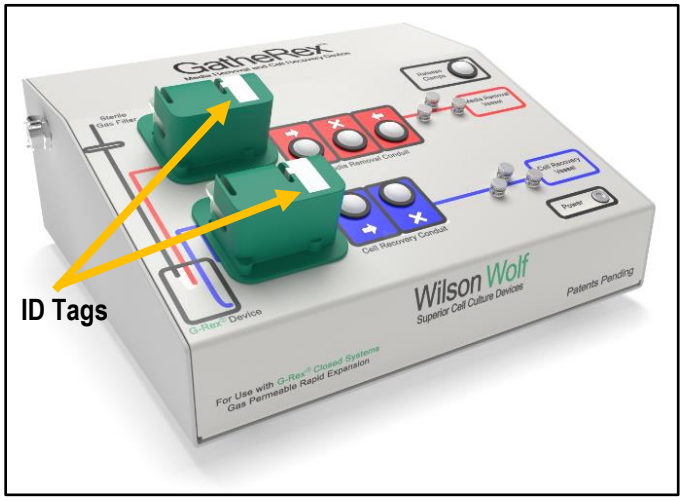
WILSONWOLF

GatheREX™ Cell Harvest Pump

REF Catalog Number **80000E / 80000Z**

- User's Manual -



PRODUCT DESCRIPTION

The GatheRex™ Cell Harvest Pump is a liquid handling device designed to work with closed system cell culture devices. The GatheRex connects to closed system devices and uses a low pressure forced air mechanism to remove media, concentrate cells and minimize storage and/or downstream processing. An internal air pump pressurizes the system by pumping air through the sterile vent filter on the cell culture device. When pressurized, excess media, or a cell fraction, is forced out of the device through the tubing assembly then into a collection receptacle.

Model 80000E is designated by **white** ID tags on the tubing pinch clamps. This version is compatible with small diameter tubing (0.160" OD; blood transfer bag style) for both media removal and cell recovery.

Model 80000Z is designated by **black** ID tags on the tubing pinch clamps. This version is compatible with large diameter tubing (0.375" OD) for media removal and small diameter tubing (0.160" OD blood transfer bag style) for cell recovery.

GatheRex Model	ID Tag Color	Media Removal - Tubing Diameter / Slot Width	Cell Recovery - Tubing Diameter / Slot Width
80000E	White	0.160 inch	0.160 inch
80000Z	Black	0.375 inch	0.160 inch

WARNINGS

1. The GatheRex is NOT a peristaltic pump. It is a positive pressure air pump regulated to reach and maintain a set pressure within a closed system G-Rex cell culture product in order to move cell culture media and cells out.
2. DO NOT consider these Instructions to be a comprehensive reference for the application of use in all cell culture protocols.
3. DO NOT use if there is damage to the product or packaging that may have occurred during shipping or storage.
4. DO NOT open equipment cabinet. Danger of electrical shock.

PRECAUTIONS

1. DO NOT sterilize this product. Equipment may be damaged or distorted.
2. DO NOT immerse or overly wet product during cleaning.
3. DO NOT attach the GatheRex to any external compressed gas source.
4. DO NOT position the equipment too closely to side wall or equipment on its left or right. Allow space to left and right of GatheRex.

CONTENTS

1. GatheRex Device
2. Tubing Assembly - for Low Pressure Outlet Port
3. Power Cord

ELECTRICAL REQUIREMENTS

1. Input: 100-240VAC, ~1.3A, 50-60Hz, Single Phase

   Fuse Type: 5ET 3.15-R, Cartridge, Time Delay, 3.15A, 250 V, 5mm x 20mm (0.2" x 0.79"), 5ET Series

   Detachable Power Cord: C13, 18AWG, 10A minimum, Grounded (3 Prong), UL 62, CSA-C22.2 No. 49

   IEC / UL: 61010-1 edition 3.1 and 61326-1:2012

LOW PRESSURE OUTPUT

1. Gauge Pressure: 120 – 180 mmHg (2.32 – 3.48 psi)
   No adjustments for altitude are needed.
2. Flow Rate: Minimum 5 mL/sec fluid transfer rate from G-Rex M-CS

ENVIRONMENTAL CONDITIONS

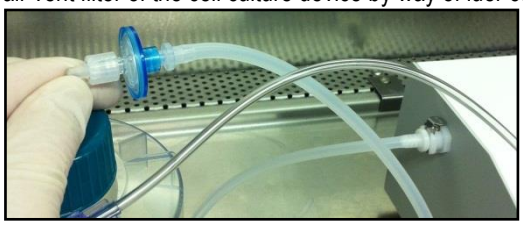
1. Temperature: 15°C to 35°C (59-95°F)
2. Humidity: ≤ 95% Relative Humidity
3. Altitude: < 2,000 meters (6,561 feet)

SET UP

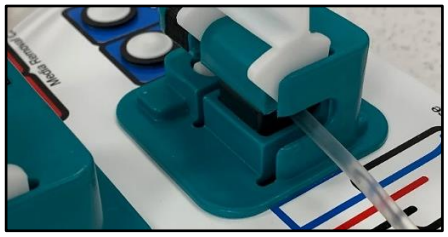
1. Set the GatheRex on a stable, level surface and plug-in power cord.

2. Place the closed system cell culture device to the left of the GatheRex.
3. Gather your desired culture media removal and cell recovery collection vessels.
    a. Using a sterile tube welder, connect your collection vessels to the proper tubing of the cell culture device.
    b. Alternatively, use aseptic technique and the luer or quick connect fittings to dock your collection vessels to the proper tubing of the cell culture device.
4. Attach the provided Tubing Assembly to the GatheRex compressed air outlet port. Note that the GatheRex is the source of compressed air.

5. Fasten the other end of the Tubing Assembly to the outlet of the sterile air vent filter of the cell culture device by way of luer connection.



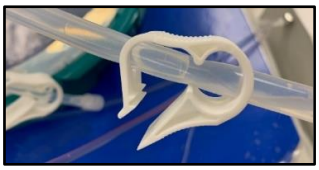
6. Position the Media Removal tubing into the GatheRex red clamp and the Cell Recovery tubing into the blue clamp.
    a. Open the covers of the pinch valve/sensor.
    b. Seat the tubing along the channel as shown.



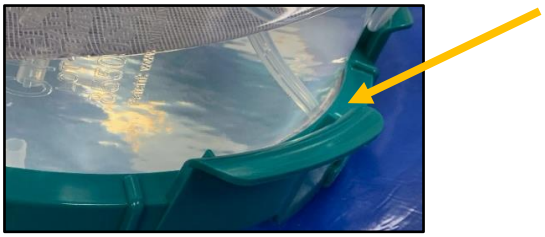
    c. Close the covers.
    d. Run the tubing through the holding pins to keep them in position.
        i. Note: Large diameter C-Flex tubing will not fit into the holding pins.
    e. Place the collection vessels to the right of the GatheRex.
7. Turn on the GatheRex by flipping the switch by the power cord plug-in.

EXAMPLE OF USE – Media Reduction and Cell Harvesting from a closed system G-Rex device

1. Ensure the pinch clamps for the selected fluid pathways are open to the media and cell collection bags.



2. Press the RED Right Arrow (→) to begin Media Removal (Reduction) through the red striped tubing or the large diameter C-Flex tubing. The headspace of a closed system G-Rex device will be pressurized moving waste media to the collection bag. This will continue until the cell culture media level reaches the end of the internal media reduction line (~1 cm from bottom). Once media removal from the G-Rex device has been achieved, media flow will stop automatically via a sensor located within the red tubing clamp.
3. Swirl the remaining volume in the G-Rex device to resuspend the cells existing on the gas permeable membrane. Tilt the device to allow the fluid to collect/pool where the internal harvest line touches the base/side of the vessel.



4. With G-Rex still tilted, press the BLUE Right Arrow (→) to begin Cell Recovery (Harvest). The G-Rex will be pressurized moving the cell population and all remaining fluid into a Cell Harvest Bag. Media flow will stop automatically via a sensor located within the blue tubing clamp.
5. **Optional Steps** to harvest any potential remaining cells in the G-Rex cell culture device by way of a rinse procedure:
    a. Partially refill the G-Rex with Media from the Red Removal Circuit by pressing the RED Left Arrow (←) button. This releases the clamp for the red striped removal conduit, allowing fluid to be gravity fed or forced back into the G-Rex by squeezing the waste media bag manually or with a pressure sleeve.
    b. When the desired volume of media has been moved back into the G-Rex, press the RED STOP (**X**) button to re-clamp the red striped removal conduit.
    c. Swirl the fluid within the G-Rex to capture and resuspend any remaining cells.
    d. With device tilted towards the internal harvest line, press the BLUE Right Arrow (→) button for cell harvest. Media flow will stop automatically via a sensor located within the blue tubing clamp.
6. Clamp the reduction line and the harvest line to seal the waste media collection bag and cell collection bag.
        a. Alternatively, simply seal the collection bags with a sterile tube sealer.

7. Press the release clamps on GatheRex Pump and remove the tubing.
8. Seal the collection bags with a sterile tube sealer.
9. Discard the G-Rex vessel and the waste culture media.
10. See examples of setup with G-Rex at end of this document.

MAINTENANCE AND SERVICE

Maintenance – There are no maintenance items on the GatheRex other than periodically wiping down of the exterior of the device with 70/30 IPA. Use care not to over saturate or immerse device.

If the power cord becomes damaged contact Wilson Wolf for a replacement.

All repairs and service must be performed by Wilson Wolf.

Air Pressure (verification) – Note that the internal pressure regulator cannot be adjusted (i.e., output pressure can only be verified). To measure pressure output, connect a calibrated pressure gauge to compressed air outlet port and tubing. See Appendix at the end of this document for Supplemental Instructions.

Fuse Replacement – Unplug cord from wall outlet. Remove Cord from Power Module on back of GatheRex. Pry open top of access door of Power Module with flat screwdriver. Use flat screwdriver to pry side of Fuse Carrier for removal. Inspect and replace fuse (see page 1 for fuse type). Re-insert Fuse Module into GatheRex with appropriate voltage positioned at the top (i.e., 115V or 230V). Close Power Module door and verify the desired voltage is shown through window in Power Module door. Re-install Power Cord and plug into wall outlet.

TROUBLESHOOTING

If Flashing Red Power LED - If system is unable to build pressure (i.e., system leak) the GatheRex will run for approximately 33 seconds and then stop the air pump. The red power LED will flash red. To reset, turn device off and then back on again. Fix system leak prior to restarting cycle.

If GatheRex Air Pump will not run longer than 6 seconds – Verify that tubing is fully seated in pinch clamp and that fluid fills tubing within 6 seconds. If air is present in tubing the pump will stop.

If Green Power LED will not light - Confirm outlet has power. Verify that power cable is fully seated in outlet and back of device. Confirm GatheRex power switch is turned ON. Inspect and/or replace Fuse per Maintenance and Service instructions.

MANUFACTURED BY

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Patent: www.wilsonwolf.com/patents
G-Rex® is a registered trademark of Wilson Wolf Corporation
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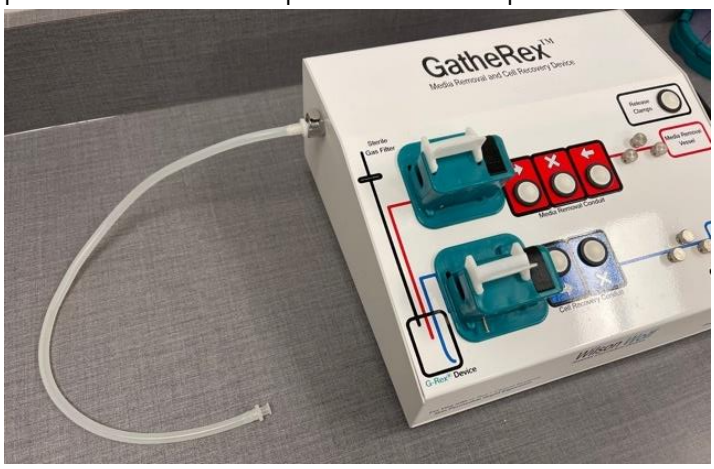
EXAMPLE OF SETUP - GatheRex 80000E and G-Rex100M-CS:

EXAMPLE OF SETUP - GatheRex 80000Z and G-Rex500M-CS:

Appendix:

Supplemental Instructions for Pressure Verification (optional steps):

1) Start with Tubing Assembly attached to GatheRex as shown per the IFU. This tubing assembly is already provided with GatheRex product. Please note that pressure verification prior to each use is optional and should not be considered mandatory.

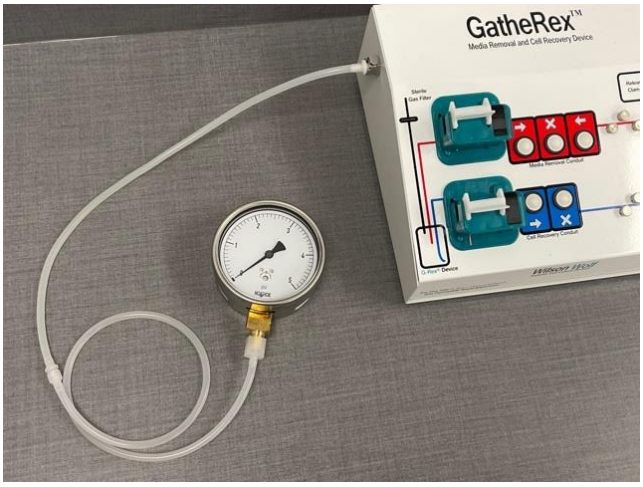


GatheRex shown with Tubing Assembly attached

2) Create a Pressure Verification Gauge Assembly. An example is shown below with the following components.
   a. **0-5 psi analog gauge** shown (a digital gauge will also work, but the values could bounce around due to pressure pulses created by the internal GatheRex pump).
   b. **¼" OD x 1/8" ID Silicone Tubing, 24" length** (shorter tubing length could increase pressure reading bounce and longer tubing length could reduce bounce). If too much bounce is observed, you may consider adding an inline filter to further increase the internal volume of the tubing assembly.
   c. **Male Luer Connector with 1/8" Barbed** (this luer will connect to the provided GatheRex Tubing Assemblies female luer connector.
   d. **¼" NPT Female connector to 1/8" ID Barbed Connector** (note that the NPT size may be different for your specific pressure gauge).

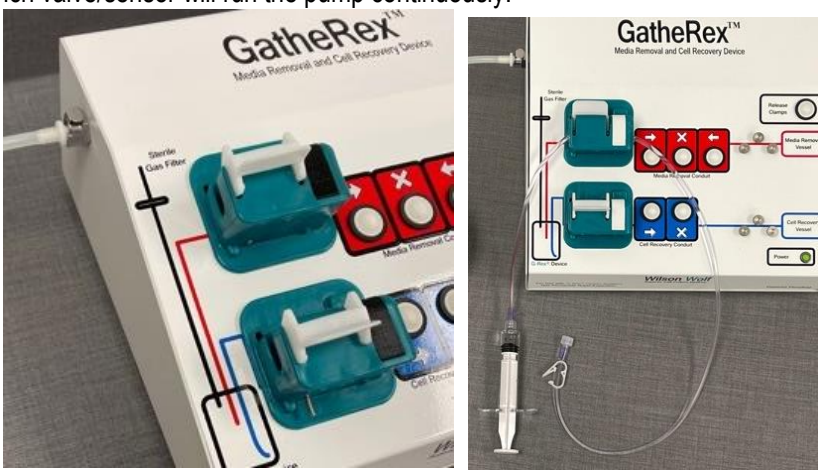
Example of pressure verification gauge assembly

3) Connect the gauge assembly to the GatheRex Tubing Assembly as shown



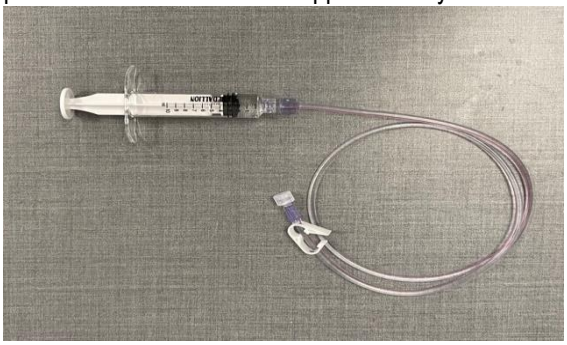
GatheRex with Pressure Verification Gauge Assembly

4) Press either the Red or Blue → button to initiate air pump. This will immediately begin to register a pressure reading on the gauge. Verify that the reading is between 120-180mmHg (2.32 – 3.48 psi). Note that after approximately 6 seconds the GatheRex pump will stop (time out) due to the pinch valve/sensor not sensing a liquid filled tube. The pressure in the tubing assembly will automatically vent after the pump stops. Depressing the Red or Blue → key will initiate another cycle if desired. If more time is needed to verify the pressure reading a liquid filled tube assembly will need created to be installed into the pinch clamp. Utilizing a fluid filled tube in the pinch valve/sensor will run the pump continuously.



Pinch Valve/Sensor shown empty (left) and with fluid filled tubing (right)

5) Example of optional fluid filled tubing assembly
   a. **10mL Syringe** (or larger)
   b. Wilson Wolf Replacement Tubing Assembly for G-Rex 500M-CS (part number **AY11-00093-1**) which includes luer cap and pinch valve. PVC tube has approximately 0.160" OD.



Fluid Filled Tubing Assembly