MAKERS OF RESPIRATORY VALVES SINCE 1938
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Data Sheet and Instructions for Use...

NON-DIFFUSING
GAS COLLECTION BAGS

Series 6000, 6005, 6015, 6030, 6060, 6100, 6170

Product Features

- Six standard bag sizes and custom sizes available on request.
- Multi-layer polyethylene thermoplastic laminate with Aluminum Foil center layer.
- Designed to eliminate or absolutely minimize permeation in and out of the bag.
- Aluminum Foil layer functions as a total barrier.
- Inner most inert layer of polyethylene prevents chemical reactions with gas contents and will not absorb or adsorb to any degree.
- Excellent Oxygen and Moisture Vapor barrier material.
- Bag mounted 35mm ID Oring Primary Bag Adapter (PBA) with two Female Luer sampling ports. PBA is the connection to the breathing system. Custom adapters available.
- Bag mounted On-Off 6.3mm Hose Barb Valve for filling and evacuation.
- Grommets installed for hanging the bag assembly.
- Bag laminate replacement and rebuild program available.

Specifications

Materials	
Bag Laminate	5 Layer Polyethylene (PE) with Aluminum (AL) Foil Center Layer
Primary Bag Adapter (PBA)	Thermoplastic Polyester (PET)
On-Off Hose Barb Valve	Thermoplastic Polycarbonate (PC)
Orings & Gaskets	Neoprene (Polychloroprene) synthetic rubber
Washers	Thermoplastic Polyamide (PA, nylon)
Sampling Ports	Thermoplastic Polyamide (PA, nylon)
Grommets	Brass
Tubing	Silicone Rubber

General Information

- **Intended Use:** Single patient rebreathing studies or for multi-use gas collection applications. The Hans Rudolph Non-Diffusing Gas Bags are designed for respiratory studies that require collection of gases or delivery of gases that depend on their accuracy on the stability of the gas concentration in the collection bag. There is no validated method to disinfect the interior of the bag so the application is defined as single patient use for rebreathing studies or multi-use when used for gas delivery or collection purposes.
- **Indications & Environment for use:** For use with general patient population in pulmonary function testing, exercise testing, challenge testing and respiratory research in hospitals and other clinical settings by individuals that have at least minimal instructions or training on the use of the bag as well as the devices to which the bags are intended to connect.
- **Warning!**
  - Do Not use for rebreathing applications unless specified as single patient use
  - There is no validated process to disinfect or sterilize the interior of this bag
  - Do Not over or under inflate while patient is using as reservoir
- **Caution!**
  - Do Not pressurize the contents of this bag
  - Do Not disassemble this product
  - Packaged Clean, nonsterile
  - Operational Temperature & Humidity: 5-40º C, 0-95% RH
  - Federal law restricts this device to sale by or on the order of a physician
- **Packaged:** Individually packaged in corrugate container

Physical Characteristics

- **Primary Bag Adapter (PBA):** 35mm ID Oring (2) Slip-Sealing fit for mating 35mm OD ports. There are two Female Luer sampling ports, one samples directly at the PBA and the other samples from the center location of the bag assembly through a connecting 1.6mm ID tube.
- **On-Off Hose Barb Valve:** Barb end threads in and out of valve body for On (open) and Off (closed) control. Barb end for 6.3mm ID tubing connection can be used for filling or evacuation of the bag contents.
- **Bag Laminate:** 5 layer inert polyethylene thermoplastic laminate with an Aluminum Foil center layer, 4 mils nominal thickness, excellent oxygen and moisture vapor barrier, heat sealable. Designed as a barrier to permeation of gases in and out of the bag. Inert inner most layer (PE) reduces potential for chemical reaction with the gas contents.

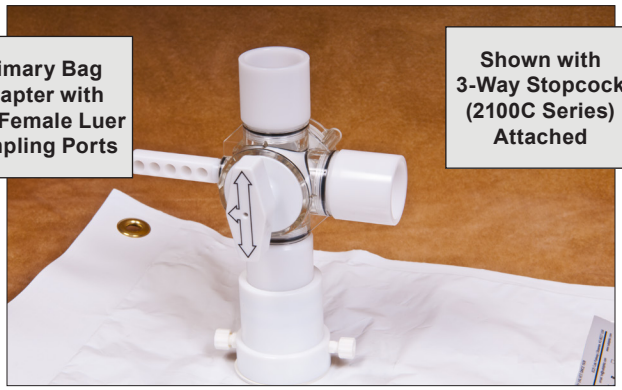
Order Information

Description	Listed in order by Bag Functional Volume of the Standard Sizes					
Part Number Assembly	**112115**	**112110**	**112113**	**112376**	**112377**	**112449**
Series #	6005	6015	6030	6060	6100	6170
Functional Volume (Liters)	5	15	30	60	100	170
Overall Size (cm)	25 x 71	41 x 69	61 x 71	61 x 86	81 x 86	81 x 145
Weight (gm)	164	220	285	295	340	482
Tube (666216) Length (cm)	38.1	38.1	48.3	55.9	61.1	88.9

Replacement Components

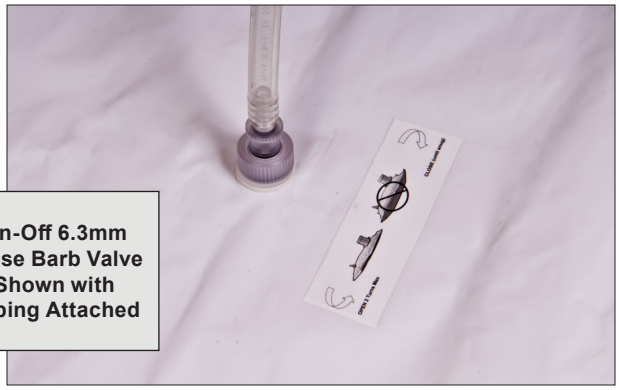
1. **171185:** Female Luer with opposite end Hose Barb for 1.6mm ID tubing (666216). Female Luer is mounted in PBA with internal 1.6mm tubing connected for gas sampling in center of bag.
2. **666216:** Tubing 1.6mm ID flexible Silicone Rubber. Connects to Female Luer 171185 on PBA for gas sampling in center of bag. Tubing Lengths for the different Bag volumes are indicated in the table above.
3. **171159:** Female Luer mounted in PBA for sampling at the PBA.

5 Liter Non-Diffusing Gas Bag



Primary Bag Adapter with Two Female Luer Sampling Ports

Shown with 3-Way Stopcock (2100C Series) Attached



On-Off 6.3mm Hose Barb Valve Shown with Tubing Attached

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Service Life
When handled properly and according to instructions provided for multi-use gas collection applications the bag assembly should function within specifications for 100 reuses. If used for rebreathing studies then this bag is specified as single patient use.

Risks
The risk of any harm to patients, clinicians, and bystanders caused by the use of these NDGBs is remote. Steps have been taken in their design to greatly reduce the probability of occurrence of these existing potential hazards:

1. Bag leakage or diffusion
2. Bag contaminants (particulates or microbes)
3. Biosensitivity to NDGB materials
4. Interference with tidal volume efforts

Ambient Conditions
1. Temperature: 5ºC to 40ºC,
2. Relative Humidity 0-95% RH (Non Condensing)

Recommendations for Disposal
Treat as conventional solid waste in accordance with local and federal regulations.

Bag ONLY Replacement & Rebuild instructions
1. Contact HRI for Return Authorization Number (RAN) for return of the Primary Bag Adapter, On-Off Hose Barb Valve, and Main Bag Label of your present bag.
2. Cut off the Primary Bag Adapter, On-Off Valve and Main Label from your present bag and send to HRI.
3. Dispose of the used Bag material
4. HRI will confirm the HRI part number for the appropriate bag replacement/ rebuild when the RAN is established for the returned components. HRI will require a Purchase Order in order to process the bag replacement and rebuild.

Cleaning and Maintenance
The Non-Diffusing Gas Collection Bags fall into the semi-critical device category based on potential risk of infection if used for rebreathing studies on more than one patient. Disinfection or Sterilization methods are not validated for the interior of this bag. This bag if used for rebreathing studies should be specified as single patient use or as multi-use if used for gas collection purpose only.

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