



ResTrial GastroEndo s.r.o.

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Patient Informed Consent Form with High Resolution Esophageal Manometry

Patient:

.....
name, surname, personal birth number

Dear Patient,

Your informed consent form is essential for the conduct of the examination recommended to you. To help you make your decision regarding undergoing the procedure we inform you hereby about the method, the importance, as well as any potential complications of the examination.

Why do we recommend the High Resolution Esophageal Manometry?

High Resolution Manometry (HRM) is a functional examination of the esophagus, which is performed especially in the case of swallowing disorders and thus distinguishes among various types of esophageal motility disorder, it is also useful for patients before or after antireflux surgery and also in investigating the cause of certain non-specific symptoms (e.g. pain in the chest). The goal is therefore to establish an accurate diagnosis, on the basis of which appropriate treatment can be recommended.

How do I prepare for a High Resolution Esophageal Manometry?

You will be required to fast, avoiding food and drink starting 6 hours prior to the procedure. In patients with suspected esophageal achalasia, longer fasting is necessary (determined by the referring physician). You will need to stop the use of some medication (prokinetics, anticholinergisc, spasmolytics). In any case, all medication and the necessity of possible discontinuation must be consulted with the referring physician.

Examination process

While you are sitting up, the doctor puts numbing gel with Mesocain in your nose and a catheter guides through your nostril into the esophagus until it reaches the stomach, swallowing water helps to make the catheter easier to insert.

Once the catheter is in place, you'll be asked to lie on your back on an exam table. During examination you swallow small sips of water (5ml) at intervals as instructed. As you do, a computer connected to the catheter records the pressure, speed and pattern of your esophageal muscle contractions.

When the test is over, the catheter will be removed slowly. You can return to your normal activities (eat, drink, and take the discontinued medication) after an uncomplicated examination immediately.

Alternative examination options

There is no adequate alternative to this examination.

Possible risks

Complications during High Resolution Manometry are extremely rare and at the same time they are not serious conditions. You might, however, have some discomfort when the tube



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passes into your throat, a slight nosebleed may occur if the mucous membrane of the nasal cavity or throat is bruised.

Ask any questions or for any clarification.

I hereby represent and confirm that I have received full guidance and explanation about what this informed consent form contains. I declare that I have understood the above-stated and I have had a sufficient opportunity to ask the physician any additional questions to which he/she answered in a clear and satisfactory manner, and I hereby agree with High Resolution Esophageal Manometry.

I have made this decision freely and with full awareness of my actions.

In Prague on: Patient's signature:

Physician's name: Physician's signature:

In case of your first visit please fill out the following:

Diseases you are being treated with:

.....

Medicines you take:

.....

Allergies:

Operations:

Suffered accidents:

Alcohol: yes x no Smoker: yes x no

Have you ever undergone a stomach examination – Gastroscopy? Year.....

Your address.....

Tel.: E-mail:

Completed by the doctor

Eckardt skóre	Dysphagia	Regurgitation	Restrosteral pain	Weight loss (kg)
0	None	None	None	None
1	Occasional	Occasional	Occasional	< 5
2	Daily	Daily	Daily	5 - 10
3	Each meal	Each meal	Each meal	> 10