

# Instructions for use: Axess™ Scavenging Circuits



Axess™ RFS™ Scavenging Circuits (52006, 53006)

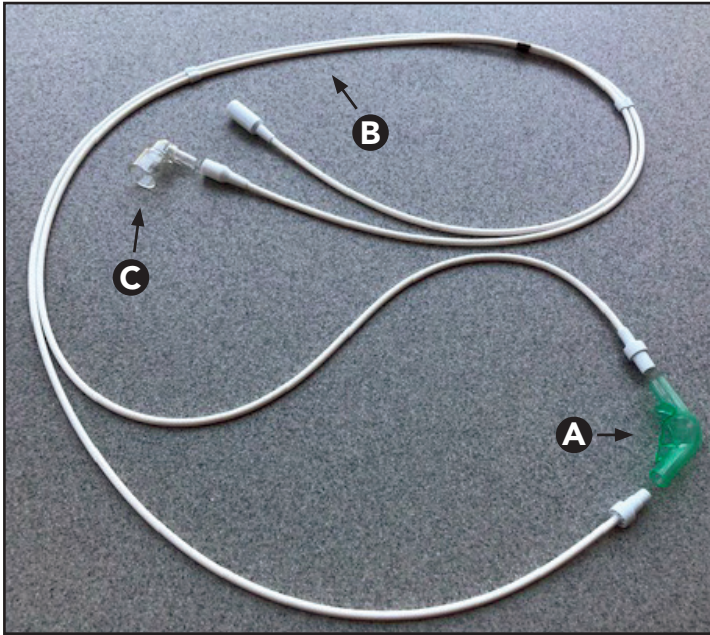


Figure 1



Figure 2

**A** 53034-9, 53034-12, 53034-16, 53035-9, 53035-12, 53035-16, 53037-9, 53037-12, 53037-16, **B** 28624-FRU, **C** 28417-FRU, **CC** 28463-FRU, **DD** 28559-FRU

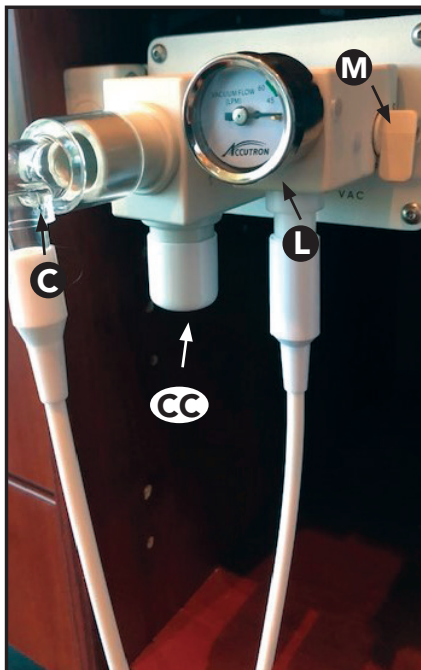


Figure 3

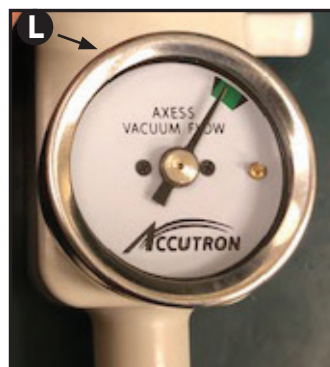


Figure 4

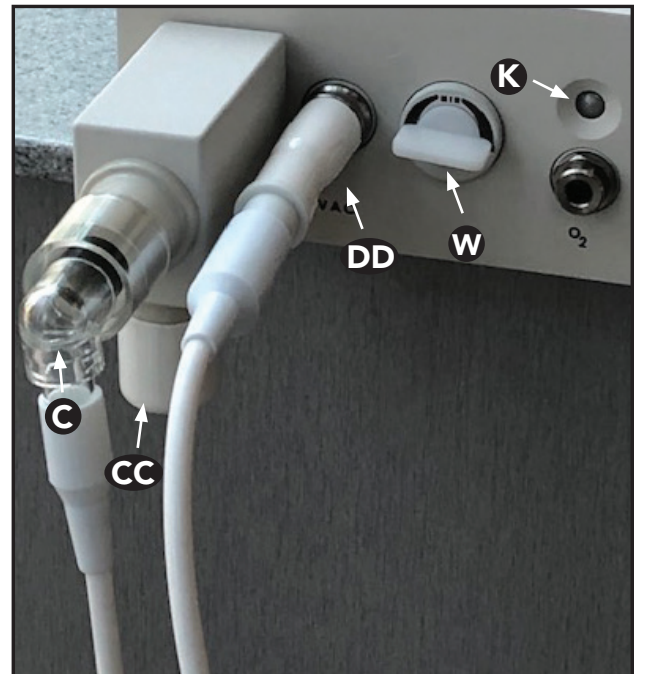


Figure 5

Axess™ Inline Circuits (52005, 53005)

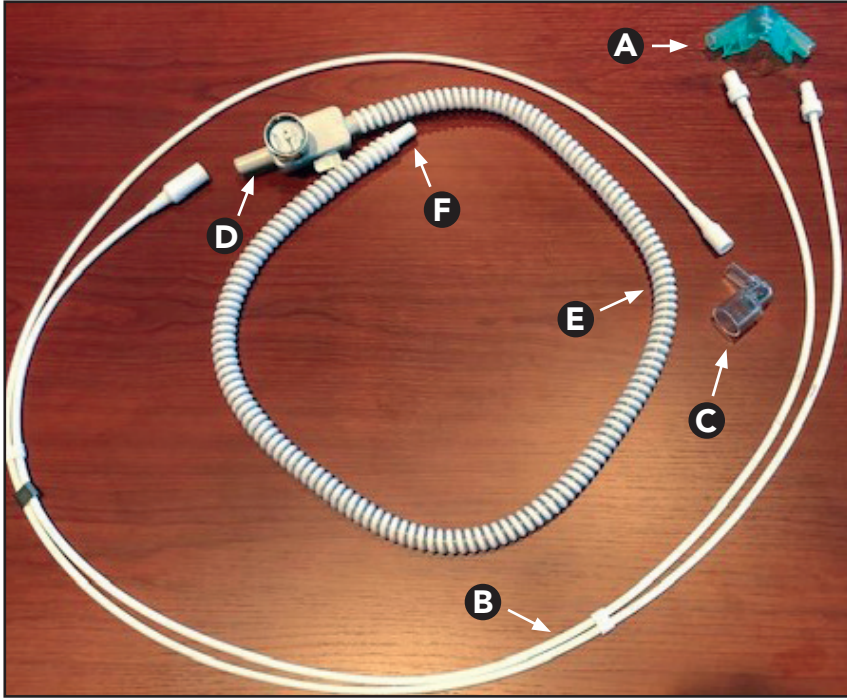


Figure 6

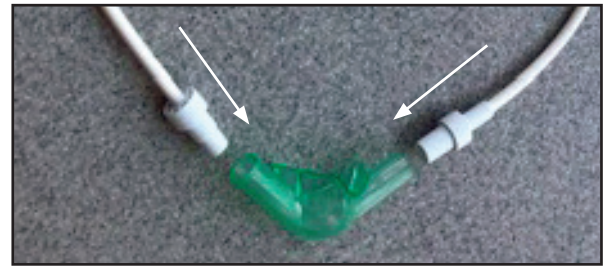


Figure 7

- A** 53034-9, 53034-12, 53034-16, 53035-9, 53035-12, 53035-16, 53037-9, 53037-12, 53037-16, **DB** 28625-FRU, **C** 28417-FRU, **D** 28530-FRU, **E** 25591
- F** 26254

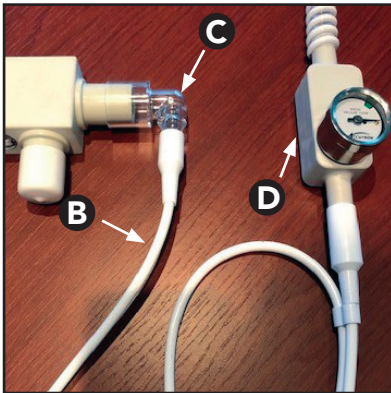


Figure 8

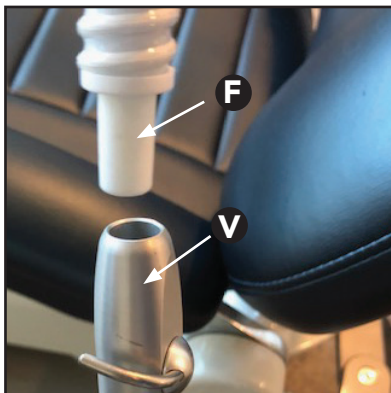


Figure 9



Figure 10

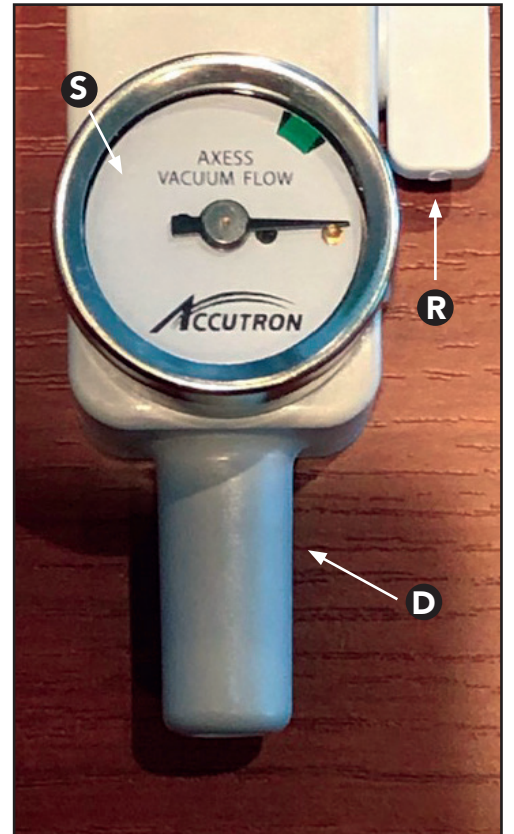









Figure 11

## System Setup

1. Remove the reservoir bag from the flowmeter and install the plug  per Figures 3, 5 and 8. Note: Plug will pop off if the gas flow line is kinked or blocked.
2. Install the mask on the circuit per Figure 7. It does not matter which line goes into which side of the mask.
3. Connect right angle adapter  to bagtee outspout per Figures 3, 5 and 8.
4. **RFS™ Scavenging Circuits:** Connect the Axess™ RFS Circuit to the RFS Outlet per Figure 3. Fittings are sized to only fit one way.  
**Accu-Vac™ Vacuum Controller:** Connect the Axess RFS Circuit to Accu-vac Controller per Figure 5. Note that the Accuvac Adapter  (28559-FRU) is required. Do not use with standard fitting.  
**In-line:** Connect the Axess In-line Circuit per Figure 8. Note: the vacuum connection must be made on the gauge side.  
Connect the spiral vacuum tube from the controller to a vacuum source in the operatory. Some options are shown in Figures 9 and 10.  
Caution: Only one vacuum controller can be used at one time. Do not connect an In-line controller to the RFS Circuit or Accu-vac Controller.
5. Place the circuit and mask on the patient per Figure 2 making sure that the slide is snug under the chin to minimize mask movement.

## Scavenging Vacuum Operation

6. **RFS™ Scavenging Circuits:** Adjust the flow on the RFS Vacuum Controller using knob  so that the needle is in the green zone of the gauge  per Figure 4.  
**Accu-Vac™ Vacuum Controller:** Adjust the flow on the Accu-vac Controller to fully open (horizontal) using knob  per Figure 5. Disregard light colors as they do not function with Axess™ Circuits.  
**In-line:** Adjust the flow on the In-line controller using knob  until the needle is in the green zone per Figure 4.  
It is recommended that the gauge is checked periodically during the procedure as facility vacuum pressure can change from time to time.

## Gas Flow Operation

**Digital Ultra™ Flowmeters:** Turn on the unit. It should start at TOTAL FLOW of 5 lpm with 0% N<sub>2</sub>O. Gradually increase TOTAL FLOW and %N<sub>2</sub>O until desired effect is reached. Use the Titration method when adding N<sub>2</sub>O to avoid negative patient reactions. See note 8 below. At the end of the procedure, reduce %N<sub>2</sub>O to 0 for five minutes.

**Ultra PC™ Flowmeters:** Turn the unit on and adjust the Total Flow to 5 lpm. Gradually increase TOTAL FLOW and %N<sub>2</sub>O until desired effect is reached. Use the Titration method when adding N<sub>2</sub>O to avoid negative patient reactions. See Note 8 below. At the end of the procedure, reduce %N<sub>2</sub>O to 0, increase Total Flow (oxygen) to 9 lpm.

**Ultra DC™ Flowmeters:** Turn unit on. O<sub>2</sub> flow should start at 3 lpm. Gradually increase N<sub>2</sub>O flow using the Titration method until desired effect is reached. If needed increase O<sub>2</sub> flow. See note 8 below. At the end of the procedure, reduce N<sub>2</sub>O flow to 0 and increase O<sub>2</sub> flow to 9 lpm.

NOTE: Axess™ Systems do not operate in the same fashion as standard reservoir bag systems because of the small tubing and lack of bag. A reservoir bag system can provide up to three times the amount of gas flow during inhalation as the bagless system. Because of this, the flows must be higher and room air must often be pulled in through special ports to compensate. Whenever room air is pulled into the gas flow, the N<sub>2</sub>O is diluted. To achieve the same effect on most patients, higher flows and max N<sub>2</sub>O percentages must often be used. As a precaution, the max %N<sub>2</sub>O from the flowmeter is limited to 70% to keep the N<sub>2</sub>O concentration at a safe, reasonable level for patients of all ages. The scavenging vacuum flow is capable of removing these flows so that the staff remains safe.

*Axess™ Circuits can be reprocessed per 26613 or 26613-INT. Do not exceed 134° C for 4 minutes.  
UDI Product Tag included for product traceability purposes.*

## Indications for use:

To be used in nitrous oxide/oxygen sedation systems for delivering to a patient a mixture of nitrous oxide and oxygen gases with a maximum nitrous oxide concentration of 70%.

Axess™ Nasal Masks are single use only.

## Contraindications:

Contraindications for use of nitrous oxide/oxygen inhalation may include patients with:

- Some chronic obstructive pulmonary diseases
- Severe emotional disturbances or drug-related dependencies
- First trimester of pregnancy
- Treatment with bleomycin sulfate
- Methylenetetrahydrofolate reductase deficiency
- Severe asthma

Whenever possible, appropriate medical specialists should be consulted before administering analgesic/anxiolytic agents to patients with significant underlying medical conditions (e.g., severe obstructive pulmonary disease, congestive heart failure, sickle cell disease, acute otitis media, recent tympanic membrane graft, acute severe head injury.<sup>1</sup> Operator must review patient history with regard to these health issues.

<sup>1</sup> American Academy of Pediatric Dentistry. Clinical Guidelines: Guidelines on Use of Nitrous Oxide for Pediatric Dental Patients. *Pediatr Dent* 2009;31(6):148-151. Available at: "<http://www.aapd.org/media/policies.asp>". Accessed February 23, 2010.

Do not use this device for the administration of general anesthesia or as part of, or in conjunction with, a general anesthesia administration system.

## Warnings:

To be used only by a licensed and trained professional in the use of nitrous oxide, using titration method. Patient should always be closely monitored during nitrous oxide use. If patient has an adverse reaction, reduce or stop the flow of nitrous oxide as needed.

The O<sub>2</sub> flush button can be used to rapidly purge the lines of N<sub>2</sub>O. If patient does not show signs of quick recovery, remove nasal hood and treat with pure oxygen from either the O<sub>2</sub> resuscitator fitting or an auxiliary oxygen tank using a demand valve, oxygen assisted manual resuscitator, or equivalent. Call for emergency assistance if rapid response is not achieved.

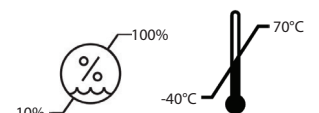
## Cautions:

Federal (U.S.) law restricts this device to sale by or on order of a dentist or physician.

**BROWARD A&C**  
MEDICAL GAS SPECIALISTS

954-725-1470 Ext. 403

CE MD  
0482



No expiration date required.  
Not made with natural latex rubber.

Made in USA

Part No. 28904 / REV C - 03/2021

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	Consult instructions for use	Gebrauchsanweisung lesen	Consulte as instruções de utilização	Consulter le mode d'emploi	Raadpleeg gebruiksinstructies	Consulte las instrucciones de uso	См. инструкцию по использованию	Consultare le istruzioni per l'uso	Patrz instrukcja użycia
	Caution	Achtung	Precaução	Avertissement	Opgelet	Precaución	Внимание!	Attenzione	Przeostroga
	Single use only	Nur zum Einmalgebrauch	Utilização única	Usage unique seulement	Uitsluitend voor eenmalig gebruik	De un solo uso	Только для одноразового использования	Monouso	Wyłącznie do użytku jednorazowego
	Manufacturing lot number	Chargennummer	Número de lote de fabrico	Numéro de lot de fabrication	Partijnummer productie	Número de lote de fabricación	Номер производственной партии	Codice del lotto	Numer partii produkcyjnej
	Prescription only (USA)	Verschreibungspflichtig (USA)	Apenas com prescrição médica (EUA)	Sur ordonnance uniquement (États-Unis)	Alleen op voorschrift (VS)	Sujeto a prescripción médica (EE. UU.)	Только по рецепту (США)	Solo su prescrizione (USA)	Wyłącznie na receptę (USA)
 yyyy/mm	Date of manufacture	Herstellungsdatum	Data de fabrico	Date de fabrication	Productiedatum	Fecha de fabricación	Дата производства	Data di fabbricazione	Data produkcji
	Manufacturer	Hersteller	Fabricante	Fabricant	Producent	Fabricante	Производитель	Fabbricante	Producent
	European Representative	EU-Bevollmächtigter	Representante Europeu	Représentant européen	Europese vertegenwoordiger	Representante en Europa	Представитель в Европе	Rappresentante autorizzato nella Comunità Europea	Przedstawiciel w Europie
 0482	Approved for European Union, notified body	In der EU zugelassen, benannte Stelle	Aprovado para a União Europeia, organismo notificado	Approuvé pour l'Union européenne, organisme notifié	Goedgekeurd voor Europese Unie, erkende instantie	Aprobado por la Unión Europea, organismo notificado	Одобрено для применения на территории Европейского Союза, уполномоченный орган	Approvato nell'Unione Europea, organismo notificato	Produkt dopuszczony do stosowania w Unii Europejskiej, jednostka notyfikowana
	Catalog number	Bestellnummer	Número do catálogo	Référence catalogue	Catalogusnummer	Número de catálogo	Номер по каталогу	Numero di catalogo	Numer katalogowy
	Medical Device	Medizinprodukt	Dispositivo médico	Dispositif médical	Medisch apparaat	Producto sanitario	Медицинское устройство	Dispositivo medico	Urządzenie medyczne
	Unique Device Identifier	Eindeutige Produktkennung	Identificação única do dispositivo	Identification Unique du Dispositif	Unieke apparaatidentificatie	Identificador de producto único	Уникальный идентификатор устройства	Identificativo unico del dispositivo	Unikatowy identyfikator wyrobu
	Keep away from sunlight	Vor Sonnenlicht schützen	Mantener afastado da luz solar	Éviter toute exposition à la lumière du soleil	Uit de buurt van zonlicht houden	Manténgase lejos de la luz solar	Хранить в защищенном от света месте	Tenere lontano dalla luce	Chronić przed światłem słonecznym