KCI Product Inspection and Cleaning/Disinfection Process

Important Information

This presentation depicts the process for inspecting, cleaning, and disinfecting KCI® products.

Although the KCI® Products (ACTIV.A.C.™ Therapy System (Standard & RTM), V.A.C.RX4™ Therapy System, V.A.C.ULTA™ Therapy System (Acute Care & Home Care; Standard & 4 Therapy), INFOV.A.C.™ Therapy System, V.A.C. FREEDOM™ Therapy System, V.A.C. SIMPLICITY™ Therapy System, CELLUTOME™ Epidermal Harvesting System, and ABTHERA™ Open Abdomen Negative Pressure Therapy System) are physically different, this process should be applied in a similar manner for all products, while adhering to any additional guidance provided on the product-specific pages, as appropriate.

Therapy systems and physical components shipped directly from manufacturing or an approved repair center are considered clean and only require completion of a Quality Control Checklist to become Branch Ready.



Precautions

- Teams should always be on alert and take precautions when performing work on units in areas that are concealed from the standard inspection, cleaning, and disinfection process.
 - Examples include, but are not limited to:
 - Battery Housing / Compartments
 - Hanger Arm Assemblies
 - UDI Door Assemblies
 - Instill Roller Cover Assemblies
- During such tasks, teams should:
 - Uninstall or disassemble the item in the designated Dirty/Processing Area.
 - Perform the inspection, cleaning, and disinfection that may be needed.
 - Perform the installation or assembly in the designated QC Area.
- > If damage is noted during the inspection, cleaning, and disinfection process:
 - Complete the inspection, cleaning, and disinfection per this process.
 - Document all damage.
 - Enter Repair Notes in the system (where applicable); include any step failure information.
 (These notes are helpful to Technical Services as they repair the unit.)
 - RMA the unit.



Buttons & Display





















Note: Pictures are for illustration purposes. Labeling may not be current. See applicable work instructions for labeling information.



Items Needed

Documentation:

- WI-19-30 (Hand Hygiene Guidelines)
- WI-19-31 (Standard Precautions and PPE)
- WI-19-33 (Cleaning/Disinfection Solutions)

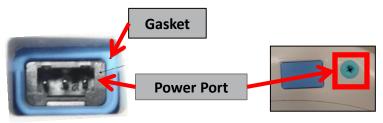
Materials:

- Approved Cleaning/Disinfection Solutions
 - o Follow the manufacturers' Directions For Use, as well as their recommended contact/wet time.
- Rubber Bands



Process

- Remove the unit from packaging and dispose of all single-use items associated with the KCI® Product.
 - Inspect returned items for any materials with patient specific Information and dispose of according to KCI policy.
 - If material is contained within a KCI-approved literature pouch, refer to WI-19-170 for inspection, cleaning, and disinfection criteria.
 - Dispose of any fabric carrying cases upon return from the customer.
- Inspect the unit for exterior damage.
 - Verify there is no obvious damage (including chips, cracks, sharp edges, peeling, cuts, tears, gouges, discoloration, loose parts, missing screws, etc.) to:
 - Top / Bottom / Sides (including recess areas)
 - o Handles / Housings / Receptacles
 - Screens / Interface Panels / Buttons
 - Ports / USB Isolators / Filter Inlets



When checking for damage, refer to VA-QA-70 for RMA guidelines.





Filter Inlet



- Review the Battery History (413885) and PM information (as applicable, by product). Ensure that there is alignment between any Battery History or PM labeling present on the device and the information that is identified within the system, prior to beginning the QC process.
 - If the batteries have expired, replace at the service center or RMA the unit, as applicable.

Procedure:

- Remove the battery history label.
- Remove the battery cover.
- o Remove all SVC-replaceable batteries from the unit until any wiring connectors are accessible.
- Disconnect the batteries and take action, as applicable.
 - The installation of new batteries is identified within the QC process. Batteries may be installed and/or charged prior to beginning the QC process.



- Remove any removable components (use tweezers, as needed).
 - Inspect, clean, and disinfect any interface seals, grommets, and bellows.
 - o If damaged, discard.
 - o These components are reusable and will be re-installed during the QC process.









- Discard any exhaust filters.
 - New components will be installed during the QC process.







Clean and disinfect the unit.

- Wipe down the unit to remove heavy soil prior to cleaning and disinfection.
 - Wipe down the sides of the unit.
 - Wipe down the back and front of the unit.
 - o Wipe down the top and bottom of the unit.
 - Wipe down any wireless features/accessories.
- Gently clean and disinfect the seal around the screen.
 - Caution must be taken when wiping down the screens or keypads so as not to allow fluid ingress into the screens or into the areas surrounding the keypad (on units with screens and/or keypads).
 - o Tilt the unit so that liquid will not drip or pool onto the screen area (on units with screens).
- Gently clean and disinfect along the edges of any wireless features/accessories.
- Use a cotton-tipped applicator, as necessary, to clean hard to access surface areas (side recess areas, undersides of tie-downs or rubber feet, power connector openings, screw heads, etc.).
- Move the unit into the designated Clean and Waiting QC Area and allow the unit to air dry.
 - After the unit is dry, inspect for chemical residue on the display screen.
 - o A non-abrasive cloth may be used to remove residual marks on the screen.
- Reinspect the unit for any remaining debris, adhesive residue, and overall cleanliness prior to moving to QC area.



- Inspect, clean, and disinfect the power cord, power supply, accessories, and transit cases (where used).
 - Ensure the power cords and plugs are undamaged.

Evaluate plugs, cords, and female ends on detachable cords for any damage and replace with a KCI-approved replacement cord.



Acceptable Plugs-230V (International Only) No Ground Spade



Acceptable Plugs-115V





Acceptable Power Supply Plugs



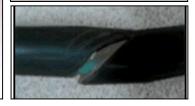


Not Acceptable Plugs (Replace)
Round/Solid Ground Spade or Damaged





Not Acceptable Power Cords (Replace)



- Inspect, clean, and disinfect the power cord, power supply, accessories, and transit cases (where used). (cont.)
 - While wiping the power supply and power cord, wrap the power cord (in a looping loose fashion) and secure with a rubber band or a power cord restraining strap, where used.
 - Always leave excess cord on each end to allow the unit to be plugged in (if needed) before and during the QC process.
 - Return or dispose of damaged power supplies per the following guidance for the US (for OUS, follow local organizational guidance):
 - WI-VC-187 (ACTIV.A.C.™ & V.A.C. SIMPLICITY™)
 - WI-VC-268 (V.A.C. FREEDOM™)
 - Technical Bulletin 48638 (V.A.C.ULTA™)









- Inspect, clean, and disinfect the power cord, power supply, accessories, and transit cases (where used). (cont.)
 - Ensure the accessories and transit cases are NOT damaged. Replace as needed.
 - Clean and disinfect the exterior and the interior of the molded carrying case with an approved cleaning/disinfection solution.
 - Allow to air dry.











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- Proceed to the product-specific pages for additional guidance by product.
 - ABTHERA™ Open Abdomen Negative Pressure Therapy System
 - ACTIV.A.C. ™ & V.A.C. SIMPLICITY™ Therapy Systems (Standard & RTM)
 - CELLUTOME™ Epidermal Harvesting System
 - INFOV.A.C.™ Therapy System
 - V.A.C. FREEDOM™ Therapy System (No additional guidance. Proceed to <u>Approval</u>.)
 - V.A.C.RX4[™] Therapy System
 - V.A.C.ULTA™ Therapy System (Acute Care & Home Care) (Standard & 4 Therapy)



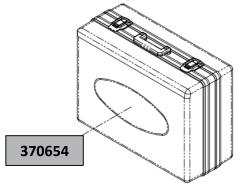
ABTHERA™

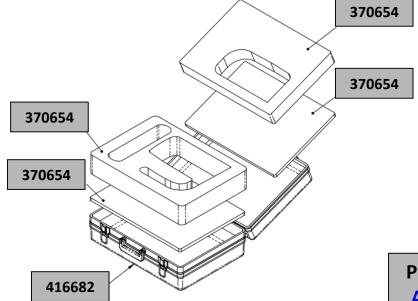
- Use caution when wiping the face of the therapy unit.
- Verify the hanger arm is secure, operates correctly, and:
 - Does not bind or catch when extended or returned.
 - Is not damaged or broken in any way.





Transit Case (where used)





Proceed to **Approval**.

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ACTIV.A.C.™ & V.A.C. SIMPLICITY™ (Standard & RTM)





- The power cord retainer straps are single-use only.
 - Dispose upon return from the customer.



Proceed to Approval.



CELLUTOME™

Examine the handle.

Inspect AC Receptacle is secure and undamaged.



Inspect rubber feet and stand insert for damage.



Nesting Area is not damaged.

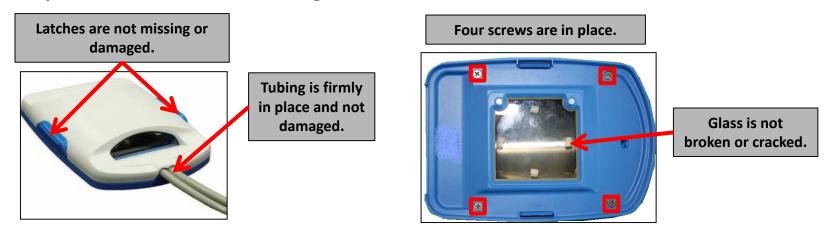


- Inspect the tubing connectors and latches for:
 - Damage
 - Cuts
 - Strains
 - Cracks



CELLUTOME™ (cont.)

Inspect the vacuum and tubing heads.



➢ If obvious damage is noted to the vacuum head assembly during the inspection, cleaning, and disinfection process, replace the assembly.

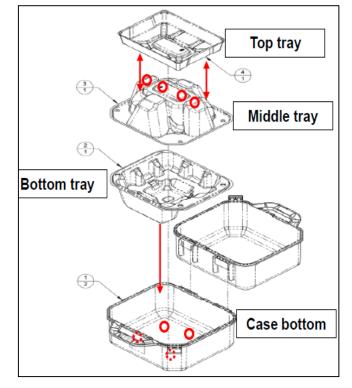
CELLUTOME™ (cont.)

Inspect the internal plastic trays.

- If damaged, replace the plastic trays in the QC area.
- Apply the adhesive dots (where used) as shown.
 - o Ensure the dots are in place.
 - Remove one side of the plastic over the glue dot and apply to shown locations.
 - Remove the other side of plastic and press bottom tray into case bottom and top tray onto middle tray.



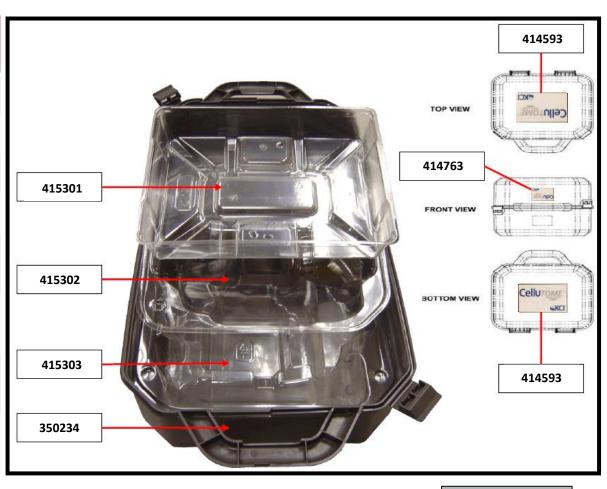






CELLUTOME™ (cont.)

PART NUMBER	DESCRIPTION
415308	ASSY, CELLUTOME CARRY CASE
350234	CASE, ULTA EMEA CARRYING
415302	TRAY, CELLUTOME LOWER
415303	TRAY, CELLUTOME UPPER
415301	TRAY, CELLUTOME INSTRUCTIONAL (LIT TRAY)
414763	LABEL, CELLUTOME CASE LOGO, (SMALL)
414593	LABEL, CELLUTOME CARRYING CASE (LARGE)
44000548	ADHESIVE, LARGE TACKY DOT CLEAR







INFOV.A.C.™



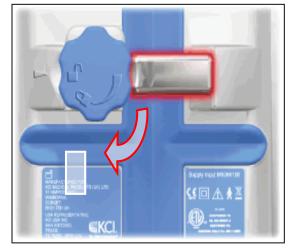




- Inspect, clean, and disinfect the stylus (PN M3268567) and UDI (User Data Interface) door (PN M3268563).
 - If damaged, discard.
- Inspect, clean, and disinfect the power and canister buttons.
 - If damaged or illegible, RMA the unit.



Verify the hanger arm, rubber block, and rubber "V" channels are secure, operate correctly, and are not damaged.

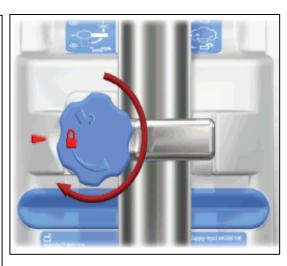


The metal hanger arm can only move back and forth in the 90° arch pictured above. Note: The hanger arm can only be swung when it is all the way in.



The Hanger Arm is spring loaded.

Verify that the spring mechanism is working correctly.

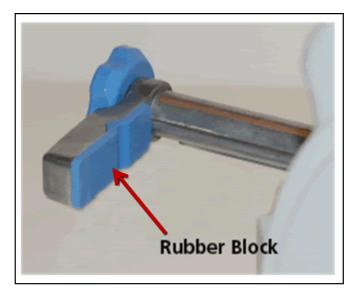


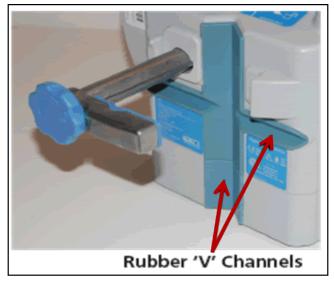
Turning the knob cinches in the Hanger Arm and locks it in place.

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- Verify the hanger arm, rubber block, and rubber "V" channels are secure, operate correctly, and are not damaged. (cont.)
 - If the rubber block needs to be repaired or replaced, proceed to the next slide.
 - If the rubber "V" channels on the battery housing are loose, discolored, or missing, replace the battery housing (PN M3268561).





Rubber Block Replacement:

The purpose of this procedure is to provide a recommended method to repair or replace the rubber block located on the hanger arm assembly.

This procedure <u>IS NOT</u> part of the normal service process, but is included here to facilitate potential repairs to the rubber block.

Parts and Equipment Needed:

- Loctite® 411™ Cyanoacrylate adhesive
- Isopropyl alcohol
- Cleaning cloth
- An appropriate-sized tool for removing any residual old adhesive (a standard flat blade screwdriver may work)
- Protective gloves
- Rubber block (PN M3240627), if required



Rubber Block Replacement: (cont.)

- Using an appropriate tool, ensure all residual hot-melt adhesive is removed from the interior of the cast metal hanger arm hook.
- Use isopropyl alcohol to clean the interior of the cast metal hanger arm hook.
- Allow to air dry.
- Apply several drops of Loctite® 411™ adhesive to both interior sides of the cast metal hanger arm hook.

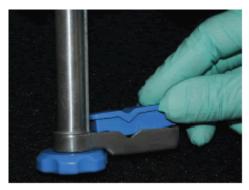




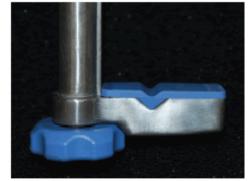


Rubber Block Replacement: (cont.)

- Inset the rubber block into the hook cavity, ensuring the adhesive remains inside the hook cavity.
- Press the rubber block into place.
- Immediately remove any excess adhesive on the block, hanger arm, or cast metal hook.
- Follow the manufacturers' Directions for Use to allow the adhesive to fully set before use.



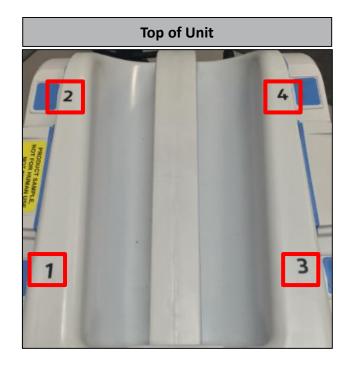


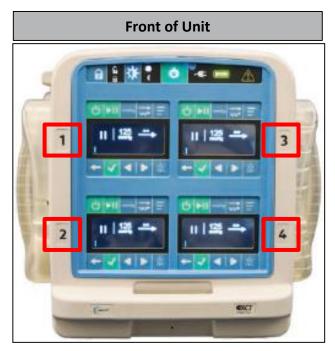






V.A.C.RX4™





Inspect and ensure the Channel Numbers are legible.





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If a wireless accessory is installed, this door will not open.

Inspect, clean, and disinfect the stylus (PN M3268567) and UDI (User Data Interface) door (PN 350079).

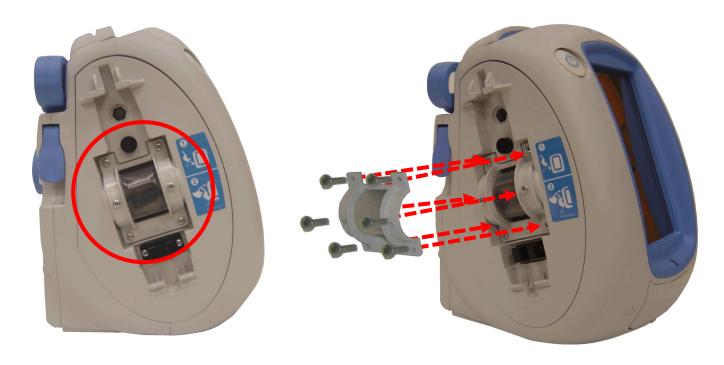
(Not available on units with wireless accessory.)

- If damaged, replace.
- If magnets are missing, RMA the unit.
- If pins are missing, replace UDI door.



Rev L

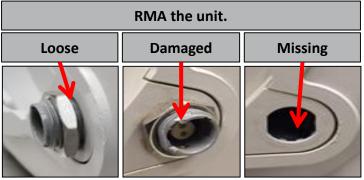
- Verify the instill roller cover assembly (PN 350039) is not damaged.
 - If damaged, discard.
 - o Remove the six screws indicated below.
 - o Replace the roller cover.

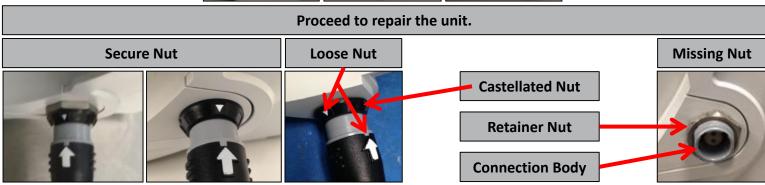




Verify the black castellated nut on the power port is secure.

Note: Over time, the black castellated nut can unscrew causing the power cord to fall into the unit. If the black castellated nut is loose or requires replacement, it is possible to repair ONLY IF both the silver retainer nut and grey connection body are present, secure, and undamaged.







Verify the black castellated nut on the power port is secure. (cont.)

Parts and Equipment Needed:

- Castellated Nut Driver (PN 44001669)
- Castellated Nut (PN 44001660)





Repairing or replacing a black castellated nut:

- Ensure white triangle is in the top center position.
- If replacing, thread a castellated nut onto the connection body.
- Use a castellated nut driver to rotate the nut clockwise.
- Tighten until the white triangle is back in the top center position.

Connector Slots



- Verify the hanger arm, rubber block, and rubber "V" channels are secure, operate correctly, and are not damaged.
 - If the hanger arm assembly (PN 350274) is damaged, replace. Return any damaged hanger arms to the approved repair center.



The hanger arm assembly is spring loaded. Verify that the spring mechanism operates correctly. Hanger arm must be extended in order to lock.

Screw PN 400372



Turn the knob clockwise to lock the hanger arm assembly in place.

Label PN 350166

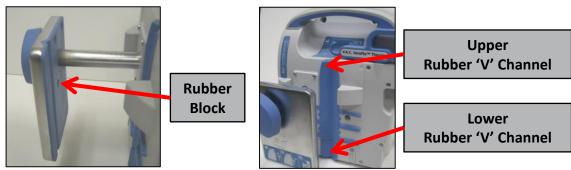


Turn the knob counterclockwise to unlock the hanger arm assembly.

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- Verify the hanger arm, rubber block, and rubber "V" channels are secure, operate correctly, and are not damaged. (cont.)
 - If the upper rubber "V" channel on the unit is loose, discolored, or missing, RMA the unit.
 - If the lower rubber "V" channel on the battery housing is loose, discolored, or missing, replace the battery housing (PN 350232).



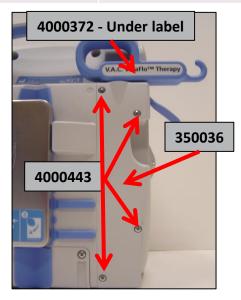
- The I.V. pole hanger arm should extend, retract, and lock in both places.
 - If damaged, repair.
 - Remove the four screws.
 - Replace parts, as needed. For PNs, refer to next slide.

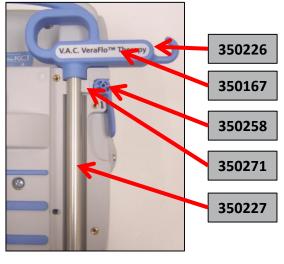


Lift to unlock. Lower to lock.



Part Number	Description
350226	Arm, I.V. Hanger Weldment
350167	Label, V.A.C. Ulta™ Hanger Arm Logo
350036	Cover, I.V. Hanger
350258	Lever, Locking
350271	Pawl, I.V. Hanger
350227	Pole, I.V. Hanger
4000372	Screw to Secure Arm to Pole
4000443	Four Cover Screws





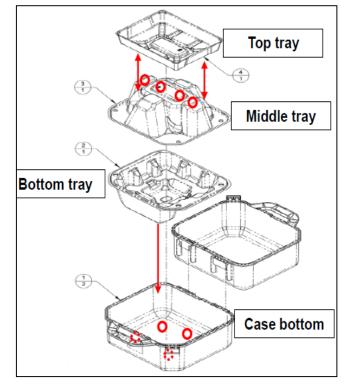


Inspect the internal plastic trays.

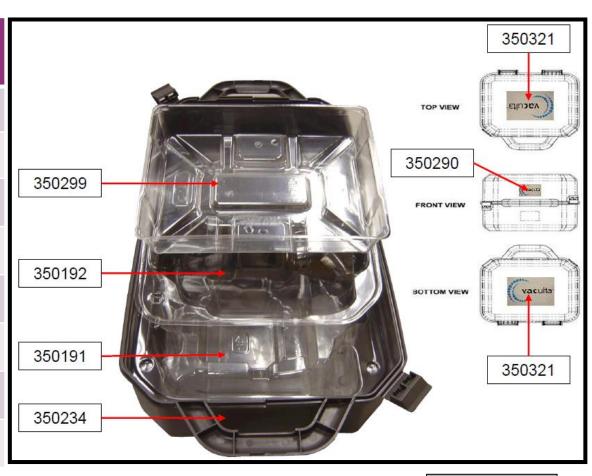
- If damaged, replace the plastic trays in the QC area.
- Apply the adhesive dots (where used) as shown.
 - o Ensure the dots are in place.
 - Remove one side of the plastic over the glue dot and apply to shown locations.
 - Remove the other side of plastic and press bottom tray into case bottom and top tray onto middle tray.







Part Number	Description
350235	CARRY CASE COMPLETE ASSEMBLY
350234	CARRY CASE HALF (PLASTIC CASE ONLY)
350191	BOTTOM TRAY
350192	MIDDLE TRAY
350299	TOP TRAY (LITERATURE TRAY)
350290	SMALL LOGO LABEL
350321	LARGE LOGO LABEL
44000548	ADHESIVE/GLUE DOTS FOR TRAYS









Rev L

Approval

- Be sure to remove PPE (dispose as appropriate) and perform Hand Hygiene.
 - Always follow proper prevention and infection control guidelines.
- ➤ Each Product / Serial # must have a record indicating that the product conforms to the inspection, cleaning, and disinfection criteria identified within this process and on what date this was confirmed. It is to be available or accompany the unit to the next step of the QC.





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