

Please fill out with printed capital letters.

Name:

Mothers' name:

Date of birth:

SSN:

Information and consent form on contrast-enhanced mammography examination

— Dear Patient,

Please carefully read all the information about the examination process, your tasks, and possible adverse effects.

— General information

This type of examination is always done as an **additional test** after the initial mammography and is always indicated by a physician. This special method uses dual-energy imaging. During the examination, after the intravenous administration of the contrast material, the scan produces two-way images of both breasts. The scan produces native and contrast-enhanced two-view images of both breasts. To ensure excellent image quality and to reduce radiation exposure, the breasts are compressed using a plexiglass plate, which can sometimes cause minor, tolerable pain. Less discomfort occurs in the first week after menstruation, so it is advisable to schedule the scan for that week if possible. The examination includes some radiation exposure. This procedure should not be performed on pregnant or breastfeeding women.

When visiting, please bring your previous breast-related reports, final reports, films, and CDs, and provide them to the receptionist or assistant.

— Examination procedure

Do not eat for 4 hours before the examination, but drink plenty of fluids. Take your regular medications with water before the scan. Before the examination, the radiologist will review based on your history which lesion of which breast will be assessed. The assistant will insert a peripheral cannula into the vein in your elbow pit, through which the contrast agent is injected. This is not painful; it feels like a needle prick for a blood test. After injecting the contrast agent, the breasts are first compressed in the appropriate position using an acrylic sheet. Two or three images of each breast are then obtained. During the contrast agent is administered, you may feel a warm sensation, develop a metallic taste in your mouth or experience an urge to urinate. These are all perfectly normal and will pass after a few seconds. After the scan, the contrast agent is excreted by the kidneys and then passes into the urine and out of your body.

You will have to stay in the waiting room for 20 minutes after the contrast-enhanced scan so that any side effects caused by the contrast agent can be identified and, if necessary, appropriate treatment can be initiated.

— Possible hazards, adverse effect and their avoidance and prevention

For the administration of iodinated contrast agent required during the contrast-enhanced mammography, the following must be considered in case of patients taking medication for diabetes in case of certain products:

Patients with diabetes taking METFORMIN:

1. **NO CHANGE NEEDED** in the administration of METFORMIN, if
 - they have no acute renal insufficiency,
 - their eGFR value > 30 ml/min /1.73 m²
2. **THE TAKING OF METFORMIN-BASED MEDICINE MUST BE SUSPENDED FOR 48 HOURS FOLLOWING THE ADMINISTRATION OF THE CONTRAST AGENT**, then it may be resumed afterwards only if the control eGFR value has not changed significantly in case of patients who
 - have no acute renal insufficiency and the eGFR value < 30 ml/min /1.73 m²

Please check if you are taking diabetes medicinal product containing metformin, if yes, then consult with your physician on the method of its administration! With normal kidney function, the contrast agent will not damage the kidney, but it is **IMPORTANT** to consume ample amount of liquid (min. 1.5-2 litres!) in the days before and after the contrast-enhanced mammography.

In case of contrast-enhanced mammography the contrast agent is usually introduced into the body through the cephalic vein, usually using a pump (injector). You may feel warmth, hot sensation for a short time during injection. Metallic taste, possibly nausea, rarely vomiting may occur. In case of those prone to it, the contrast agent may exit from the blood vessels, causing a stretching, stinging sensation. Should such sensation occur, please notify us! This does not cause any damage, absorbs without trace. The bandaging of the limb is recommended.

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The contrast agent is a chemical compound containing iodine which is suitable for outlining the blood vessels and the examination of the circulation of organs and tissues. The contrast agent, as any other medicine, may trigger hypersensitivity. The hypersensitivity may occur not only due to the iodine itself but to the complex of the iodine and the molecule attached to it, that is, the compound. Contrast agent hypersensitivity (allergy) occurs rarely. Symptoms: swelling of face, lips, tongue, throat, coughing, itching, nose running, sneezing, urticaria, dyspnea, sensation of suffocation. Should these or other symptoms occur after the administration of the contrast agent, immediately notify the examining assistant. Be advised that these symptoms may occur later, within 24 hours, in such case please report to your attending physician or at the nearest emergency patient care center. In most cases the allergy is mild, severe allergy is rare. It is extremely rare to have anaphylactic (hypersensitivity) shock state which, in extreme cases, may lead to circulatory collapse and cardiac arrest. Our institute is equipped and prepared to prevent a possible allergic reaction; the necessary clinical background is available.

Consume a lot of liquid following the administration of the contrast agent for the faster discharge of the contrast agent even if you do not need any liquid restriction due to a disease.

For any additional questions, feel free to ask the medical personnel performing the examination or the specialist overseeing it!

Like any diagnostic examination, contrast-enhanced mammography requires your consent as per the law on health. Without your signature on the informed consent, the examination cannot be performed.

— Thank you for your cooperation, we wish you good health.

Examination questionnaire

Please answer the questions below, marking your answer with an X using the check box.

Are you pregnant?

Yes/ It is possible No

Please note that if the answer is Yes/It is possible, you have to fill out the relevant pregnancy questionnaire & consent form before undergoing an examination that involves radiation.

Are you aware of having/ do you have hypersensitivity to any kind of medicine? Yes

No

Have you ever been administered contrast medium during a CT, angiography (DSA) or X-ray examination?

Yes

No

If yes, did you have any kind of allergic symptoms?

Yes

No

Do you have asthma?

Yes

No

Do you have hypertension (high blood pressure)?

Yes

No

Do you have diabetes?

Yes

No

Do you have gout?

Yes

No

Do you have any kind of untreated thyroid disease?

Yes

No

Do you have any kind of kidney disease (previous kidney surgery, proteinuria)?

Yes

No

Do you have a contagious disease (tuberculosis, hepatitis, etc.)?

Yes

No

Do you have any other significant diseases?

Yes

No

Other significant disease

Height (cm)

Body weight (kg)

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Consent form

I, the undersigned, hereby declare that I have been fully informed both in written and verbal form, especially about the nature, purpose and steps of the procedure in a way that I can understand. I have also been informed about the possible complications, benefits and risks of a missed examination, and my rights about consenting to the examinations and interventions.

I was given the opportunity to ask further questions, my questions about the procedure (if I had any) were answered to my satisfaction, and I understand what was said. I was given the opportunity to learn the name, qualification and position of the personnel directly involved in the procedure. I have no further questions and I do not need further time to think. I have been given sufficient time to make my decision and I give my consent under no duress and of sound mind.

I understand the nature of the examination and agree to the contract-enhanced mammography.

Signature of the patient (or legal representative)

If the PATIENT CANNOT MAKE A STATEMENT and/or sign on their own behalf, the reason for this

- Minor (under the age of 18)
- Vulnerable adult (diminished capacity/incapacitated)
- Other – please specify

Full name of legal representative
(Please completed with printed letters.)

Date of signing the statement