

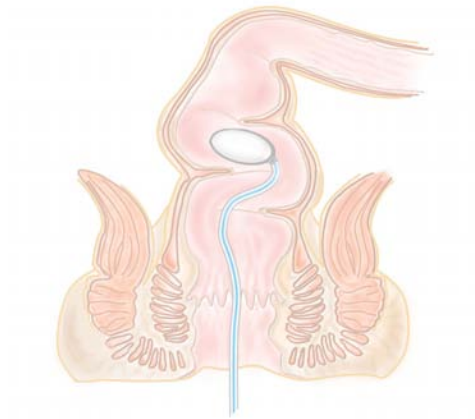


**Medtronic**

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# POLYGRAM NET™

Anorectal Function Testing Application



**User Guide**



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At the time of printing / transfer to the CD-ROM, this manual correctly described the device and its functions. However, as modifications may have been carried out since the production of this manual, the system package may contain one or more addenda to the manual. This manual including any such addenda must be thoroughly read, before using the device.

The following situations void any guarantee(s) and obligations for Medtronic A/S:

- The device is not used according to the enclosed manuals and other accompanying documentation
- The device is installed or modified by persons other than Medtronic A/S service technicians

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# Introduction

## Basic information

The POLYGRAM NET™ Anorectal Function Testing (A.F.T.) Application is used to assess the function of the anorectal canal. Data are collected in the anorectal canal using sensors and a recording device, and then analyzed. The results are used to help diagnose pelvic floor function disorders. Furthermore, this application can be used to assess the function of other areas in the GI tract such as the esophagus, stomach, duodenum, Sphincter of Oddi, small bowel and the colon.

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

**WARNING** The device is not compatible for use in an MRI magnetic field.

## Indications for Use

The Polygraf ID in conjunction with the POLYGRAM NET™ Application software is intended to record, store, view, and analyze Pressure, pH, EMG, Swallow, and Respiratory data online anywhere in the gastrointestinal tract (pharynx, esophagus, stomach, duodenum, Sphincter of Oddi, small bowel, colon and anorectal area including rectum and pelvic floor) to assist in the diagnosis and evaluation of gastrointestinal and swallowing disorders.

Designated catheters are required for measurement in each specific area.

**CAUTION** Physicians should exercise diligence in their interpretation of results from this system. It is always advisable to check analysis results against the signal tracings when a major consequence such as surgery occurs as a result of an investigation.

## System Checklist

The following is a checklist of items included with the system or which can be ordered separately:

- POLYGRAM NET™ Anorectal Function Testing Application software
- Polygraf ID data-acquisition device
- Hardware manual
- Power supply
- USB cable

The following items can also be supplied with the system:

- PC (with Trolley)
- Printer

### Accessories

- Manometry catheters (solid state, water perfused)
- Calibration chamber
- Water perfusion system
- Pressure transducers
- EMG sensor
- Catheter Puller

## Additional Items required

The following additional items, listed below, are required to perform Anorectal Function Testing procedures with the system:

- Examination gloves
- Lubricating gel
- 60 cc syringe
- Gauze pads (4x4'/ 10x10cm)
- Warm (body temperature) water
- 2 l graduated cylinder
- Adhesive tape

## *Clinical Guidelines*

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### **Before the Study**

Before starting the study, explain the whole procedure to the patient so as to increase cooperation and comfort level.

In general, the rectum should be emptied of fecal debris. If the patient is chronically constipated, a Fleet's enema should be given more than 2 hours before the examination to ensure that the rectal canal is free from obstructions.

If prior to the examination the rectal ampulla still contains stool, a tap water enema is then recommended.

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### **Patient's Position**

The patient should usually be examined in the left lateral decubitus position with knees flexed. Their hips should be as near to 90° as is comfortable for them.

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### **Catheter Insertion**

The requirements for catheter insertion vary between recording types.

#### *Stationary Pull-Through*

When using radial catheters, insert the catheter to 6 cm from the anal verge. Check the orientation of the catheter and adjust if necessary. This is usually done by ensuring that the radiopaque strip (if one is present) that indicates the position of channel one is in the preferred position.

When using staggered catheters, insert the catheter to a depth where the most proximal sensor is 6 cm from the anal verge.

#### *Continuous Pull-Through*

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**CAUTION** This recording only supports the use of radial catheters. This method, or profilometry, enables demonstration of asymmetry within the anal canal. It generates the distribution of pressures within the anal canal and allows for determination of the length of the anal canal in each of the quadrants, if using a 4-channel catheter. Staggered catheters are not suitable for this method.

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**CAUTION** Do not use a catheter with a rectal balloon attached for this recording. The balloon may cause the catheter to twist while it is being withdrawn; this will alter the orientation of the sensor and reduce the accuracy of the results.

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Insert the catheter to 8 cm from the anal verge. This is to ensure that the pressure sensors are located above the anal canal. The depth of insertion is then used to calculate what the length of the pull has to be, to ensure that the catheter will be fully withdrawn from the patient when the pull has been completed.

Check the orientation of the catheter and adjust if necessary. This is usually done by ensuring that the radiopaque strip (if one is present) that indicates the position of channel one is in the preferred position.

#### *Fixed Position Catheter*

Insert the catheter to a depth where the most proximal annular balloon is just inside the anal verge.

To ensure that the catheter's position does not change during the recording, tape it to the patient's buttocks. If that is not possible then the catheter should be checked regularly during the recording.

---

## Inserting or Attaching EMG Sensors

### *Inserting Sponge and Plug Electrodes*

1. Lubricate the electrode with an appropriate type of gel.
  - For anal sponge electrodes, if they are to be used at the same time as a manometric study is carried out, the catheter should be placed in the slit in the sponge, before insertion.
2. Insert the electrode anally or vaginally, depending on the electrode type.
3. When the electrode is in position, connect it to the Polygraf ID cable.
4. Place the ground electrode on the patient's thigh or hip and connect it to the ground cable.
5. Using adhesive tape, secure the plug electrode's cable close to the anus.

### *Attaching Pre-gelled Adhesive Surface Electrodes*

Clean and degrease the anus. Apply 2 surface electrodes (in the 3 and 9 o'clock positions) as close as possible to each side of the anus, without them touching the mucous membrane. Place the ground electrode on the patient's thigh or hip and connect it to the ground cable. Using adhesive tape, secure the plug electrode's cable close to the anus. Secure the cable connections in a position where they will not be exposed to any liquids during the study.

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**NOTE** Always allow the patient at least 5 minutes to relax and become accustomed to the presence of the catheter or sensor before starting the procedure

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## During the Study

To ensure the best possible results, the patient should try to be as relaxed as possible, and should not do anything that may alter the data collected. Actions such as coughing, talking or laughing will all affect the quality of the recording.

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## After the Study

Patient may resume his/her normal activities and restart any discontinued medication.

# Start Anorectal Function Testing Application



Turn on the computer and start POLYGRAM NET™ by double-clicking the icon on your Windows® desktop.

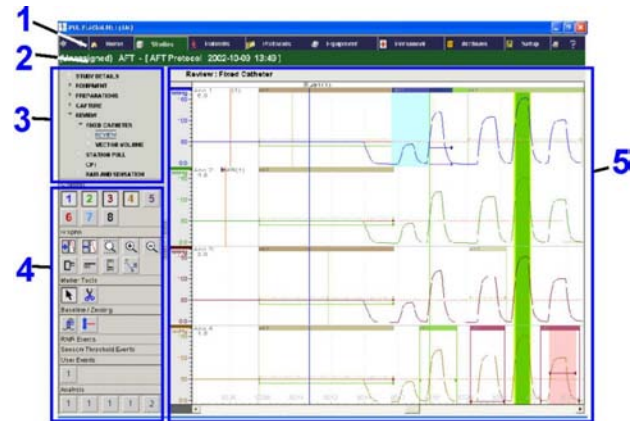
The program will start on the Home page from where you can have access to an ongoing study, or create a new one. From the Home page, you can also navigate to all the other areas of the program.



1. Home
2. Studies
3. Patients
4. Protocols
5. Equipment
6. Personnel
7. Archives
8. Setup

## Workspace

This illustration displays the main areas of the workspace in the application window to familiarize you with the terminology used in the manual.



1. Navigation Bar
2. Title Bar
3. View Selection Area
4. Tool Area
5. View Area

## Create Study

To create a new Study, select a *Protocol* under *Routine Protocols* in the View Selection Area of the Home page, and fill out the *Study Details* page with the necessary information.

From the *List* of patients on the right, you can now choose an existing patient, or create a new one by clicking *Create New Patient* button in the Tool Area.

Study Details

## Equipment Preparation

In routine use, the equipment does not need to be configured before starting each study. For a detailed description of how to do this, refer to the *Equipment Configuration* section in the Reference Manual.

### Connect Sensors

The information in this section is a general example of how the sensors could be connected to the device.

#### Example

1. Make sure the Polygraf ID is connected to the computer and turned on. The blue light on the front of the device should be lit.
2. Click Equipment in the Navigation Bar. Select the equipment configuration you want to use.
3. Click Verify and then Connections in the View Selection Area on the computer Screen.
4. Start by connecting the input for the EMG sensor to channel 1 on the Polygraf ID.

**NOTE** As each channel is connected, the program immediately verifies that the sensor type is correct and notifies you on the screen, in the affected channel, by changing the color of the status indicator from red to green and displaying a message in case of error.

5. Connect the proximal pressure sensor to channel 2 on the Polygraf ID, the middle pressure sensor to channel 3 and the distal sensor to channel 4.

- When all the sensors have been recognized by the program, proceed to *Calibrate Channels*.

## Calibrate Channels

The channels can be calibrated manually, or you can have the program prompt you to hold the catheter at the low and high positions.

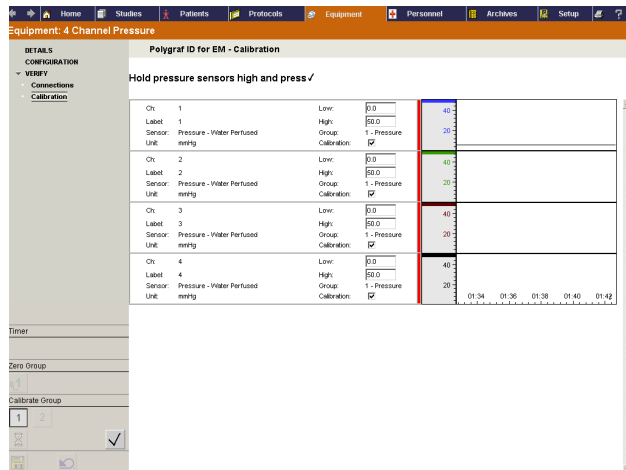
### Manual Calibration

#### Verify—Calibration

1. Click the *Calibrate Group* button that corresponds to the parameter you want to calibrate
2. Expose the sensor(s) to the low value (0.0 mmHg) and click the *Check Mark* button
3. Expose the sensor(s) to the high value (50 mmHg) and click the *Check Mark* button.
4. Look at the trace display to the right on the screen to verify the calibration pressure values in each channel.

### Calibrating with a Timer

When using this option, the program makes it easy for one person to perform the calibration by prompting him/her to hold the catheter/pressure level at the high and low levels. It is done in the following manner:



Equipment Verify-Calibration

## Unsuccessful Calibration

If the calibration was not successful, the color bar, on the left edge of each channel in the trace area, turns red, and you are given information as to the potential cause of the problem. Make the required adjustments and calibrate again. If one or more channels fail to calibrate properly, we recommend that you re-calibrate all channels.

## Zero-Set

When using the Zero-Set option, all selected channels in that study will be set to Zero.

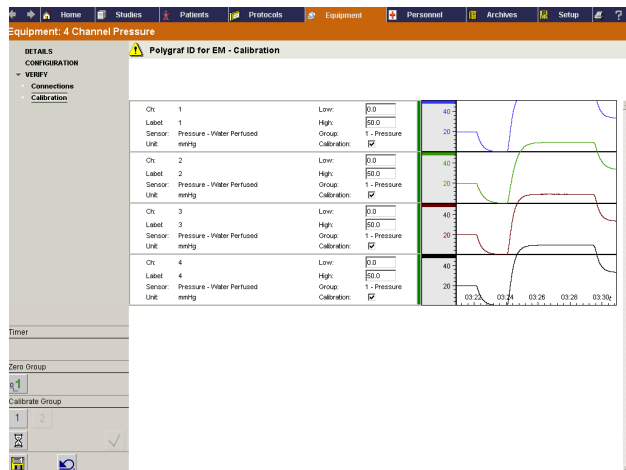
- When ready, click *Capture*.

## Verify-Calibration

1. Click the *Timer* button in Tool Area
2. Click the *Calibrate Group* button.
3. A timer is displayed on the screen to prompt you when to expose the sensor(s) to the low-pressure value.
4. Hold the sensors steady at the low level (0 mmHg) while the timer counts down to zero.
5. Prepare to expose the sensors to the high-pressure value.
6. Hold the sensors steady at the high level (50 mmHg) while the timer counts down to zero
7. Wait for the calibration results to be displayed.

## Successful Calibration

The color bar, on the left edge of each channel in the trace area, turns green for the channels in which the calibration was successful.



Equipment-Successful Calibration






# Capture

## Recording Data

The following Anorectal Function Testing recordings can be performed in Capture:


- Stationary Pull-Through
- RAIR and Sensory Threshold
- Continuous Pull-Through
- Fixed Position Catheter
- Generic

## Stationary Pull-Through



1. Click **Capture** in the View Selection Area and select a recording in which **Stationary Pull-Through** has been enabled.
2. Click the **Record** button to begin saving the data.
3. When the catheter is in place, click the **Catheter Depth**  button, and type in the correct catheter depth.
4. **Rest:** Click the **Rest**  button then ask the patient to rest quietly without squeezing or pushing for a period of 20-30 seconds. This should be repeated 1-2 times.
5. **Squeeze:** Click the **Squeeze**  button and ask the patient to squeeze as hard as they can, to simulate holding back a stool, for 10-20 seconds. This maneuver should be repeated 1-2 times, with at least 30 seconds resting time in between.
6. **Strain:** Click the **Strain**  button and ask the patient to strain as if trying to defecate for 10-20 seconds. This maneuver should be repeated 1-2 times, with at least 30 seconds resting time in between.
7. Withdraw the catheter 1 cm, adjust the catheter depth (reduce it) using the  button.
8. Repeat steps 5-7 for insertion depths of 5,4,3,2, and 1 cm, assuming that the initial insertion depth was 6 cm.

## RAIR and Sensory Threshold

### *Recto Anal Inhibitory Reflex (RAIR)*

1. Click **Capture** in the View Selection Area and select a recording in which **RAIR** has been enabled.
2. Click the **Record** button to begin saving the data.
3. Insert the catheter to a depth of 2-3 cm (where the highest resting pressure was recorded); use the  button to increase the depth of insertion to the required value.
4. Inflate the rectal balloon with known volumes of air or body temperature water, starting at 10 ml and increasing to 50 ml. The air should be withdrawn no more than 5 seconds after it has been introduced.





In cases of megarectum, much larger volumes are likely to be needed.

5. Enter the volume injected.
6. If RAIR is present click  if not, click .

### *Sensory Threshold*

1. Click **Capture** in the View Selection Area and select a recording in which **Sensory Threshold** has been enabled.
2. Click the **Record** button to begin saving the data.
3. Fill the rectal balloon with 10 ml of air or body temperature water and wait for 20 seconds.
4. Ask the patient whether they felt anything or not, and if they did was the sensation temporary or constant.
5. If the patient felt a sensation, then insert the appropriate marker.
6. Enter the volume injected.
7. Repeat the procedure filling the balloon in fixed increments with accommodation periods between the inflations.

## Sensory Markers

Marker	Description
	No sensation
	First sensation
	Constant sensation
	Maximum tolerable

## Continuous Pull-Through (C P T)

The following steps are only valid if the withdrawal of the catheter is carried out manually, or when using a mechanical Puller device.

1. Click **Capture** in the View Selection Area and select a recording in which Continuous Pull-Through has been enabled.
2. Click the **Save** button to begin saving the data.
3. This step is the same for both **Resting** and **Squeeze** maneuvers.



Withdrawal of the catheter can be carried out either manually or by using a mechanical puller device. The POLYGRAM NET™ program can be set up to provide a start signal and a metronome rhythm to assist the operator.

4. Click one of the **Start Pull** buttons.

If selected, a countdown timer will be displayed on screen. When the timer reaches zero the computer will make a single "beep" sound. This is the signal to start to withdraw the catheter, either by hand or using a mechanical puller.

If configured, the computer will then generate a series of rhythmic "beeps". This is the metronome function, which helps the operator to control the pull rate when withdrawing the catheter manually.

The recordings should be repeated 1-2 times, with at least 30 seconds resting time in between. The patient should be asked not to move, and breathe quietly between pulls.

5. **Resting:** Click the **Start Pull Resting**  button. Ask the patient not to move and to breathe quietly during the pull. Carry out the recording as described in step 4.
6. **Squeezing:** Click the **Start Pull Squeezing**  button. Ask the patient to squeeze throughout the pull. Carry out the recording as described in step 4.

## Using a Catheter Puller


The Catheter Puller can be started by activating the Start Pull Resting or the Start Pull Squeezing buttons on the device (steps 5–6).

If using a mechanical puller, operate the puller according to the manufacturer's instructions.

**NOTE** The Stop Puller icon is only available after the Start Puller icon has been activated.

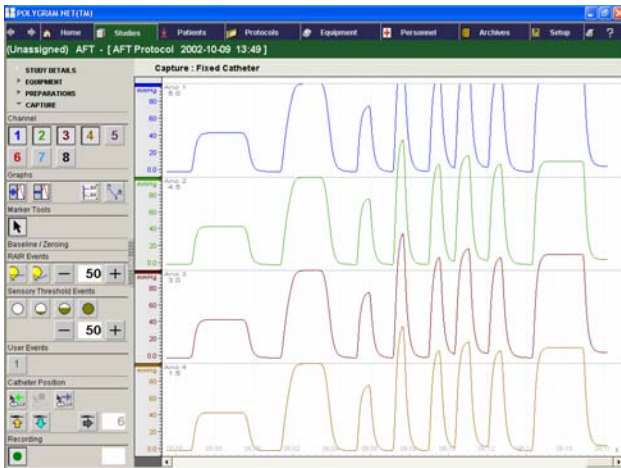
**NOTE** The Return Puller icon is only available for the Catheter Puller.

## Fixed Position Catheters

1. Click **Capture** in the View Selection Area and select a recording in which Fixed Position Catheter has been enabled.
2. Proceed as for steps 2-6 in a Stationary Pull-Through recording. Do not move the catheter. The only exception to this is that the catheter depth (step 3) is not entered.
3. **Cough:** Click the **Cough**  button. This maneuver should be repeated 1-2 times,

with at least 30 seconds resting time in between.

4. Evaluate the Recto Anal Inhibitory Reflex in the RAIR recording.
5. Evaluate Rectal Volume Sensory Thresholds as in the Sensory Thresholds recording.



Capture—Fixed Position Catheter Recording

## Zero-set



When choosing the Zero-Set option in Capture, the recording/tracing will be set to zero.

**NOTE** Only the last Zeroing sequence can be undone.

- When ready to review the captured data, click *Review*.

## Baseline



Rectal Baseline



Autoset Baseline

- The Baseline is used as a reference—usually set to zero.
- Setting a baseline makes it easy to detect changes in pressure.
- Set Baselines are valid until new Baselines are defined.
- Baselines can be autoset.

## Review

From Review you will have access to the recordings where data have been captured, allowing you to analyze and interpret the results.

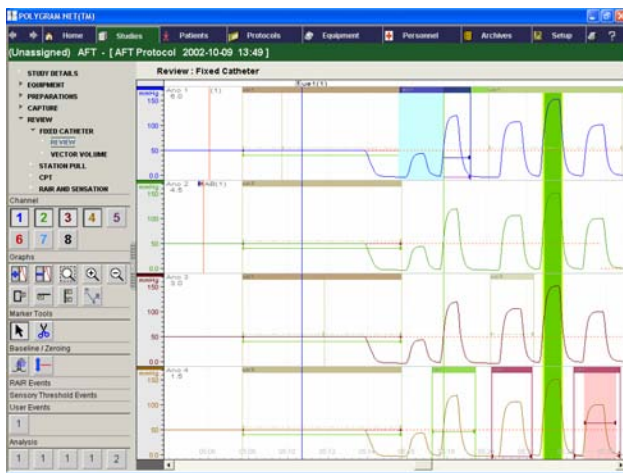
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All the System Events, User Events, and User Periods in Capture are also available in Review.

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To work with the general tools, please refer to the [Working with Tools](#) section in this manual.

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*AFT Review*

Analysis Markers can be inserted manually over specific areas of interest like:

- Resting Analysis
- Contraction Analysis
- RAIR Analysis
- User Defined Periods

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Vector Volume calculations are available under Review in the View Selection Area.

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## *Report Items*

To access a report of an AFT study, select *Report* in the View Selection Area.

A selection of the following information can be included in the report:

- Study Details
- Patient Details
- Analysis Results
- Graphs and Clip Outs
- Normal Values

---

**NOTE** The content of the report depends on the protocol report settings.

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# Working with Tools

## General Tools

The following General Tools are available in Capture and Review Views.

### Channels



To view the tracings of a specific channel, click the channel's corresponding button in the Tool Area.

### Selection Tool



Click the Selection tool to set a Marker to its normal position after marking artifacts.

### Zoom Area



Click the Zoom Area button to maximize the view of a specific area.

### Zoom In/Out



Click the Zoom In/Out button to maximize or minimize the graph view.

### Scale Down



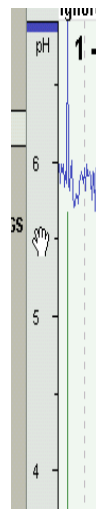
Click the Scale Down button to decrease the scale of all pressure channels.

### Scale Up



Click the Scale Up button to increase the scale of all pressure channels.

## Raise / Lower or Compress / Expand Tracing



If the tracing goes outside the visible area on the screen, you can raise or lower the tracing for each channel separately. To do this, place the pointer over the scale bar. Click and drag the scale up or down.

To compress or expand the scale, you can right-click the scale bar in the desired channel and select Scale Up/Scale Down from the menu. Scale Up will expand the scale and increase the resolution making the trace larger. Scale Down does the opposite.

## Measuring / Calculation Tools

### Vertical Cursor



Switch On/Off by clicking the Vertical Cursor button in the Tool Area. When the line is selected, the values and time for that position will be displayed. To move the line to another position, select it, then holding down the left mouse key drag the line to the required position.

### Horizontal Cursor



Switch On/Off by clicking the Horizontal Cursor button in the Tool Area. When the line is selected, the values for that position will be displayed. To move the line to another position, select it, then holding down the left mouse key drag the line to the required position.

### Rectangular Selection Box



Switch On/Off by clicking the Rectangular Selection Box in the Tool Area. When the rectangle is selected, the values for that portion will be displayed. To move the rectangle to another position, select it, then holding down the left mouse key, drag it to the required position. The size of the Rectangular Selection Box can be changed by dragging its left or right borders.

## *Service Centers*

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