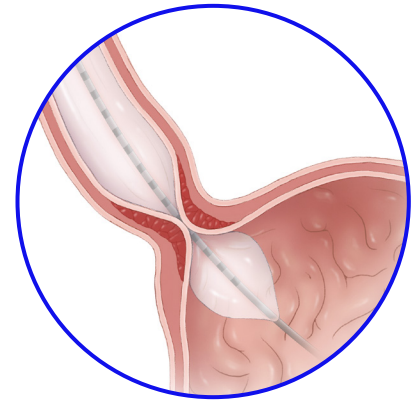


# Standard protocol quick reference guide<sup>1,2</sup>



### EF-322N catheter<sup>2,3</sup>

1. Insert catheter with endoscopic visualization and advance until 2-3 sensors are positioned distal to the EGJ.
2. Remove endoscope.
3. Press **"Inflate"** and allow the balloon to fill to 30 ml. Press **"Stop"** when the balloon has reached 30mL volume.
4. If needed, reposition the catheter balloon across the waist-like constriction of the EGJ.
5. Initiate the standard protocol by pressing the **"Inflate"** button. The balloon will be automatically inflated in a stepwise approach to a pre-determined volume each time the **"Inflate"** button is pressed. After each fill, wait 15 seconds for the EGJ to stabilize.  
  
Fill volumes of the standard protocol are 40, 50, 60, and 70ml. For custom protocols, refer to the Endoflip™ 300 IFU for instructions.
6. Wait an additional 30-60 seconds for the system to record data (see complete list of data below). Press **"Inflate"** again to advance to the next fill volume.
7. To complete the procedure, press the **"Deflate and Finish"** button. Allow the balloon to empty before removing the catheter.

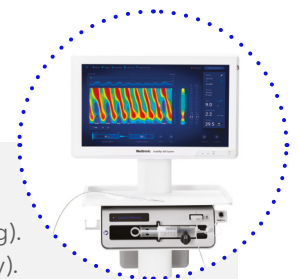
### EF-325N catheter<sup>2,4</sup>

1. Insert catheter with endoscopic visualization. Advance the catheter until the center of the balloon is positioned across the EGJ (approximately 8 sensors should be distal to the EGJ).
2. Remove endoscope.
3. Press **"Inflate"** and allow the balloon to fill to 20 ml. Press **"Stop"** when the balloon has reached 20ml.
4. If needed, re-position the balloon across the waist-like constriction of the EGJ.
5. Initiate the standard protocol by pressing the **"Inflate"** button. The balloon will be automatically inflated in a stepwise approach to a pre-determined volume each time the **"Inflate"** button is pressed. After each fill, wait 15 seconds for the EGJ to stabilize.  
  
Fill volumes of the standard protocol are 30 and 40 ml. For custom protocols, refer to the Endoflip™ 300 IFU for instructions.
6. Wait an additional 30-60 seconds for the system to record data (see complete list of data below). Press **"Inflate"** again to advance to the next fill volume.
7. To remove the catheter, press the **"Deflate and Finish"** button. Allow the balloon to empty before removing the catheter.

### Data captured by the Endoflip™ 300 system when using the standard protocol

- Diameter (mm) of the narrowest luminal area.
- EGJ distensibility index (EGJ-DI) (mm<sup>2</sup>/mmHg).
- Intra-bag pressure (mmHg).
- Esophageal contractile pattern (EF-322N only).

Additional information can be manually recorded by using the snapshot feature at each fill volume.



1. Endoflip™ impedance planimetry system Operators Manual, PT00136604 (2023)

2. Savarino, Edoardo, et al. "Use of the functional lumen imaging probe in clinical esophagology." *The American journal of gastroenterology* 115.11 (2020): 1786.

3. Endoflip™ EF-322N Catheter Instructions for Use, PT00178191 (2023)

4. Endoflip™ EF-325N Catheter Instructions for Use, PT00178192 (2023)

Please see the package insert for the complete list of indications, warnings, precautions, and other important medical information.

Potential complications include: Arrhythmia, Anaphylaxis, Aspiration/inhalation, Bacterial infection, Bleeding/hemorrhage, Delay to treatment/therapy, Dental trauma, Dysphagia, Hypersensitivity/allergic reaction, Laceration of the esophagus, Misdiagnosis/misclassification, Pain, Perforation of the esophagus, Thermal burn, Vasovagal response.