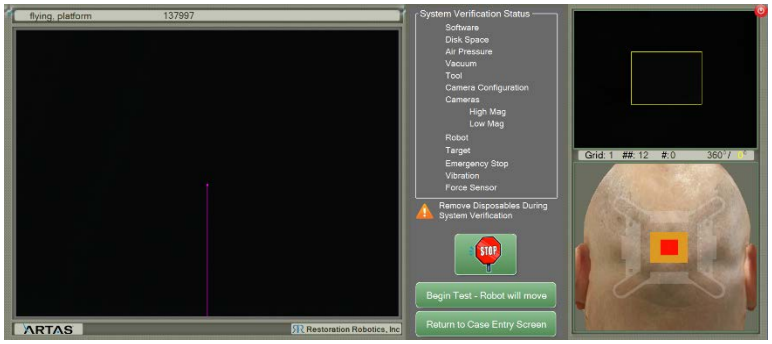
To perform System Verification:

1. Open the cover on the System Cart so the calibration checkerboard target is visible (Figure 71). The camera and vibration verification require the ability to see the target.

Figure 71: Calibration Target

2. Select **Begin Test** (Figure 72) – The Robotic Arm will move to begin verification.

Figure 72: System Verification Display

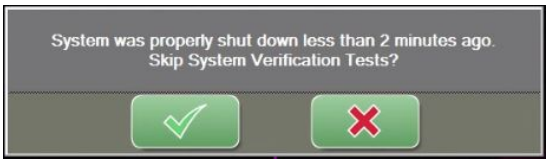


3. The System Verification display shows an image from the cameras. The display is updated with a green checkmark as each element passes the verification. If an element does not pass, a red 'X' will show next to the element and an error will be displayed on the lower portion of the screen. System Verification errors are discussed in Appendix A. When the System Verification is complete, select **System Ready** (Figure 72).

Figure 73: System Verification Passed

If the system has already performed verification that day, a dialog is shown that allows the verification to be skipped or repeated if desired (Figure 74).

Figure 74: Skip System Verification Dialog

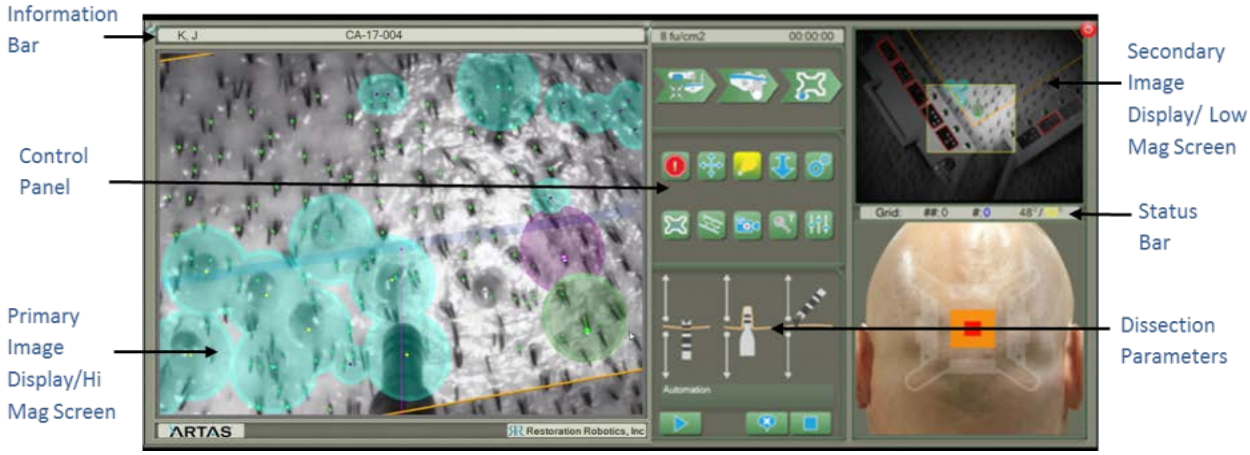


5 The ARTAS™ System User Interface

After System Verification is completed successfully, the Main User Screen of the User Interface is displayed. Elements of the Main User Screen include:

- Primary and Secondary Image Displays (Section 5.1)
- Information & Status Bars (Section 5.2)
- Puncture Image View (Section 5.3)
- Main Control Panel (Section 5.4)
- Dissection/Incision Parameters and Control Panel (Section 5.5)

Figure 75: Main User Screen



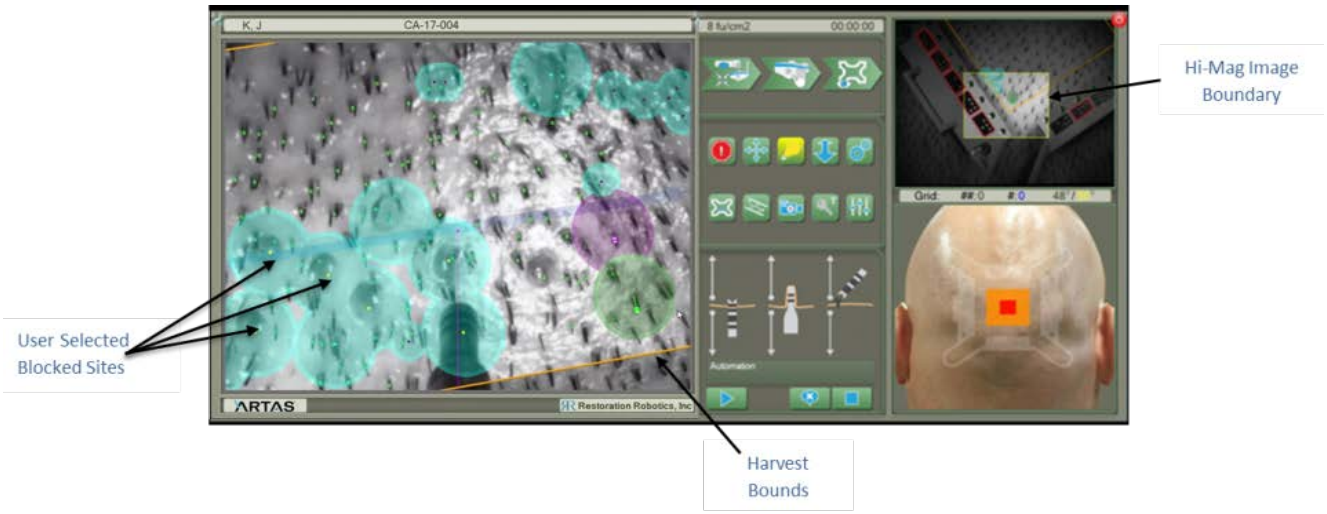
5.1 Primary and Secondary Image Displays

5.1.1 Image Displays for the Harvesting Procedure

Two image displays are visible on the Main User Screen during the harvesting procedure—a primary display, or high magnification, on the left and a smaller, secondary display, or low magnification, on the right.

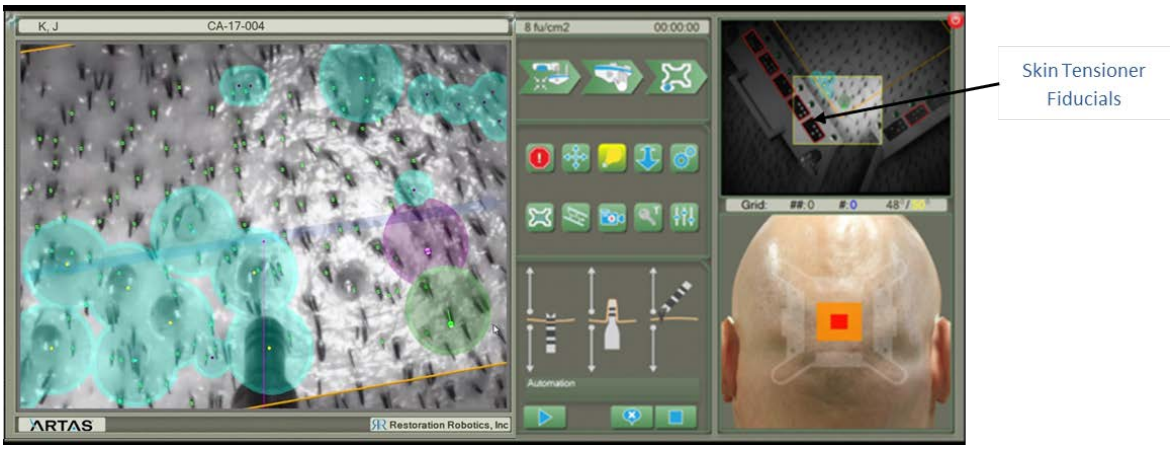
The primary display shows a live image with interactive graphical overlay (Figure 75). A high magnification, or hi-mag, camera view is shown on the left. This display includes a pink line showing the needle centerline. A dot along the line shows where the needle should enter the skin at the base of the hair to be harvested. The line ends at the tip of the punch when it is fully extended. The blue circles with a yellow dot in the center indicate blocked sites around previous harvests (Section 7.4.1). The area closer to the tensioner is darkened to indicate the boundaries of the harvest region (Section 7.4.2). The hi-mag image boundary is displayed in the secondary image display in the upper right of the User Interface.

Figure 76: Standard Harvesting Hi-Mag Image Display



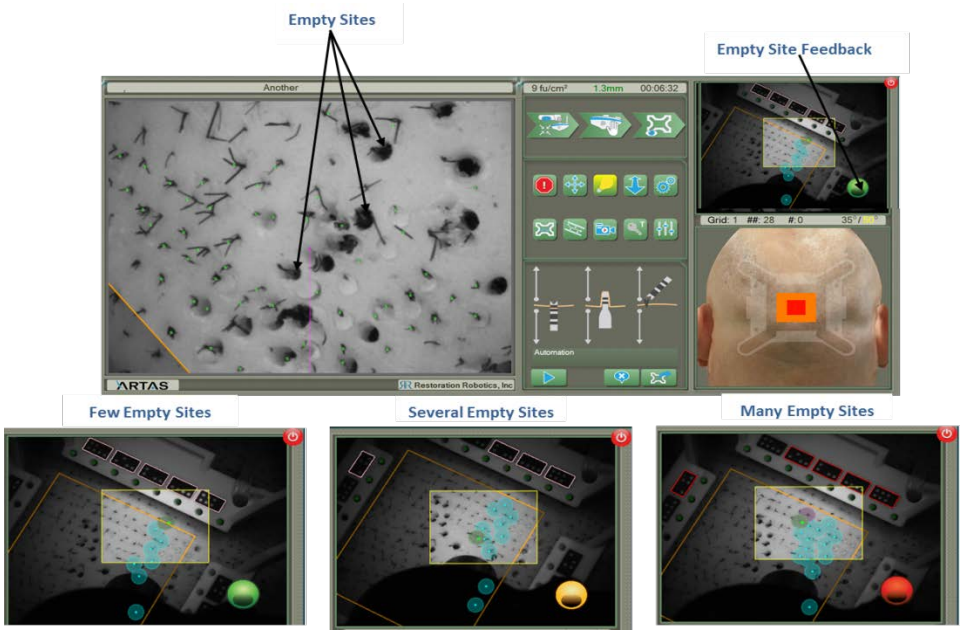
The secondary display in the upper right corner of the User Interface is the Low Magnification, or Low-Mag, Image display (Figure 77). This display shows similar information to the standard hi-mag camera display, but from the low-mag camera. As a result, it shows a wider field of view with lower resolution. The tensioner fiducials are also graphically highlighted in this display.

Figure 77: Harvesting Low Mag Image Display



The Empty Site Feedback display appears in the Low-Mag Image display (Figure 78). Dissection parameters should be monitored accordingly when an empty site warning appears.

Figure 78: Empty Site Warning Display



5.1.2 Image Display for the Site Making Procedure

During the Site Making Procedure, one image display is visible in the Main Viewing Screen of the User Interface. This display shows a live image with interactive graphical overlay (Figure 79). The image display during Site Making offer a wide field of view in order to provide an easy, overall view of the procedure area. The Main Viewing Screen can be zoomed in and out by the user. Hover over the screen with the mouse cursor and use the wheel to zoom in and out.

This display includes a pink line showing the needle centerline. The green dots are terminal follicles the system will avoid when creating incisions. The blue circles indicate an incision has been created. The area closer to the tensioner is darkened to indicate the boundaries of the incision region.

Figure 79: Site Making User Interface Image Display

In the Virtual Fiducial Platform window, the system places a dot when an incision is made. This information given is as follows:

- White Dot – Incision Created
- Green Dot – Incision Created, 1 Existing Follicular Unit Avoided
- Blue Dot – Incision Created, 2 or more Existing Follicular Units Avoided
- Grey Dot – Incision Created in the Hairline
- Black Dot – Manual Incision Created

5.2 Information & Status Bar

5.2.1 Information & Status Bar for the Harvesting Procedure

The bar at the top of the User Interface during harvesting displays information regarding the procedure (Figure 80). Information includes, from left to right, Patient Name, Patient ID, Measured Hair Density (right-click to view other option including Today's Date, Avg Distance, and Empty Harvest Sites), Average Hair Length, and Local Time (right-click to view other options including Elapsed Time Since First Harvest, Average Speed, Current Grid Time and Total Grid Time).

The measured hair density and average hair length is calculated at the beginning of each grid when acquiring the Tensioner (Sections 7.3.1 & 7.3.2.3).

In order for the system to perform accurately and optimally, the hair should be trimmed to 1.1-1.3 mm in length. The hair length display indicates the average hair length per grid, which is color-coded to help the user optimize shaving of the scalp.

- **Less than 1.0 mm**: Displays the hair length value in RED color
  - System will harvest, but it may not be able to recognize all of the very short hairs
- **1.0 – 1.3 mm**: Displays the hair length value in GREEN color
- **1.3 – 1.5 mm**: Displays the hair length value in ORANGE color
  - It is suggested to trim the hair shorter
- **Greater than 1.5 mm**: Displays the hair length value in RED color
  - System will harvest, but it may not recognize the longer hairs – suggest trimming the hair

Figure 80: Harvesting User Interface Information Bar

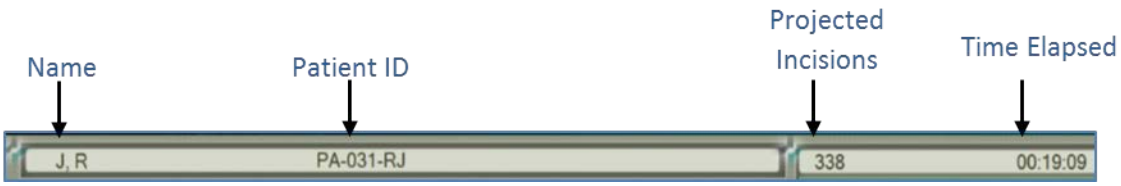
The Status Bar (Figure 81) is located in the middle right of the User Interface. Information regarding the status of the procedure can be found in this section. Information includes, from left to right, Grid Number, Total Number of Harvests, Number of Harvests in Current Grid, and Average Elevation Angles of the hairs in current view.

Figure 81: Harvesting User Interface Status Bar

5.2.2 Information & Status Bar for the Site Making Procedure

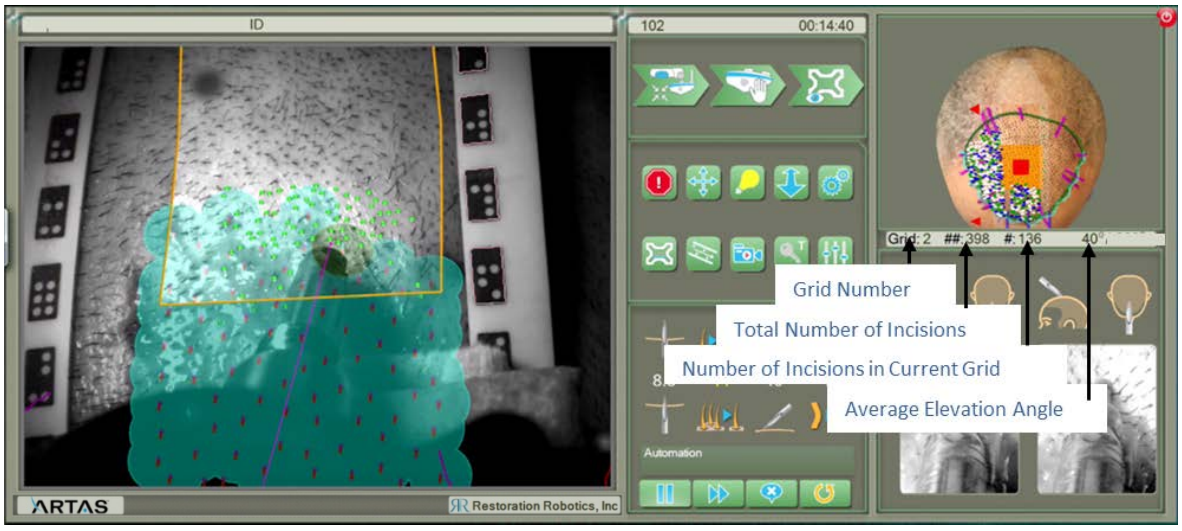
The bar at the top of the User Interface during site making displays information regarding the procedure (Figure 82). Information includes, from left to right, Patient Name, Patient ID, Planned Grid Sites with Bounds (right-click to view other options including Today's Date, Total/To Go/Completed Sites and Planned Grid Sites), and Local Time (right-click to view other options including Elapsed Time Since First Incision, Average Speed, Current Grid Time and Total Grid Time).

Figure 82: Site Making User Interface Information Bar



The Status Bar (Figure 83) is located in the middle right of the User Interface. Information regarding the status of the Site Making Procedure can be found in this section. Information includes, from left to right, Grid Number, Total Number of Incisions, Number of Incisions in Current Grid, and Average Elevation Angles of the hairs in current view. The second angle is a directional angle in relation to the nose, 0°.

Figure 83: Site Making User Interface Status Bar



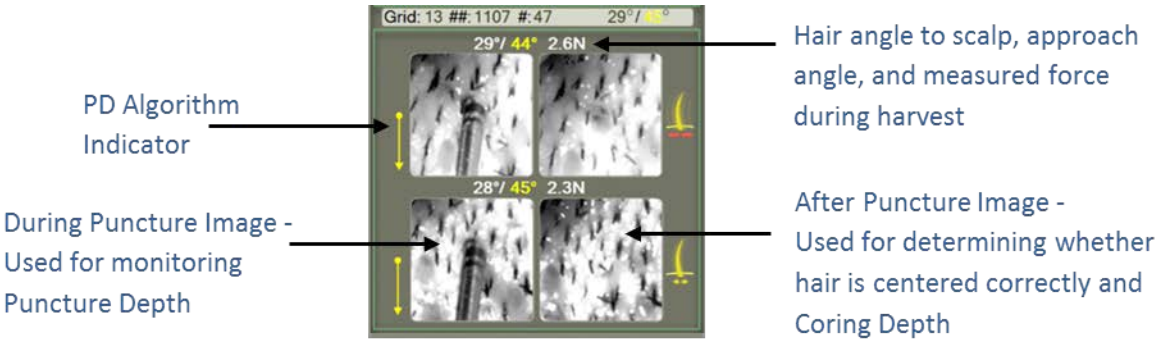
5.3 Puncture Image View

5.3.1 Puncture Image View for Harvesting

The Puncture Image View displays images from the 2 most recent harvests (Figure 84):

- The top 2 images correspond to the most recent harvest
  - Above each set of images, the elevation angle, approach angle and measured force in Newtons is displayed
- The bottom 2 images correspond to the 2nd to last harvest
- The left images show the needle during puncture, which is used for viewing puncture depth
- The right images are captured just after the needle and punch are retracted. It shows the position of the hair within the dissected follicle, which allows the user to visually verify the follicle is centered and whether the punch depth needs adjustment

Figure 84: Harvesting User Interface Puncture Images

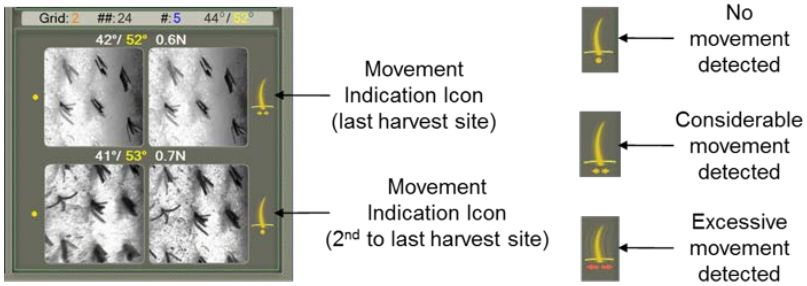


Puncture Depth (PD) Algorithm Indicators are located next to the left-hand image in the Puncture Image View display (Figure 84).

- A down arrow indicates the PD will be shallower for the next harvest
- An up arrow indicates the PD will be deeper for the next harvest
- A solid dot indicates there will be no change for the next harvest
    - Yellow dot – the bands on the needle are detected, and there will be no change
    - Gray dot – the bands on the needle are not visible, and there will be no change
    - Red dot – the bands on the needle cannot be identified by the system, and there will be no change

The Patient Movement Indicator is located next to the right-hand image in the Puncture Image View display (Figure 85).

Figure 85: Harvesting Patient Movement Indicator

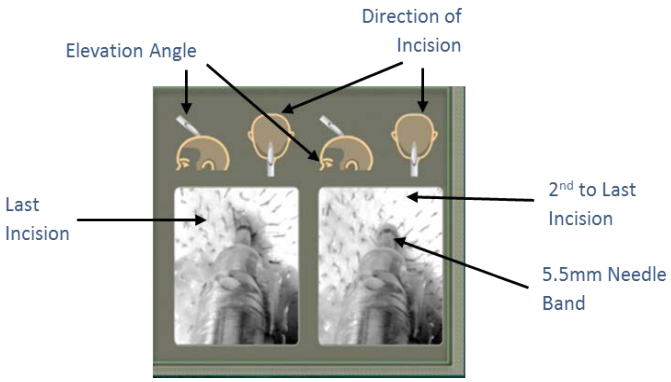


5.3.2 Puncture Image View for Site Making

During the Site Making Procedure, the Puncture Image View displays images from the last 2 incisions created in the lower right corner of the User Interface (Figure 86).

- The left image is of the last incision
- The right image is the 2nd to last incision
- Above each image are 2 illustrations showing a visual of the elevation angle and direction of the incision in the image

Figure 86: Site Making Puncture Images



Monitoring depth during the Site Making Procedure can be done by watching the Puncture View Images. When using a provided needle to create recipient sites, the depth is monitored by watching the needle band. The band is 5.5mm from the tip of the needle.

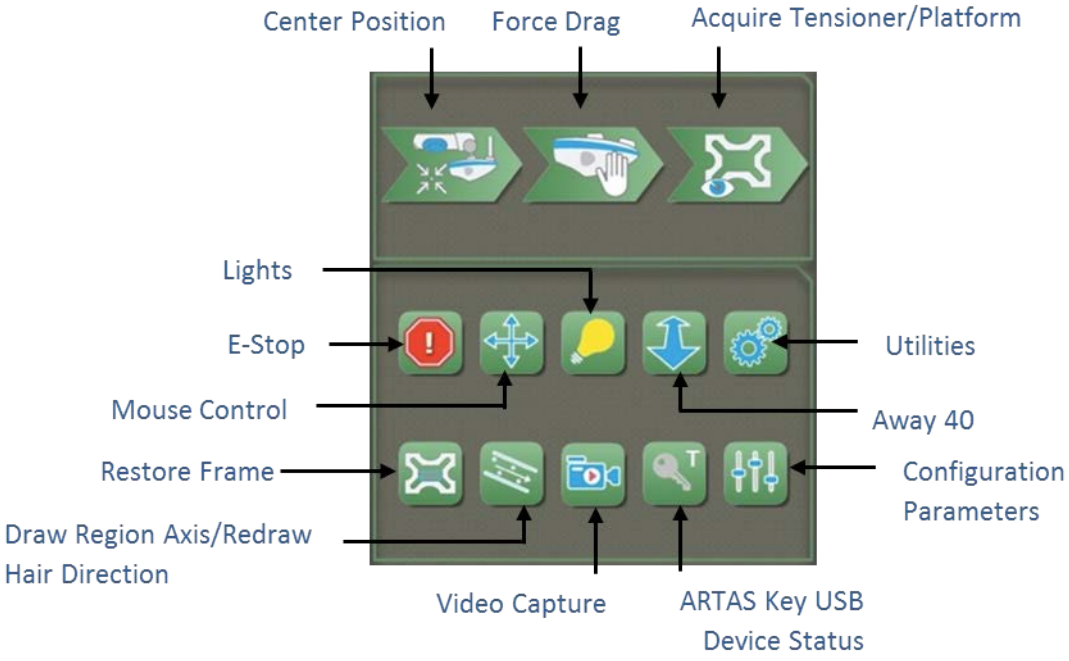
When using the ARTAS™ Site Making Blade Holder, the shoulder of the Collet should just touch the patient's scalp to achieve the proper depth. See Section 8.5.4.1.2 for details.

5.4 Main Control Panel

The Main Control Panel (Figure 87) allows the user to quickly step through the steps leading to dissection or recipient site creation and also provides controls to view and capture harvesting and site making information. Use of the control panel is described in subsequent sections:

- Center Robot (Sections 7.3.2.1 & 8.4.1)
- Force Drag (Sections 7.3.2.2 & 8.4.2)
- Acquire Tensioner/Platform (Sections 7.3.1, 7.3.2.3 & 8.4.3)
- E-stop (Section 2.4.3.2)
- Mouse Control Menu (Section 5.4.1)
- Lights (Section 5.4.2)
- Away 40 (Section 5.4.3)
- Utilities (Section 5.4.4)
- Restore Frame (Section 5.4.5)
- Draw Region Axis/Redraw Hair Direction (Section 5.4.6)
- Video Capture (Section 5.4.7)
- ARTAS KEY™ USB Device Status (Section 5.4.8)
- Configuration Parameters (Section 5.4.9)

Figure 87: Main Control Panel for User Interface



5.4.1 Main Control Panel – Mouse Control Menu

Caution  *The following commands result in Robotic Arm movement* Caution 

5.4.1.1 Mouse Drag

In the Mouse Control Menu (Figure 88), a user can make fine position adjustments once the Needle Mechanism is in place over the Tensioner using the Mouse Drag Function.

Figure 88: Main Control Panel - Mouse Control Menu

To use Mouse Drag:

1. Select the Mouse Control Menu icon on the User Interface.
2. A cross will display in the hi-mag screen. With the mouse, click in the image window, hold and move the mouse cursor across the display. The image shifts as the Robotic Arm moves. Repeat the click-and-move motion until the Robotic Arm and Needle Mechanism are in the desired position.
    a. Mouse Drag mode can also be activated by holding the CTRL + SHIFT keys on the keyboard while using the click-and-move motion (Figure 89)
    b. To use Mouse Drag with the Touchscreen, touch 3 fingers to the screen and drag to the desired location

NOTE: *Since Mouse Drag is typically used to move the Robotic Arm near the patient, ensure that any personnel near the patient are aware of the impending movement.*

Figure 89: Mouse Drag Shortcuts

CTRL + Shift Shortcut

Use 3 Fingers on Touchscreen

5.4.1.2 Focus, Towards & Away Functions

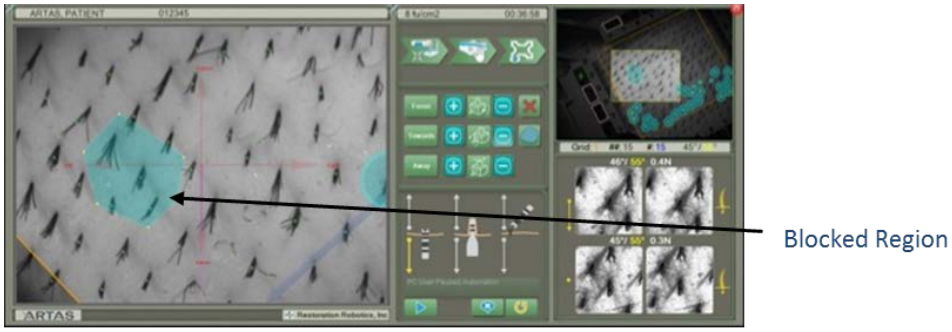
In the Mouse Control menu, the user can use the Focus, Towards and Away icons to focus the cameras.

- Focus Icon – Select and hold the icon to automatically move the Robotic Arm closer or further from the patient to focus the cameras
- Away & Towards Icons – Used to manually focus the cameras
- Rotation Icons – 6 icons used to control the rotation around the needle tip

5.4.1.3 Block Region

The Block Region (Figure 90) or Blue Blob function is used to help mark reserved harvest regions from which hairs will not be selected for harvest. This is typically used to avoid harvesting near scars, moles, or previously harvested areas.

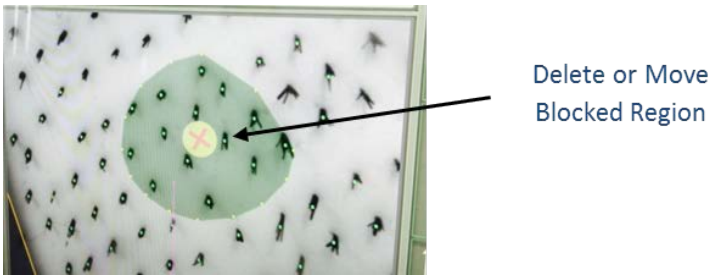
Figure 90: Block Region



Using the touchscreen, starting within the Tensioner/Platform Boundary, use 1 finger to draw the desired area to be blocked and release. The end point may be inside or outside the Tensioner/Platform boundary. There is a minimum size. If the region drawn is not the minimum size, no region will be drawn.

- To delete a blocked region on the touchscreen, use 1 finger, select a previously drawn region. An 'X' will appear in the center of the selected region (Figure 91). Use 1 finger, touch and release the 'X' without moving the finger.
- To move a blocked region on the touchscreen, use 1 finger, select a previously drawn region. An 'X' will appear in the center of the selected region. The selected region can be moved by touching 1 finger to the 'X' and dragging the region to the desired location. Release.

Figure 91: Delete or Move Blocked Region



To use this feature with the keyboard and mouse, click on the  Block Region icon, then right-click around the area in which you want to avoid, ending by right-clicking at the start location.

Click on the  Block Region icon to complete the shape. This will create a new blocked region.

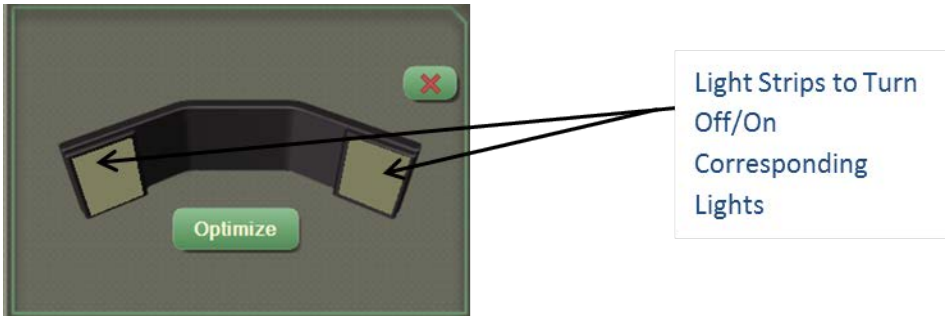
- To delete a blocked region, right-click in the existing region and right-click the 'X' icon
- To move a blocked region, right-click in the existing region and right-click and drag on the 'X' to the desired location

5.4.2 Main Control Panel – Lights

Lighting is important for both the physician and the cameras. To reduce glare, it is possible to switch between two banks of lights on either side of the cameras. Selecting the **Lights** icon leads to a second menu (Figure 92), which is used to:

- Manually Set Lighting - Selecting light strips illuminates or turns off the corresponding lights on the Needle Mechanism
- Automatically Set Lighting - Selecting **Optimize** when the scalp is in view, tests different lighting configurations and selects the one with best image quality

Figure 92: Main Control Panel - Lights



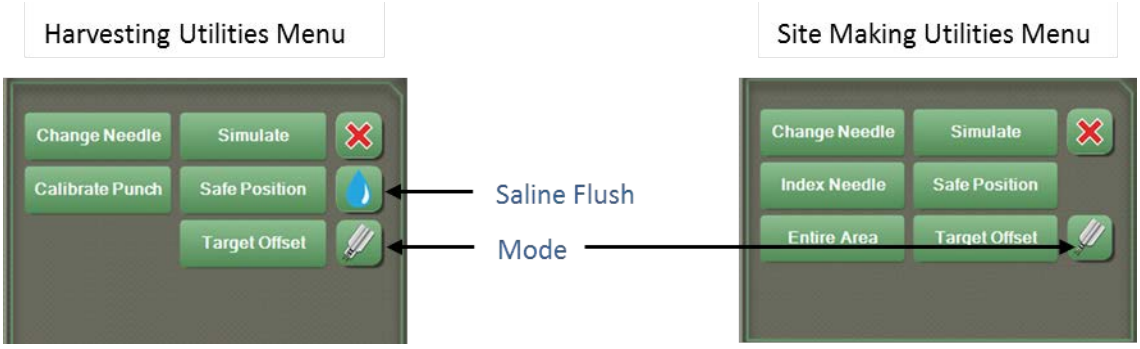
5.4.3 Main Control Panel – Away 40

Away 40 is one way a user can suspend automation during a procedure. When the **Away 40** icon is selected, the Inner Needle and Dissection Punch are retracted, and the Needle Mechanism moves away 40 mm.

5.4.4 Main Control Panel – Utilities

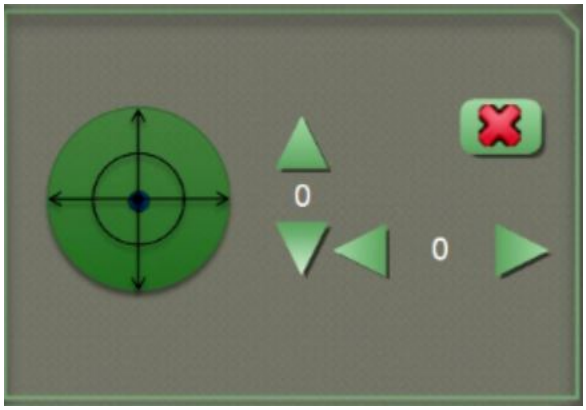
The **Utilities** icon opens a second menu (Figure 93) that includes:

Figure 93: Main Control Panel – Utilities Menu



- **Change Needle** - Moves the Robotic Arm to a pre-taught location where the disposable and reusable components can be changed conveniently
- **Calibrate Punch (Harvesting)** - Ensures that the follicle is properly centered in the punch during harvest. This is done by moving the Robotic Arm to a pre-taught location to measure the punch with the stereo cameras (Section 7.1.7)
- **Index Needle (Site Making) –** Ensures that the needle/blade is centered properly and that the orientation is correct (Section 8.2.6.6)
- **Simulate** - Moves the Robotic Arm to the punch calibration/index needle location and extends the punch and needle for checking that the harvest process is operating properly. Harvests performed in this mode are not counted against the licensed harvest limit on the ARTAS KEY™ USB device. When in site making mode, the needle or blade will be extended in order to check that the incision process is operating properly
- **Target Offset** - Used only when punch calibration has been performed and verified, but follicle centering is still off (Figure 94)
    - The Target Offset is automatically determined during the system verification by the system

Figure 94: Target Offset



- **Safe Position** - Moves the Robotic Arm to Safe Position to allow the patient to enter or exit the chair
- **Saline Flush (Harvesting)** - Moves the Robotic Arm to the saline station to flush the needle and punch with saline (Section 7.1.9)
- **Mode** – Allows the users to switch between Harvesting and Site Making mode
- **Area** – Gives the user the option to create incisions in the *Entire Area, Treatment Area* or *Hairline*
    - **Entire Area –** Includes the hairline and recipient area indicated in the Hair Pattern Design
    - **Treatment Area –** Includes only the recipient indicated in the Hair Pattern Design, excluding the hairline
    - **Hairline –** Will only create incisions in the hairline indicated in the Hair Pattern Design, excluding the recipient area

5.4.5 Main Control Panel – Restore Frame

Positions the Needle Mechanism to the last harvested hair or recipient site created. May be used after the Needle Mechanism is moved Away40.

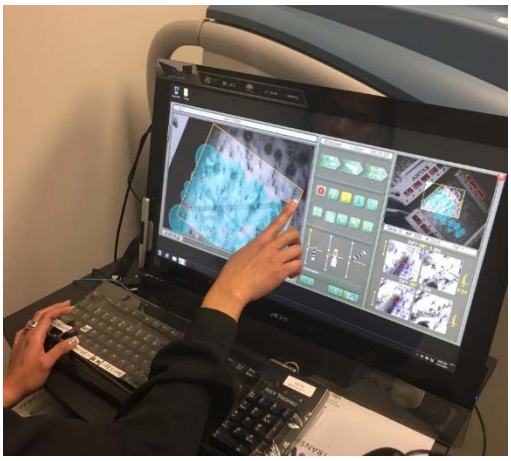
5.4.6 Main Control Panel – Draw Region Axis/Redraw Hair Direction

5.4.6.1 Draw Region Axis

During the harvesting procedure, this icon allows the user to draw the Region Axis (Figure 95). The Region Axis is the blue arrow displayed in the Hi-Mag screen. This indicates the direction in which the ARTAS™ System will harvest. The default begins in the bottom left of the tensioner moving from left-to-right, bottom-to-top.

- To use this function, select the **Draw Region Axis** icon
- Using the touchscreen, touch 1 finger anywhere in the Hi-Mag screen and drag in the desired direction of the Region Axis and release
- Using the Mouse, click and drag in the desired direction of the Region Axis and release

Figure 95: Draw Region Axis Using the Touchscreen



5.4.6.2 Redraw Hair Direction

During the Site Making Procedure, this icon allows the user to make minor changes to the direction in which the incisions will be created (Figure 96).

- To use this function, select the **Redraw Hair Direction** icon
- Using the touchscreen, touch 1 finger anywhere in the Hi-Mag screen and drag in the desired direction of the recipient sites and release
    - The direction should be drawn from back to front
- Using the Mouse, click and drag in the desired direction of the recipient sites and release
- NOTE: Hair Direction should always be indicated in the plan created in ARTAS Hair Studio

Figure 96: Redraw Hair Direction Using the Touchscreen

5.4.7 Main Control Panel – Video Capture

This function will allow a user to capture a left-right pair of video files in the default data directory. It is not recommended to record long periods of video.

Select the **Video Capture** icon to start recording. To stop the recording, select the **Video Capture** icon again.

5.4.8 Main Control Panel – ARTAS KEY™ USB Device Status

Select the icon to view the number of remaining harvests, harvest procedures or site making procedures (Figure 97).

Figure 97: Main Control Panel - ARTAS KEY™ USB Device Status

5.4.9 Main Control Panel – Configuration Parameters

The **Configuration Parameters** menu allows the user to set additional parameters for harvesting and site making.

5.4.9.1 Harvesting Configuration Parameters

The function of the Harvesting Configuration Parameters (Figure 98) is described in Table 5 below.

Figure 98: Main Control Panel - Harvesting Configuration Parameters

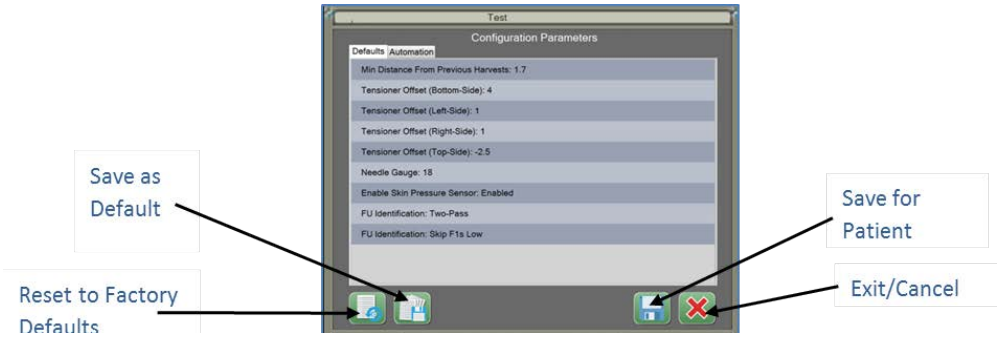


Table 5: Harvesting Configuration Parameters Description

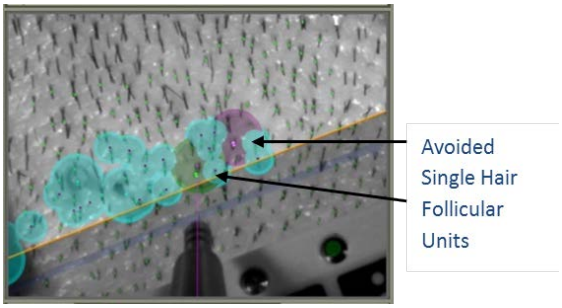
Parameter	Description	Default Value
Min Distance From Previous Harvests	Minimum distance for allowed harvest sites from previous sites (mm). This parameter defines the radius of the blue circles on the display. This can be adjusted depending the size of needle, size of donor area, and size of case	1.7
Tensioner Offset Left Side/ Right Side	Additional distance by which the specified side of the harvest rectangle should be shifted inwards (mm). A positive value shifts the edge inwards; a negative value shifts the edge outwards	Varies
Tensioner Offset Top-Side/Bottom-Side	Additional distance by which the specified side of the harvest rectangle should be shifted inwards (mm). A positive value shifts the edge inwards; a negative value shifts the edge outward.	Varies
Needle Gauge	Choose the appropriate needle and punch size	18g
Enable Skin Pressure Sensor	Interrupts harvesting if there is too much pressure from patient skin	Enabled
FU Identification: Skip F1s	Allows user to avoid F1s in harvesting	Skip F1s Low
FU Identification: One or Two Pass	Allows the user to perform a second harvesting pass when avoiding single hair follicular units	One Pass

5.4.9.1.1 Avoiding Single Hair Follicular Units and Two Pass Harvesting

The user can avoid up to 20% of single hair follicular units (F1s) using the FU Identification feature in the **Configuration Parameters** Menu.

- Skip F1s Low – Works at a faster pace while still avoiding single hair follicular units
- Skip F1s High – Keeps single hair follicular units at a minimum
- Display of skipped single hair follicular units may be shown on the User Interface with either setting (Figure 99)
    - Skipped F1s are displayed as a small blue circle with a purple dot in the center

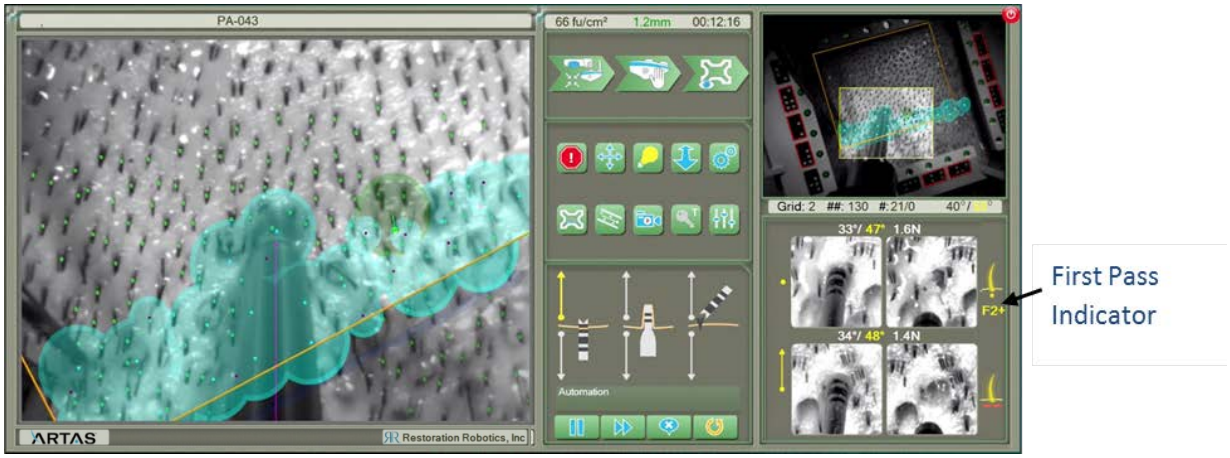
Figure 99: Avoided Single Hair Follicular Units



When avoiding single hair follicular units using the FU Identification (Skip F1s) feature, the user can also perform a second harvesting pass.

- In the first pass, follicular units with 2 or more hairs (F2+) will be targeted (Figure 100)
    - F2+ will be displayed below the Patient Movement Indicator when the first pass is being performed

Figure 100: Avoiding Single Hair Follicular Units - First Pass



- In the second pass, all follicular units including single hair follicular units (F1s) will be targeted
- Figure 101)
    - F1+ will be displayed below the Patient Movement Indicator when the 2nd pass is being performed

Figure 101: Avoiding Single Hair Follicular Units - Second Pass

5.4.9.2 Site Making Configuration Parameters

The function of the Site Making Configuration Parameters (Figure 102) is described in Table 6 below.

Figure 102: Site Making Configuration Parameters

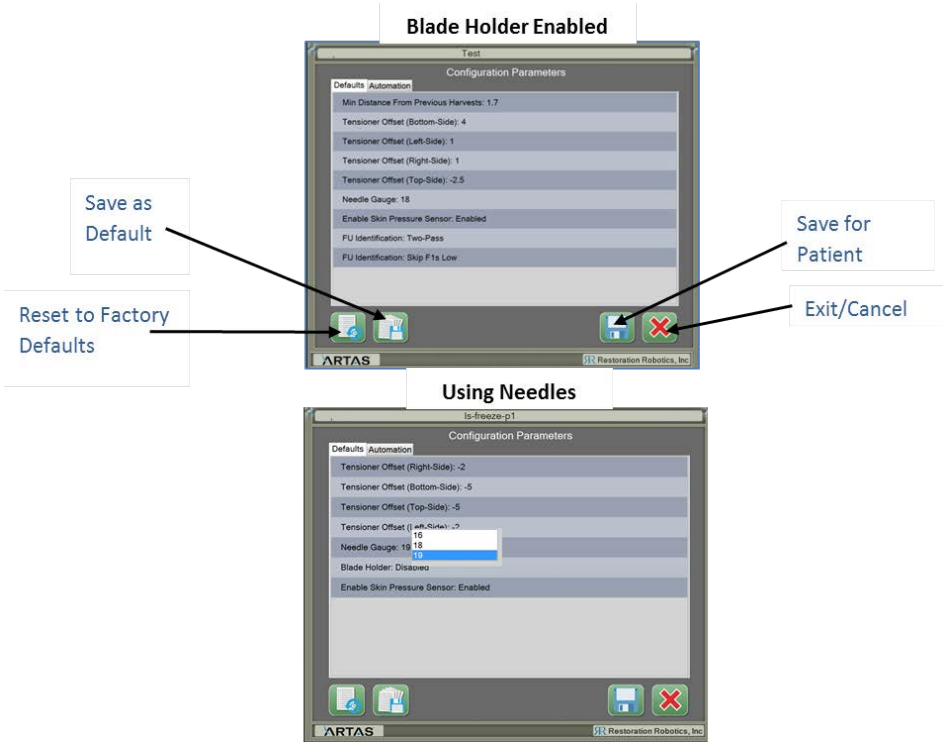


Table 6: Site Making Configuration Parameters Description

Parameter	Description	Default Value
Tensioner Offset Left Side/ Right Side	Additional distance by which the specified side of the harvest rectangle should be shifted inwards (mm). A positive value shifts the edge inwards; a negative value shifts the edge outwards	Varies
Tensioner Offset Top-Side/Bottom Side	Additional distance by which the specified side of the harvest rectangle should be shifted inwards (mm). A positive value shifts the edge inwards; a negative value shifts the edge outward.	Varies
Needle Gauge	Choose the appropriate needle gauge when using the ARTAS™ Site Making Needles Visible only when the Blade Holder is DISABLED	19g
Blade Thickness	Choose the appropriate blade thickness when using the ARTAS™ Blade Holder Visible only when the Blade Holder is ENABLED	.25
Blade Width	Choose the appropriate blade width when using the ARTAS™ Blade Holder Visible only when the Blade Holder is ENABLED	1
Blade Holder	Should be disabled when using the provided solid core needles and enabled when choosing to use the ARTAS™ Blade Holder	Disabled
Enable Skin Pressure Sensor	Interrupts harvesting if there is too much pressure from patient skin	Enabled

5.5 Dissection/Incision Parameters and Control Panel

The Dissection/Incision Parameters Panel controls the parameters of dissection in harvesting and parameters on incisions during site making. The Control Panel controls actions associated with harvesting and site making. In pre-automation mode (Figure 103), select the **Begin** icon to start automation or the **End of Grid** icon to perform a saline flush or return to the safe position at the end of a grid (Figure 103).

Figure 103: Harvesting Dissection Parameters

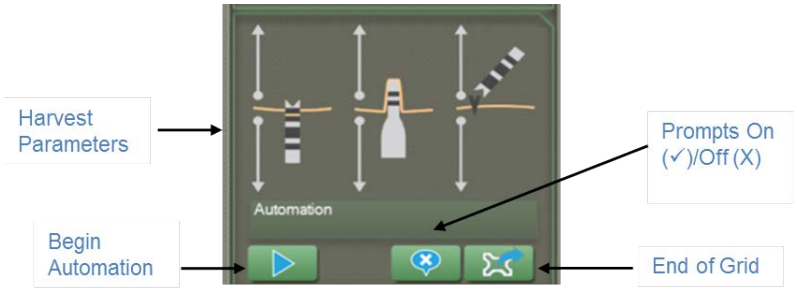
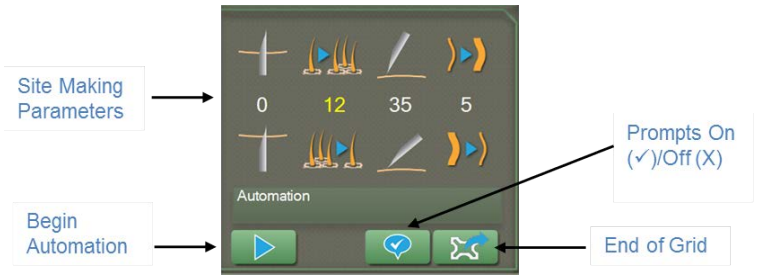
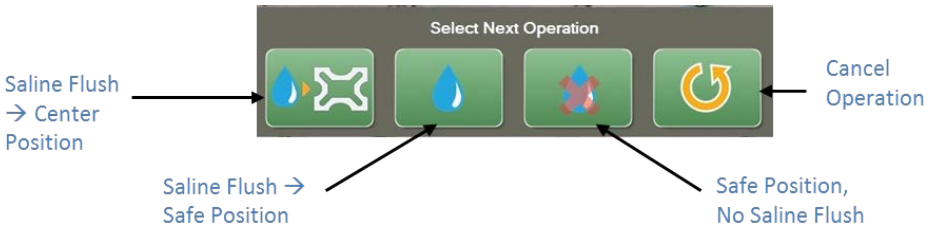


Figure 104: Site Making Incision Parameters



When the **End of Grid** icon is selected when a grid is finished during a site making procedure, the user is prompted to return to Safe Position. When the **End of Grid** icon is selected at the end of a grid during the harvesting procedure, the user has 4 selections for the next position – Saline Flush → Center Position, Saline Flush → Safe Position, Safe Position and Cancel (Figure 105).

Figure 105: End of Grid Options – Saline Flush



In Automation Mode (Figure 106), selecting **Cancel** returns to pre-automation mode. During the harvesting procedure, selecting a hair in the primary vision display will cause the Robotic Arm to orient relative to the selected hair. When prompts are off, the Robotic Arm will harvest the hair then move on to subsequent hairs. When prompts are on, selecting ✓ will initiate a harvest, and selecting **x** will cause the Robotic Arm to select and move to a subsequent hair (Figure 107).

During the site making procedure, there is no need to select a hair prior to making incisions. The system will automatically orient itself to the bottom of the Fiducial Platform. When prompts are off, the Robotic Arm will select and incision site and fire the needle/blade. When prompts are on, selecting ✓ will initiate the incision, and selecting **x** will cause the Robotic Arm to select and move to a subsequent incision site. When beginning the site making procedure, prompts are on by default.

Figure 106: Automation Mode Icons

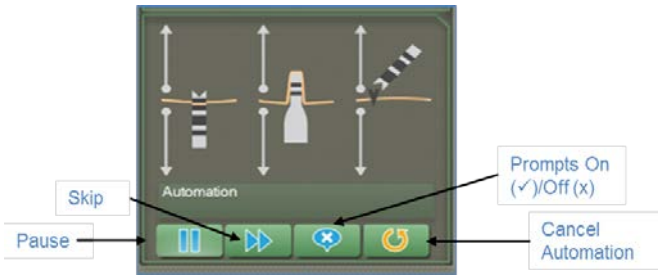
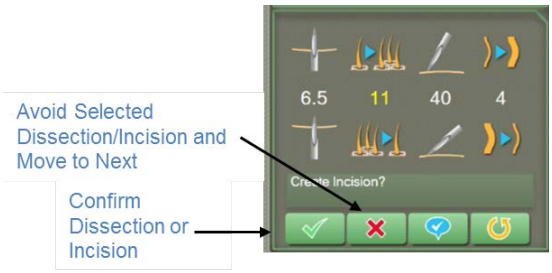


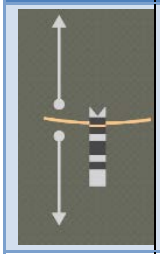
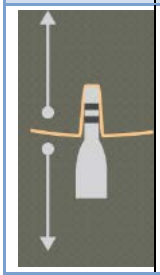
Figure 107: Prompts On Selections



5.5.1 Harvesting Dissection Parameters

The dissection parameters on the procedure control panel are described in Table 7. Descriptions of how to modify these parameters are in Section 7.5.

Table 7: Harvesting Dissection Parameters Description

Image	Parameter	Description
	Puncture Depth (PD)	Controls depth of the Inner Needle.
	Coring Depth (CD)	Controls depth of the Dissection Punch.
	Approach Angle (ANG)	Minimum approach angle of the Inner Needle/Dissection Punch to the scalp (in degrees). At times, the hair is at a low angle to the scalp. When it is below the minimum value of this parameter, it is difficult for the needle to penetrate the scalp. -Minimum Approach Angle is 35°

5.5.2 Site Making Incision Parameters

The incision technique can be controlled by the physician using the incision parameters at the bottom of the middle column on the User Interface. The following parameters described in Table 8 can be changed at any time during automation to control incision quality. Descriptions of how to modify these parameters are in Section 8.5.4.

Table 8: Site Making Incision Parameters Description

Image	Parameter	Description
	Puncture Depth (PD)	Controls depth of the needle or blade. -Has a hard stop to prevent incision from being deeper than intended -When using the provided needles, the default PD is 5 -When the Blade Holder is enabled in the Configuration Parameters menu, the default PD is 0
	Density	The number of incisions per square centimeter. -Based on the density indicated in the creation of the Hair Pattern Design) -Maximum setting is 50 incisions per cm^2
	Angle (ANG)	Minimum approach angle of needle. -Default is 35° (Set in the creation of the Hair Pattern Design) -Minimum angle is 30°
	Terminal Follicular Unit Thickness (Hair Caliber Setting)	Minimum thickness setting existing hair must be in order for the system to recognize it as a terminal hair. -Default is 5

6 Patient Preparation for the Harvesting and Site Making Procedure

The patient preparation step for both harvesting and recipient site creation should be completed prior to beginning the harvesting and/or site making procedure.

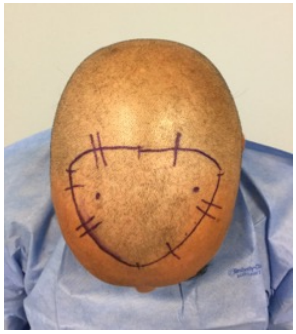
1. Trim the patient's recipient and donor area hair to 1.1-1.3mm using steady, upward pressure.
    a. It is important to achieve the ideal length of 1.1-1.3mm so that the system can recognize existing follicles for harvesting and to avoid when creating recipient sites.
2. Remove any loose, trimmed hairs from the area.
3. Mark out the donor area for harvesting (Figure 108).

Figure 108: Marking the Donor Area

NOTE: The following steps are only required if performing the site making procedure.

4. Mark the recipient area surgical plan using a surgical marker.
5. Mark 4-5 surgical markers/landmarks in the anterior portion of the recipient area and 3-4 in the posterior (Figure 109).
    a. It is recommended to use clear concise lines for these landmarks.
    b. These landmarks will be used in the site making procedure to align the treatment plan.

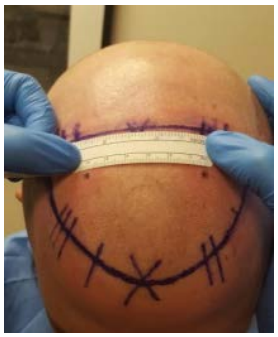
Figure 109: Marking the Recipient Area



6. Mark 2 side-to-side dots within the surgical plan approximately 6-7 cm apart.
7. Measure the distance from dot-to-dot and record. This will be used for creating the 3D dome (Figure 110).

a. Also take a front-to-back measurement of the marked recipient area and record. This will be used to confirm the 3D dome is to scale.

Figure 110: Measuring the Recipient Area



8. Anesthetize as appropriate to minimize patient discomfort and bleeding.
    a. If performing the harvesting procedure first, anesthetize the donor area first. The recipient area should be anesthetized just before beginning recipient site making.
    b. If performing the site making procedure first, anesthetize the recipient area first. The donor area should be anesthetized just before beginning the harvesting portion of the procedure.

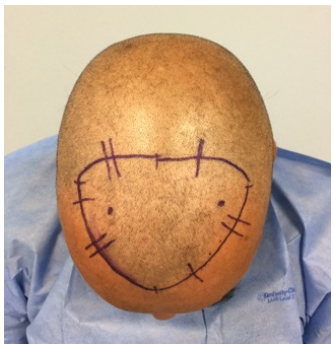
6.1 Patient Photo for Site Making Procedure

One photo of the top of the patient's head is required for creating the 3D dome for the site making procedure (Section 8.2). Photos may be taken with any camera device including an iPad, iPhone, or digital camera. Note: if not performing the site making portion of the procedure this step is not required.

Follow these guidelines for the photos needed to create the 3D dome for site making.

- Align the camera in a portrait orientation
- Use a solid background
- Take the image straight on with no distortion
- Reduce glare and shadows
- The patients head should fill the frame of the photos (Figure 111)

Figure 111: Top Photo Example for 3D Dome



7 The ARTAS™ System Harvesting Procedure

7.1 Preparing for the Harvesting Procedure

In this section, we will discuss how to prepare for the harvesting portion of the ARTAS™ procedure. It is important to have harvests or harvest procedures loaded onto the ARTAS KEY™ USB device (Section 3.2) prior to beginning the procedure. Clinical accessory kits should be in inventory, including the Reusable Clinical Kit (Section 3.3.1.1) already cleaned and sterilized according to the Instructions for Use, the Sterile Disposable Clinical Kit (Section 3.3.1.2), and the Non-Sterile Disposable Clinical Kit (Section 3.3.1.3).

The following list (Table 9) of additional clinic site items contains items that are expected to be available at the clinical site in sufficient supply for the procedure. For a complete list of clinical supplies, refer to the Physician Preparation Guide (MK-270).

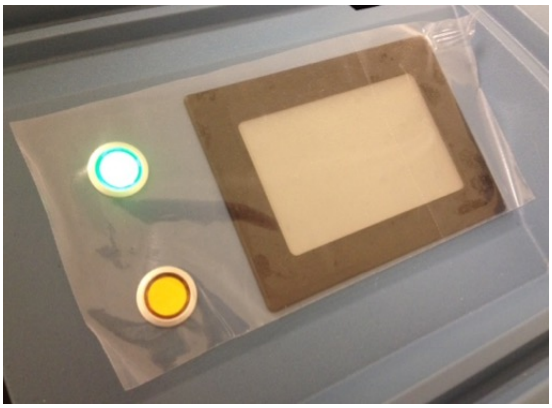
Table 9: Clinic Items for Harvesting

Clinic Site Items for Harvesting
Foerster Forceps
Cotton-tipped applicators
Local Anesthetic
Gloves
Sodium Chloride Solution
Scissors
4x4 Gauze
Telfa Pads
Micropore Tape
Petri Dishes
Cooling Towers
Sterile Drapes
Large Sharps Disposal Container
Germicidal Cloths
Large Stainless Bowl
Membrane Cover Roll, PRT-22690 (Barrier Film)
10-ml Luer Lock Syringes

7.1.1 Area Preparation

- Place Barrier Film over the Cart Control Panel (Figure 112)

Figure 112: Barrier Film Over Cart Control Panel



- Apply Barrier Film to the Force Drag Handle of the Needle Mechanism (Figure 113)

Figure 113: Needle Mechanism with Barrier Film

- Cover the Face Cushion with a waterproof covering. Place the disposable Face Cushion Overlay over the Face Cushion before covering the cushion with the Face Pillow Cover. If desired, secure the Face Pillow Cover in place with Micropore tape
- Refer to Section 4.1.1 for proper Patient Chair placement.

7.1.2 Prepare the Physician Instrument Tray for Harvesting

Place the following items on a sterile, draped instrument tray (Figure 114):

- Forceps
- Gauze
- Cotton-tipped applicators
- Cooling tower with ice and petri dish
- Tumescent solution
- Saline in bowl or spray bottle

- Tension Tool
- Skin Tensioner in Tensioner Tray

Figure 114: Physician Instrument Tray for Harvesting

7.1.3 Patient Preparation for the Harvesting Procedure

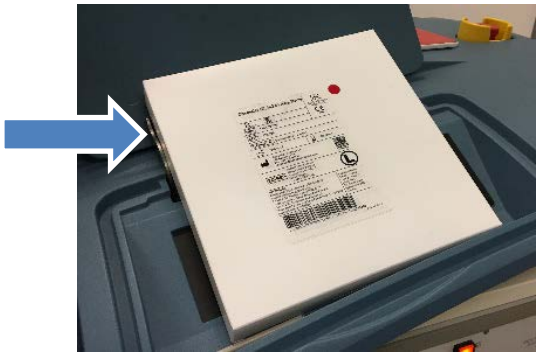
See Section 6 for patient preparation steps for the harvesting procedure. Section 4.1.1 reviews proper chair positioning for the harvesting procedure.

7.1.4 Scanning the Harvesting Procedure Kit

Caution		Caution
	***The following commands result in Robotic Arm movement.***	

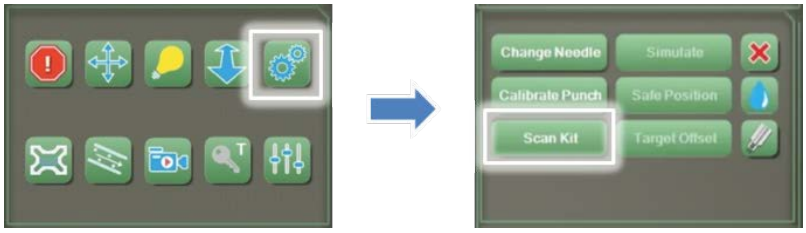
1. Align the ARTAS Procedure Kit with the System Cart Control Panel Door.

Figure 115: Align Harvesting Kit to Scan



2. Select **Utilities → Scan Kit**.

Figure 116: Scan Kit Icon



3. From the **Scan Kit** window, confirm that the kit is in place and select the **Scan Kit** icon. The Needle Mechanism will move to a position over the QR code on the kit, and scan. The Reference number, Lot Number and Expiration Date will populate. Once the kit information is populated, confirm by selecting the ✓.

Figure 117: Confirm the Kit Scan Information

4. Remove the kit from the System Cart Control Panel and select the ✓. The Needle Mechanism will move to Safe Position. You are now ready to install harvesting disposables.

Figure 118: Remove the Procedure Kit and Confirm

7.1.5 Installation of the Harvesting Disposables and Re-usables

Gloves should be worn by the user when installing these clinical accessories.

Caution *The following commands result in Robotic Arm movement.* **Caution**

7.1.5.1 Positioning the Needle Mechanism for Installation

1. Make sure the area around the Robotic Arm and Needle Mechanism is clear and can move freely to the Change Needle position**.**
2. In the ARTAS™ application, select **Change Needle** from the **Utilities** menu on the UI**.**
3. Press the **Manual** button on the Cart Control Panel. The button will illuminate yellow. In this mode, the operator cannot power up and move the Robotic Arm from the User Interface.

7.1.5.2 Inner Needle Installation

Warning *Puncture risk. Exercise caution to prevent needle sticks to user.* **Warning**

1. Remove the Needle Clip from the Needle Mechanism.
2. Keeping the needle protector engaged to protect the tip of the needle, feed the needle tubing through the spindle of Needle Mechanism (Figure 119).

Figure 119: Installing Inner Needle Tubing Through Needle Mechanism

3. Ensure the tubing passes completely through the needle guide in the back of the Needle Mechanism.

4. Then using your right hand, pull the remainder of the tubing through the assembly until the plastic hub of the Inner Needle is fully seated in the oval pocket of the tubing guide (Figure 120).

Figure 120: Properly Installed Inner Needle

5. Thread the tubing through the guide on the Robotic Arm.
6. Unscrew the plastic needle protector and set aside for future use.
7. Install the Harvesting Needle Clip (from the Non-Sterile Disposable Clinical Kit) by snapping it over the plastic hub of the Inner Needle (Figure 121). The rubber cushioning should face the needle tip.

Figure 121: Harvesting Needle Clip Installed

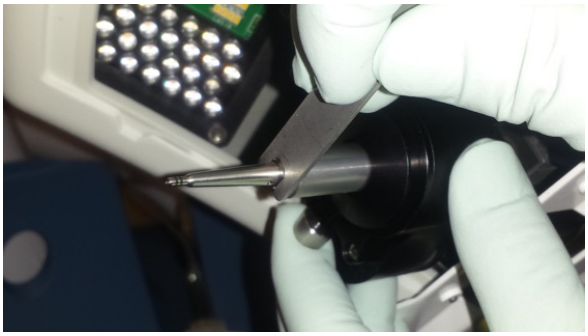
7.1.5.3 Dissection Punch Installation

1. Ensure the area around the Needle Mechanism is clear and select **Extend Punch** on the Cart Control Panel. The spindle extends forward and is ready for the next step.
2. Starting with the threaded end of the Dissection Punch, carefully guide the Dissection Punch over the sharp end of the Inner Needle.
3. Slide the Dissection Punch on until it comes in contact with the spindle of the Needle Mechanism and hand-tighten until the spindle spins with the Dissection Punch.
4. Tighten the Dissection Punch (Figure 122):
   - With the left hand, locate and press the Spindle Lock button on the side of the spindle that faces the Robotic Arm
   - With the right hand, use the punch wrench to gently tighten the Dissection Punch

i. Do NOT over tighten

5. Select **Retract Punch** on the System Cart Control Panel.

Figure 122: Installing the Dissection Punch



7.1.5.4 Follicle Trap Installation

1. Wrap the outside of the Follicle Trap with gauze.
2. Snap the Follicle Trap and gauze into the silver bracket on the System Cart (Figure 123).

Figure 123: Follicle Trap Installation

3. Remove the white plug from the end of the Inner Needle tubing. Keep for future use (

4. Figure 124).

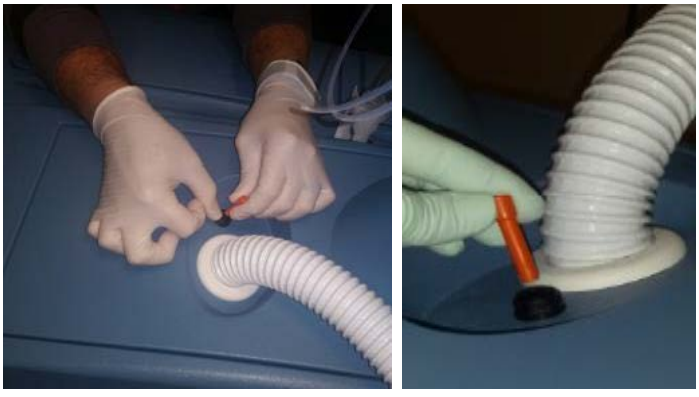
Figure 124: Remove White Plug from Needle Tubing

5. Gently connect the end of the needle tubing to the small tube of the Follicle Trap (Figure 125).

Figure 125: Connect Needle Tubing to Follicle Trap

6. Remove the orange vacuum plug by pressing on the vacuum seal on top of the cart while pulling up on the plug (Figure 126). Keep the plug for future use.

Figure 126: Remove Vacuum Plug



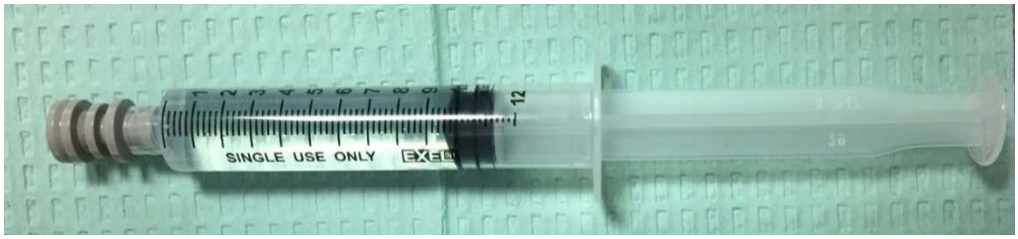
6. Insert the large tube from the Follicle Trap into the vacuum port (Figure 127).

Figure 127: Install Follicle Trap to Vacuum

7.1.5.5 Saline Station Installation

1. Obtain a 10cc Luer lock syringe and fill it with saline.
2. Attach the Saline Nose Cone to the end of the syringe (Figure 128).

Figure 128: Saline Nose Cone with Syringe



3. Open the Saline Station cover and push back the actuator.
4. Place the assembled syringe and Saline Nose Cone into the Saline Station (Figure 129).
    a. The recessed part Saline Nose Cone should fit into the bracket to ensure it is not too far back or forward.

Figure 129: Installing the Saline Station

7.1.6 Verify Installation

7.1.6.1 Vacuum and Pressure Check

Verify the internal vacuum system is activated by confirming the vacuum gauge on the Cart Control Panel reads between 24 and 30 mmHg (Figure 65).

- If the vacuum reads to low, check the seal and tubing connections of the Vacuum Canister Liner

Verify that the pressure gauge located on the Cart Control Panel reads 40±1 psi (Figure 65).

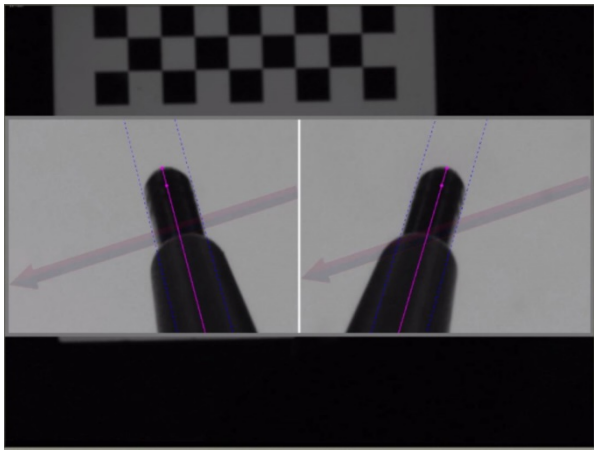
7.1.6.2 Needle Mechanism Test

1. Select **Demo Harvest** (Figure 65) on the Cart Control Panel.
   - The tool performs a test harvest
     - The Inner Needle should fire
     - After, the Dissection Punch should rotate and extend
     - The Inner Needle and Dissection Punch should retract together
     - The Needle Clip should stay in place
   - Repeat until all inspection points are checked
2. Deactivate the **Manual** button on the Cart Control Panel. The amber light will go off.

7.1.7 Calibrate the Punch

Once the Inner Needle, Dissection Punch and other disposables are installed, follow these steps to calibrate the punch. It is important to select the correct needle gauge being used in the harvesting procedure in the **Configuration Parameters** menu (Section 5.4.9.1) prior to calibrating the punch. Figure 130 shows a typical pair of Punch Calibration images. Note that after the proper adjustments, the blue Dissection Punch bounds are symmetric about the punch centerline, and the pink dot is precisely at the tip of the Dissection Punch.

Figure 130: Punch Calibration Images



Warning *Puncture risk. Exercise caution to prevent needle sticks to user.* **Warning**

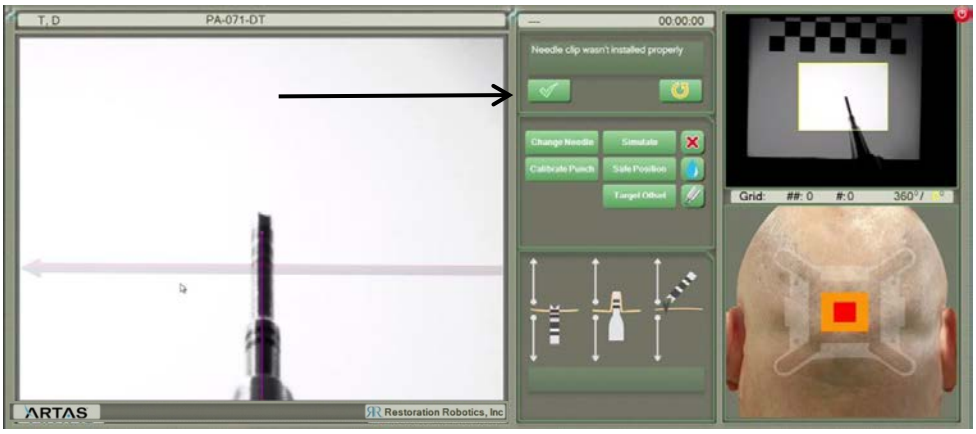
Caution *The following commands result in Robotic Arm movement.* **Caution**

1. In the Main User Screen, select **Utilities → Calibrate Punch** (Figure 131).

Figure 131: Calibrate Punch

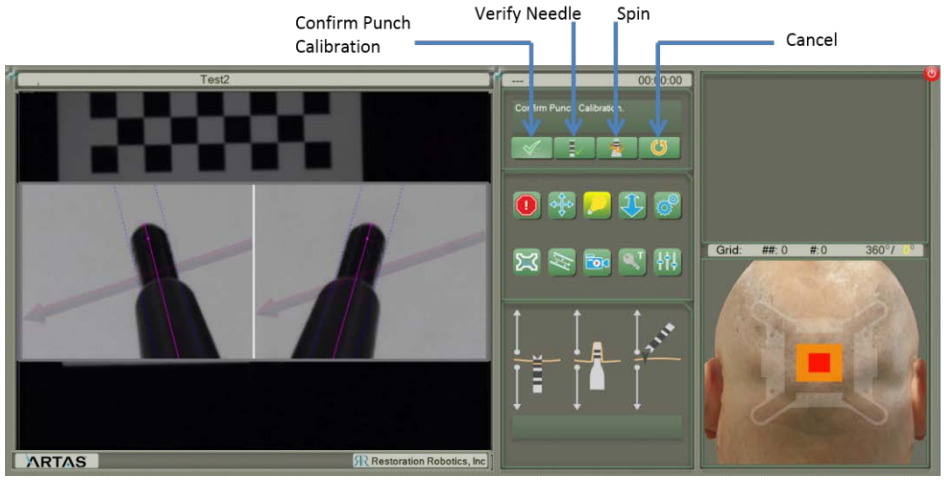
2. First, the ARTAS™ System will extend the Inner Needle to ensure that the Needle Clip is properly installed. The user will be prompted as seen in Figure 132, if the Needle Clip was not installed properly.
    a. If the Needle Clip needs to be reinstalled, select the green checkmark and position the Needle Mechanism to Change Needle position in the Utilities menu.
    b. Re-install the Needle Clip according to the instruction in Section 7.1.5.2.
    c. Once re-installed, select **Calibrate Punch** from the Utilities menu to continue.

Figure 132: Needle Clip Not Properly Installed Error



3. If the Needle Clip is properly installed, the Inner Needle will retract and the 2 images of the Dissection Punch will be visible on the Main User Screen (Figure 133).

Figure 133: Punch Calibration Screen



4. Ensure that the Dissection Punch is in the center of the blue lines in both images (Figure 134). If an adjustment needs to be made in the left image, use the left CTRL key on the keyboard and ← or → keys to adjust the blue lines. If an adjustment needs to be made in the right image, use the right CTRL key on the keyboard and ← or → to adjust the blue lines (Figure 134).

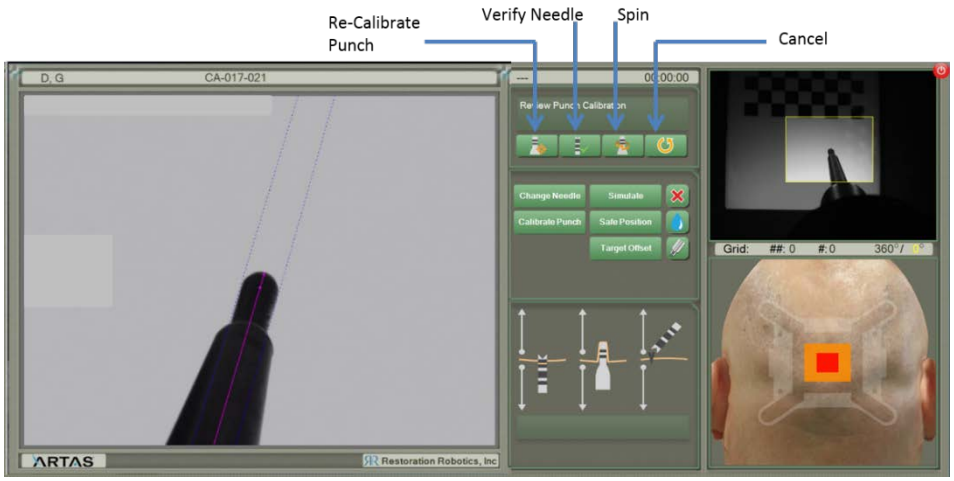
Figure 134: Keyboard Controls for Punch Calibration

5. Next, verify that the pink line is centered on the Dissection Punch and the dot is at the distal tip of the Dissection Punch. If an adjustment needs to be made in the left image, use the left CTRL key and ↑ or ↓ keys to adjust the pink line. If an adjustment needs to be made in the right image, use the right CTRL key and ↑ or ↓ to adjust the pink line (Figure 134).
    a. It is important that the pink line is precisely aligned with the center and tip of the punch. Otherwise, follicle harvesting may not be properly centered.
6. After all adjustments are complete, select the **Spin** icon (Figure 133) to ensure the Dissection Punch does not wobble beyond the blue lines. When satisfied select the ✓.
    a. If there is a wobble, verify that the Dissection Punch is tightened onto the spindle. Do NOT over tighten.

7.1.8 Verify Punch and Verify Needle

Anytime **Calibrate Punch** is selected from the Utilities menu after the initial punch calibration, it will default to a *Verify Punch* position. The menu will also vary slightly (Figure 135).

Figure 135: Verify Punch Screen

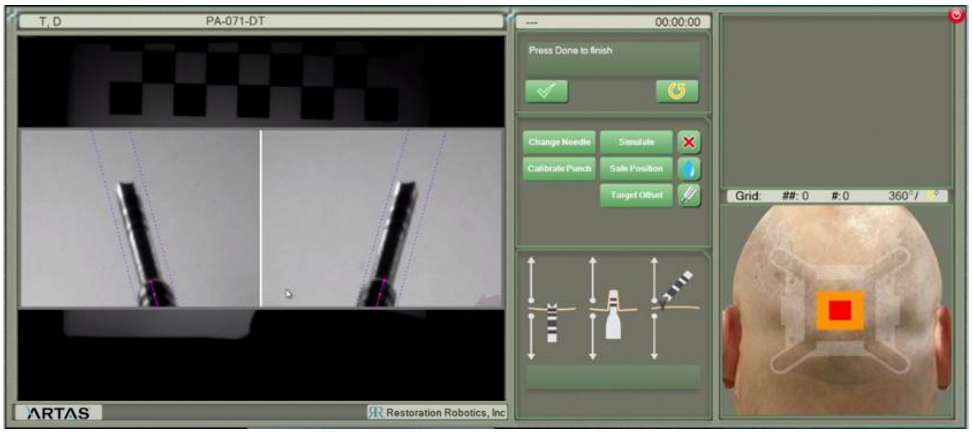


Verify Punch and/or Verify Needle can be used as a double check to make sure the Dissection Punch/Needle are properly centered.

If needed, the Dissection Punch can be re-calibrated. This may be required if, for example, the disposables were changed. Select the **Re-Calibrate Punch** icon in Figure 135.

To verify the Inner Needle, select the **Verify Needle** icon as seen in Figure 135. The Inner Needle will extend, and 2 views of the Needle will be visible in the Main User Screen (Figure 136). Select ✓ when complete.

Figure 136: Verify Needle Screen



7.1.9 Perform Saline Flush

Before beginning the harvesting procedure, perform one saline flush after the disposables are installed and the punch is calibrated. This will ensure that the saline and vacuum system is properly installed.

To do this, select the **Saline Flush** icon from the **Utilities** menu (Section 5.4.4).

7.2 Skin Tensioner Placement & Removal

The placement of the Skin Tensioner is an important step in the harvesting procedure. When placing the Skin Tensioner, it is recommended that the physician has someone assisting them.

7.2.1 Engage Skin Tensioner with Tensioner Tool

1. Align the tabs of the Skin Tensioner with the Skin Tensioner Tool.
2. Slightly compress to engage the lock of the Tensioner Tool. The lock will fall into place.
3. Remove the engage Skin Tensioner and Tensioner Tool from the Tensioner Tray.
    a. There is no need to squeeze the Tensioner Tool at this time because the Skin Tensioner is already engaged with the Tensioner Tool.
    b. You are now ready to apply the Skin Tensioner.

7.2.2 Applying the Skin Tensioner

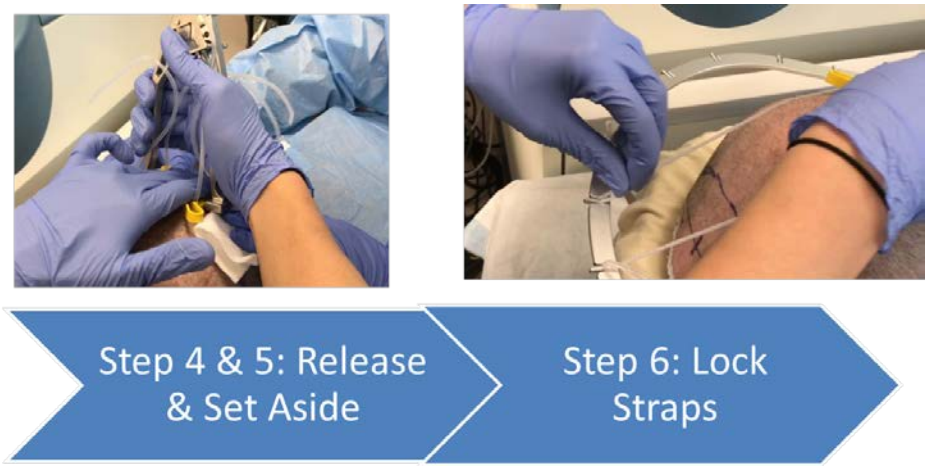
1. Fully compress the Skin Tensioner.

2. Manually stretch the skin superiorly. The Physician's assistant should then stretch the skin laterally.
3. With even pressure, apply the Skin Tensioner to the scalp. Using your fingers, press the Skin Tensioner pins into the skin.

Figure 137: Applying the Skin Tensioner Steps 1-3

4. Release the lock on the Tensioner Tool by lifting up on the lock with your thumb while compressing.
5. Set the Tensioner Tool on the clinical stand.
6. Keeping even pressure on the Skin Tensioner, apply a slight superior pull on the Skin Tensioner and attach the straps to the slots in the halo.
    a. The superior straps of the Skin Tensioner should be locked in first.
    b. The straps should be locked into the adjacent slot in the halo.
    c. The straps should not be adjusted while they are engaged in the halo.

Figure 138: Applying the Skin Tensioner Steps 4-6



7. Check the Skin Tensioner Placement.
    a. Ensure the pins remain engaged with the scalp.

b. Check for skin blanching and firmness within the Skin Tensioner.
c. Test for minimal superior movement of the Skin Tensioner.

8. To maintain consistent graft quality, inject tumescent within the corners of each grid.
   a. No more than 2cc per grid, or .5cc per corner, should be injected.

Figure 139: Applying the Skin Tensioner Steps 7 & 8

7.2.3 Skin Tensioner Grid Overlapping

Skin Tensioner grid overlapping is important to prevent gaps in the donor area. When placing the Skin Tensioner, there should be approximately 2 visible rows of previously harvested sites to prevent these gaps. Skin Tensioner borders should be adjusted according as discussed in Section 7.4.2.

Figure 140: Skin Tensioner Overlap

7.2.4 Removing the Skin Tensioner

At the end of each harvesting grid, the Skin Tensioner should be removed and prepared to place in the next grid location.

1. Engage the tabs of the Skin Tensioner with the Tensioner Tool. Slightly compress to engage the lock.
    a. Do not fully compress.
2. Release the Tensioner Straps from the halo.
3. Fully compress the Tensioner Tool and lift the Skin Tensioner from the patient's scalp.
4. Place the Skin Tensioner and Tensioner Tool in the Tensioner Tray until ready to apply the next grid (Figure 36).

7.3 The ARTAS™ Workflow for Harvesting

The ARTAS™ Workflow is done at the beginning of each harvesting grid. When using the colored Skin Tensioner, the workflow is completed in one step. When using a grey Skin Tensioner, the workflow will consist of 3 steps.

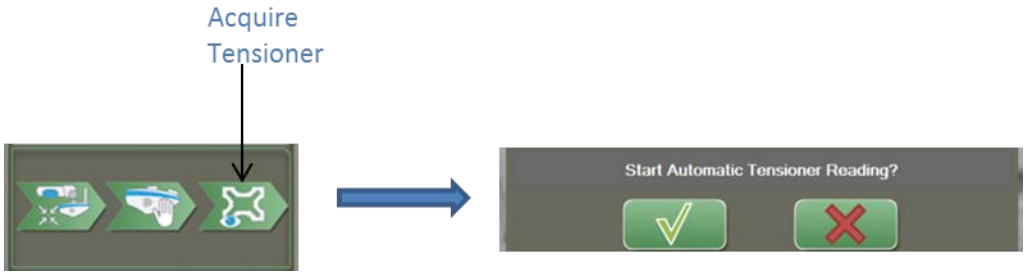
7.3.1 Colored Tensioner Workflow for Harvesting

The colored cameras automatically detect the colored Skin Tensioner allowing the Needle Mechanism to automatically position itself over the patient and acquire the Skin Tensioner in one step.

Caution  ***The following commands result in Robotic Arm movement.*** Caution 

At the start of each grid with the Skin Tensioner applied to the patient, select the **Acquire Tensioner** icon (Figure 141) on the User Interface (Section 5.4). The user will be prompted to *Start Automatic Tensioner Reading.* Select ✓ to begin. The Needle Mechanism will locate the Skin Tensioner automatically, move to a position over the patient and acquire the Skin Tensioner.

Figure 141: One Step Harvesting Workflow



- The Robotic Arm moves around the perimeter of the Skin Tensioner until at least two fiducials are seen on each side
- Next, it moves to the center of the Skin Tensioner, makes a density and average hair length calculation (Section 5.2.1), and finally moves to the lower left corner of the Skin Tensioner in position for the first harvest

If the automated tensioner location procedure fails, the user is prompted with a retry dialog. Select ✓ to retry. If the retrying process fails, select **X** and move the Needle Mechanism to Safe Position (Section 5.4.4).

- Verify that the fiducials on the Skin Tensioner are clean
- Reposition the patient's head or the Patient Chair so that the Skin Tensioner and fiducials are easily visible
- Select the **Acquire Tensioner** icon or button to retry the process

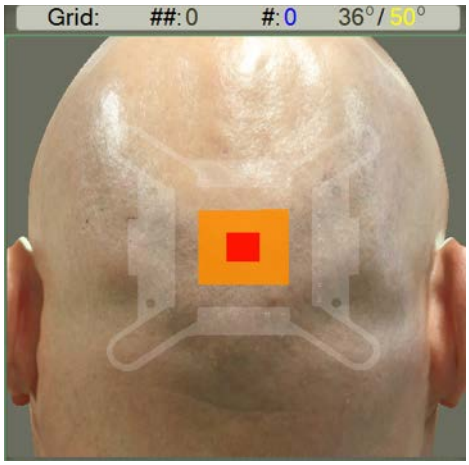
If after cleaning the Skin Tensioner and repositioning the patient, the process still fails; follow the steps for the ARTAS™ Workflow using the grey Skin Tensioner in Section 7.3.2.

The fiducials located in this step are used to plan and perform automated harvesting. If the Skin Tensioner ever shifts or pops off during the procedure, after reseating it on the scalp it is important to repeat the Acquire Tensioner step to assure that the harvest region is properly calculated.

7.3.1.1 Virtual Grid Display

Use the Virtual Grid Display window (Figure 142) to move the virtual tensioner to the corresponding location on the virtual head.

Figure 142: Virtual Grid Display



Select and drag the red square to move the tensioner location around the 3D head model.

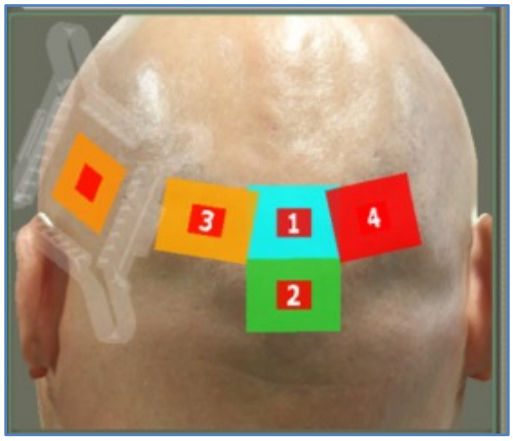
Each time the Virtual Grid Display (Figure 143) is shown, the grid number is incremented. The grid number is used in the treatment report and allows the physician to correlate dissection results to Skin Tensioner locations on the head.

The Virtual Grid Display will feature the Empty Site Detection feedback given in each grid. This is discussed in Section 5.1.1. This display correlates with the feedback given in the Low-Mag

Image Display (Figure 78). Dissection parameters should be monitored accordingly when an empty site warning appears.

- Blue Square – No empty site warning in the grid
- Green Square – Few empty sites warning in the grid
- Yellow Square – Several empty sites warning in the grid
- Red Square – Many empty site warning in the grid

Figure 143: Grid Location with Empty Site Warning



7.3.2 Grey Tensioner Workflow for Harvesting

7.3.2.1 Center Position

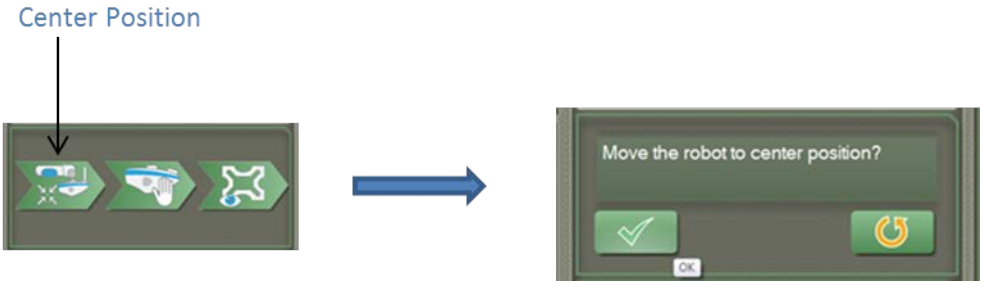
Caution

The following commands result in Robotic Arm movement.

Caution

Select **Center Position** on the User Interface and then ✓ in the dialog (Figure 144) to center the Needle Mechanism behind the patient. Verbalize "centering robot." Set the grid location by selecting the red center of the virtual tensioner and dragging it to the corresponding location on the virtual head in the bottom right window of the User Interface (Section 7.3.1.1).

Figure 144: 3 Step Harvesting Workflow - Center Position



7.3.2.2 Force Drag

Caution *The following commands result in Robotic Arm movement.* Caution

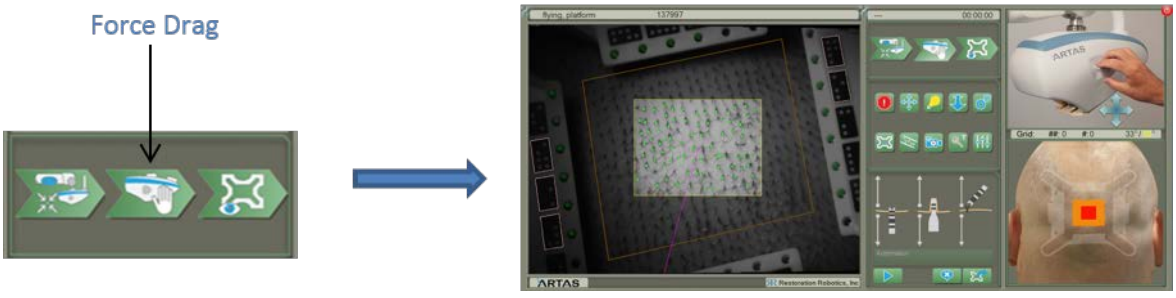
Force Drag is a way for the physician to position the Needle Mechanism over the Skin Tensioner by simply applying force to a handle on the mechanism.

The forces are detected by a force sensor, which commands slow, controlled motion in the direction of the force.

Force Drag is automatically enabled following Center Position. If it is necessary to manually enable Force Drag mode, both the User Interface operator and the physician can enable it. An image of the Needle Mechanism will appear in the upper right corner of the User Interface when Force Drag is enabled (Figure 145).

- To enable Force Drag mode, the User Interface operator touches and the **Force Drag** icon (Figure 145).

Figure 145: 3 Step Harvesting Workflow - Force Drag



7.3.2.2.1 Translation Force Drag

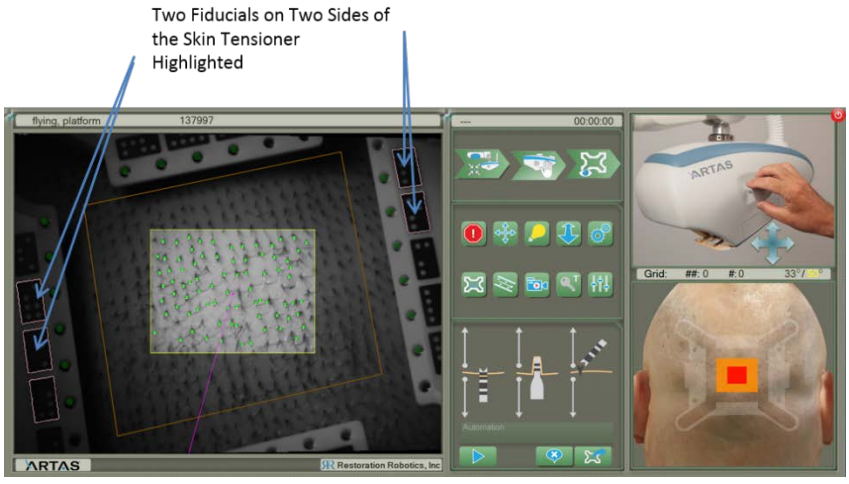
Once Force Drag is enabled, follow the steps below to properly position the Needle Mechanism.

1. Standing next to the patient within easy reach to the Force Drag handle of the Needle Mechanism, press and hold the **Force Drag** button on the ARTAS™ Hair Pendant or ARTAS™ Workflow Remote.
2. Gently apply force to the Force Drag handle (Figure 146) to move the Needle Mechanism towards the center of the Skin Tensioner.

Figure 146: Force Drag Handle

3. Move towards the Skin Tensioner until the lights begin to blink. This ensures that the cameras are in focus on the fiducials.
4. Once the fiducials are visible by the cameras, the Needle Mechanism will align itself to the angle of the existing hair.
5. Release the Force Drag button on the ARTAS™ Hair Pendant or ARTAS™ Workflow Remote to disable Force Drag mode.
6. Verify that at least 1 fiducial is recognized on the Skin Tensioner. The fiducials will be highlighted as shown in Figure 147 if recognized.

Figure 147: Fiducials Highlighted During Force Drag



Warning

It is important that the physician not apply force to the handle until AFTER the Force Drag button is pressed on the ARTAS™ Hair Pendant or ARTAS™ Workflow Remote. At the moment, the button is pressed the zero force is recorded and all motion is relative to that force level.

If force is applied to the handle at the time the Force Drag button is pressed, releasing the handle can cause Robotic Arm motion. If this happens, release the Force Drag button and the Force Drag handle, and start again by pressing the Force Drag button first.

Warning

The main function of Force Drag is to bring the Robotic Arm from the Center Position to the harvest area. Force Drag can also be used to move the Robotic Arm away from the patient when access to the harvest area is required. If using Force Drag to move the Needle Mechanism away from the Skin Tensioner, the Needle Mechanism will reorient itself to the startup orientation when fiducials are not present.

While in Force Drag mode, any control of the Robotic Arm by the operator from the User Interface is disabled, including automatic hair harvest.

NOTE: ***If at any point the user releases the Force Drag button, the Robotic Arm decelerates to a stop.***

7.3.2.2.2 Rotation Force Drag

The default movement type of the Robotic Arm during Force Drag is translation. To rotate the Needle Mechanism around the needle tip:

1. Ensure Force Drag mode is initiated.
2. Hold the Force Drag button on the ARTAS™ Hair Pendant or ARTAS™ Workflow Remote for more than 2 seconds without touching the handle on the Needle Mechanism.
3. With gentle pressure on the Force Drag handle, rotate the Needle Mechanism. ARTAS™ software indicates rotational movement by showing the rotational movement icon (Figure 148).

Figure 148: User Interface Images for Force Drag

Translational Movement

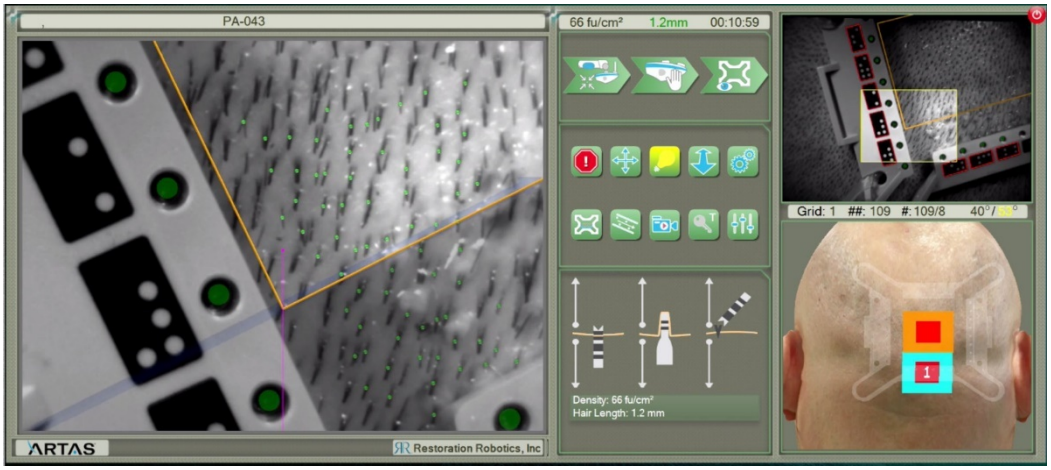
Rotational Movement

7.3.2.3 Acquire Tensioner

Caution		Caution
	***The following commands result in Robotic Arm movement.***	

1. The Skin Tensioner has a series of coded fiducial markings around its perimeter to teach the Robotic Arm the boundaries of the Skin Tensioner so that the dissection can proceed automatically.
2. To locate the Skin Tensioner, select **Acquire Tensioner** from the User Interface (Figure 141). Select ✓ to start the function. The Robotic Arm moves around the perimeter of the Skin Tensioner. Then it moves to the center of the Skin Tensioner, makes a density and average hair length calculation, and finally moves to the lower left corner of the Skin Tensioner in position for the first harvest (Figure 149).

Figure 149: Harvesting Starting Position



7.4 Avoiding Areas to Harvest

Because of scarring or previous harvests in the harvesting area, the user may need to mark certain areas as no harvest zones.

These no harvest zones are stored relative to the Skin Tensioner fiducials when acquiring the tensioner. Therefore, this step can only be performed AFTER acquiring the tensioner fiducials.

There are 4 ways to mark areas that should be avoided while harvesting with the ARTAS™ System:

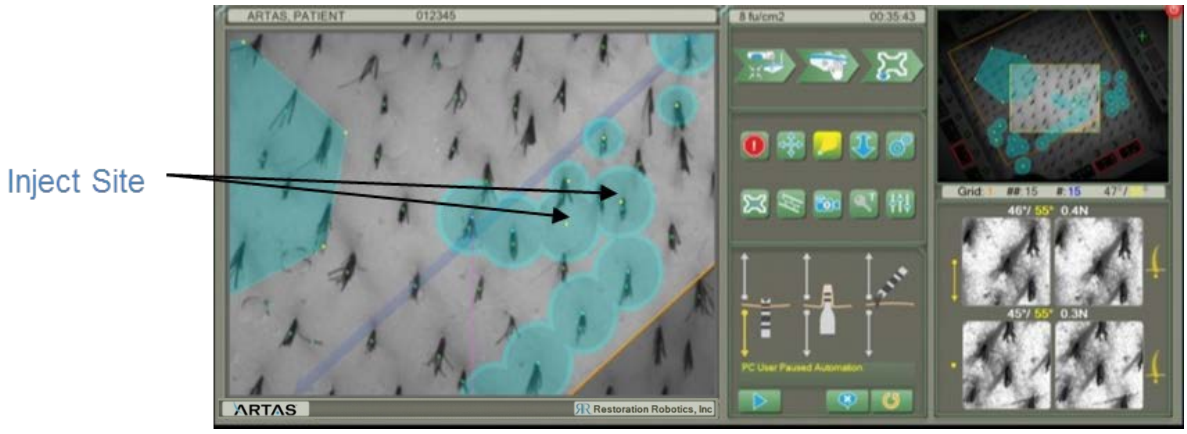
- Inject Sites (Section 7.4.1)
- Adjust Skin Tensioner Borders (Section 7.4.2)
- Skip (Section 7.4.3)
- Block Region (Section 5.4.1.3)
- Automatic Scar Detection (Section 7.4.4)

7.4.1 Inject Site

The user can define individual points as blocked harvest sites before or during automatic harvesting of the system (Figure 150) as defined below. Inject site may be created in both the hi-mag and low-mag screens of the User Interface.

- Using the Touchscreen
    1. Touch the desired point to block within the Skin Tensioner borders with 2 fingers. A blue circle with a yellow dot will show the injected, or blocked, site.
    2. To move an injected site, touch on the yellow center dot with 1 finger. The circle will turn yellow. Drag to the desired location.
    3. To delete an injected site, touch on the yellow center dot with 1 finger and release.
- Using the Mouse
    1. Right-click on the desired point to block within the Skin Tensioner borders. A blue circle with a yellow dot will show the injected, or blocked, site.
    2. To move an injected site, hover over the site until it turns yellow. Right-click and drag the site to the desired location.
    3. To delete and injected site, right-click on the yellow center dot.

Figure 150: Inject Sites

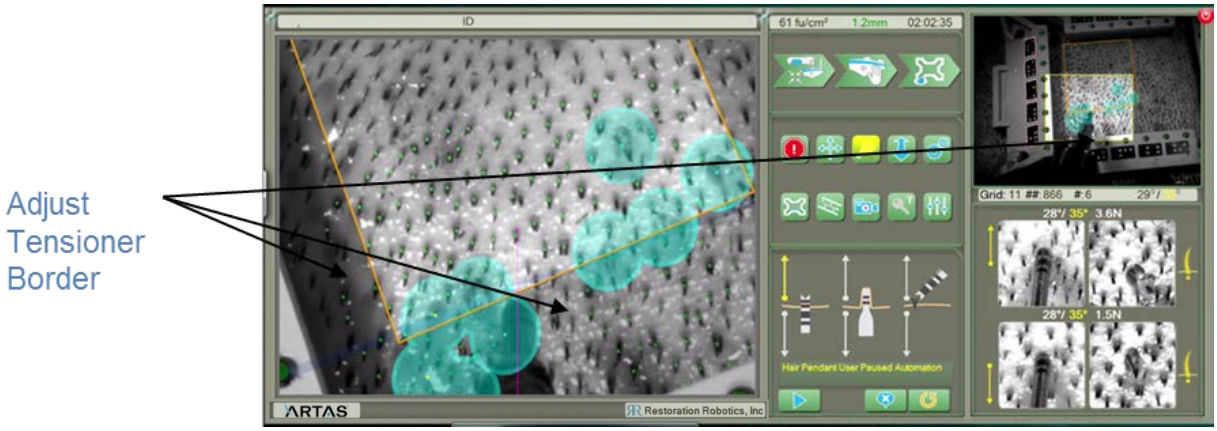


7.4.2 Adjust Skin Tensioner Border

The yellow Skin Tensioner border can be adjusted to avoid previously harvested sites (Figure 151). The border may be adjusted in both the hi-mag and low-mag screens of the User Interface. The user may adjust the borders before or during automation.

- Using the Touchscreen
  - Touch 1 finger outside of the yellow Skin Tensioner border (in the dark grey area) and drag to the desired location
- Using the Mouse
  - Right-click outside of the yellow Skin Tensioner border (in the dark grey area) and drag to the desired location

Figure 151: Adjust Skin Tensioner Borders

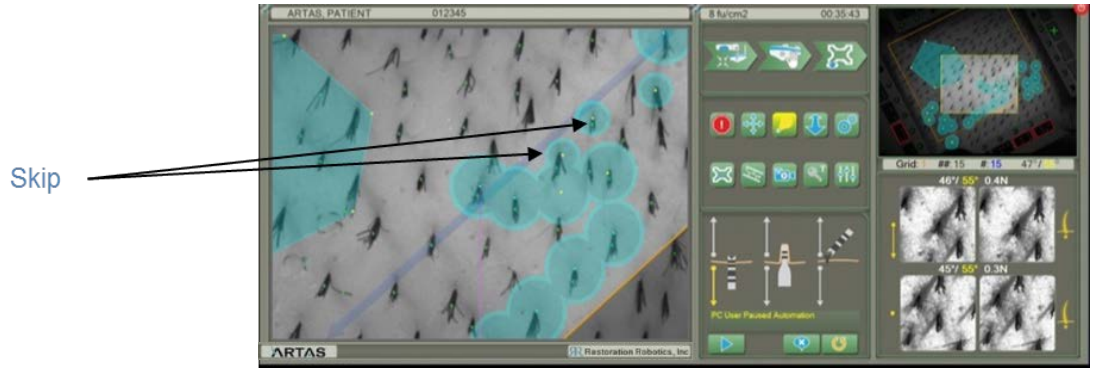


7.4.3 Skip

The user may skip the current targeted follicle using the Skip function (Figure 152). This method of avoiding areas to harvest may only be performed during automation. A skipped follicle will be marked with a small blue circle with a yellow dot in the center. Skipped follicle cannot be moved or deleted.

- Using the Touchscreen
  - When the current follicle is selected, it will be denoted by a green circle on the User Interface. Before the Inner Needle and Dissection Punch fire, select the **Skip** icon on the User Interface
- Using the Keyboard
  - Before the Inner Needle and Dissection Punch fire, select the **"S"** key on the keyboard

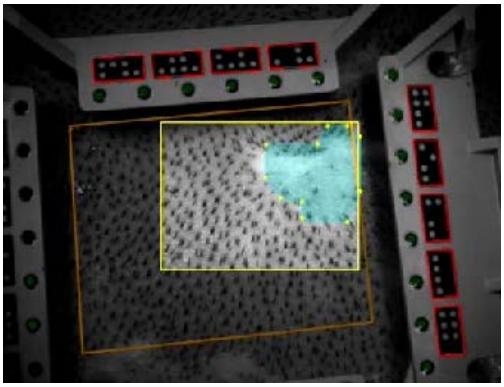
Figure 152: Skip Function



7.4.4 Automatic Scar Detection

After acquiring the Skin Tensioner, the ARTAS™ System detects in areas within the boundaries with little to no density. The system will mark this area as a scar to prevent harvesting in the area (Figure 153). If the user would like to move or delete the marked area, see Section 5.4.1.3 for steps on moving or deleting a blocked region.

Figure 153: Automatic Scar Detection



7.5 Monitoring and Adjusting Harvesting Dissection Parameters

There are 3 harvesting dissection parameters discussed in Section 5.5.1, Puncture Depth (PD), Coring Depth (CD), and Angle (ANG) that should be monitored throughout the harvesting procedure and adjusted if needed.

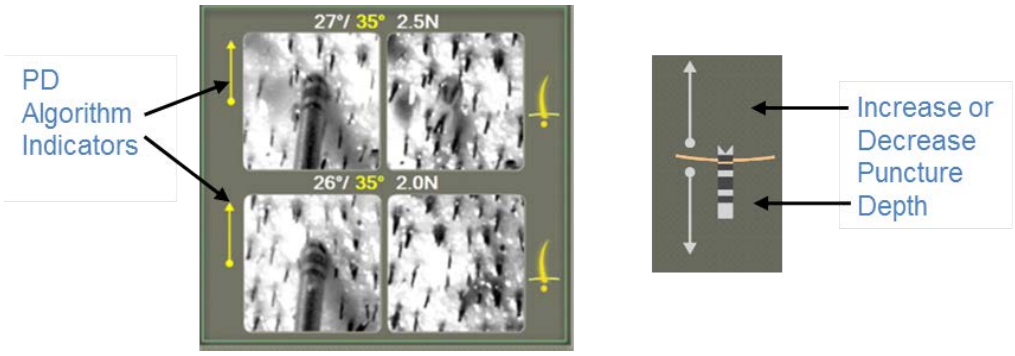
The first dissections in the first grid are typically performed with *Prompts On* to verify the depth of the puncture of the Inner Needle and the coring depth of the Dissection Punch. This will also allow the user to check graft quality under a microscope at the beginning of the grid to ensure all parameters are set properly.

1. Ensure **Prompts On**  is selected so that harvests are not performed automatically.
2. Double-tap on a hair or select  to allow the Robotic Arm to orient itself in position to dissect the selected hair follicle.
3. Select ✓ to harvest or **X** to move to another hair.
4. Perform approximately 10 harvests. Examine the PD, CD and ANG setting as described in the sections below.
5. Extract the first harvests completed and examine under a microscope.
6. Make any necessary adjustments.
7. Once the dissection parameters are set, turn **Prompts Off**  to begin automation.

7.5.1 Puncture Depth (PD)

Puncture Depth, or PD, controls the depth of the Inner Needle. During the harvesting procedure, examine the PD in the image in the lower right corner of the User Interface (Figure 154).

Figure 154: Monitoring & Adjusting Puncture Depth



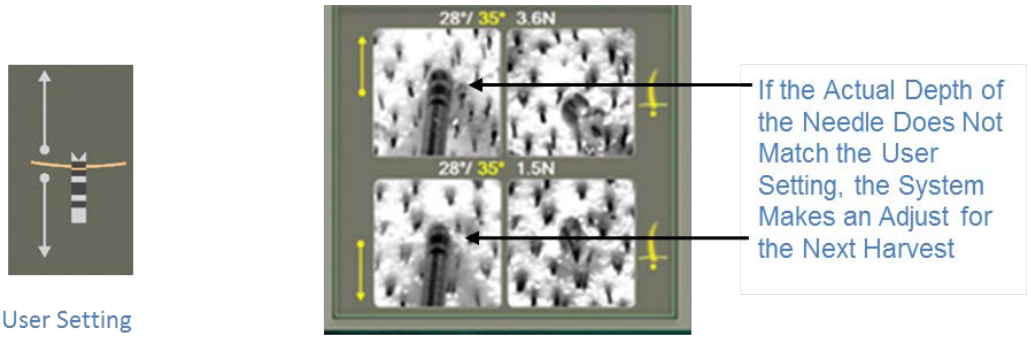
1. Adjust the PD user setting in the dissection parameters section of the display if necessary. The needle will increment upward (deeper depth) or downward (shallower depth) according to the adjustment made by the user. The orange skin of the user setting represents the depth the system will maintain. The system will automatically adjust puncture depth control for that location. See Section 7.5.1.1.
2. As the dissection proceeds, continue to monitor these images to ensure that depth remains adjusted properly. The depth may vary somewhat depending on skin toughness, skin tension, and angle of puncture.

7.5.1.1 Automatic Puncture Depth (PD) Algorithm

Once the user has set the desired Puncture Depth, the ARTAS™ System's Automatic PD Algorithm will consistently make adjustments to achieve the desired depth. See Figure 155, if

the actual depth of the Inner Needle does not match the user setting, the system will make an adjustment accordingly for the next harvest. The adjustment the system is automatically making is noted by the PD Algorithm Indicators to the left of the image. These are discussed in Section 5.3.1.

Figure 155: Automatic PD Algorithm



7.5.2 Coring Depth (CD)

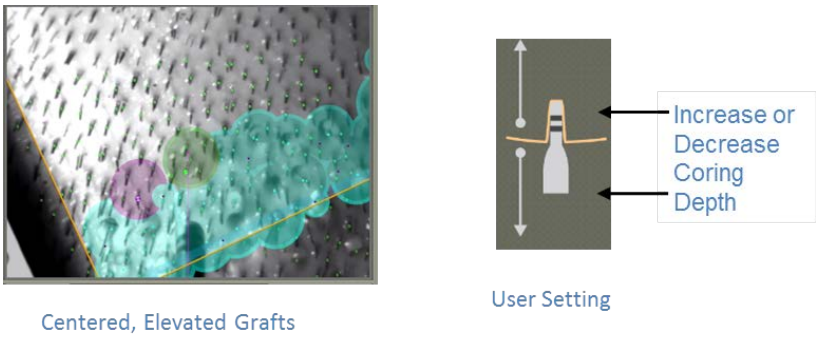
Coring Depth, or CD, controls the depth of the Dissection Punch. During the harvesting procedure, examine the CD on the User Interface (Figure 156).

- The harvested grafts should elevate
- There should not be consistent empty sites
- The Dissection Punch shoulder should not push down too firmly on the skin

Monitor the graft quality continuously to determine if the CD should be adjusted. The

1. Adjust the CD user setting in the dissection parameters section of the display if necessary. The punch will increment upward (deeper depth) or downward (shallower depth) according to the adjustment made by the user. The orange skin of the user setting represents the depth the system will maintain. The system will automatically adjust coring depth for that location.
2. As the dissection proceeds, continue to monitor the User Interface and graft quality to ensure that depth remains adjusted properly. The depth may vary somewhat depending on skin toughness, skin tension, and angle of puncture.

Figure 156: Monitoring & Adjusting Coring Depth

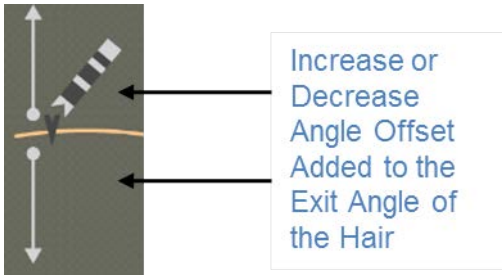


7.5.3 Approach Angle (ANG)

The approach angle to the scalp is maintained automatically by the software. The ARTAS™ System measures the exit angle of the existing hair and compensates for the difference in the angle of the follicle beneath the skin and the exit angle of the hair. You can adjust the angle of the punch to the scalp in the harvesting dissection parameters (Figure 157) by increasing or decreasing the offset added to the average exit angle of the hair. A grey shadow remains as a reference to the default setting. If you adjust the angle for the current hair, this information will be used to automatically shift the angle for future dissections.

Note: The minimum Approach Angle for the harvesting procedure is 35°.

Figure 157: Adjusting Approach Angle

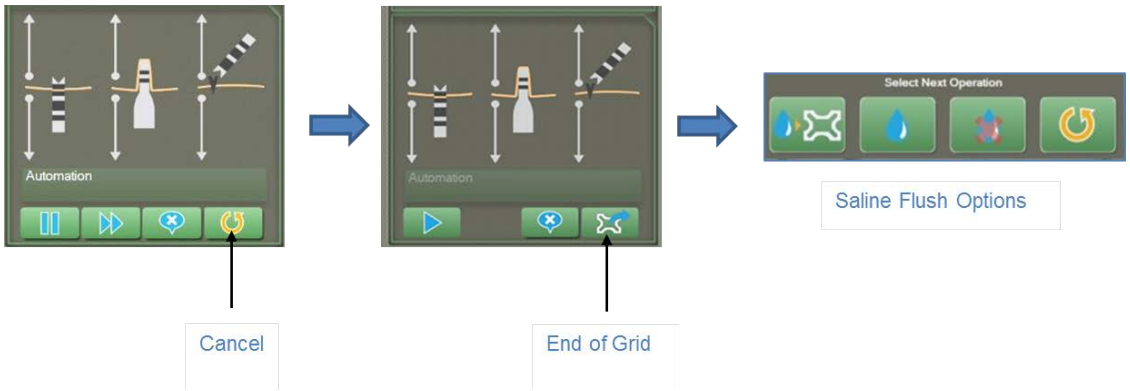


7.6 Complete the Harvesting Grid

Once harvesting of a grid is complete:

1. Select **Cancel** to stop automation.
2. Select **End of Grid** (Figure 158) to return the Robotic Arm to a safe position while the physician moves the Skin Tensioner.
3. The system will prompt the user with a menu of saline flush options. See Figure 105.
    a. A saline flush should be performed after each grid. The Robotic Arm safely moves away from the patient and to the saline station on the System Cart.
    b. The system will report an error if the syringe is not properly detected. If necessary, reseat the syringe and Saline Nose Cone and manually attempt the saline flush a second time by selecting the **Saline Flush** icon in the **Utilities** menu.
    c. The system will also report an error if the syringe is empty. If necessary, refill the syringe and reseat in the saline station. Perform another saline flush. It is recommended to empty the Follicle Trap anytime the syringe is refilled.
    d. The system will also report an error if there is a Vacuum Obstruction. To remove an obstruction, use the Needle Stylet as described in Section 3.3.1.1.3.

Figure 158: Ending the Harvesting Grid



4. Once the saline flush is performed, continue the procedure by reapplying the Skin Tensioner to the next area to harvest and following all previously defined steps. Continue until the harvesting is complete.

7.7 Post-Dissection Procedures

7.7.1 Count the Follicular Units

Use the ARTAS™ Hair Counter App to count follicular units. The app can be downloaded from the iTunes App Store https://itunes.apple.com/us/app/artas-hair-counter/id969259342?mt=8. See MK-225 for more information on how to use the ARTAS™ Hair Counter App.

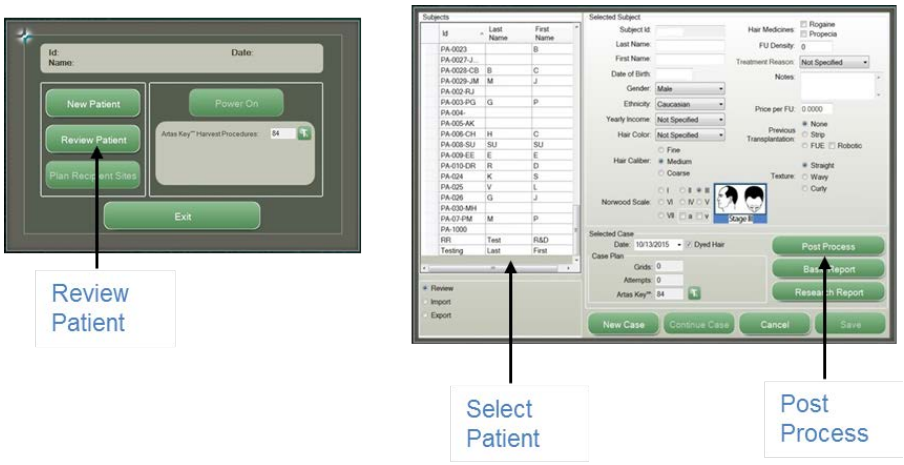
7.7.2 Enter Dissection Information into Post Process Form

Information entered into the Post Process Form will be used to create a Treatment Report at the end of the ARTAS™ Procedure.

When the technicians finish counting follicles with the FU Counter application, enter this information into the Post Process form (Figure 160):

1. On the ARTAS™ Hair Counter app:
   a. **Save File.**
   b. Send an email from the app. This email will contain a *.FU* file attachment that should be saved to a thumb drive.
   c. Insert the thumb drive into the ARTAS™ User Interface monitor USB port.
2. Select **Review Patient** on the Startup form. Select the corresponding patient (Figure 159).
3. Select **Post Process**.

Figure 159: Where to Find Post Process



4. Select **Import** and choose the *.FU* file containing the follicular unit Count information from the thumb drive.
    a. If the ARTAS™ Hair Counter App was not used, the information can also be entered into the fields manually
5. Select **Save** on the **Post Process** form.

Figure 160: Post Process Form

7.8 Harvesting Disassembly

Now that the harvesting procedure is complete, the system should be disassembled in preparation for the next procedure.

7.8.1 Clear the Needle Tubing

Flush the needle tubing connected to the Follicle Trap by selecting the **Saline Flush** icon from the **Utilities** menu. Perform at least 2 saline flushes, or until the tubing is clear, after the harvesting procedure.

7.8.2 Position the Needle Mechanism for Disassembly

Caution		Caution
	***The following commands result in Robotic Arm movement.***	

1. Make sure the area around the Needle Mechanism is clear and can move freely to the Change Needle position.
2. Verify the Robotic Arm is in Safe Position.
3. In the ARTAS™ System application, select **Change Needle** from the **Utilities** Menu.
4. Enable Manual Mode (Figure 161) by pressing the Manual button on the Cart Control Panel. The amber light will illuminate to indicate Manual Mode is enabled.

Figure 161: Enable Manual Mode

7.8.3 Remove the Dissection Punch

1. Make sure the area around the Needle Mechanism is clear and select **Extend Punch** on the Cart Control Panel.
2. Make sure the Inner Needle is not visible before proceeding.
3. Loosen the Dissection Punch (Figure 162):
    a. With the left hand, locate and press the spindle lock button
    b. With the right hand, use the Punch Wrench to loosen the Dissection Punch
    c. Once loosen, continue to unscrew the Dissection Punch by hand.
4. When the Dissection Punch is completely out of the threads on the tool carefully slide it off of the Inner Needle.
5. Properly discard the Dissection Punch in a sharps container.

Figure 162: Loosen Dissection Punch

Caution  ***The Inner Needle is exposed. Take care not to touch the Inner Needle tip when removing the Dissection Punch.*** Caution 

7.8.4 Remove the Inner Needle

1. Remove and dispose of the Needle Clip.
2. Re-install the grey needle protector.
3. Disconnect the needle tubing from the Follicle Trap. Re-insert the white tubing plug into the end of the needle tubing.
4. Carefully remove the Inner Needle and tubing from the spindle assembly. Gently pull the needle tubing out of the Needle Mechanism from the end that exits the front of the Needle Mechanism. Continue pulling until all of the tubing is fully removed from the Needle Mechanism.
5. Dispose of the Inner Needle and tubing into the sharps and biohazards container.

7.8.5 Remove the Follicle Trap and Saline Station

1. Disconnect the Follicle Trap from the vacuum by pressing down on the black seal while pulling up on the Follicle Trap tube.
2. Re-insert the orange vacuum plug.
3. Empty the contents of the Follicle Trap into a petri dish.
4. Properly discard of the Follicle Trap in a biohazard container.
5. Remove the saline syringe and Saline Nose Cone from the saline station and discard in a biohazard container.

7.8.6 Replacement of the Needle Clip and Vacuum Canister Liner

1. Install a new harvesting Needle Clip from the Non-Sterile Disposable Clinical Kit (Section 3.3.1.3).
2. Remove the Vacuum Canister Liner from inside the System Cart and dispose of properly.
3. Install a new Vacuum Canister Liner from the Non-Sterile Disposable Clinical Kit.
    a. Connect the red tube to the port labeled “vacuum”
    b. Connect the clear the to the L-shaped nozzle labeled “patient”
    c. Close any unused ports
4. Verify the Vacuum Canister Liner was installed properly.
    a. The vacuum readout on the Cart Control Panel should have a stable reading between 24 and 30 mmHg, depending on altitude.
        i. If a stable reading cannot be attained, verify all connections on the Vacuum Canister Liner are secure, and the outer edge of the Vacuum Canister Liner is completely sealed onto the Vacuum Canister around the entire edge

7.8.7 Exit Change Needle Mode

1. Select **Retract Punch** on the Cart Control Panel of the System Cart.
2. Press the **Manual** button and resume from the User Interface by selecting the flashing stop sign in the upper right corner of the UI (Figure 163).

Figure 163: Manual Mode User Interface Warning

7.8.8 Re-Usable Accessories Recovery

Items in the Reusable Clinical Kit (Section 3.3.1.1) including the Tensioner Tool, Tensioner Tray, Needle Stylet, and Punch Wrench must be inspected for damage and cleaned immediately after each use. Refer to the Instruction for Use for cleaning instructions.

8 The ARTAS™ System Site Making Procedure

8.1 Preparing for the Site Making Procedure

In this section, we will discuss how to prepare for the site making portion of the ARTAS™ procedure. It is important to have site making procedures loaded onto the ARTAS KEY™ USB device (Section 3.2.1) prior to beginning the procedure. Clinical accessory kits should be in inventory, including the Reusable Clinical Kit (Section 3.3.2.1) already cleaned and sterilized according to the Instructions for Use and the Sterile Disposable Clinical Kit (Section 3.3.2.3).

The following list (Table 10) of additional clinic site items contains items that are expected to be available at the clinical site in sufficient supply for the procedure. For a complete list of clinical supplies, refer to the Physician Preparation Guide (MK-270).

Table 10: Clinic Supplies for Site Making

Clinic Site Items for Site Making
Cotton-tipped applicators
Local Anesthetic
Gloves
Sodium Chloride Solution in Spray Bottle
4x4 Gauze
Telfa Pads
Micropore Tape
Sterile Drapes
Large Sharps Disposal Container
Germicidal Cloths
Large Stainless Bowl
Membrane Cover Roll, PRT-22690 (Barrier Film)
Surgical Marker
Measuring Tape

8.1.1 Area Preparation

Prepare the surgical area as discussed in Section 6. Refer to Section 4.1.2 for proper Patient Chair placement.

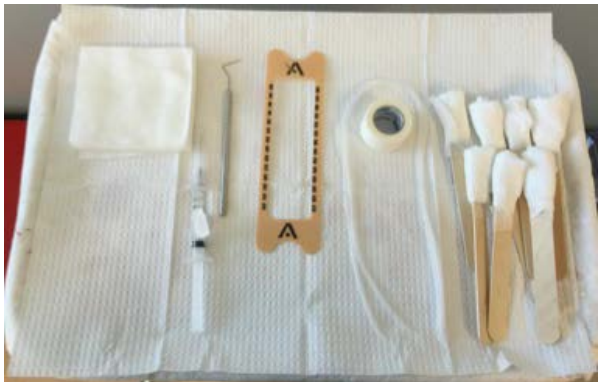
8.1.2 Prepare the Physician Instrument Tray for Site Making

Place the following items on a sterile, draped instrument tray (Figure 164):

- Gauze wrapped swabs or tongue depressors
- Gauze
- Probe
- Surgical Tape

- ARTAS™ Site Making Platform
- Spray Bottle with Saline

Figure 164: Site Making Physcian Tray Setup



8.1.3 Patient Preparation for the Site Making Procedure

See Section 6 for patient preparation steps for the site making procedure. Section 4.1.2 reviews proper patient chair positioning for the site making procedure.

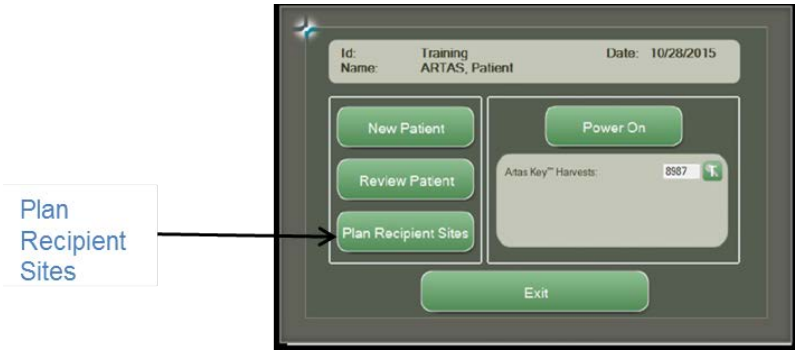
8.2 Creating the Surgical Plan for Recipient Site Making

The recipient surgical plan is created using ARTAS HAIR STUDIO™ on the User Interface. You will use the stylus and the photo taken in the patient preparation step to create the surgical plan.

8.2.1 Import Photo

1. Access the ARTAS HAIR STUDIO™ software, by selecting **Plan Recipient Sites** from the Power On screen (Figure 165).
   - The ARTAS HAIR STUDIO™ software will open
   - The Patient ID and First/Last Name will automatically populate from the information entered into the ARTAS™ Application

Figure 165: Accessing ARTAS HAIR STUDIO™ for Site Making



2. Import the photo taken by plugging in the camera device used in the patient preparation step into the User Interface Monitor.
   - If using an iPad or iPhone, select **Trust** when asked whether to Trust this Computer

- Select the Top photo icon (Figure 166)
  - A File Explorer Window will pop-up
  - Navigate to the file location of the Top photo and select **Open**
  - Rotate the photo using the **Rotate** icon if needed
    - The nose of the patient should point either up or down
- After the photo has been selected, select the ✓
  - To cancel the function, select the red **Cancel** icon

Figure 166: Import Photo

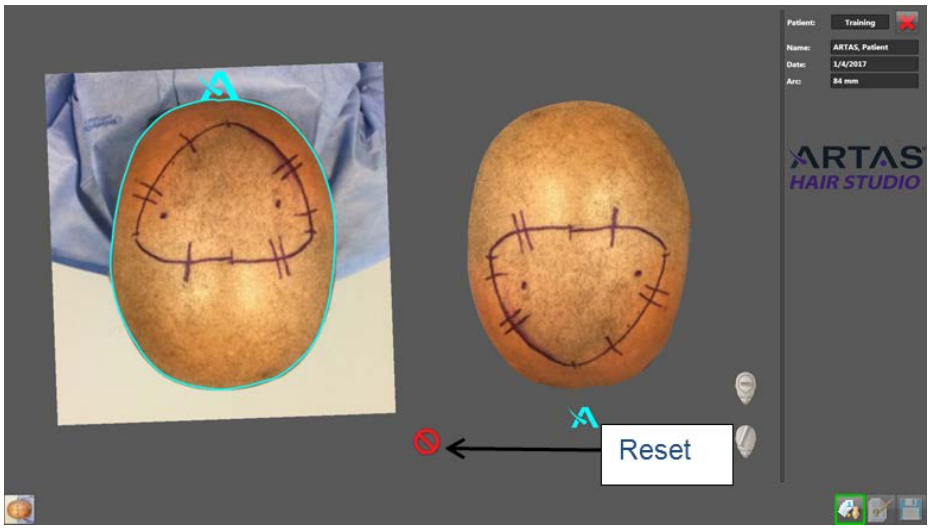
8.2.2 Phase 1 – Create 3D Dome

This phase allows the user to create an accurate 3D Dome of the patient's recipient area to create recipient sites with the ARTAS™ System.

After importing the photo, the user will see a 2D photo of the top of the patient's head on the left and the resulting 3D Dome on the right of the screen. In the bottom right corner of the interface, the 1st icon is outlined in green, indicating Phase 1 of the application is in use.

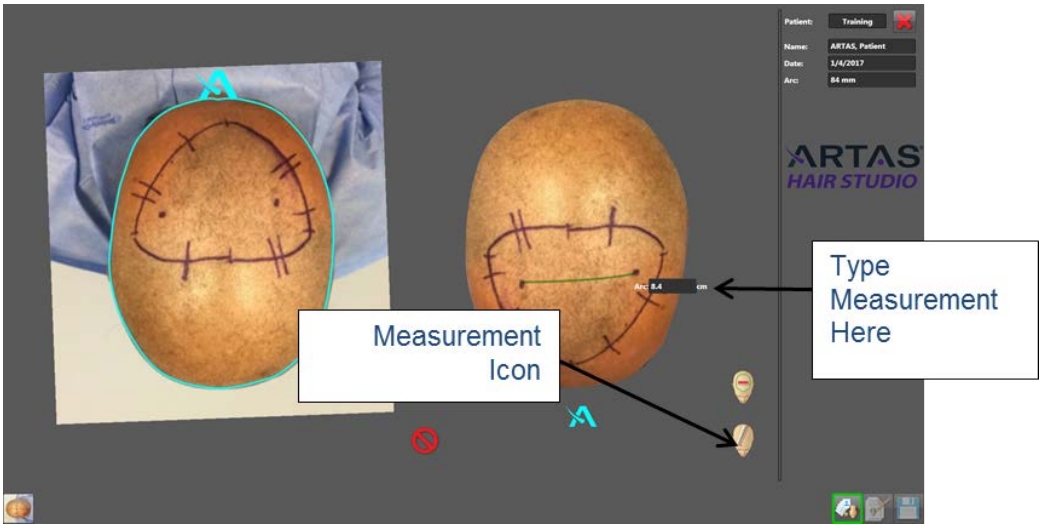
1. Beginning at the center of the patient's nose, trace the perimeter of the patient's head as accurately as possible with the stylus.
   a. The user can reverse the tracing and begin again to correct an area
   b. To delete and start again, select the red **Reset** icon in the bottom center of the screen
2. When the outline changes to light blue, lift the stylus.
3. The Stylized ARTAS "A" will represent the nose to ensure the model is oriented properly (Figure 167).

Figure 167: Trace Top Photo



4. Scale the 3D Dome with the measurement taken dot-to-dot in the patient preparation step (Figure 168).
    a. Select the **Measurement** icon so that it is illuminated
    b. With the stylus, draw a line from dot-to-dot
        i. The dots should be marked medial-to-lateral
    c. In the Arc field, type in the measurement taken in the preparation step and press the Enter key on the keyboard

Figure 168: Scale the 3D Dome



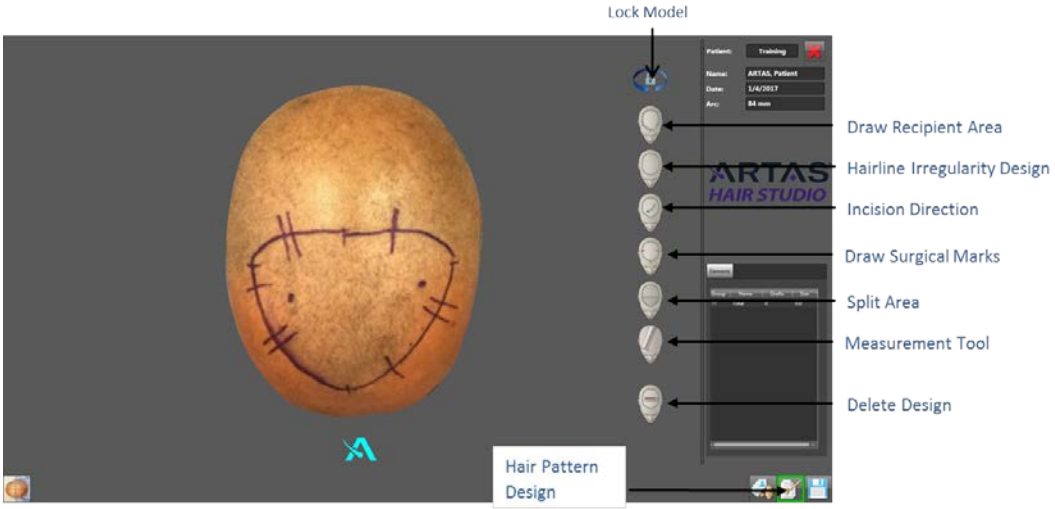
5. Verify the 3D Dome by using the stylus to measure front-to-back and compare to the measurement taken in the patient preparation step.

8.2.3 Phase 2 – Creating Hair Pattern Design

Phase 2 in creating the surgical plan is creating the Hair Pattern Design. To enter this phase, select the second icon in the bottom right corner of the ARTAS HAIR STUDIO™ application. The icon will be outlined in green. The 3D dome will appear in the center of the main viewing window along with the design icons (Figure 169).

In this phase, the user will define the desired area and incision parameters that will be later used in the site making procedure.

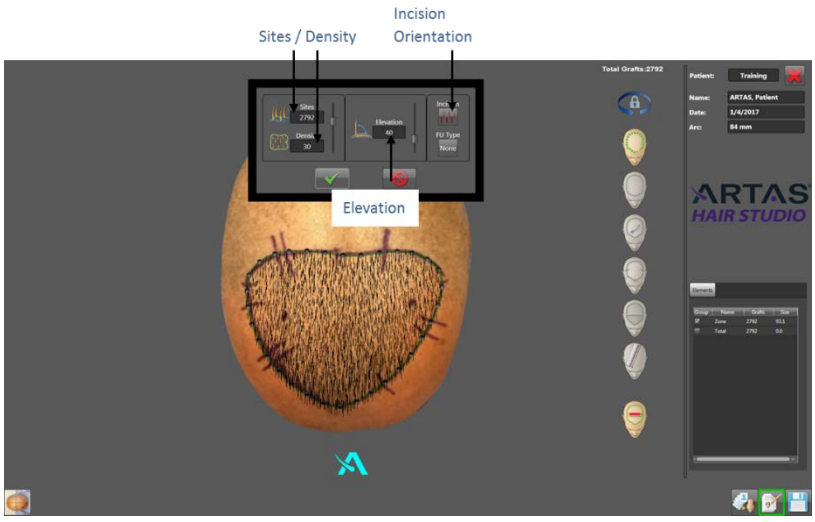
Figure 169: Creating Hair Pattern Design Icons



8.2.3.1 *Outlining the Recipient Area*

Use the Recipient Area feature to outline the desired area for the design (Figure 170):

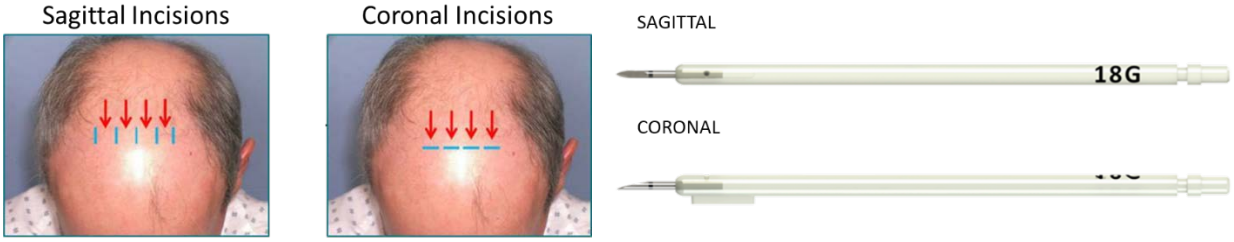
Figure 170: Draw Recipient Area



1. Enlarge the 3D Dome if needed. Lock the 3D Dome to prevent movement while creating Hair Pattern Design by selecting the **Lock** icon.

2. Select the **Draw Recipient Area** icon to enable the Recipient Area mode. The icon will illuminate indicating the mode is active.
3. With the stylus, trace over the surgical area indicated in the patient preparation step on the 3D dome, and release the stylus to complete the shape. A pop-up window will appear containing Recipient Area information.
4. Adjust the Recipient Area parameters inside the pop-up window.
   - Sites – Denotes the total number of incisions to be created within the area
     - Increase or Decrease Total Number of Incisions: Slide the bar up or down
     - Enter Precise Number of Incisions : Select the number field and enter in the number desired
   - Density – Denotes the total number of incisions to be created per square centimeter
     - Increase or Decrease Density: Slide the bar up or down
     - Enter Precise Density: Select the number field and enter in the number desired
   - Elevation – Denotes the elevation angle (angle off the scalp) of the incision sites
     - The default angle is 35°
     - The lowest angle is 30°
     - Increase (more obtuse) or Decrease (more acute) Elevation Angle: Slide the bar up or down
   - Incision – Indicate the orientation of the needle/blade when creating incisions
     - The orientation of the needle/blade can be selected so that the incisions are in either the sagittal/vertical or coronal/horizontal plane (Figure 171)
     - Sagittal Sites: Incisions will be made with the bevel of the Needle oriented in the anterior-to-posterior direction. The incisions will appear longitudinal. The bevel will face to the side and the sites will be parallel to the hair growth
     - Coronal Sites: Incisions will be made with the bevel of the Needle oriented in the medial-to-lateral direction. The incisions will appear laterally. The bevel will face up, and the sites will be perpendicular to the hair growth

Figure 171: Sagittal vs. Coronal Incisions

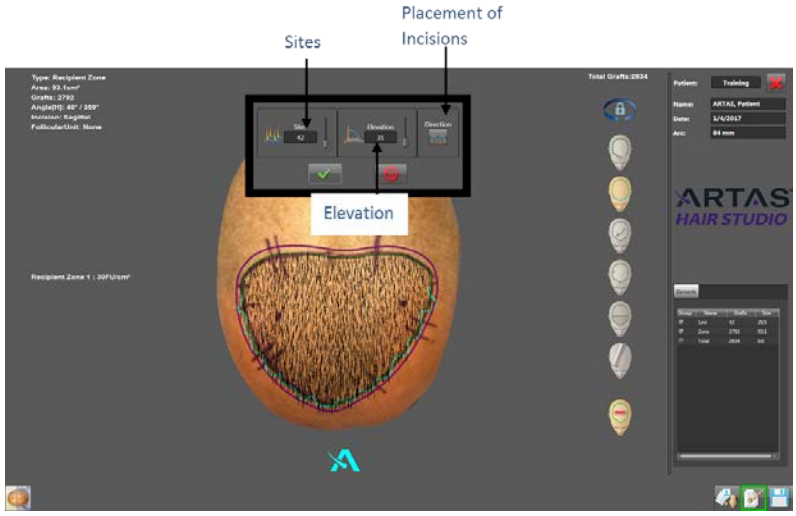


5. Select the ✓ save the Recipient Area and parameters.
   - Select the **Cancel** icon to cancel and not save the recipient area or parameters
     - o After the Recipient Area and the parameters are saved, the Recipient Area mode will de-activate automatically

8.2.3.2 Design the Hairline Irregularity

Use the Hairline Design feature to add a hairline irregularity to an existing recipient area. Macro density variation must be designed by the user, and the system will add micro density variation (Figure 172).

Figure 172: Designing the Hairline Irregularity



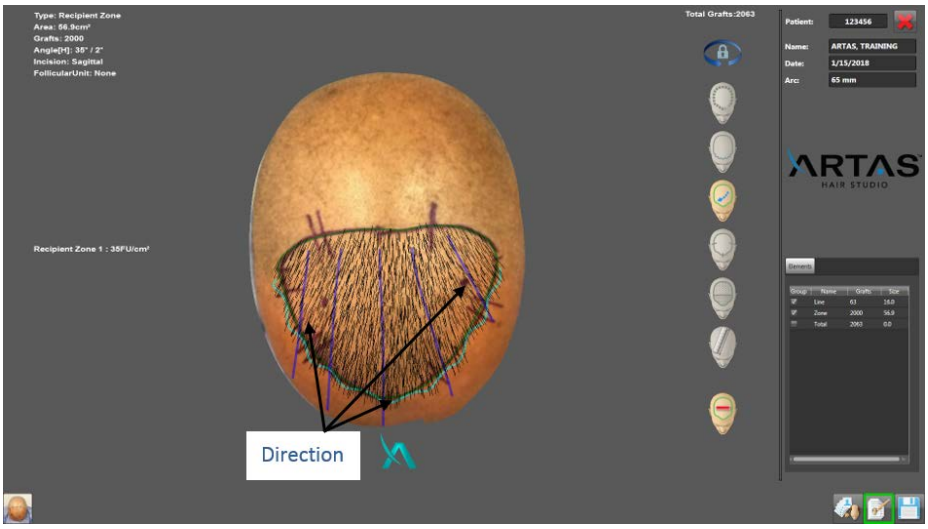
1. Select the **Hairline Irregularity Design** icon to enable the hairline feature. The icon will illuminate indicating the mode is active. A purple line will appear 5 mm away from the existing recipient area drawn in the step before. Use this as a guide when designing the hairline irregularity.
2. With the stylus, touch and drag to draw the desired hairline irregularity.
   - Draw the irregularity between the existing recipient area and the purple line
3. When the line is complete, release the stylus, and a pop-up will appear with the hairline design parameters.
4. In the parameters window, choose the following:
   - Total Sites – Adjusts the total number of incisions in the Hairline Irregularity
     - Increase or Decrease the number of incisions: Slide the bar up or down
     - Enter Precise Number of Incisions : Select the number field and enter in the number desired
     - NOTE: This will add to the total number of incisions in the Hair Pattern Design
5. Elevation – Adjusts the elevation angle (angle off the scalp) of the incision sites created in the hairline irregularity.
   - The default angle is 35°
   - NOTE: If the angle of the hairline is different than the recipient area, the angle will be adjusted gradually in the transition from the hairline to the recipient area
6. Direction (Hairline Placement) – This icon allows the user to indicate whether the incisions should be created in front of or behind the line drawn.
7. Select the ✓ to save the Hairline Design and parameters.
   - Select the **Cancel** icon to cancel and not save the hairline design or parameters

- After the Hairline Irregularity and the parameters are saved, the Recipient Area mode will de-activate automatically

8.2.3.3 Incision Direction

Use the Incision Direction feature to indicate the in-plane direction of the incision sites (Figure 173).

Figure 173: Incision Direction

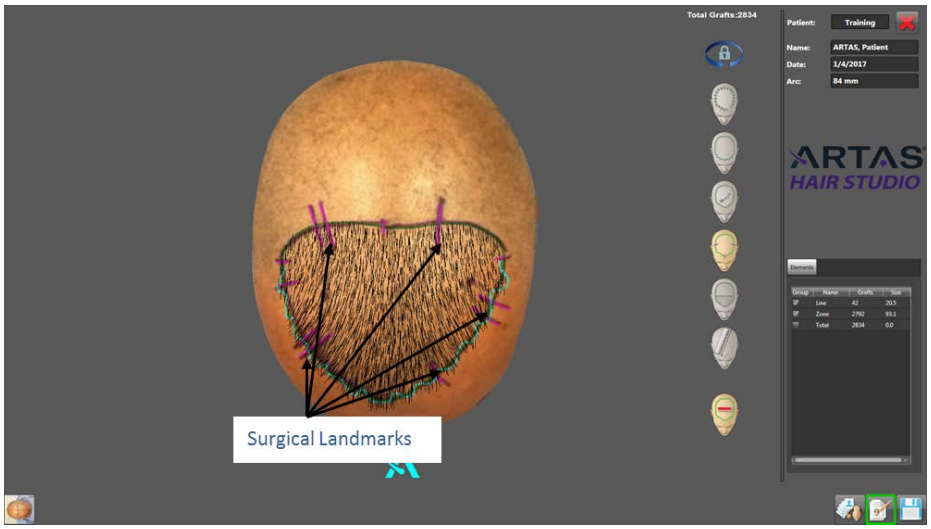


1. Select the **Incision Direction** icon to enable the Incision Direction mode. The icon will illuminate indicating the mode is active.
2. Using the stylus, draw lines to indicate the desired direction inside the treatment area. Draw the lines from the back of the recipient area to the front on the model. The lines should begin within the recipient area indicated and end outside of the recipient area. It is recommended to slightly fan out the direction on the sides to ensure consistency.
3. Draw approximately 3-5 directional lines from the back of the recipient area (within the boundary) to the front of the recipient area (outside the boundary). Incision direction lines will appear purple
   - Incision sites between direction lines will change gradually resulting in a smooth transition
4. To disable Incision Direction mode, select the **Incision Direction** icon. The icon will de-illuminate indicating the mode is no longer active.

8.2.3.4 Draw Surgical Landmarks

The Surgical Marker feature allows for easy alignment of the plan during the site making procedure (Figure 174).

Figure 174: Draw Surgical Landmarks

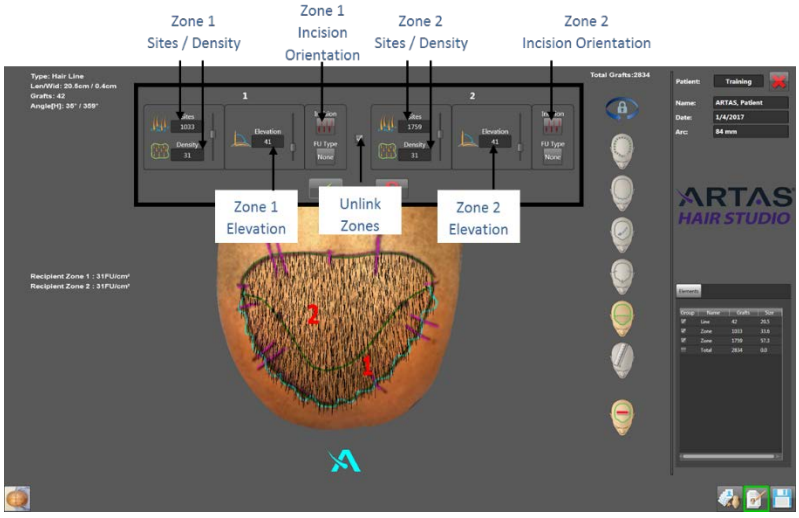


1. To enable the Surgical Marker mode, select the **Surgical Mark** icon. The icon will illuminate indicating the mode is active.
2. With the stylus, trace the surgical landmarks that were drawn on the patient's scalp in the initial patient preparation.
   - Surgical markers will appear pink once drawn
3. To disable the Surgical Mark mode, select the **Surgical Marker** icon. The icon will de-illuminate indicating the mode is no longer active.

8.2.3.5 Split Recipient Area

This step is optional. The Split Recipient Area mode allows the user to indicate different densities throughout the recipient area. The system will gradually change density across the areas (Figure 175).

Figure 175: Split Recipient Area



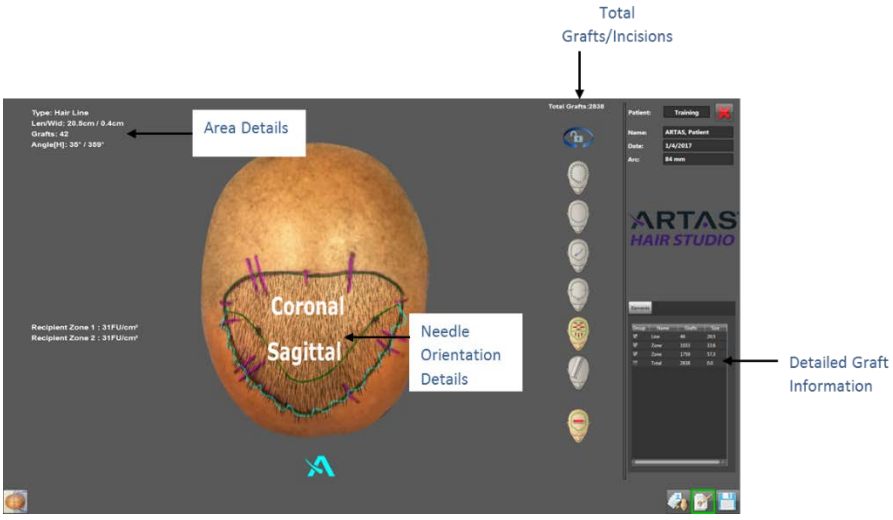
1. To enable the Split Recipient Area mode, select the Split Recipient Area icon. The icon will illuminate indicating the mode is active.
2. With the stylus, touch and drag across the recipient area where the split is desired. Begin outside the recipient area (while still on the dome) and drag to the other side, ending outside the recipient area (while still on the dome).
3. The recipient area will split into two sections, labeled 1 and 2. A pop-up window will appear with the parameters.
   - Adjust the number of incisions or density of each area using the corresponding section labeled 1 or 2 in the pop-up window
     - To increase or decrease the incisions or density: Slide the bar up or down
     - To indicate in a specific number of incisions or density: Select the number field and enter the desired number
   - By default, the total number of incisions in both areas combined will remain the same
     - Therefore, increasing the number of incisions in Area 1 will decrease the number of incisions in Area 2
     - This is indicated by a ✓ in the box between each section
     - To unlink the two sections and change the number of sites in only one section, touch on the box to uncheck it
   - Select the orientation of the needle/blade for each section of the recipient area by using the *Incision* icon
     - The incisions may be created in a sagittal or coronal orientation. See Section 8.2.3.1 for additional information regarding the orientations
4. To accept the parameters chosen, select the ✓. To cancel, select the **Cancel** icon to delete the split areas.
5. The user may create only 2 areas at a time. To create additional areas, split 1 of the 2 areas now created. Follow the same steps.
6. To disable Split Recipient Area mode, select the **Split Recipient Area** icon. The icon will de-illuminate indicating the mode is no longer active.

8.2.3.6 Viewing and Editing Design Parameters

The total number of incision sites including all recipient areas and hairlines is shown in the top right corner of the main viewing screen above all Hair Pattern design feature icons.

- View parameters of individual recipient areas and hairlines by hovering over the desired recipient area (Figure 176)
  - The details will be shown in the upper left corner of the main viewing window: surface area, total number of sites, density and elevation angle
  - Details can also be viewed in the *Elements* box on the right side of the ARTAS HAIR STUDIO™ application

Figure 176: Viewing Recipient Area Information

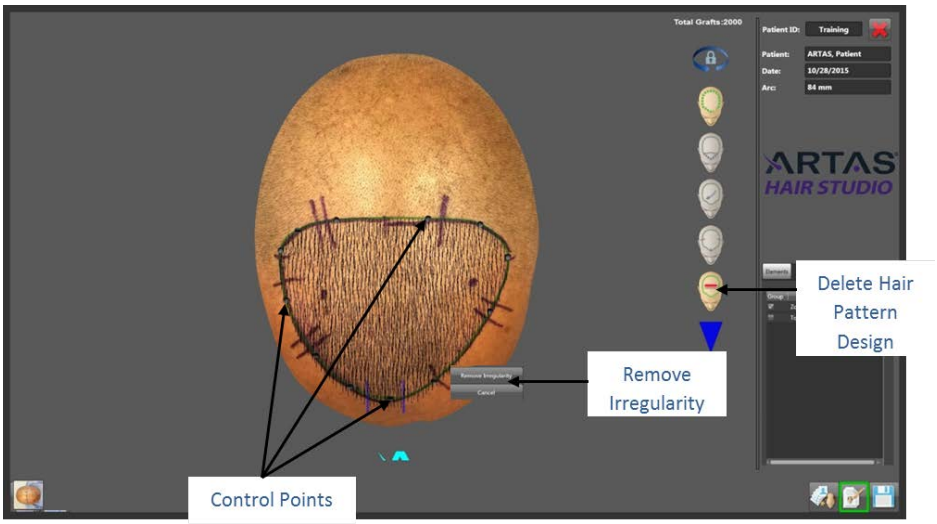


- The Hair Pattern Design features can be edited by re-enabling each feature
  - Individual recipient areas or hairline parameters:
    1. Select the **Draw Recipient Area** icon
    2. Touch inside the desired recipient area or hairline
    3. Edit the parameters inside the pop-up window and select the ✓
  - Recipient area or hairline shape:
    1. Select the **Draw Recipient Area** icon
    2. Touch and drag on any round control point
       - The shape will change as each control point is moved
       - Create additional control points by drawing a line across the recipient area border where you would like the control point to appear

NOTE: If you change the surface area of the recipient zone by moving control points, the number of sites in the plan will change. The density will remain consistent. The software will calculate the number of sites according to the density originally entered into the plan

  - Delete individual recipient areas, hairlines, directional lines or surgical marks
    1. Tap and hold the stylus on the curve of the desired entity until the white circle appears.
    2. Release the stylus.
    3. Select **Remove.**
  - Delete entire Hair Pattern Design
    1. Select the **Remove All** icon.
    2. Select the ✓ to confirm the deletion or the **Cancel** icon to keep the design.

Figure 177: Edit Design Parameters

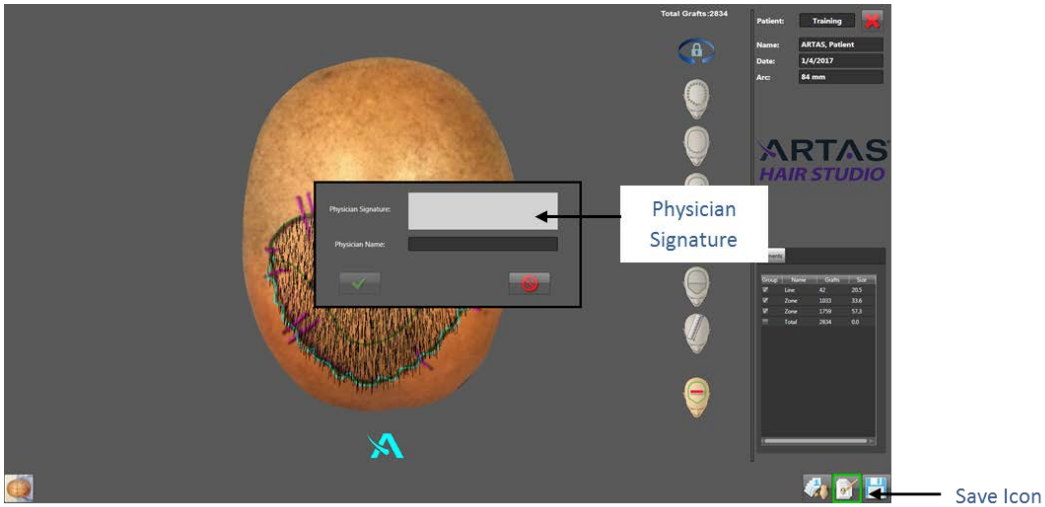


8.2.3.7 Save the Hair Pattern Design

- When all edits are complete, save the Hair Pattern Design to use in the site making procedure by selecting the **Save** icon in the bottom right corner of the ARTAS HAIR STUDIO™ application (Figure 178).

1. A pop-up will appear where the physician will sign the surgical plan.
    a. Type the physician name
    b. This will only appear the first time the plan is saved
2. Select the ✓ to accept.
3. A *Saving* dialog will appear.
    a. Once the save is complete the dialog will disappear
4. Close the ARTAS HAIR STUDIO™ application by selecting the **X** in the upper right corner of the application.
    a. The *Power On* screen will appear

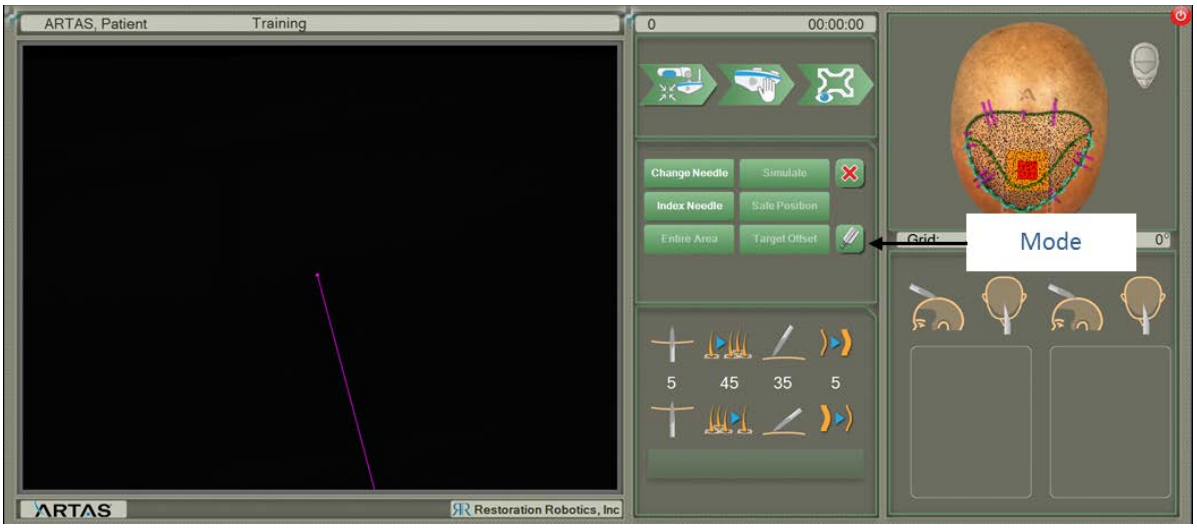
Figure 178: Save and Sign the Hair Pattern Design



8.2.4 Power On the ARTAS™ System: Site Making Mode

1. Ensure the ARTAS KEY™ USB device is plugged directly into the USB port on the ARTAS™ System monitor.
2. Select **Power On** to launch the ARTAS™ software.
3. In the **Utilities** menu, select the **Mode** icon to switch from *Fast Harvesting* to *Site Making* (Figure 179).
4. The Site Making plan created will automatically load into the upper right corner of the User interface.

Figure 179: Change to Site Making Mode

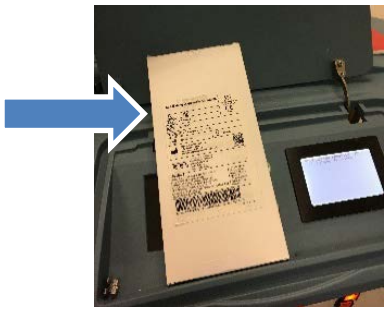


8.2.5 Scanning the Site Making Procedure Kit

Caution *The following commands result in Robotic Arm movement.* **Caution**

1. Align the ARTAS Procedure Kit with the System Cart Control Panel Door.

Figure 180: Align Site Making Kit to Scan



2. Select **Utilities** → **Scan Kit** (Figure 116).

3. From the **Scan Kit** window, confirm that the kit is in place and select the **Scan Kit** icon. The Needle Mechanism will move to a position over the QR code on the kit, and scan. The Reference number, Lot Number and Expiration Date will populate. Once the kit information is populated, confirm by selecting the ✓ (Figure 117).

4. Remove the kit from the System Cart Control Panel and select the ✓**.** The Needle Mechanism will move to Safe Position. You are now ready to install site making disposables and re-usables (Figure 118).

8.2.6 Installation of the Site Making Disposables and Re-usables Using ARTAS™ Site Making Needles

Gloves should be worn by the user when installing these clinical accessories.

Caution		Caution
	***The following commands result in Robotic Arm movement.***	

8.2.6.1 Positioning the Needle Mechanism for Installation

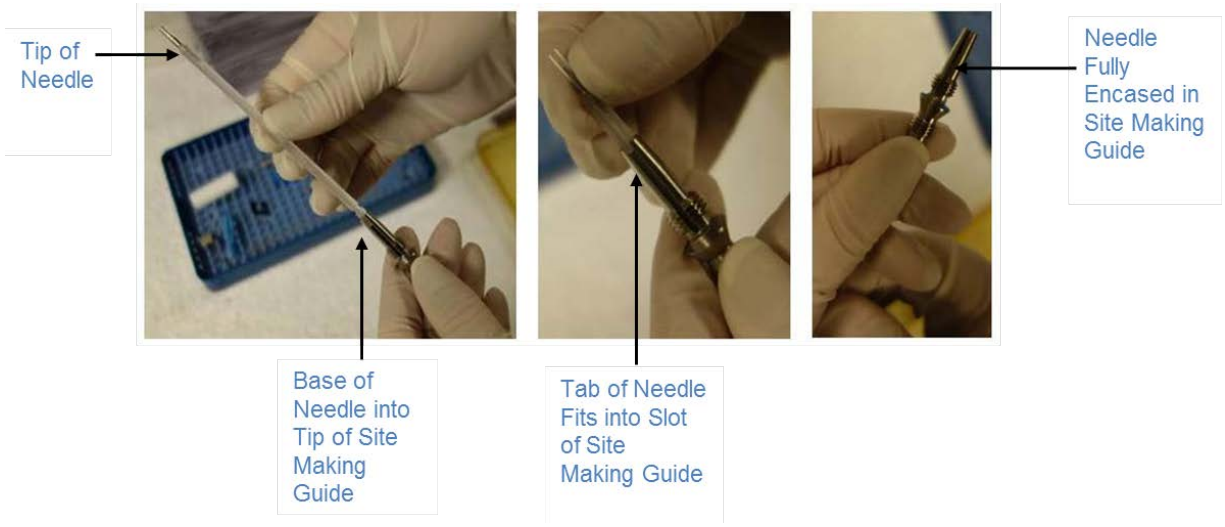
1. Make sure the area around the Robotic Arm and Needle Mechanism is clear and can move freely to the Change Needle position**.**
2. On the User Interface, select the **Mode** icon in the **Utilities** menu to switch to Site Making Mode. The plan created in the previous steps will automatically load in the upper right corning of the User Interface.
3. Next, select **Change Needle** from the **Utilities** menu on the UI**.**
4. Press the **Manual** button on the Cart Control Panel. The button will illuminate yellow. In this mode, the operator cannot power up and move the Robotic Arm from the User Interface.

8.2.6.2 Assembling the Needle and Re-usable Kit

Warning		Warning
	***Puncture risk. Exercise caution to prevent needle sticks to user.***	

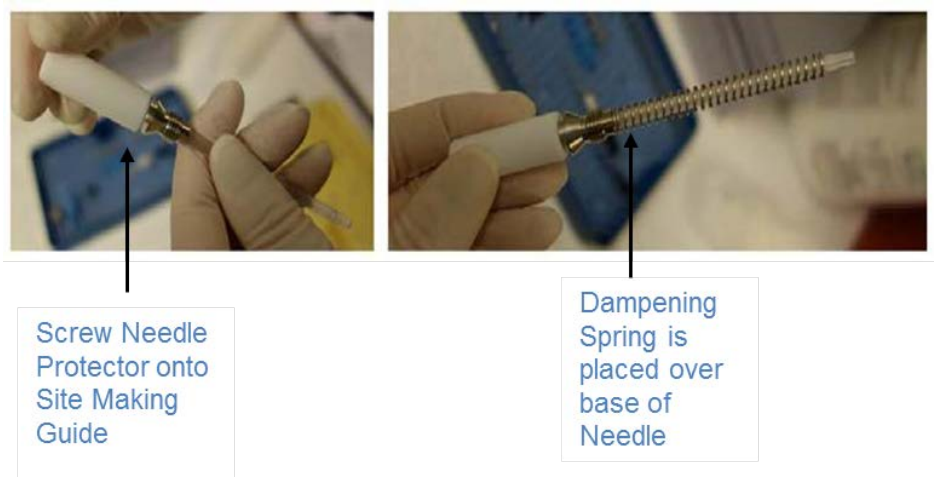
1. Choose the desired needle gauge. First, remove the protective covering from the needle tip and discard. Next, Insert the base of the Needle into the tip of the Site Making Guide so that the tab on the Needle fits through the slot in the Site Making Guide. The Needle tip should be encased in the Site Making Guide (Figure 181).

Figure 181: Assembling Needle in Site Making Guide



2. Screw on the Needle Protector onto the Site Making Guide.
3. Place the Dampening Spring over the base of the Needle (Figure 182).

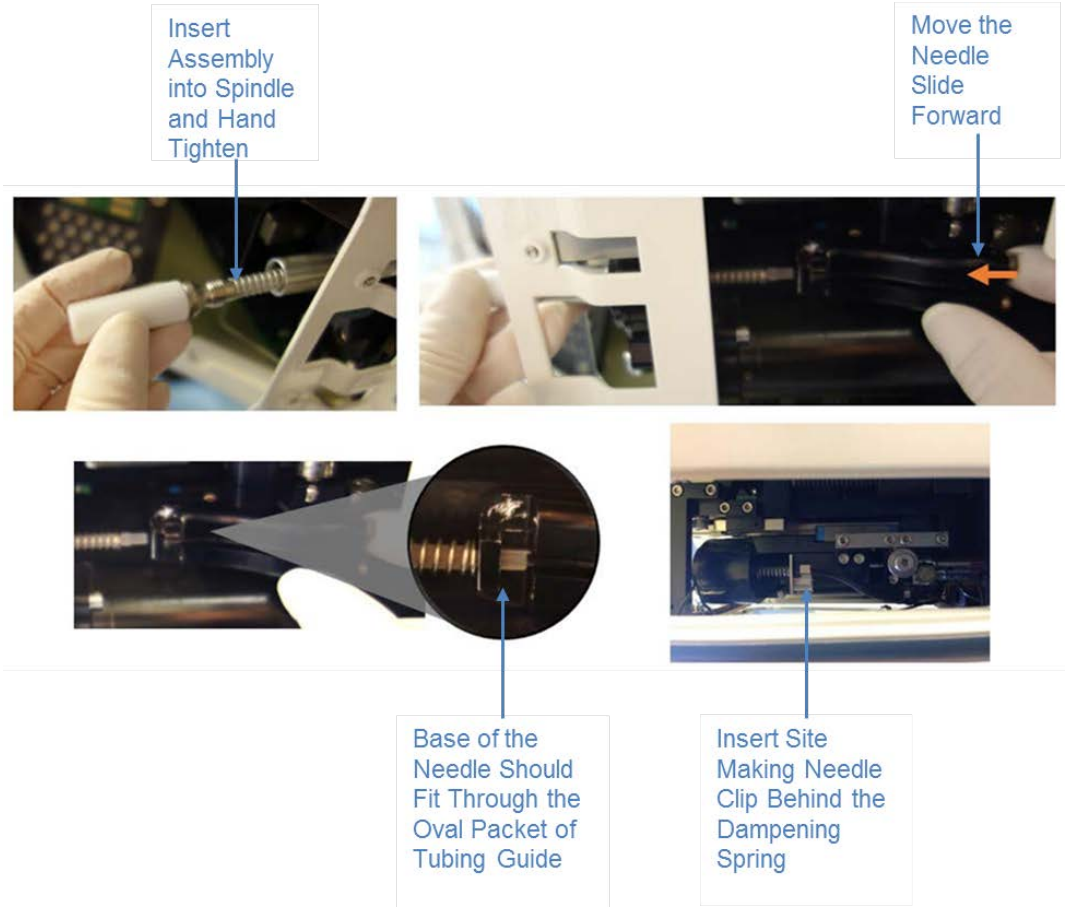
Figure 182: Installing Needle Protector and Dampening Spring



8.2.6.3 Installing Needle Assembly and Needle Clip

1. Remove the Harvesting Needle Clip and keep for later use.
2. Feed the Needle Assembly through the spindle of the Needle Mechanism. Hand-tighten the assembly into the spindle. Move the needle slide forward to ensure the needle hub on the base of the needle is fully seated in the oval pocket of the tubing guide on the needle slide.
3. Install the Site Making Needle Clip with the flat end facing toward the Needle tip. Ensure that the Needle Clip is attached behind the Dampening Spring so that it moves freely along the base of the needle (Figure 183).
    - NOTE: The Site Making Needle Clip is NOT to be used in place of the Harvesting Needle Clip.

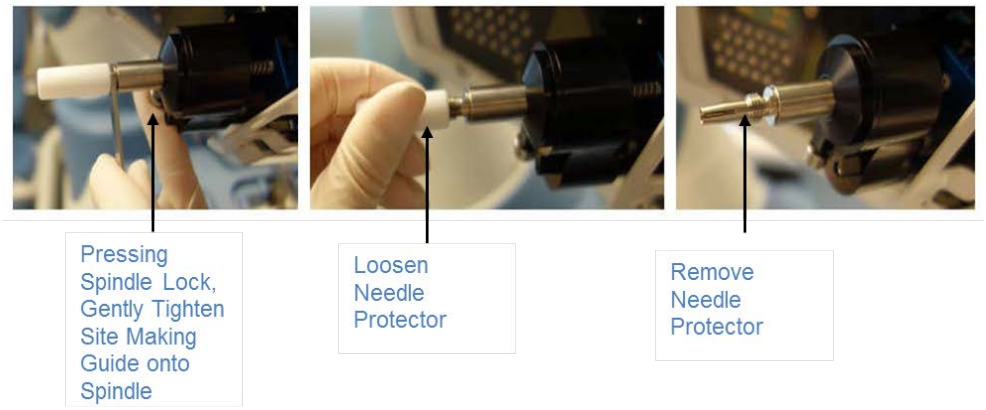
Figure 183: Installing Needle Assembly & Needle Clip



8.2.6.4 Installing Site Making Guide

1. Select **Extend Punch** on the Cart Control Panel touchscreen on the System Cart.
2. Press the spindle lock with your left hand and use the wrench from the reusable kit with your right hand to gently tighten the Site Making Guide using the notch of the Site Making Guide. Do NOT over tighten (Figure 184).
3. Unscrew the Needle Protector from the Site Making Guide by holding the spindle with your right hand and loosening the Needle Protector with you left hand. Set aside for future use.
4. Push the needle slide forward to expose the needle tip. Remove the protective covering and discard.
5. Select **Retract Punch** on the Cart Control Panel touchscreen of the System Cart.

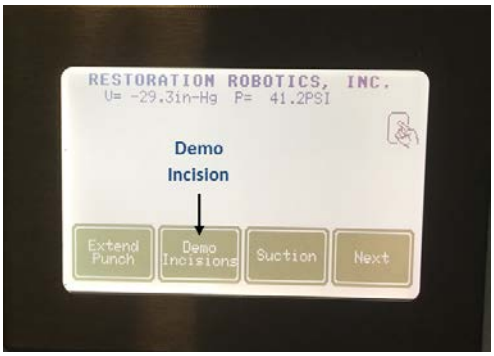
Figure 184: Tighten Site Making Guide to Needle Mechanism



8.2.6.5 Verify Installation

1. To verify correct installation, select **Demo Incision** (Figure 185) from the Cart Control Panel touchscreen on the System Cart.
2. The system will simulate a site making incision. Ensure that the Needle Clip stays secure and the Needle extends and retracts normally.
3. To complete installation and return to software mode, press the **Manual** button on the Cart Control Panel of the System Cart. Select **Resume** from the User Interface.

Figure 185: Demo Incision



8.2.6.6 Select Site Making Needle Gauge in Configuration Parameters

Select the appropriate needle gauge of the Site Making Needle being used in the Configuration Parameters menu discussed in Section 5.4.9.2.

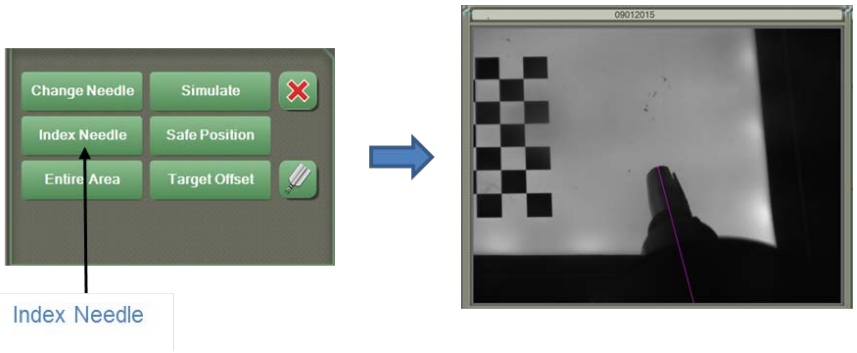
8.2.6.7 Index Site Making Guide (Index Needle)

1. First, disable the Blade Holder in the Configuration Parameters menu.
2. With the Control Panel lid on the System Cart open, select **Index Needle** in the **Utilities** menu on the User Interface (Figure 186).
3. The Needle Mechanism will move to the calibration plate on the Cart Control Panel and extend the Needle. The system will automatically index the Site

Making Guide by rotating the Site Making Guide and return to Safe Position when the process is complete.

4. During a site making procedure, it is important to confirm that the needle/blade orientation is correct. To confirm, look at the Site Making Guide and needle/blade after indexing. If the orientation selected was sagittal, the bevel of the needle will be facing the side, or the blade will be vertical. If the orientation selected was coronal, the bevel of the needle will face up, or the blade will be horizontal (Figure 171).

Figure 186: Index Needle



8.2.7 Installation of the Site Making Disposables and Re-usables Using ARTAS™ Site Making Blade Holder

Gloves should be worn by the user when installing these clinical accessories.

Caution *The following commands result in Robotic Arm movement.* **Caution**

8.2.7.1 Positioning the Needle Mechanism for Installation

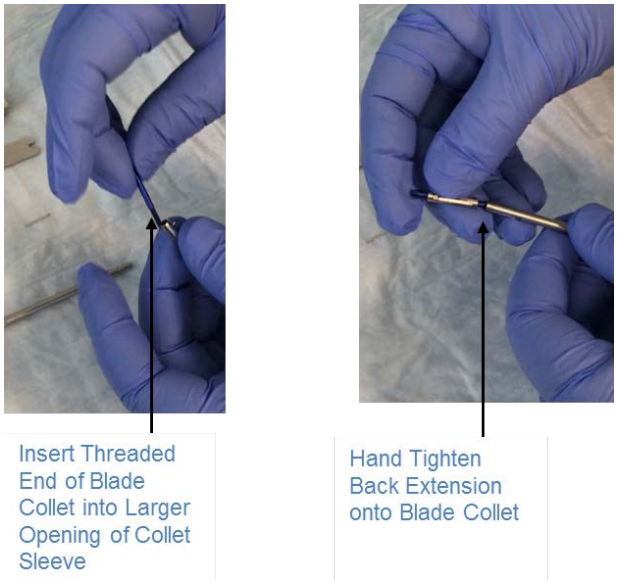
Follow the steps in Section 8.2.6.1.

8.2.7.2 Assemble the ARTAS™ Blade Holder

Warning *Puncture risk. Exercise caution to prevent needle sticks to user.* **Warning**

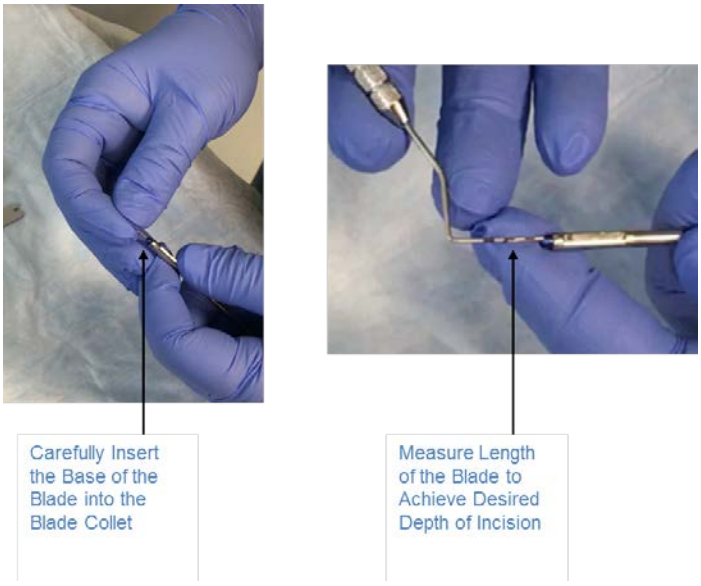
1. Select the appropriate Blade Collet size according to the preferred blade (not included).
2. Insert the threaded end of the Blade Collet into the larger opening of the Collet Sleeve.
3. Hand-tighten the Back Extension onto the threaded end of the Blade Collet. Do NOT over tighten (Figure 187).

Figure 187: Assembling the ARTAS™ Blade Holder



4. Carefully insert the base of the selected blade into the Blade Collet (Figure 188).
5. Using the Probe as a measurement guide, insert the blade into the Blade Collet to the appropriate length.
    - The length of the blade extending out of the Blade Collet should match the desired incision depth
    - If working with lower angles, 1mm should be added to the desired depth of the incision

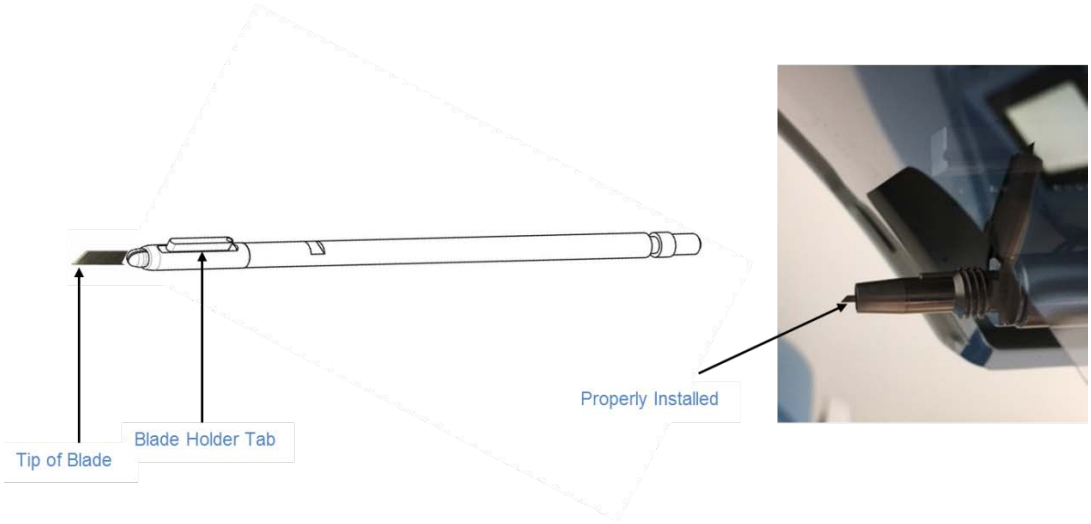
Figure 188: Install the Blade to the ARTAS™ Blade Holder



4. Note: If using a 45°, it important that it is installed properly (Figure 189).

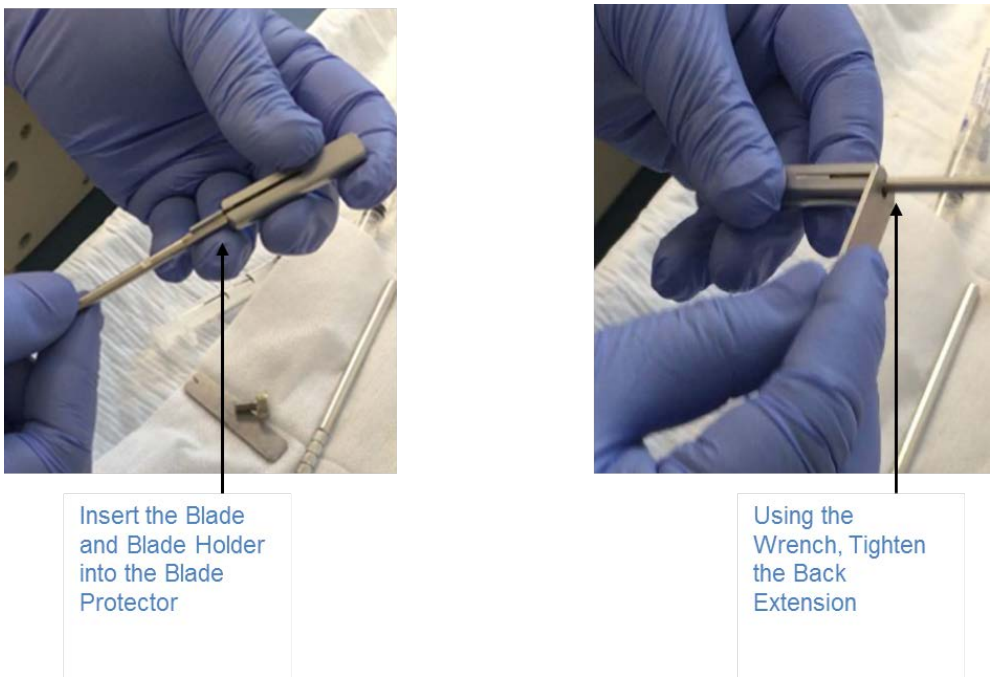
- Insert the blade so that the tip is on the bottom in relation to the tab of the Blade Holder

Figure 189: Proper Installation of a 45° Blade



2. Insert the blade and Blade Holder into the Blade Protector (Figure 190).
3. While firmly holding the Blade Protector in the left hand and using the Blade Holder Wrench with the right hand, tighten the Back Extension fully onto the Collet Sleeve.
4. Remove the assembled Blade Holder from the Blade Protector.

Figure 190: Tighten the ARTAS™ Blade Holder



8.2.7.3 Install Site Making Guide, Protector and Dampening Spring

See Section 8.2.6.2 for steps to install the Site Making Guide, Protector and Dampening Spring to the Blade Holder.

8.2.7.4 Installing the Blade Assembly& Site Making Needle Clip to Needle Mechanism

See Sections 8.2.6.3 & 8.2.6.4 for steps to install the Blade Assembly, Site Making Needle Clip and secure to the Needle Mechanism.

8.2.7.5 Verify Installation

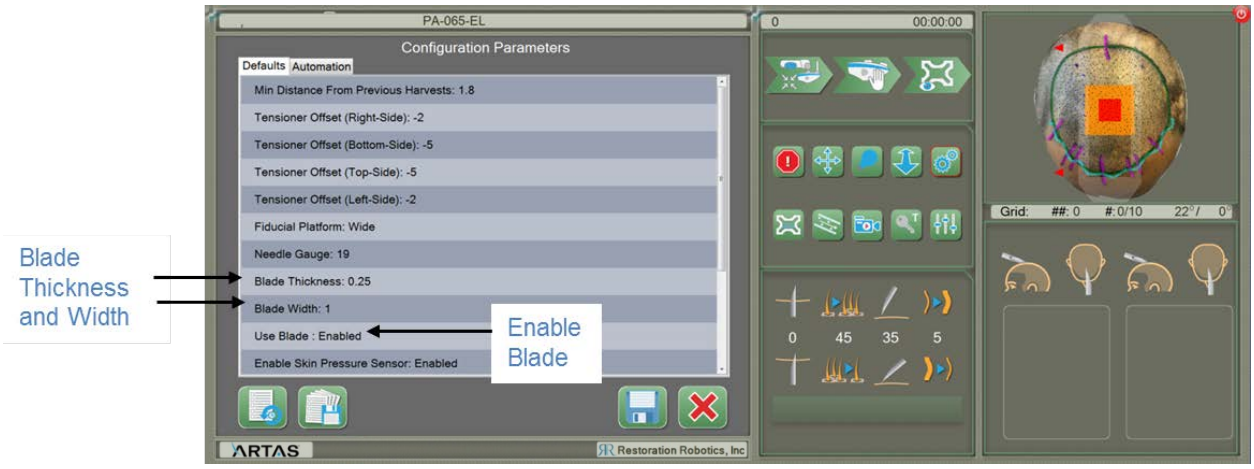
See Section 8.2.7.5 for steps to verify the installation of the ARTAS™ Site Making Blade Holder.

8.2.7.6 Enable the Blade Holder

The Blade Holder now should be enabled in the Configuration Parameters menu and save (Section 5.4.9.2). The default PD will change to 0 (Figure 191).

- Enable Blade Holder
- Select Blade Width
- Select Blade Thickness

Figure 191: Blade Holder Parameters



8.2.7.7 Index Site Making Guide

See Section 8.2.6.6 for steps to Index the Site Making Guide. The Blade Holder must be enabled in the Configuration Parameters menu prior to indexing the Site Making Guide (Section 8.2.7.6).

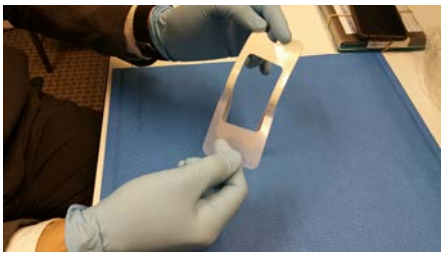
8.3 Self-Adhesive Site Making Fiducial Platform Placement

1. Hold the Fiducial Platform at one of the rounded corners (Figure 192).

Figure 192: Properly Hold the Platform

2. Gently peel the transparent backing completely off and discard (Figure 193).

Figure 193: Remove Transparent Backing from the End of the Platform

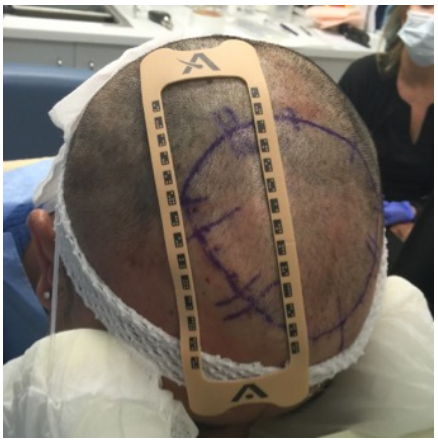


3. Adhere the Fiducial Platform over the desired incision area on the Patient's scalp in an anterior-to-posterior orientation with the ARTAS™ "A" in an upright position (Figure 194).
    - Begin on the patient's right side, furthest from the cart
    - Do not distort the shape of the platform
    - The platform should be immobile but not creating any tension or depression on the scalp
    - The platform should be flush to the scalp
    - Ensure there is 1 fiducial below the most anterior portion of the marked surgical area
4. Fluid runs down away from the field of view. You should only need gauze wrapped tongue depressors to absorb the fluid.

When a grid is complete, move the Fiducial Platform towards the System Cart and allow for 2-3 rows of overlap of previous incisions. These can be marked with a surgical marker so the borders can be adjusted at the User Interface appropriately. Continue until the entire treatment area is complete.

NOTE: It is not recommended to create sites in the crown or temporal peaks using the ARTAS™ System at this time.

Figure 194: Apply Fiducial Platform



8.4 The ARTAS™ Workflow for Site Making

The ARTAS™ Workflow is a 3-step process done at the beginning of each site making grid to move the Needle Mechanism over the recipient area.

8.4.1 Center Position

Caution *The following commands result in Robotic Arm movement.* Caution

Select **Center Position** on the User Interface and then ✓ in the dialog (Figure 195) to center the Needle Mechanism behind the patient. Verbalize "centering robot." Set the grid location by selecting the red center of the virtual Fiducial Platform and dragging it to the corresponding location on the 3D dome in the upper right window of the User Interface (Figure 196).

Figure 195: Site Making Worklflow - Center Position

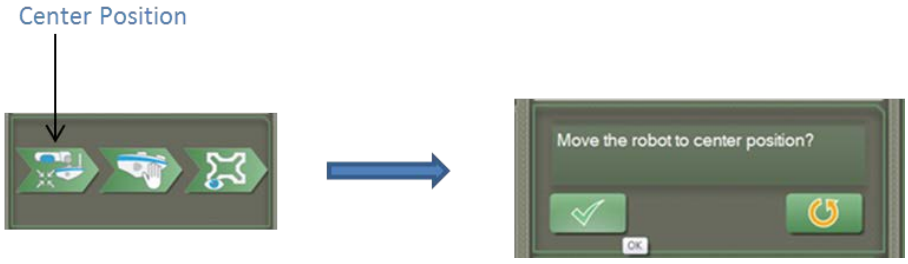
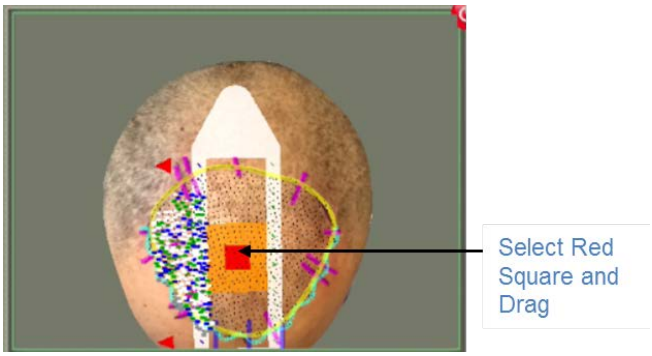


Figure 196: Select Grid Location on 3D Dome



8.4.2 Force Drag

Caution *The following commands result in Robotic Arm movement.* Caution

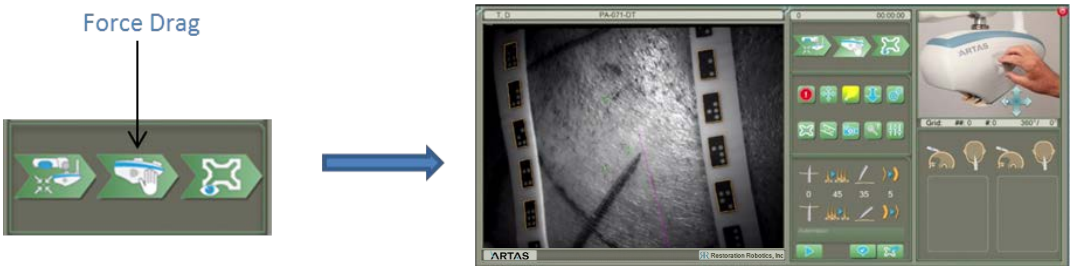
Force Drag is a way for the physician to position the Needle Mechanism over the Fiducial Platform by simply applying force to a handle on the mechanism.

The forces are detected by a force sensor, which commands slow, controlled motion in the direction of the force.

Force Drag is automatically enabled following Center Position. If it is necessary to manually enable Force Drag mode, both the User Interface operator and the physician can enable it. An image of the Needle Mechanism will appear in the upper right corner of the User Interface when Force Drag is enabled (Figure 197).

- There are two ways to initiate Force Drag:
  - The User Interface operator selects the **Force Drag** icon (Figure 198)

Figure 197: Site Making Workflow - Force Drag

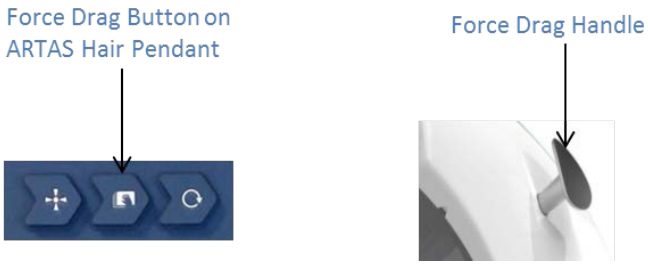


8.4.2.1 Translation Force Drag

Once Force Drag is enabled, follow the steps below to properly position the Needle Mechanism.

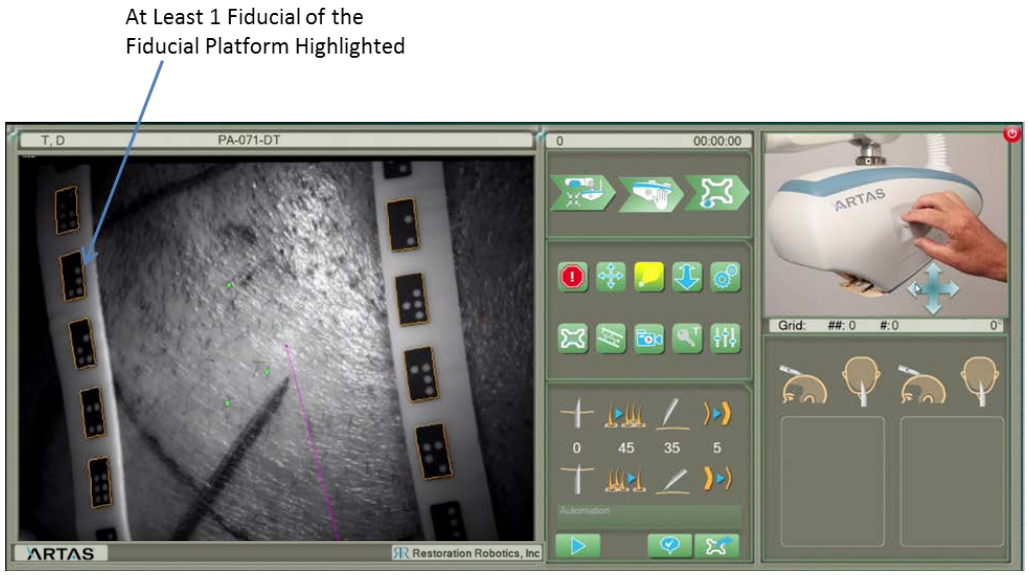
1. Standing next to the patient within easy reach to the Force Drag handle of the Needle Mechanism, press and hold the **Force Drag** button on the ARTAS™ Hair Pendant or the ARTAS™ Workflow Remote.
2. Gently apply force to the Force Drag handle (Figure 198) to move the Needle Mechanism towards the center of the Fiducial Platform.

Figure 198: Force Drag Button and Handle



3. Move towards the Fiducial Platform until the lights begin to blink. This ensures that the cameras are in focus on the fiducials.
4. Once the fiducials are visible by the cameras, the Needle Mechanism will align itself to the curvature of the platform.
5. Release the Force Drag button on the ARTAS™ Hair Pendant or ARTAS™ Workflow Remote to disable Force Drag mode.
6. Verify that at least 1 fiducial is recognized on 1 side of the Fiducial Platform. The fiducial will be highlighted as shown in Figure 199 if recognized.

Figure 199: Fiducial Highlighted on Platform



Warning 

*It is important that the physician not apply force to the handle until **AFTER** the Force Drag button is pressed on the ARTAS™ Hair Pendant or ARTAS™ Workflow Remote. At the moment the button is pressed the zero force is recorded and all motion is relative to that force level.*

If force is applied to the handle at the time the Force Drag button is pressed, releasing the handle can cause Robotic Arm motion. If this happens, release the Force Drag button and the Force Drag handle, and start again by pressing the Force Drag button first.

Warning 

The main function of Force Drag is to bring the Robotic Arm from the Center Position to the harvest area. Force Drag can also be used to move the Robotic Arm away from the patient when access to the recipient area is required. If using Force Drag to move the Needle Mechanism away from the Fiducial Platform, the Needle Mechanism will reorient itself to the startup orientation when fiducials are not present.

While in Force Drag mode, any control of the Robotic Arm by the operator from the User Interface is disabled, including automatic recipient site creation.

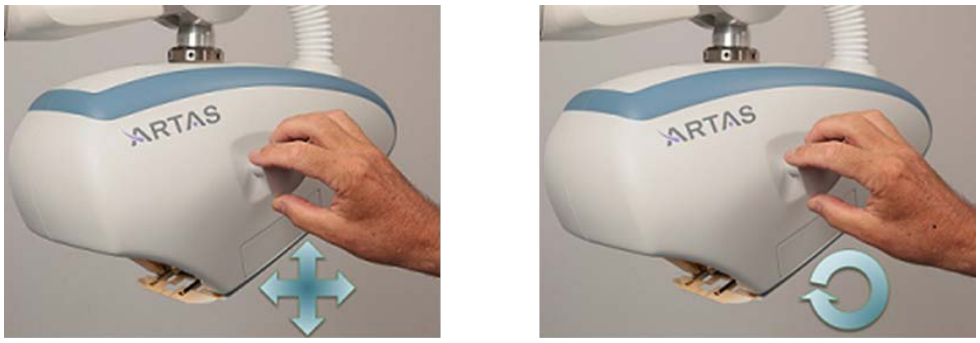
NOTE: ***If at any point the user releases the Force Drag button, the Robotic Arm decelerates to a stop.***

8.4.2.2 Rotation Force Drag

The default movement type of the Robotic Arm during Force Drag is translation. To rotate the Needle Mechanism around the needle tip:

1. Ensure Force Drag mode is initiated.
2. Hold the Force Drag button on the ARTAS™ Hair Pendant or ARTAS™ Workflow Remote for more than 2 seconds without touching the handle on the Needle Mechanism.
3. With gentle pressure on the Force Drag handle, rotate the Needle Mechanism. ARTAS™ software indicates rotational movement by showing the rotational movement icon (Figure 200) until Force Drag mode is disabled.

Figure 200: Site Making Workflow - Rotational Force Drag



Translational Movement

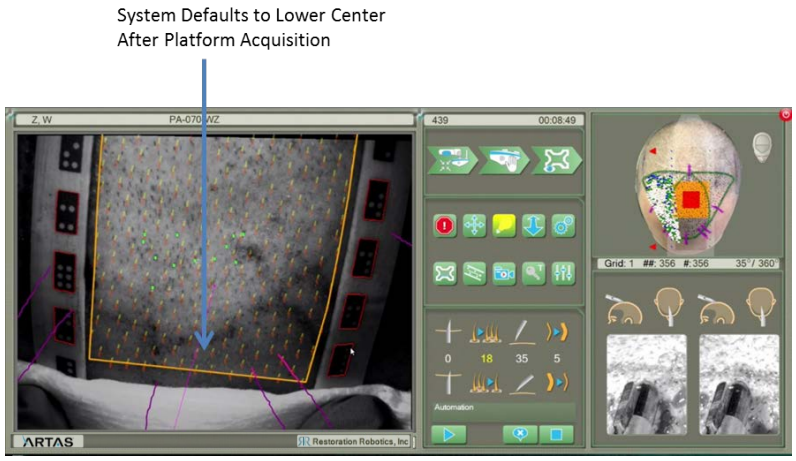
Rotational Movement

8.4.3 Acquire Platform

Caution		Caution
	The following commands result in Robotic Arm movement.	

1. The Fiducial Platform has a series of coded fiducial markings around its perimeter to teach the Robotic Arm the boundaries of the platform so that the recipient site creation can proceed automatically.
2. To locate the Fiducial Platform, select **Acquire Platform** from the User Interface. If Acquire Platform is initiated from the User Interface, select ✓ to start the function. The Robotic Arm moves around the perimeter of the Fiducial Platform and moves to the lower center of the platform (Figure 201).
3. After acquisition of the platform is complete, a footprint of the needle on the skin will show as orange and yellow marks.

Figure 201: Site Making Workflow - Acquire Platform



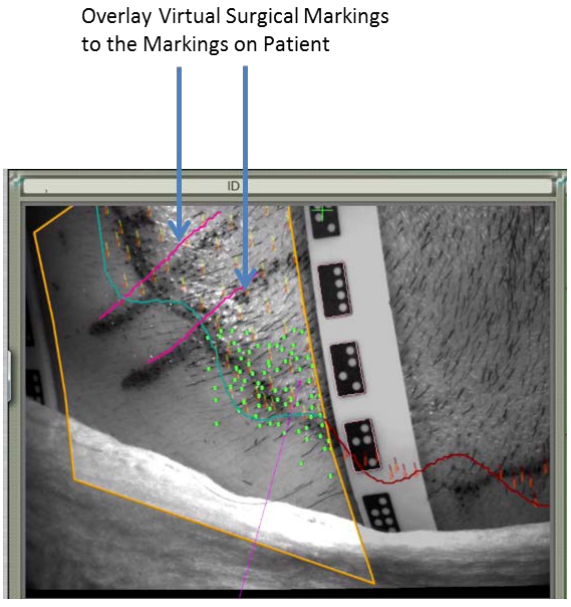
8.5 Beginning Site Making Automation

8.5.1 Overlay the Hair Pattern Design

The Hair Pattern Design is virtually displayed in the viewing window of the User Interface and is shown with the blue hairline and pink surgical markings. The virtual design must be aligned properly by overlaying the virtual design atop the surgical markings on the patient. Using the Main Viewing Window, move the virtual design over the surgical markings accordingly (Figure 202).

- Translate Design Overlay
  - Using one finger on the touchscreen, touch the pink surgical marking and drag the virtual design to the desired location
  - Using the mouse, place the cursor over the pink surgical marking, right-click and drag the virtual design to the desired location
- Rotate Design Overlay
  - Using the index finger of each hand, place one as an anchor point on the virtual design. Use the 2nd index finger to rotate the virtual design on the anchor point to the desired location
    - This may require the user to use the *Translate* function following the rotation
  - Using the mouse, place the cursor over the pink surgical marking, click the left and right mouse button simultaneously to rotate the virtual design
- Scaling Design Overlay
  - If needed, it is possible to scale the Hair Pattern Design
  - Using the touchscreen, touch the thumb and index finger to the pink surgical marking and move together to scale down (make smaller). To scale up (make larger), move the thumb and finger further apart
  - Using the wheel of the mouse, scroll in or out while right-clicking the mouse to make the design smaller or larger

Figure 202: Overlay Virtual Surgical Marks to Patient



8.5.2 Grid Preparation

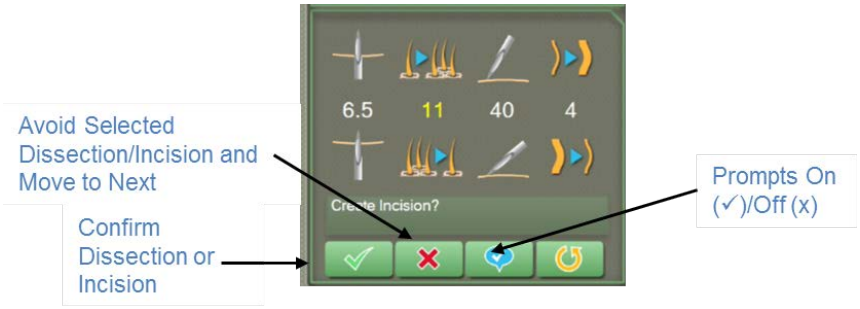
Block off recipient areas not ideal for creating incisions using the same methods as with the harvesting application (Section 7.4).

8.5.3 Create First Incisions & Begin Automation

In the first grid, the **Prompts On** feature is on by default. This will allow the user to find the appropriate depth within the first incisions made.

1. Begin with **Prompts On** (Figure 203).
    a. When prompted "Create Incision?" select ✓ to create the incision or the **X** to move to the next incision location.
    b. After 5 incisions, select the **Away 40** icon and check the depth of the incision using the probe (Figure 205)
        i. If the incision is too shallow or too deep, make adjustment to the PD (Section 8.5.4.1) and create another 5 incisions with **Prompts On**
        ii. Repeat until the proper depth is achieved
    c. Once the proper depth is achieved, turn **Prompts Off** by selecting the icon. This will begin Automation

Figure 203: Site Making Prompts On



8.5.3.1 Manually Selecting Incisions

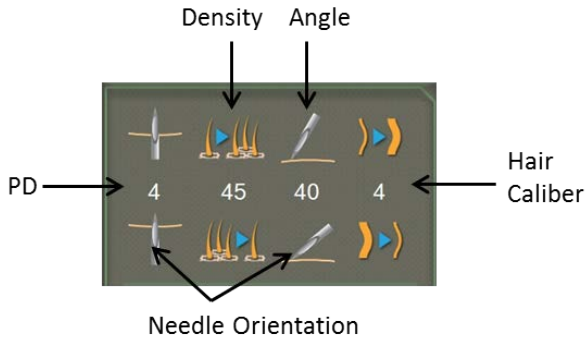
The user may manually select sites within the borders of the Fiducial Platform to create incisions.

Left-click or use 1 finger on the touchscreen to select the incision site you would like to create. Select **Begin**. More than 1 incision may be selected at a time.

NOTE: An incision site can be selected outside of the original Hair Pattern Design.

8.5.4 Monitoring & Adjusting Site Making Incision Parameters

Figure 204: Monitoring & Adjusting Incision Parameters



8.5.4.1 Site Making Puncture Depth (PD)

Puncture Depth, or PD, controls the depth of the site making needle or blade. During the site making procedure, examine the PD in the images in the lower right corner of the User Interface. Verify the depth by measuring the incision with the probe provided in the Reusable Clinical Accessories Kit (Figure 205). To ensure the measurement is accurate, the probe should be inserted into the incision at the same angle in which the incision was created.

Figure 205: Check Incision Depth Using Probe

- The site making PD has a hard stop to prevent the incision from being deeper than intended
- Due to lack of tension, the setting may appear deeper than the actual depth depending on how the tissue adapts (depresses) as the incision is made
- Make necessary adjustment to the PD
    - Shallow incisions may cause implanted grafts to be longer than the incisions
        - Increase PD Setting
        - Ensure the Fiducial Platform is flush to the scalp
        - Apple gentle tension to the posterior portion of the Fiducial Platform

- Deep incisions may cause the sites to be larger than the grafts implanted
  - Decrease PD Setting

8.5.4.1.1 Site Making PD Using Needles

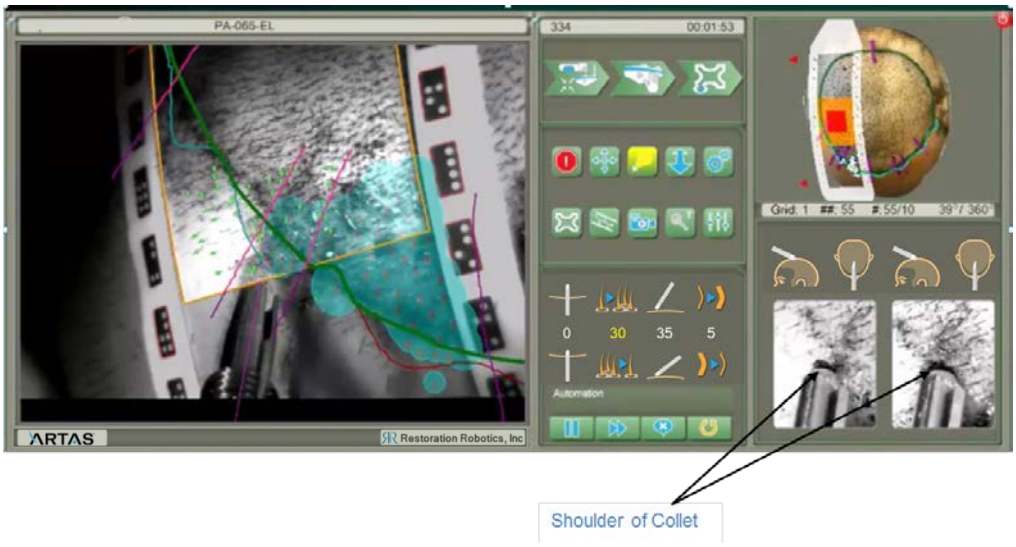
When using the disposable needles in the Sterile Disposable Clinical Kit, the default PD setting is 5. When monitoring the PD setting, the images in the lower right of the User Interface show the needle depth for the last 2 incisions. The band on the needle is 5.5mm from the tip of the needle (Figure 206).

Figure 206: Monitoring PD Using Needles

8.5.4.1.2 Site Making PD using ARTAS™ Blade Holder

When using the ARTAS™ Blade Holder, the default PD setting is 0. When monitoring the PD setting, the images in the lower right of the User Interface show the needle depth for the last 2 incisions. The shoulder of the Collet should just touch the skin (Figure 207). See Section 8.2.7.2 on how to properly assemble the ARTAS™ Blade Holder.

Figure 207: Monitoring PD Using ARTAS™ Blade Holder



8.5.4.2 Density (DEN)

The Density incision parameter controls the number of incisions made per square centimeter. The user sets this when creating the surgical plan in ARTAS HAIR STUDIO™. The maximum setting is 50 incisions per square centimeter. This setting can be adjusted at any time during the site making procedure.

- When Density is manually adjusted from the User Interface during automation, the system will adjust the density for the current area and slowly default back to the density indicated in the Hair Pattern Design
- The physician may wish to manually adjust the density during automation based on the desired treatment i.e. there may be a discrepancy in the total number of incisions made due to existing terminal hair

8.5.4.3 Angle (ANG)

The Angle incision parameter controls the minimum approach angle, or elevation off of the scalp, of the needle/blade. The default setting is 35°, and the minimum angle is 30°.

- The physician may wish to adjust this setting manually during automation if patient anatomy requires more obtuse angles or allows for more acute angles

8.5.4.4 Terminal Follicular Unit Thickness (Hair Caliber Setting)

The Terminal Follicular Unit Thickness incision parameter is the minimum thickness existing hair must be in order for the system to recognize it as a terminal hair. The default setting is 5. The number used as the setting is an abstract number. All recognized hairs will be identified by a green dot on the User Interface and avoided when creating incisions. The user will be prompted to confirm this setting prior to making incisions (Figure 208).

- A physician may wish to adjust this setting based on the patient's thickness of terminal hairs and indications
- NOTE: Making an incision over a terminal follicle may inflict long term damage

Figure 208: Confirm Terminal Follicular Unit Thickness

8.5.5 Completing the Grid

1. Continue to create incisions until the entire grid (platform area) is complete.
2. As the robot creates incisions, move the bottom platform border to follow.
3. When the grid is complete, move the Needle Mechanism to Safe Position by selecting the **End of Grid** icon.
4. If more Fiducial Platform placements are required to complete the Hair Pattern Design, move the Fiducial Platform to the next area and continue (Section 8.3).
    a. Follow the Site Making Workflow to begin a new grid
    b. Realign the Virtual Platform
    c. Overlay the Hair Pattern Design
    d. Begin
5. Once the Hair Pattern Design is completed and no more grids are necessary, move the Needle Mechanism to Safe Position to facilitate system disassembly.

8.6 Site Making Disassembly

8.6.1 Position the Needle Mechanism for Disassembly

Caution

The following commands result in Robotic Arm movement.

Caution

1. Make sure the area around the Needle Mechanism is clear and can move freely to the Change Needle position.
2. Verify the Robotic Arm is in Safe Position.
3. In the ARTAS™ System application, select **Change Needle** from the **Utilities** Menu.
4. Enable Manual Mode (Figure 209) by pressing the Manual button on the Cart Control Panel. The amber light will illuminate to indicate Manual Mode is enabled.

Figure 209: Dissassemble Site Making Components - Manual Mode

8.6.2 Remove the Site Making Needle/Blade Assembly

1. Remove the Site Making Needle Clip. DO NOT DISCARD. Set aside for sterilization.
2. Select **Extend Punch** on the Cart Control Panel of the System Cart. Install the Needle Protector over the Site Making Guide.
3. Press the Spindle Lock with your left hand and loosen the Needle/Blade Assembly using the Wrench in your right hand. Unscrew the Needle/Blade Assembly together until free from the spindle.
4. Remove the entire assembly from the spindle: Needle Protector, Site Making Guide, Needle/Blade and Dampening Spring.
5. If using the Site Making Needles, properly discard of the needle in a sharps container. Set aside the Needle Protector, Site Making Guide and Dampening Spring for sterilization.
6. If using the ARTAS™ Blade Holder, set aside the Needle Protector, Site Making Guide and Dampening Spring for sterilization. Follow the steps in Section 8.6.4 to disassemble the ARTAS™ Blade Holder.

8.6.3 Exit Manual Mode

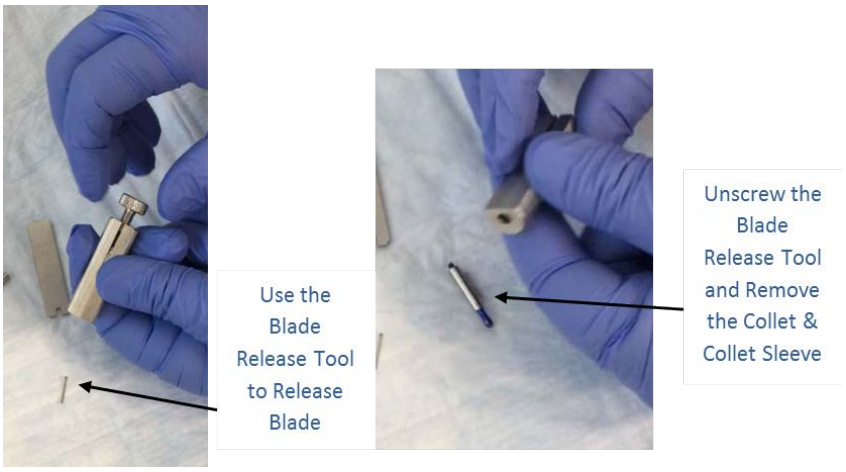
1. Select **Retract Punch** from the Cart Control Panel. Thoroughly clean the Needle Mechanism and Spindle (Section 9.1).
2. Re-Install a new Harvesting Needle Clip. Note: The Harvesting Needle Clip has a rubber pad attached.
3. Press the **Manual** button on the Cart Control Panel and resume from the User Interface by selecting the flashing stop sign.

8.6.4 Disassemble the ARTAS™ Blade Holder

Once the assembly is removed from the Needle Mechanism (Section 8.6.2), disassemble the Blade Holder for sterilization.

1. Slide the Blade Protector of the tip of the Blade and Blade Holder.
2. While firmly holding the Blade Protector in the left hand and using the Blade Holder Wrench in the right hand, loosen the Back Extension fully from the Collet Sleeve.
3. Screw the Blade Release Tool (Thumb Screw) onto the base of the Blade Protector to release the blade and Blade Collet from the other end of the Protector.
4. Unscrew the Blade Release Tool from the Protector.
5. Remove the Collet Sleeve from the base of the Protector.

Figure 210: Disassemble Blade Holder - Remove Blade



6. Discard the Blade in the sharps container.
7. Set aside all Blade Holder Components for sterilization.
8. Clean according the Instructions for Use.

9 Cleaning the ARTAS™ System

Restoration Robotics recommends cleaning the ARTAS™ System after each procedure.

Caution

Only the external surfaces of the ARTAS™ System can be cleaned.

- ***Do not drip liquid onto the System, the power/motor areas, the buttons, or the display.***
- ***Do not use any spray cleaners, because fluid should not enter openings.***

Caution

1. Dampen a soft cloth in water premixed with a mild detergent or an alcohol-based hospital-grade wipe.
2. Wring out any excess liquid and wipe the ARTAS™ System.
3. Immediately dry the device with a dry cloth to ensure that no liquid remains on the surface.

The reusable components of the System, included as part of the Reusable Clinical Kit, should be cleaned and sterilized after each procedure in preparation for the next procedure.

For the cleaning and sterilization details for Reusable Clinical Kit refer to the Instructions for Use that is included with the kit.

9.1 Cleaning the Needle Mechanism

1. Disengage the Robotic Arm by pressing the **Manual** button on the Cart Control Panel.

Caution

Do not disengage the Manual Control until operations are completed. Keep hands clear since the system is now under software control.

Caution

2. From the **Utilities** menu in the system control panel, select **Change Needle** in ARTAS™ application.
3. Obtain a Germicidal Wipe and a cotton-tipped applicator stick from the supplies onsite.
4. Wrap the Germicidal Wipe around the tip of the applicator.
5. Wipe down the metal surfaces of the tool by probing with the cotton tipped applicator.
6. To clean the Spindle, use a peroxide dipped swab. Clean the spindle and needle slide. Use swabs until completely free of debris.

9.2 Cleaning the Site Making Headrest

Remove the headrest and wipe clean with a hospital grade germicidal cloth. Replace the harvesting halo.

9.3 Cleaning the Splatter Shield

It is important that the optical path is clear of debris.

1. Inspect the acrylic protective cover, Splatter Shield, for blood or tissue stains using a flashlight or overhead light.
    - The Splatter Shield may be cleaned with alcohol wipes
    - Avoid leaving streaks
2. If any damage is found, the Splatter Shield must be replaced:
    - Gently pull the cover by the top edge and discard
    - While wearing powder free gloves, install a new cover onto the mechanism

9.4 Cleaning the Touchscreen User Interface

Use a touchscreen computer monitor cleaner for the Touchscreen User Interface.

10 Create a Treatment Report

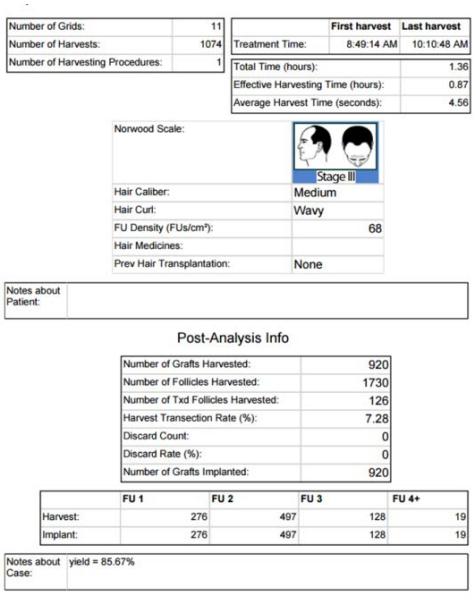
A Treatment Report (Figure 211 through Figure 216) is a summary of the most recent treatment for a specific patient. Report on the post-process screen of the current patient creates a Treatment Report.

After all counted follicle information from the harvesting portion of the procedure has been entered (Section 7.7) and the site making portion of the procedure is complete, locate the patient in the **Review Patient** screen and select **Post Process**.

1. Select **Research Report** to generate a full treatment report (Figure 159).
2. Select **Export PDF** at the top of the display to save a PDF format data file to the USB flash drive for printing.

Page 1 of the treatment report (Figure 211) contains overall statistical information, such as total time, total number of harvests, patient summary information, and result information.

Figure 211: Treatment Report - Page 1



Number of Grids:	11
Number of Harvests:	1074
Number of Harvesting Procedures:	1

	First harvest	Last harvest
Treatment Time:	8:49:14 AM	10:10:48 AM

Total Time (hours):	1.36
Effective Harvesting Time (hours):	0.87
Average Harvest Time (seconds):	4.56

Norwood Scale:	Stage III
Hair Caliber:	Medium
Hair Curl:	Wavy
FU Density (FUs/cm²):	68
Hair Medicines:	
Prev Hair Transplantation:	None

Notes about Patient:	

Post-Analysis Info

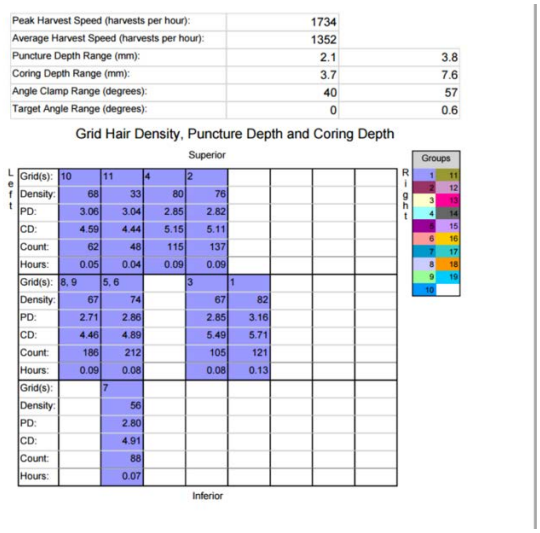
Number of Grafts Harvested:	920
Number of Follicles Harvested:	1730
Number of Txd Follicles Harvested:	126
Harvest Transection Rate (%):	7.28
Discard Count:	0
Discard Rate (%):	0
Number of Grafts Implanted:	920

	FU 1	FU 2	FU 3	FU 4+
Harvest:	276	497	128	19
Implant:	276	497	128	19

Notes about Case:	yield = 85.67%

Page 2 of the treatment report (Figure 212) contains details on treatment parameters used, and grid-by-grid treatment parameter values, with a focus on puncture and coring depth. It also contains a table of harvest information by group.

Figure 212: Treatment Report - Page 2



Peak Harvest Speed (harvests per hour):	1734	
Average Harvest Speed (harvests per hour):	1352	
Puncture Depth Range (mm):	2.1	3.8
Coring Depth Range (mm):	3.7	7.6
Angle Clamp Range (degrees):	40	57
Target Angle Range (degrees):	0	0.6

Grid Hair Density, Puncture Depth and Coring Depth

Superior

Left	Grid(s):	10	11	4	2				
	Density:	68	33	80	76				
	PD:	3.06	3.04	2.85	2.82				
	CD:	4.59	4.44	5.15	5.11				
	Count:	62	48	115	137				
	Hours:	0.05	0.04	0.09	0.09				
	Grid(s):	8, 9	5, 6		3	1			
	Density:	67	74		67	82			
	PD:	2.71	2.86		2.85	3.16			
	CD:	4.46	4.89		5.49	5.71			
	Count:	186	212		105	121			
	Hours:	0.09	0.08		0.08	0.13			
	Grid(s):		7						
	Density:		56						
	PD:		2.80						
	CD:		4.91						
	Count:		88						
	Hours:		0.07						

Inferior

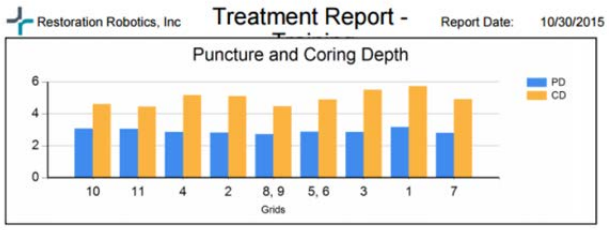
Right

Groups

1	11
2	12
3	13
4	14
5	15
6	16
7	17
8	18
9	19
10	

Page 3 of the treatment report (Figure 213) shows a histogram of the puncture depth and coring depth values used, and harvest times.

Figure 213: Treatment Report - Page 3

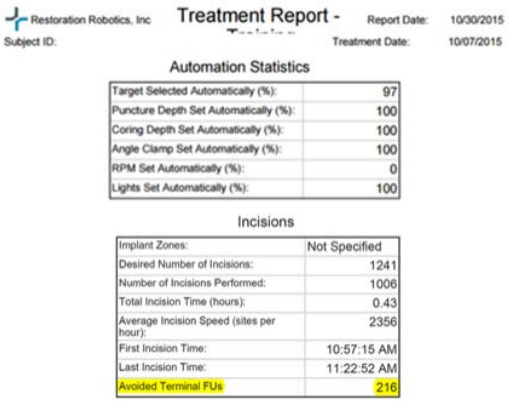


Pages 4, 5 and 6 of the treatment report (Figure 214) show histograms of time per harvest and distributions of the puncture depths, coring depths and angle clamps used.

Figure 214: Treatment Report - Page 4, 5 and 6

Page 7 of the treatment report (Figure 215) shows the automation statistics and incision information, including the number of terminal hairs avoided.

Figure 215: Treatment Report - Page 7



Restoration Robotics, Inc. Treatment Report - Report Date: 10/30/2015

Subject ID: Treatment Date: 10/07/2015

Automation Statistics

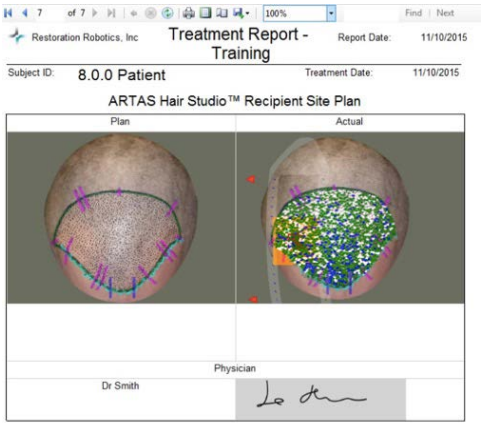
Target Selected Automatically (%):	97
Puncture Depth Set Automatically (%):	100
Coring Depth Set Automatically (%):	100
Angle Clamp Set Automatically (%):	100
RPM Set Automatically (%):	0
Lights Set Automatically (%):	100

Incisions

Implant Zones:	Not Specified
Desired Number of Incisions:	1241
Number of Incisions Performed:	1006
Total Incision Time (hours):	0.43
Average Incision Speed (sites per hour):	2356
First Incision Time:	10:57:15 AM
Last Incision Time:	11:22:52 AM
Avoided Terminal FUs	216

Page 8 of the treatment report (Figure 216) shows the planned recipient area, sites created, and hairs avoided.

Figure 216: Treatment Report - Page 8



Restoration Robotics, Inc. Treatment Report - Training Report Date: 11/10/2015

Subject ID: 8.0.0 Patient Treatment Date: 11/10/2015

ARTAS Hair Studio™ Recipient Site Plan

Plan Actual

Physician

Dr Smith

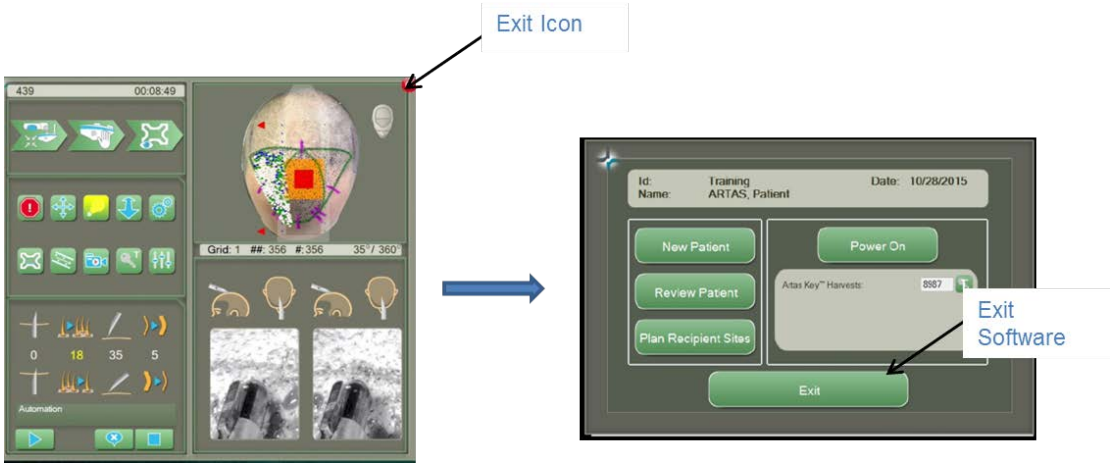
11 Shutting Down the ARTAS™ System

After the procedure is completed, the Needle Mechanism is disassembled (Sections 7.8 & 8.6) and cleaned (Section 9), and the treatment report is prepared (Section 10), follow these steps to properly shutdown the ARTAS™ System.

11.1 Exit the ARTAS™ Software

1. Select the red **Exit** icon in the upper right corner of the ARTAS™ software.
2. The start-up screen will appear. Select the **Exit** icon at the start-up screen to shut down the software (Figure 217).

Figure 217: Shutting Down the ARTAS™ System - Exit Software



11.2 Power Off the ARTAS™ System Cart and Computer

1. Press and hold the green button on the Cart Control Panel of the System Cart for 3 seconds, until the cart shuts down.
2. Shutdown Windows by selecting **Shut Down** in the Start menu on the User Interface.

11.3 Power Off the UPS and Main Power

11.3.1 Powering Off the UPS for Systems 1001-2041

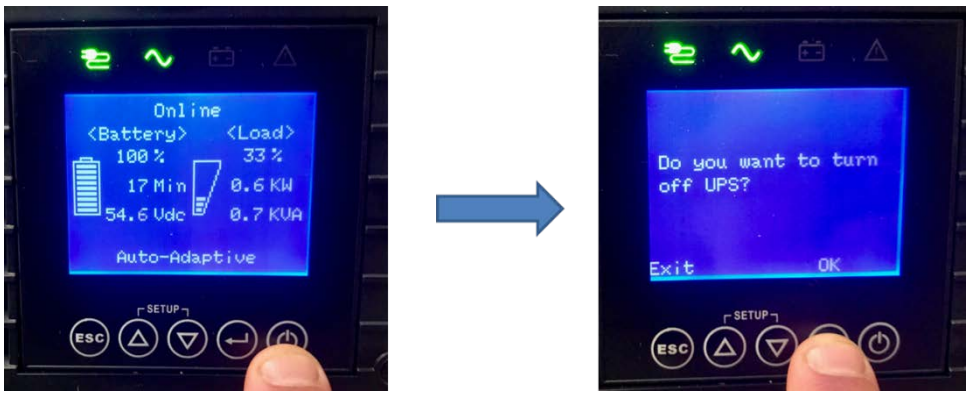
1. Wait for Windows to completely shut down. Open the right-side panel of the System Cart. Press and hold the **Off** button on the UPS until it beeps. Release.
2. Turn the red AC switch on the back of the System Cart to the (-) position.

11.3.2 Powering Off the UPS for Systems 2042 and Higher

1. Wait for Windows to completely shut down. Open the right-side panel of the System Cart. Press and hold the **Off** button on the UPS until it beeps. Release.

2. A prompt will ask *Do you want to turn off UPS?*. Press the button below **OK** (Figure 218)**.** Wait a few seconds for the UPS to completely power off.

Figure 218: Turning Off the UPS for Systems 2042 and Higher



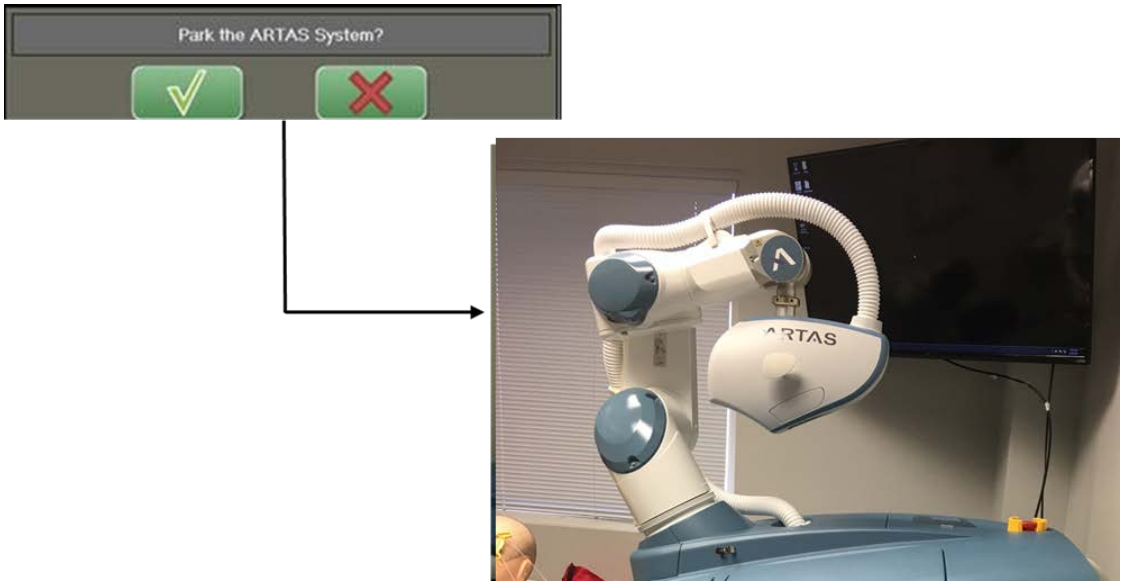
3. Turn the red AC switch on the back of the System Cart to the (-) position.

11.4 Robotic Arm Park Position

The Robotic Arm can also be put into the Park Position if desired. This is done by running the ARTAS™ Park Application 

from the desktop prior to shutting down windows. A dialog box will be shown prompting the user to move to park position (Figure 219).

Figure 219: Shutting Down the ARTAS™ System - Park Position



12 Touchscreen and Mouse/Keyboard Functions

Table 11: Touchscreen and Mouse/Keyboard Functions

Function	Application	Touchscreen	Mouse/Keyboard
Select an Icon	Harvesting & Site Making	Touch and release 1 finger to the desired icon.	Left click on the desired icon with mouse.
Select a Hair	Harvesting	Touch and release 1 finger to a green dot in the High Mag screen.	Left click on a green dot in the High Mag screen.
Select an Incision Manually	Site Making	Touch and release 1 finger to the desired location of the incision. A Stick will show where the incision will be made.	Left click within the platform boundary on the desired location of the incision.
Adjust Tensioner/Platform Borders	Harvesting & Site Making	Touch 1 finger outside the Tensioner/Platform boundary and drag the border to the desired location. The border closest to the initial touch location is the border that will adjust.	Left click outside the Tensioner/Platform boundary and drag the border to the desired location.
Redraw Region Axis/Redraw Hair Direction	Harvesting & Site Making	Select the **Region Axis** icon on the User Interface. Touch 1 finger anywhere in the High Mag screen and drag in the desired direction of the Region Axis (harvesting) or Hair Direction (site making) and release.	Left click on the **Region Axis** icon on the User Interface. Left click and drag the mouse cursor anywhere in the High Mag screen in the desired direction of the Region Axis (harvesting) or Hair Direction (site making) and release.
Move Region Axis	Harvesting	Using 1 finger, touch the blue Region Axis and drag up or down on the High Mag screen.	Left click on the blue Region Axis and drag up or down on the High Mag screen.
Block Region	Harvesting & Site Making	Starting within the Tensioner/Platform Boundary, use 1 finger to draw the desired area to be blocked and release. The end point may be inside or outside the Tensioner/Platform boundary. There is a minimum size. If the region drawn is not the	Select the **Block Region** icon in the **Mouse Control** menu. Right click around the area that should be avoided. Left click on the **Block Region** icon to complete the shape.

		minimum size, no region will be drawn.	
Delete Block Region	Harvesting & Site Making	Using 1 finger, select a previously drawn region. An **X** will appear in the center of the selected region. Use 1 finger, touch and release the **X** without moving the finger.	Right click on the existing region. Right click on the **X** to delete.
Move Block Region	Harvesting & Site Making	Using 1 finger, select a previously drawn region. An **X** will appear in the center of the selected region. The selected region can be moved by touching 1 finger to the **X** and dragging the region to the desired location. Release.	Right click on the existing region. Right click and drag the **X** to the desired location.
Hair Pattern Design Translation	Site Making	Using 1 finger, touch the hairline or surgical marking of the Hair Pattern Design and drag to the desired location and release. If the Hair Pattern Design is touched during automation, automation will be canceled.	Right click on the hairline or surgical marking of the Hair Pattern Design and drag to the desired location. If the Hair Pattern Design is touched during automation, automation will be canceled.
Move Virtual Tensioner	Harvesting	Using 1 finger, touch the red square in the center of the virtual tensioner and drag to the desired location. Release.	Left click on the center red square of the virtual tensioner and drag to the desired location. Release.
Translate Virtual Platform	Site Making	Using 1 finger, touch the red square in the center of the virtual platform and drag to the desired location. Release.	Left click on the center red square of the virtual platform and drag to the desired location. Release.
Rotate Virtual Platform	Site Making	Using 1 finger, touch the orange square in the center of the virtual platform and drag to rotate. Release.	Left click on the outer orange square of the virtual platform and drag to rotate. Release.
Inject Site	Harvesting & Site Making	Using 2 fingers touch and release on the desired area to inject a site.	Right click on the desired area to inject or block a site.
Move an Inject Site	Harvesting & Site Making	Using 1 finger, touch a previous Inject Site in the center and drag to the desired location. Release.	Hover over the injected site until it turns yellow. Right click and drag site to desired location.

Delete an Inject Site	Harvesting & Site Making	Using 1 finger, touch and release a previous Inject Site in the center.	Hover over the injected site until it turns yellow. Right click to delete the site.
Hair Pattern Design Rotation	Site Making	Using the index finger of each hand, place one as an anchor point on the virtual design. Use the 2nd index finger to rotate the virtual design on the anchor point to the desired location	Press the left and right buttons of the mouse on the hairline or surgical marking of the Hair Pattern Design and drag to rotate.
Mouse Drag	Harvesting & Site Making	Using 3 fingers touch and drag the screen to the desired location of the grid. Release to disable **Mouse Drag** mode.	Hold the CTRL + SHIFT keys on the keyboard. Cross arrows will appear. Click and drag the Main Viewing screen to desired view.
Mouse Drag	Harvesting and Site Making	Select the **Mouse Control** icon on the User Interface to enable **Mouse Drag**. Touch 1 finger to the screen and drag to the desired location. Release. Exit **Mouse Drag** mode by de-selecting the **Mouse Control** icon.	Select the **Mouse Control** icon on the User Interface to enable **Mouse Drag**. Click and drag the Main Viewing screen to the desired location. Release. Exit **Mouse Drag** mode by de-selecting the **Mouse Control** icon.
Right Click Mouse Context Menus	Harvesting and Site Making	Touch and hold for the context menu to appear.	Right click on the icon to reveal menu.

Appendix A Errors and Troubleshooting

Errors and troubleshooting for the ARTAS™ System are shown in Table 12: Errors & Troubleshooting. Restoration Robotics Customer Support number is 855-88 ARTAS (855-882-7827).

Table 12: Errors & Troubleshooting

Problem & Potential Cause	Solution
After starting the ARTAS™ application, a warning message appears about disk space	Contact Restoration Robotics Customer Support.
Replace Batt LED on UPS is lit, and UPS alarm periodically emits beeps	Leave the main power on for 12 hours to ensure the UPS is fully charged. If the problem persists, contact Restoration Robotics customer support to replace the battery.
Fault, Bypass, or Overload LED on UPS is lit	Contact Restoration Robotics customer support.
Robotic Arm does not move when commanded to move Robotic Arm is close to a motion limit	Return the Robotic Arm to the safe position, make proper Patient Chair adjustments and try again.
Robotic Arm does not move when commanded to move Robotic Arm is powered off	Normally, any power off is detected and a **Resume** dialog displays and is used to re-enable power. Force the power off by pressing and releasing an E-Stop button. Select **Resume** to restore Robotic Arm power.
Unable to power on the Robotic Arm from the ARTAS™ System software Startup Menu	Perform the following quick checks: • Ensure that all E-Stop buttons are clear • Restart the ARTAS™ System software and power on from the Startup Menu. If this problem occurs repeatedly, call Restoration Robotics customer support
Glare makes hair or fiducials hard to see	Select **Lights** (in the Main Control Panel in the UI) and choose **Optimize** to attempt to automatically tune the lighting. If that does not work, reduce artificial and natural light in the OR.
E-Stop detected by the Force Sensor error	The force sensor detected excessive force. This can occur during Force Drag or if the Needle Mechanism is pushed against the System Cart, Robotic Arm or other hard surface. Attempt to determine why the error occurred and resolve.

Imminent Collision error prevents Robotic Arm motion This occurs when the Needle Mechanism is moving too close to the Robotic Arm or cart, and is in danger of hitting itself.	Select Resume from the User Interface. Move the Needle Mechanism to Center Position. Rotate the patient's head or reposition the Patient Chair so that the Needle Mechanism is able to move clear of the System Cart and Robotic Arm. Force Drag the Needle Mechanism back to the Skin Tensioner/Fiducial Platform. Select **Restore Frame** on the UI.
Tool USB Error A communication error occurred between the control computer and the Needle Mechanism.	Select **Resume** to try to restore communication and continue. If this error persists, call Restoration Robotics customer support.
The System is unable to Acquire Tensioner/Acquire Platform	Use Force Drag to move the Robotic Arm around the perimeter of the Skin Tensioner/Platform with the fiducials in view, to ensure that at least three fiducials are highlighted on two sides of the Skin Tensioner or Platform. Retry Acquire Tensioner/Platform. If it is still not able to acquire, there are several ways to resolve the issue: • If using the Colored Skin Tensioner, remove all items of similar color from the field of view. • Clean the fiducials with a swab and use Force Drag to move within the Skin Tensioner/Platform again to ensure that at least three fiducials are recognized on two sides. If successful, restart Acquire Tensioner/Platform. • Verify that the Site Making Fiducial Platform is not stretched out of its natural shape. • If trouble identifying all the fiducials still occurs, use the rotation function of Force Drag to ensure that the Needle Mechanism and cameras are square to the Skin Tensioner/Platform. • Use Force Drag translation to move within the Skin Tensioner/Platform again, and ensure that at least three fiducials are recognized on two sides. Restart Acquire Tensioner/Platform.
Robotic Arm oscillates during Force Drag. There are certain locations in the Robotic Arm's work area where it is possible for small oscillations to occur during Force Drag	To reset, release the Force Drag button on the ARTAS™ Pendant and the Force Drag handle. Press the Force Drag button on the ARTAS™ Pendant while your hand is off or loosely touching the Force Drag handle, and then carefully start guiding the Force Drag handle toward the desired location with two fingers.

	This reset procedure might have to be followed again if the oscillation proves troublesome. If oscillation is a persistent problem, call Restoration Robotics' customer support.
Tracking stops during dissection: • The Robotic Arm was unable to orient the needle relative to the hair with sufficient accuracy for harvest. This can occur if the patient moves too much, or if the vision image is insufficiently clear to the vision system • If the harvest grid disappears on the wide-angle vision display, an insufficient number of fiducials might be visible to the vision system	In such a case, choose a different hair to harvest and continue operation.
Vacuum failure, as reported during System Verification, by a screen message during operation, or by follicles being 'buried' during harvest rather than elevating above the skin.	Check that all connections to the Vacuum Canister are secure and the lid to the canister is fastened to the canister. Listen for obvious leaks in the vacuum system. Go to the **Utilities** menu and choose the saline flush option - listen for the characteristic slurping sound during saline flush. If the problem persists, call Restoration Robotics customer support.
Vacuum Obstruction Error	Use the Needle Stylet to remove any obstructions in the needle. See Section 3.3.1.1.3.
Air pressure failure, as reported during System Verification or by a screen message during operation	Listen for obvious leaks in the vacuum system and tighten fittings. Go to the **Utilities** menu and choose the saline flush option---listen for the characteristic slurping sound during saline flush. If the problem persists, call Restoration Robotics' customer support.
Saline Syringe Missing Error	If necessary, reseat the syringe and manually attempt the saline flush a second time by selecting **Saline Flush** in the **Utilities** menu.
If you cannot control the Robotic Arm with the ARTAS™ System application.	Use the Arm Brake Release Feature (Section 2.4.6).

Appendix B Robot Teach Pendant

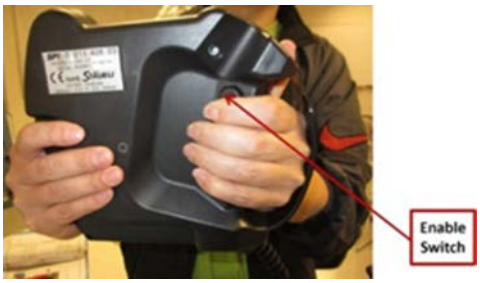
The Robot Teach Pendant (Figure 220) can be used to move the Robotic Arm in situations where the ARTAS™ System application is unable to do so, such as power supply failure or disk drive errors. The Robot Teach Pendant is only a component of systems 01001 – 01041.

Figure 220: Robot Teach Pendant

The procedure for moving the Robotic Arm is straightforward, but still requires a few simple steps:

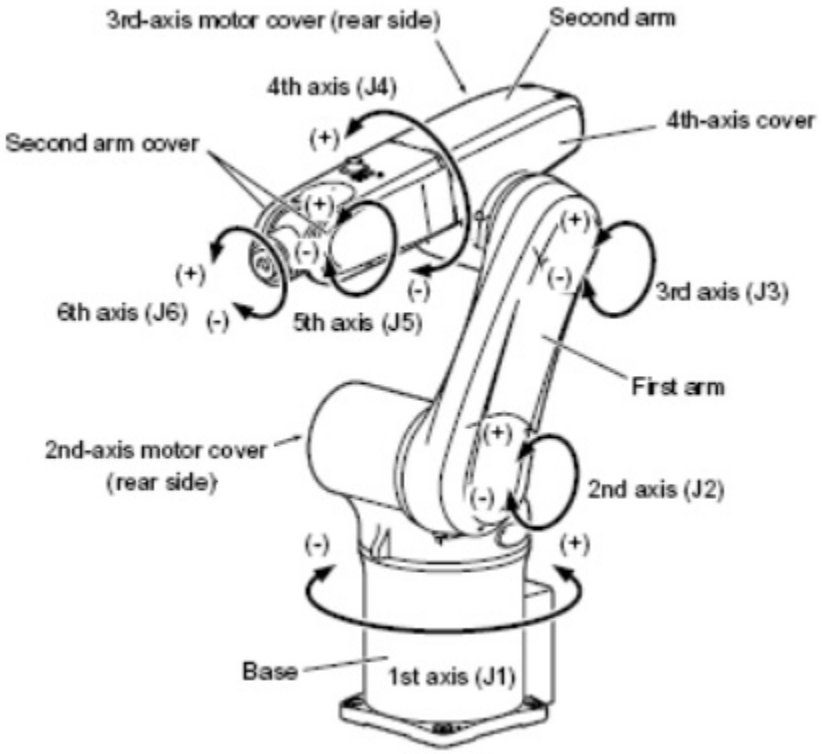
1. Press the **Mode** button until the **Manual** LED is lit. The **Manual** LED is above the hand image, next to the **Mode** button.
2. Remove the Robot Teach Pendant from its bracket.
3. Press the **Enable Switch** button under the Robot Teach Pendent half way (Figure 221).

Figure 221: Robot Teach Pendant - Enable Switch



4. While holding the **Enable Switch**, press the **Power** button on the Robot Teach Pendant.
5. Use the **Speed** button to adjust the robotic speed to 25% or less. Do NOT attempt to move the Robotic Arm at speeds greater than 25%.
6. Press the **Joint** button to enable joint movement of the Robotic Arm. Use the 6 joint buttons to move the Robotic Arm (Figure 222). Joint 1(+) is the most commonly used to move the Needle Mechanism away from the patient.
7. When the move is complete and it is appropriate to put the Robotic Arm into automatic control, press the **Mode** button until the **Remote** LED is lit. The **Remote** LED is above the lower left network image next to **Mode**.
8. Use the **Speed** button to restore the robot speed to 50%
9. Resume from the User Interface by selecting the **Resume** icon.

Figure 222: Robotic Arm Joints



Appendix C The ARTAS™ System Technical Specifications

The ARTAS™ System technical specifications are shown in Table 13.

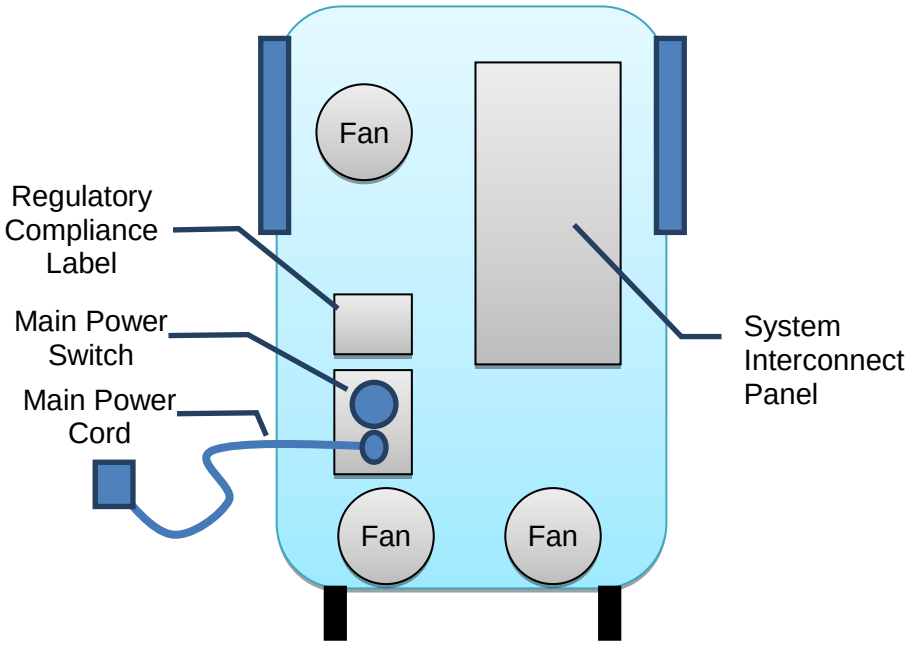
Table 13: The ARTAS™ System Technical Specifications

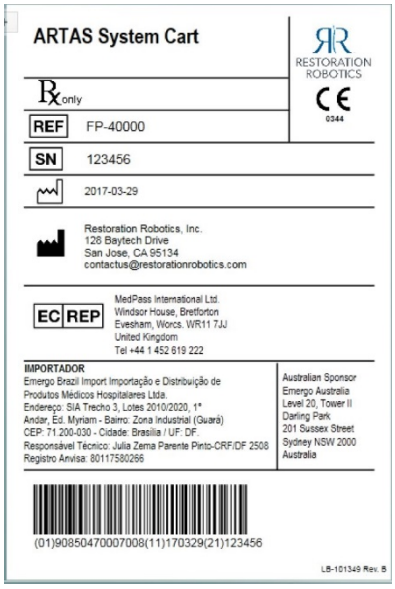
Item	Description
Cart Dimensions	Length: 37 inches (94 cm) Width: 27 inches (69 cm) Height with Robotic Arm (nominal position): 68 inches (173 cm)
Chair Dimensions	Length: 57 inches (145 cm) Width: 32 inches (81 cm) Height: 48 inches (122 cm)
Cart Weight	750 lbs. (340 kg)
Chair Weight	620 lbs. (281 kg)
Electrical	200-240 VAC, single phase, 50/60 Hz, 10A
Input Power	2000VA
Continuous Use	Yes
Vacuum	29 in-Hg (generated internally)
Pressure	40 psi (generated internally)
Connectivity	Ethernet
FDA Classification	Class II
Warranty	1-year manufacturer's warranty
Supply Connection	Class 1 (non-detachable power cord)
Water Ingress	IPX0 (ordinary, not protected equipment)
Type B Equipment	
Temperature	Operating: 15°C to 30°C Storage: 0° C to 50° C
Humidity	Operating: 20% to 80% non-condensing Storage: 0% to 90% non-condensing
Operation Mode	Continuous, as defined by IEC 60601-1.
Biocompatibility	All patient-contacting materials have been evaluated in accordance with ISO 10993-1 *Biological Evaluation of Medical Devices* and found to be biocompatible.

Appendix D Labeling and Compliance

As required by national and international regulatory agencies, appropriate regulatory compliance labels (Figure 223) have been mounted in specified locations. All treatment room staff should be familiar with the location and meaning of these labels.

Figure 223: System Cart Labeling





Electromagnetic Compliance and Warning Statement

The FP-25000 was tested and found compliant with the requirements for Class A Medical Electrical Equipment in accordance with IEC 60601-1-2. It is recommended that the ARTAS™ System be connected to a dedicated branch circuit. However, should the ARTAS™ System cause

any interference with other electrical equipment, perform the following steps to minimize the interference:

- Reorient the device receiving the interference
- Increase the separation distance between the ARTAS™ System and the equipment experiencing the interference. If possible, relocating the equipment receiving the interference until it is no longer noticeable
- If a dedicated branch circuit is not available, connect the ARTAS™ System into an outlet on a circuit different from that to which the other device(s) which are experiencing the interference are connected

If the interference continues or interference from other equipment is affecting the ARTAS™ System contact Restoration Robotics Technical Support at 1-855-882-7827 for additional assistance with addressing these issues.

Table 14: ARTAS™ Emission Test/Compliance/Electromagnetic Environment - Guidance

Emission Test	Compliance	Electromagnetic Environment - Guidance
RF emissions CISPR 11	Group 2	The ARTAS™ System must emit electromagnetic energy in order to perform its intended function. Nearby electronic equipment may be affected.
RF emissions CISPR 11	Class A	The ARTAS™ System 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.
Harmonic emissions IEC 61000-3-2	Not Applicable	
Voltage Fluctuations/ Flicker emissions IEC 61000-3-3	Not Applicable	

Guidance and Manufacturer's declaration - electromagnetic immunity			
The ARTAS™ system is intended for use in the electromagnetic environment specified below. The customer or the user of the ARTAS™ system 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	+/- 6kV contact +/- 8kV air	+/- 6kV contact +/- 8kV 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 IEC 61000-4-4	+/- 2kV for power supply lines +/- 1kV for input/output lines	+/- 2kV for power supply lines +/- 1kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	+/- 1kV line(s) to line(s) +/-2kV line(s) to earth	+/- 1kV differential mode +/-2kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines	<5% U_T (>95% dip in U_T) for 0,5 cycle 40% U_T (60% dip in U_T)	<5% U_T (>95% dip in U_T) for 0,5 cycle 40% U_T (60% dip in U_T)	Mains power quality should be that of a typical commercial or hospital environment.

IEC 61000-4-11	for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5s	for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5s	
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	0,3 A/m	If image distortion occurs, it may be necessary to position the ARTAS™ system further from sources of power frequency magnetic fields or to install magnetic shielding. The power frequency magnetic field should be measured in the intended installation location to assure that it is sufficiently low.
NOTE: U_T is the AC mains voltage prior to application of the test level.			

Guidance and Manufacturer's declaration - electromagnetic immunity			
The ARTAS™ system is intended for use in the electromagnetic environment specified below. The customer or the user of the ARTAS™ system 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	3VRMS 150kHz to 80MHz	3VRMS	Portable and mobile RF communications equipment should be used no closer to any part of the ARTAS™ System, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** $d = 1{,}2\sqrt{P}$ $d = 1{,}2\sqrt{P}$ $80MHz$ *to* $800MHz$ $d = 2{,}3\sqrt{P}$ $800MHz$ *to* $2{,}5GHz$
Radiated RF IEC 61000-4-3	3V/m 80MHz to 2.5GHz	3V/m	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 meters (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 80MHz and 800MHz, 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.

a Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV 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 ARTAS™ system is used exceeds the applicable RF compliance level above, the ARTAS™ system should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the ARTAS™ system.

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

Recommended separation distances between
portable and mobile RF communications qeuipment and the ARTAS system

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

Rated maximum output power of transmitter (W)	Separation distance according to frequency of transmitter (m)		
	150 kHz to 80MHz $d = 1{,}2\sqrt{P}$	80MHz to 800MHz $d = 1{,}2\sqrt{P}$	800MHz to 2,5GHz $d = 2{,}3\sqrt{P}$
0,01	0,12	0,12	0,23
0,1	0,38	0,38	0,73
1	1,2	1,2	2,3
10	3,8	3,8	7,3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in metres (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 80MHz and 800MHz, 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 a reflection from structures, objects and people.

Appendix E Clinical Study

A multi-center, prospective blinded, FDA-approved clinical study was performed to compare the safety and effectiveness of the ARTAS™ System to the manual hair follicle harvesting method using the Follicular Unit Extraction (FUE) approach and manual implantation following a nine-month period of post-procedural evaluation. The clinical study was conducted in healthy men, ages 30–59, which have brown or black straight hair and a clinical diagnosis of androgenic alopecia (male pattern hair loss).

Patients were screened prior to treatment. Each patient acted as their own control. Hair follicles were harvested using each harvest method (ARTAS™ procedure and manual procedure). Sixty (60) intact and transected implantable terminal hair follicles were manually implanted into two equal size (1 cm^2) implant Target Areas, one for each harvest method (ARTAS™ procedure and manual procedure).

Post-treatment follow-up included visits at Day 10, Month 6, and Month 9. Macro-photographs of the target implant areas were taken at Baseline (prior to treatment) and at Months 6 and 9 post-treatment. The hair follicle counts from the target implant area were determined from the macro-photographs by blinded readers at an independent centralized reading center.

A total of 36 patients were treated at two U.S. clinical sites. The mean age of the patients was 48.6 ± 7.5 years. Patients were predominantly Hispanic with black hair and stage V or VI baldness on the Norwood-Hamilton Classification scale. The patient population at both sites was similar. Thirty-five (35) of the 36 treated patients (97%) completed the study through Month 9.

All 36 treated patients were assessed for safety at follow-up visits on Day 10 and Month 6 and 35 of 36 treated patients were assessed at Month 9 for potential complications and adverse events. The primary safety endpoint was defined as the incidence of serious adverse events (SAEs).

The majority of complications were reported at the Day 10 Visit and occurred bilaterally in both the harvest and implant areas. Table 15 provides a summary of complications reported at Day 10 by location (harvest or implant area) and harvest technique (ARTAS™ System or manual). The only complication that occurred with the ARTAS™ System harvest method and not the manual method at Day 10 was *sensitivity* (summarized as *Other*).

Table 15: Summary of Complications Reported at Day 10 (Population: All Treated Patients

Complication	Harvest Area (n=36)			Implant Area (n=36)		
	Bilateral	Manual	*CAS	Bilateral	Manual	*CAS
Mild Pain	2 (6%)	1 (3%)	0	3 (8%)	1 (3%)	0
Itching	3 (8%)	0	0	1 (3%)	0	0
Other	1 (3%)	0	1 (3%)	0	0	0

*CAS=Computer-assisted harvest method (ARTAS™ System).

Table 16 provides a summary of complications reported beyond Day 10 by location (harvest or implant area) and harvest technique (ARTAS™ procedure and manual procedure). Complications reported beyond Day 10 were rare and included epidermoid cysts or ingrown hairs and mild pain or aching.

Table 16: Summary of Complications Reported Beyond Day 10 (Population: All Treated Patients)

Complication	Month	Harvest Area (n=36)			Implant Area (n=36)		
		Bilateral	Manual	*CAS	Bilateral	Manual	*CAS
Epidermoid Cysts (Ingrown Hairs)	6 (n=36)	0	0	1 (3%)	0	0	1 (3%)
	9 (n=35)	0	0	0	0	1 (3%)	0
Pain	6 (n=36)	0	0	0	0	0	1 (3%)†
	9 (n=35)	1 (3%)‡	0	0	0	0	0

*CAS=Computer-assisted harvest method (ARTAS™ System).
† Mild pain
‡ General aching

All complications were *Mild* in intensity as assessed by the investigator. The complication rate did not appear to be any greater using the ARTAS™ System than observed with the manual harvest method.

There were no adverse events, serious adverse events or unanticipated adverse events reported by any patients during the course of this study. None of the patients terminated the study early due to any safety-related issues.

The primary effectiveness endpoint was the difference in the number of surviving implanted hair follicles at Month 9 post-implantation between those implanted hair follicles that were harvested using the ARTAS™ System and those that were harvested using the manual method of hair harvest. For the primary effectiveness analysis, the difference in the mean hair follicle survival count at Month 9 between the implant Target Areas was less than 2 hair follicles and statistical non-inferiority was established ($p = 0.023$). The primary effectiveness endpoint of this study was achieved.

In conclusion, the ARTAS™ System was shown to be comparable to the manual harvest method when analyzing the implant results between the two harvest methods. Comparability was demonstrated for effectiveness by the terminal hair follicle counts at nine months. In terms of safety, there were no adverse events reported with either harvest method and the complication rates were similar between the two harvest methods. This clinical study was limited to only men with black or brown straight hair. Performance has not yet been characterized in women or patients with different hair types (e.g., curly or wavy hair and blonde or red hair, etc.).

The FUE approach to harvesting follicular units when performed manually has several technical challenges; it requires extensive training, it is difficult, labor intensive, tedious and requires an excessive amount of time. The ARTAS™ System is designed to address these issues and offer advantages over the current manual FUE approach and this study demonstrates that the performance and safety of the ARTAS™ System is similar to the manual method for harvesting follicular units.

Appendix F Terms, Abbreviations and Symbols

Table 17 describes symbols used by the ARTAS™ System and their meanings.

Table 17: ARTAS™ Symbols

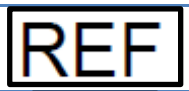
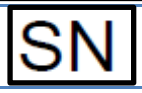
Symbol	Standard Reference	Description	Location
		Restoration Robotics Logo	Covers of cart and Needle Mechanism
	417-5007	Mains ON	Rear panel switch
	417-5008	Mains OFF	Rear panel switch
	ISO 15223-1	Catalog number	Rear panel label
	ISO 15223-1	Serial number	Rear panel label
	ISO 15223-1	Date of manufacture	Rear panel label
	ISO 15223-1	Manufacturer	Rear panel label
	IEC 60601	Type B equipment	Rear panel label
		Caution: Federal Law (USA) restricts this device to sale by or on order of a physician.	Rear panel label
		European Conformity	Rear panel label
		Authorized Representative in the European Community	Rear Panel label

Table 18 provides terms and abbreviations used within the guide.

Table 18: ARTAS™ Terms and Abbreviations

Terms and Abbreviations	
ARTAS™ Application	Software component of ARTAS™ System that runs on the operation workstation.
ARTAS™ FU Counter Application	A software program used during microscopic inspection of individual follicles after harvesting for compiling a statistical report of FU quantity and quality.
ARTAS™ Hair Pendant	Provides a convenient way for the operator to use functions such as Pause, Cancel, Skip, PD, CD, Angle and Emergency Stops. Used for systems prior to #2100. Refer to LB-102479 for user instructions.
ARTAS KEY™ USB Device	This USB security device is typically plugged into a monitor USB port to ensure that each Harvest Attempt and Site Making Procedure is tracked and counted against the number of follicular units that are licensed for harvest and procedures that are licensed for site making.
ARTAS™ Patient Chair	The reconfigurable chair used for harvesting and recipient site making on the patient.
ARTAS™ System	A combination of components used to perform the ARTAS™ procedure.
ARTAS™ System Cart	The ARTAS™ System component that holds the Robotic Arm and controls.
ARTAS™ Two-step Dissection Technique	A sharp inner needle first scores the epidermis, and a dull, rotating punch follows to gently separate the follicle from the surrounding tissue. Light suction throughout the process helps to elevate the dissected follicular unit.
ARTAS™ Workflow	Three-step process used to position the Needle Mechanism over the patient's scalp in preparation for dissection. The steps include: Center Position, Force Drag and Acquire Tensioner/Platform.
ARTAS™ Workflow Remote	An iOS application users can download onto their iOS device that provides a convenient way for the operator to use functions such as Pause, Cancel, Skip, PD, CD, Angle and Emergency Stops. Refer to LB-102241 for user instructions.
Camera Calibration Target	The location where camera accuracy is assured during system verification procedure.
Center Position	Step 1 of the ARTAS™ Workflow; moves the Needle Mechanism to a position over the back of the patient.
Control Panel Touchscreen	A display and buttons on the top surface of the ARTAS™ System Cart used to monitor the Needle Mechanism status and manually control the Needle Mechanism during servicing. The system power on and off buttons are also here.

Dissection Parameters	Numbers adjusted by the operator to optimize the harvest procedure, including puncture depth (PD), coring depth CD and angle (ANG).
Dissection Punch	The dull punch used to dissect the tissue surrounding the follicle. This punch is dulled to ensure that the follicle is not cut during dissection.
Dissection Punch Calibration	A procedure performed whenever a new dissection punch is installed on the Needle Mechanism to ensure that it is properly positioned relative to each follicle during harvest.
EPO Button	A red *Emergency Power Off* button attached to the surface of the ARTAS™ System Cart. Pressing the EPO button shuts off power to all subsystems except the computer. The EPO button must be reset before a long (approximately five minute) recovery process begins.
E-Stop Button	One of the red *Emergency Stop* buttons positioned near the physician and operator. Pressing the E-Stop button causes the Needle/Punch to retract and the power to be turned off to the Robotic Arm. Reset the E-Stop to restore power to the Robotic Arm.
Follicular Unit (FU)	A natural grouping of one to four hair follicles that is dissected as a single unit. These groups are categorized as follows: F1 = 1 hair follicle in the FU F2 = 2 hair follicles in the FU F3 = 3 hair follicles in the FU F4+ = 4 or more follicles in the FU
Follicular Unit Extraction (FUE)	The process of extracting individual FUs for implant. The ARTAS™ System performs FUE to replace older strip harvesting or plug harvesting techniques.
Force Drag	Step 2 of the ARTAS™ Workflow; allows the physician to manually move the Needle Mechanism from Center Position to the center of the Skin Tensioner of Fiducial Platform.
Grid	A grid is the area within the Tensioner or Platform.
Hair Pattern Design	The plan which was created in the ARTAS HAIR STUDIO™ software and transferred to the ARTAS™ System.
Harvest	Tissue that is the product of the two-step dissection process of the ARTAS™ System.
Harvest Snapshot Images	Two snapshots are taken and displayed after each harvest in the lower-right corner of the display. • The left-hand snapshot shows the puncture needle while it is in the scalp, which is used to evaluate the puncture depth. • The right-hand snapshot shows the harvest site after harvest, which is used to verify that the harvested follicle is well centered within the core of tissue that surrounds it.

Hi-Mag Image Display	Displays a diagonal field view of approximately 2.5 cm. The Hi-Mag (high-magnification) image display is used for locating and tracking individual hairs for dissection.
IFU	Instructions for Use. Documentation included in the Disposable and Reusable clinical kits.
Inner Needle	The sharp needle used to create a shallow incision through the scalp in preparation for dissection with the dissection punch.
Jogging	A robotic motion mode in which point-to-point moves are performed by the Robotic Arm to move to the safe position, center position, or other important locations.
Low-Mag Image Display	Displays a diagonal field view of approximately 5 cm. The Low-Mag image display is used for tracking fiducials and planning harvest spacing and direction.
Mouse Drag	A robotic motion mode in which the operator controls Robotic Arm motions using the mouse on the video screen. This mode is typically used to slowly move the Robotic Arm over the harvest area.
Needle Mechanism	The device mounted at the end of the Robotic Arm that holds the force sensor, cameras, inner needle, and dissection punch used to perform FUE.
PDU	Power Distribution Unit
Region Axis	Direction in which harvesting moves on the graphical display, as indicated by a line with an arrow drawn across the screen. This axis marks the lower bound of the area in which the system selects subsequent follicles. The axis is raised or lowered by pressing the arrow keys.
Robot Teach Pendant	Can be used to move the Robotic Arm in situations where the ARTAS™ System application is unable to do so, such as power supply failure or disk drive errors.
Safe Position	A set position in which the Robotic Arm and Needle Mechanism are oriented over the System Cart and out of the way of the dissection area.
Saline Flush Station	The location on the ARTAS™ System Cart to which the Robotic Arm moves to flush the puncture needle and dissection punch following harvest.
Skin Tensioner	A proprietary device used to expand the scalp, which provides a firm, taut surface for dissection. Each of the four sides has fiducial markings. The fiducials are tracked by the image guidance system and allows it to keep track of past, present and future harvests.
System Interconnect Panel	The upper panel on rear of ARTAS™ System Cart, which contains operator workstation and E-Stop connections.

System Power Panel	The lower panel on the rear of the ARTAS™ System Cart, which contains main power cord and overall System power switch.
System Verification	The procedure performed a system startup to ensure that the System components are operational and properly calibrated.
Transected Follicle	Damage to any portion of the hair shaft along its path from the epidermis down to the bulb. Damage may manifest itself as a cut, crushed, or stripping/bending of the hair follicle. A transection may prevent the follicle from generating new hair when implanted into a recipient site.
UPS	Uninterruptible Power Supply. Used for backup power when power is not available.
User Interface (UI)	The monitor, keyboard, and mouse for operator controlling the ARTAS™ application software. This is where the user views and interacts with the software.