



ResTrial GastroEndo s.r.o.

Klinika ResTrial, Sofijské náměstí 3404/3, Praha 4 Modřany

Tel: 242 451 010, email: gastroendo@restrial.com

Patient Informed Consent Form with **24 hours pH-metry/ impedance**

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 24 hours pH-metry?

Esophageal pH-metry is an examination that allows for the measurement of pH ("acidity") and its changes associated with the reflux (stomach contents that return from the stomach to the esophagus) which damages the mucous membrane. It is performed to diagnose gastroesophageal reflux disease for which the symptoms such as heartburn, belching, nausea are typical.

Gastroesophageal reflux disease is often accompanied by inflammation of the esophageal mucosa, which is easily treatable. In case the diagnosis is not done in time and treated correctly, it can lead to more serious health problem as is esophageal malignant cancer.

Esophageal impedance also detects the components of refluxate (stomach contents that enter to the esophagus), distinguish solid food, liquid or gas. The course of the examination for the patient is the same as during pH-metry itself.

How do I prepare for a pH-metry?

You will be required to fast, avoiding food and drink starting 6 hours prior to the procedure. Will need to pause the use of anti-secretory medication (**for at least 7 days prior** to the pH-metry procedure proton pump inhibitors, **48 hours prior** procedure H-2 receptor blockers, further prokinetic, sucralfate, bicarbonate, anticholinergic, spasmolytics, analgetic medication, **24 hours prior** examination antacids).

Sometimes is examination performed specifically during treatment with certain drugs. In any case, all medication and the necessity of possible discontinuation must be consulted with the referring physician.

Examination process

After numbing the nasal mucosa with an anesthetic gel with mesocaine we insert a thin, flexible catheter (diameter 3mm) into your esophagus through the nostril and attach it to the nose and neck skin with a patch so that it does not stick out. The catheter is connected to a small monitoring device about the size of a smartphone that you wear on a belt or over the shoulder for 24 hours. The catheter for pH-metry and impedance basically do not differ from each other in size.

You will be instructed by the doctor how to handle the device and how to record important events (lying position, food, difficulties, etc.) that are necessary for the correct assessment of the examination. The regime during the examination should be as close as possible to the normal daily regime. It is only necessary to ensure that the monitoring device does not come into contact with water (bathing, showering) and is not mechanically damaged. After 24 hours,



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you will come back to our clinic, where we will finish the measurement and we pull out the catheter. Once over, you can leave, eat, drink and take the discontinued medication again immediately.

Alternative examination options

There is no completely adequate alternative to this examination, especially considering that this examination is performed for 24 hours and thus provides information on the dynamics of acid reflux over a longer period and during a normal daily routine. Therefore, endoscopy, which shows possible inflammatory changes in the esophageal mucosa caused by reflux, does not replace esophageal pH-metry.

Possible restrictions of lifestyle and work ability

The insertion of the esophageal catheter is performed on an empty stomach, otherwise during the examination the patient performs normal daily activities.

Possible complications

Complications during pH-metry are extremely rare and at the same time they are not serious conditions. In rare cases, the mucous membrane of the nasal cavity, nasopharynx or esophagus may be slightly bruised, other possible problems (pressure in the throat, nausea, irritation to cough, etc.) are symptoms resulting from the nature of the examination.

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 24 hours pH-metry/ impedance.

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: