

WELLS JOHNSON

High Volume Precision (HVP™) Auto-Graft System

REF: 20-6200-00

INSTRUCTIONS FOR USE



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

IFU-01280 v3
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Device Description

The High Volume Precision (HVP™) Auto-Graft System is a powered medical device used for controlled transfer of autologous adipose tissue within a sterile, closed fluid pathway. The HVP System is used with adipose tissue collected using an external aspiration device and contained in a sterile collection canister.

The system consists of a peristaltic pump, sterile single-use disposable tubing set, collection canister, vibrating platform, clamps, cannulas, and two footswitches for hands-free control of system functions.

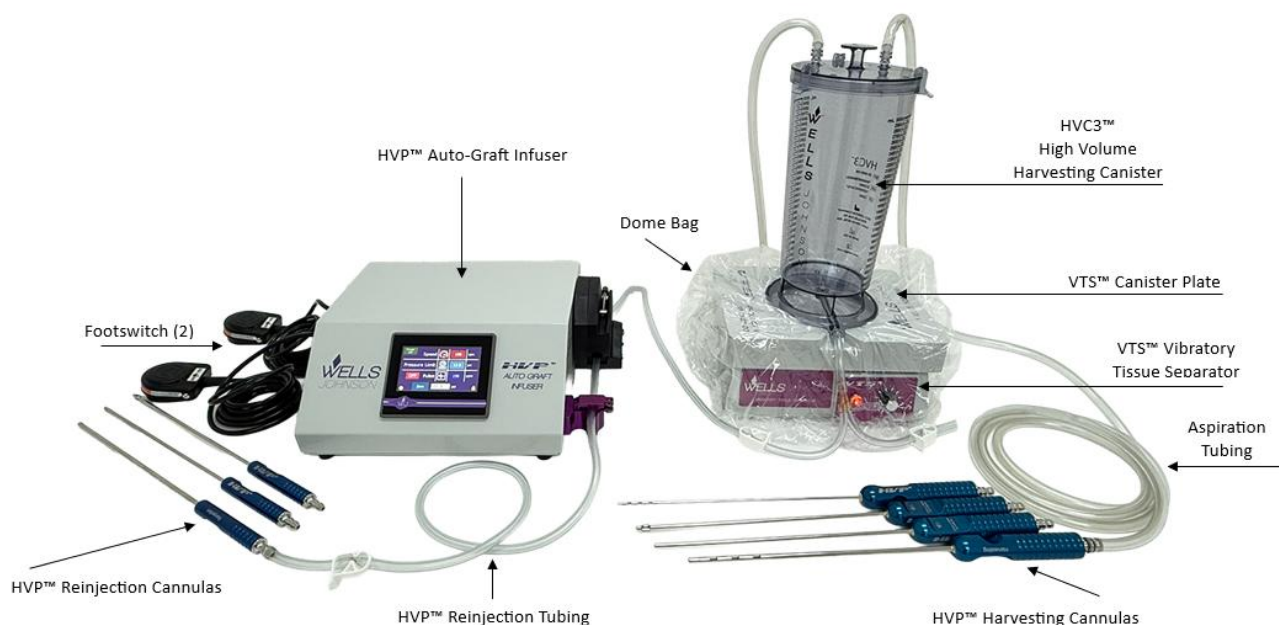
The peristaltic pump provides controlled movement of adipose tissue through the sterile fluid pathway. A touchscreen interface allows the user to control system operation and select operating parameters.

The system includes pressure monitoring that automatically stops pump operation if a preset pressure limit is exceeded to help prevent excessive pressure within the fluid pathway.

The vibrating platform facilitates the separation of harvested adipose tissue from associated fluids within the collection canister prior to transfer.

CAUTION: *Carefully read these instructions before using the Wells Johnson HVP System. Keep these instructions in a safe place for future reference.*

Device Diagram



Intended Use

The HVP System is intended to provide controlled positive pressure for the transfer of adipose tissue during liposuction procedures.

Intended Users

The HVP System is intended to be used by qualified and trained healthcare professionals, such as licensed surgeons and operating room personnel.

Use Environment

The HVP System is intended for use in healthcare settings, including operating rooms and other clinical environments where liposuction procedures are performed.

Contraindications

No known contraindications.

Setup and Operation

1. Position the HVP Auto-Graft Infuser next to the VTS Vibratory Tissue Separator on a stable, level surface in the desired location for the procedure. The HVP Cart, available from Wells Johnson, may be used to support both the HVP Auto-Graft Infuser and the VTS Vibratory Tissue Separator but is not included with the system.
2. Connect the power cord to the power inlet on the rear of the HVP Auto-Graft Infuser and then to an appropriate grounded wall outlet.

CAUTION: *Do not use the HVP Auto-Graft Infuser with power cords or power adapters that are not provided by Wells Johnson.*

3. Plug the VTS Vibratory Tissue Separator power cord into an appropriate electrical outlet.
4. Connect the pneumatic footswitches to the appropriately labeled port(s) on the side of the HVP Auto-Graft Infuser.



5. Press the power switch on the rear of the HVP Auto-Graft Infuser to turn the unit ON.

Touchscreen Interface Controls

The HVP Auto-Graft Infuser touchscreen interface allows the user to adjust operating settings and parameters by touching the appropriate area of the screen. Settings are retained when the unit is powered off.

- Speed: Allows the user to adjust the motor speed.

- **Pressure Limit:** Allows the user to adjust the maximum pressure permitted in the tubing-to-patient portion of the system. The adjustable Pressure Limit range is 0.5–13 psig.
- **Pulse:** The Pulse function is OFF by default. When turned ON, the motor starts and stops in increments, creating a pulsing effect. The Speed and Pulses per Minute settings can be adjusted to achieve the desired pulse effect.

When the HVP Auto-Graft Infuser is connected to electrical power and the rear power switch is ON, the touchscreen illuminates. Adjust the settings by touching the displayed value and entering the desired value, or by using the arrow buttons for smaller adjustments.



6. While the HVP Auto-Graft Infuser is starting up, verify that the Speed and Pressure Limit settings are selected to the desired values.
7. Place the appropriate VTS Canister Plate on top of the VTS Vibratory Tissue Separator. Two VTS Canister Plate models are available for use with either the 3000 mL or 5000 mL canister.
8. Place the selected 3000 mL or 5000 mL canister on the VTS Canister Plate.
9. Attach the Reinjection Cannula to the distal end of the HVP Tubing.
10. Rotate the pump head lever counterclockwise to open the pump head.
11. Insert the HVP Tubing into the pump head opening over the rollers. The flow direction is from right to left when facing the pump side of the machine, or from back to front when facing the front of the machine. A graphic on the unit indicates the correct flow direction.
12. Rotate the pump head lever clockwise to carefully close the pump head and clamp the tubing.



CAUTION: Make sure the HVP Tubing is not punctured or damaged by the black teeth when closing the pump head.

13. Open the pressure sensor clamp. Gently place the tubing into the pressure sensor slot and lock the clamp into place.



CAUTION: Always use the pressure sensor during operation. The pump head can generate high positive pressure. Failure to use the pressure sensor may result in pressure exceeding the specified operating range.

14. Press ZERO on the touchscreen to zero the pressure sensor.

15. Prime tubing to remove air from the HVP Tubing.

CAUTION: To prevent air infusion, always prime the tubing before transferring adipose tissue to the patient.

16. Verify that the pressure reading is 0. If the pressure reading is not zero, press ZERO again.

17. Press and hold the pneumatic footswitch to begin operation. Release the footswitch to stop operation.

Pressure Sensor Operation

The pressure sensor measures the pressure of the fluid inside the tubing. The Pressure Limit can be set using the touchscreen within an adjustable range of 0.5–13 psig. The Pressure Limit represents the maximum pressure allowed in the tubing system before the auto-reverse function is activated.

When the pressure reaches the set Pressure Limit, the auto-reverse function reduces the pressure to a near-zero value by reversing the rotational direction of the pump.

CAUTION: *Avoid excessive pulling, pushing, or tension on the tubing during and after installation to maintain pressure-sensing accuracy.*

CAUTION: *If the HVP Auto-Graft Infuser will not be used for an extended period of 30 days or longer, connect the unit to electrical power and leave it powered ON using the power switch on the rear of the unit for at least 48 hours.*

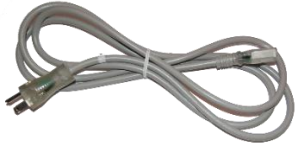
Device Specifications

Parameter for HVP Auto-Graft Infuser	Specification
Weight	11.3 lb
Dimensions	15.25 in x 11 in x 5.25 in
Maximum Pressure Without Pressure Sensor	40 psig (276 kPa, 2080 mmHg)
Maximum Flow Rate	670 mL/min with specified tubing
Speed Display Unit	rpm (revolutions per minute)
Pressure Display Unit	psi (measured as psig pounds per square inch gauge)
Pulse Display Unit	ppm (pulses per minute)
Over Pressure Protection	External pressure sensor and auto-reverse function
Pump Type	Peristaltic
Number of Rollers	4
System Power	360 W

Parameter for VTS Vibratory Tissue Separator	Specification
Weight	19 lb
Dimensions	10.5 in x 7.5 in x 4.5 in

Component Description

Item No.	Component	REF	QTY	Description
1	 The image shows a white, box-shaped HVP Auto-Graft Infuser. It has a touchscreen display on the front showing a control interface with various buttons and a graph. To the right of the screen is a black roller assembly. A purple component is visible at the bottom right. The Wells Lavender logo is on the left side of the front panel.	20-6200-00	1	A peristaltic pump that provides continuous or pulsed transfer of harvested autologous adipose tissue to the injection site under controlled pressure and flow-rate conditions.

Item No.	Component	REF	QTY	Description
2	Power Cord 	18-2820-00 Model 120 VAC 20-5101-11 Model 240 VAC	1	A detachable power supply cord used to connect the HVP Auto-Graft Infuser to an electrical outlet.
3	Pneumatic Footswitch 	20-6010-02	2	A pneumatic footswitch used for hands-free activation and control of device functions.
4	HVP Tubing 	24-6037-00	Case of 10	Sterile, single-use tubing set for transfer of autologous adipose tissue.
5	Standard Ultra-Limp Tubing 	24-5103-00	Case of 10	Sterile, single-use tubing set for aspiration of adipose tissue.
6	HVP Cannula Set 	20-1347-00	Set of 7	Reusable stainless-steel cannula set includes four Harvesting Cannulas and three Reinjection Cannulas
7	VTS Vibratory Tissue Separator 	20-1825-00 Model 120 VAC 20-1826-00 Model 240 VAC	1	An electrically powered vibratory platform that provides gentle agitation of harvested aspirate to facilitate separation of harvested adipose tissue from the lower fluid layer within the collection canister prior to transfer.

Item No.	Component	REF	QTY	Description
8	VTS Canister Plate for HVC3 Canister 3000 mL 	18-2821-00	1	The VTS Canister Plate supports and secures the selected collection canister on the VTS Vibratory Tissue Separator.
	VTS Canister Plate for High Volume Harvesting Canister 5000 mL 	18-2821-01	1	
9	HVC3 Canister 3000 mL 	20-8300-00	1	The user may select either the HVC3 3000 mL Canister or the High Volume Harvesting 5000 mL Canister. The selected canister must be used with its corresponding VTS Canister Plate.
	High Volume Harvesting Canister 5000 mL 	20-5188-00	1	
10	Dome Bag 	24-6038-00	10	Sterile, single-use protective cover placed over the vibrating platform to help maintain a sterile field.

Item No.	Component	REF	QTY	Description
11	Cannula Brushes 	20-5230-00 20-5232-00	2 2	Brushes used for manual cleaning of reusable cannulas and HVC3 drain port in accordance with the applicable IFU cleaning instructions.
12	HVP Cart 	20-5997-00	1	Optional. Not included. Mobile cart designed to support the HVP System. The HVP System is placed on the upper platform, while a compatible aspirator may be positioned on the floor beneath the cart.

Cleaning and Disinfection

Clean and disinfect the exterior surfaces of the Auto-Graft Infuser between patients and whenever contamination occurs.

1. Turn the Auto-Graft Infuser OFF and disconnect the power cord from the electrical outlet before cleaning.
2. Remove and dispose of all single-use tubing according to facility protocols.
3. Remove, clean, and sterilize reusable collection canister according to the applicable IFU.
4. Wipe the exterior surfaces of the HVP Auto-Graft Infuser with a soft, lint-free cloth moistened with an appropriate hospital-grade disinfectant. Follow the disinfectant manufacturer's instructions for application and contact time.
5. Allow the surfaces to dry completely before reconnecting the device to the power supply or using the device on another patient.

CAUTION: *Do not immerse the HVP System in water or other liquids. Do not allow liquid to enter the device, electrical connectors, switches, or other openings.*

CAUTION: *Do not spray cleaning or disinfecting solutions directly onto the HVP System.*

Disposal

Single-use tubing may present a potential biohazard after use. Handle and dispose of the tubing in accordance with accepted medical practice, facility procedures, and applicable local, state, and federal regulations.

Maintenance

No scheduled maintenance is required.

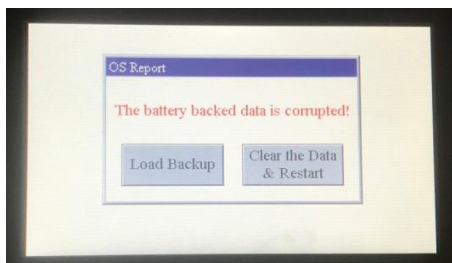
NOTE: Following a period of inactivity of 30 days or longer connect the HVP Auto-Graft Infuser to electrical power and leaving the unit powered ON for at least 48 hours before use.

WARNING: Do not modify or alter the HVP System. Servicing or modifications must be performed only by authorized personnel.

Troubleshooting

PROGRAMMING REPAIR PROCEDURE

1) If you are at this screen, press the button “Clear the Data & Restart”



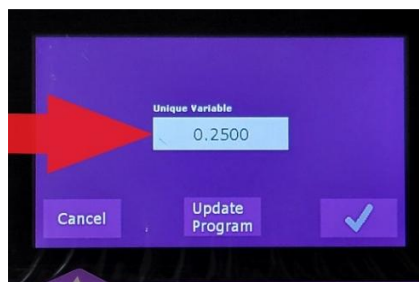
2) From the Main Screen, press the 'i' icon in the bottom left corner.
(don't have to wait for 'Please Wait' to clear)



3) Press the 'Defaults' button and a keypad will pop up. Type the password '88888888' (eight eights) and press 'Ent'.



4) Touch the box under 'Unique Variable', a keypad will open. Then check the blue tag on the back of the HVP™. There is a 4-digit decimal. Type that number into this keypad and press 'Ent', then press the check mark. **IMPORTANT: Make sure you type the period before the number**



5) Press the Power Off button in the top left of the screen, wait for the window that says "The HMI has been stopped. It is safe now to turn off the power and then switch OFF the HVP from the back.



6) Attempt operating the HVP using the footswitch. It will be working correctly now. Change to the desired speed and pressure settings.

PRESSURE LIMIT

If the system seems to be hitting the pressure limit and reversing too often:

- Reduce the pump speed. Pumping too fast can build up excessive pressure.
- Make sure the tubing is properly installed into the pump head and sensor. Be sure to follow the correct procedures for zeroing the sensor.
- Make sure there is no pressure in the tubing when zeroing.
- Increase the pressure limit. Transferring adipose tissue at 75 rpm can require a normal working pressure up to 5 or 6 psig to pump the tissue from the cannula.
- Reduce interstitial pressure. Pull the cannula back toward the insertion site, change plane or angle and begin pumping again. Repeat as necessary.
- Turn off the unit and remove the tubing from the pump head and sensor. Turn the unit back on and re-install the tubing following the correct procedures.

CIRCUIT BREAKER

To protect the equipment and reduce shock hazard, a resettable circuit breaker is installed on the back of the unit. This is integrated into the ON/OFF switch and is labeled as "RESET". If there is a voltage surge or an over-current situation, the circuit breaker will trip and switch the unit OFF. To reset

the HVP™, turn the unit back ON with the switch in the back. **If the unit fails to start**, the unit may require a cool-down period, or technical repairs may be required.



Symbols Used

Symbol	Title	Description	Standard
	Manufacturer	Indicates the medical device manufacturer	ISO 15223-1:2021, 5.1.1
	Catalog number	Indicates the manufacturer's catalog number so that the medical device can be identified	ISO 15223-1:2021, 5.1.6
	Serial number	Indicates the manufacturer's serial number so that a specific medical device can be identified	ISO 15223-1:2021, 5.1.7
	Batch Code	Indicates the manufacturer's batch code so that the batch or lot can be identified	ISO 15223-1:2021, 5.1.5
	Consult instructions for use or consult electronic instructions for use	Indicates the need for the user to consult the instructions for use	ISO 15223-1:2021, 5.4.3
	Use-by date	Indicates the date after which the medical device is not to be used	ISO 15223-1:2021, 5.1.4
	Medical device	Indicates the item is a medical device	ISO 15223-1:2021, 5.7.7

Symbol	Title	Description	Standard
	Prescription Only	Federal law restricts this device to sale by or on the order of a physician	FDA-recognized prescription-device designation under 21 CFR 801.109
	Unique Device Identifier	Indicates a carrier that contains unique device identifier information	ISO 15223-1:2021, 5.7.10
	Do not re-use	Indicates a medical device that is intended for one single use only	ISO 15223-1:2021, 5.4.2
	Do not use if package is damaged and consult instructions for use	Indicates that a medical device that should not be used if the package has been damaged or opened and that the user should consult the instructions for use for additional information	ISO 15223-1:2021, 5.2.8
QTY	Quantity	Indicates the quantity of product contained in the labeled container.	None

Warranty

- The HVP System is warranted for one (1) year for parts and labor from the date of shipment.
- Unauthorized handling, modification, or servicing of the HVP System may void the warranty.
- All returns require prior authorization from Wells Johnson Customer Service.

Customer Service and Technical Support

Report any product malfunction, adverse event, or complaint to Wells Johnson Customer Service or Technical Support:

Phone: +1 520-298-6069 or 800-528-1597

Email: customerservice@wellsgrp.com



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