

Information and medical history for patients for preparation of the required pre-procedure interview with the doctor

☐ Clinic / Doctor:

☐ Patient data:



englisch

☐ Procedure scheduled to take place on (date):

- ☐ **Defibrillator** ☐ **Pacemaker** Herzschrittmacher
 ☐ _____
- ☐ **Removal** Entfernung
 ☐ **System conversion** Systemumwandlung
Replacement Austausch:
 ☐ **Generator** Aggregat ☐ **Probes** Sonden

Dear patient,

your implanted pacemaker, pacemaker generator or implantable cardioverter-defibrillator (ICD) is to be replaced, removed or be converted to a different type of device.

This form will serve to prepare you for your pre-procedure interview with the doctor. During the interview, the doctor will explain to you the advantages and disadvantages of the scheduled procedure compared with alternative methods available, and inform you of any risks specific to your case. The doctor will answer all of your questions in order to reduce any fears or concerns you may have. You may then consent to the procedure suggested to you. Your doctor will provide you with a copy of the completed and signed form after the interview.

REASONS FOR THE PROCEDURE

Normally, a pacemaker or ICD can remain inside the body for years without having to be replaced. However, if the battery is flat or in certain instances, e.g. impaired function, infections of the generator or the probes, a replacement or removal of the pacemaker/ICD and, if needed, also of the probes may be required.

If a system conversion is required in order to be able to treat newly developed cardiac arrhythmia, this can also be carried out during the same procedure. The device can be converted, for instance, from a dual-chamber to a triple-chamber pacemaker, a defibrillator (ICD) or a combination of pacemaker and ICD can be implanted. Should a system conversion be scheduled in your case, your doctor will discuss this with you in more detail.

COURSE OF PROCEDURE

The procedure is usually carried out under local anaesthesia. Often, you will also have an analgesic and/or sedative administered to you. If the procedure is to be carried out under a general anaesthetic in your particular case, you will receive a separate information sheet. The doctor will mark the procedure planned in your case and provide you with further information regarding the procedure:

☐ **Generator replacement**

If it is only the generator that has to be replaced, the doctor will make a small incision in the skin below the collar bone and replace the generator there with a new one. The probes leading to the heart will be connected to the new device and normally do not have to be replaced.

☐ **Replacement of probes**

If one of the probes lodged in the heart is malfunctioning or has slipped, the doctor will correct the position of the probe or replace a malfunctioning probe. For probe replacement, the vein in the area of the collar bone the probe is located in will be punctured or opened surgically; a new probe is then

inserted into the heart and the old probe is either removed or will remain in place.

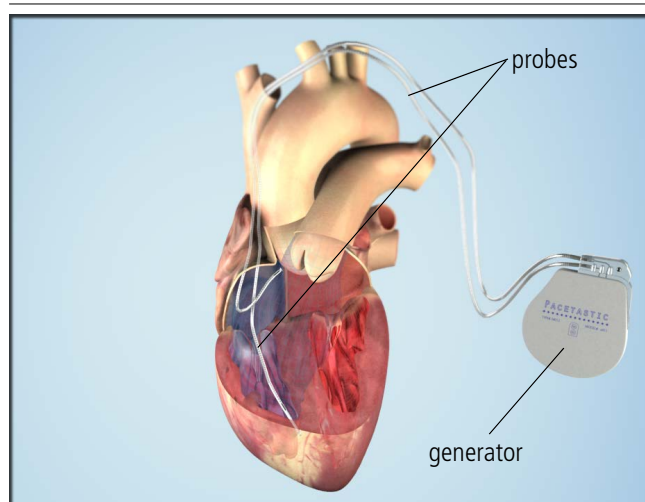
☐ **Pacemaker/ICD removal**

This procedure involves the doctor removing the generator in the area of the ribcage and also the probes leading to the heart if need be.

☐ **System conversion**

If the implanted pacemaker/ICD is to be replaced with a different pacemaker or with a defibrillator, several steps will be required depending on the situation. If necessary, the implanted electrodes will be replaced with new probes via a vein in the area of the collar bone. If necessary, further probes will be inserted, for instance into a coronary vein. Moreover, the doctor will open the skin pouch on the ribcage and replace the generator.

The following system conversion is planned:



After the procedure has been completed, it may be necessary for the doctor to carry out a test stimulation in order to test the function of the new pacemaker/defibrillator. For this purpose, you will be tranquillised to a deep sleep for a short period of time. Finally, the doctor will close the incisions and apply a dressing to the wounds.

POSSIBLE ADDITIONAL MEASURES

In some cases, removing the probe or placing it in the best-possible position will not be possible. In that event, the probes may have to be attached to the heart muscle from the outside in a separate procedure. This will require open surgery in order to access the heart. You will be informed separately if this applies to you.

ALTERNATIVE METHODS

There are no viable alternatives to replacing a generator or probes.

Instead of converting the system, various types of medication can also be used in order to treat the newly developed cardiac arrhythmia. However, the medication used has side effects of its own and may not suffice in some cases.

If your heart is extremely weak, a heart transplant may also be called for.

Your doctor will explain to you why he would recommend a system conversion in your particular case.

PROSPECTS OF SUCCESS

Once the generator has been replaced, the new device can remain in place for a further few years. After that, another replacement can be carried out.

Probe replacement or system conversion can improve the performance of your heart or prevent severe cardiac arrhythmia. However, it will not always be possible to place the new probes in the ideal location. Your doctor will explain to you which outcome is most likely in your particular case.

DIRECTIONS FOR PREPARATION AND AFTERCARE

Please follow the instructions of the doctor and of the nursing personnel closely. Unless specifically instructed otherwise, please adhere to the following guidelines:

Preparation:

Medication: Please inform your doctor of any medication you take or inject on a regular basis (in particular any anticoagulant agents such as Aspirin® [ASA], Marcumar®, Heparin, Plavix®, Ticlopidin, Clopidogrel, Eliquis®, Lixiana®, Xarelto®, Pradaxa® and metformin-containing antidiabetic medicines, so-called biguanides) or have taken irregularly over the course of the past eight days prior to the procedure (for instance painkillers such as ibuprofen, paracetamol). This includes any over-the-counter medication and herbal remedies. Your doctor will let you know if and for how long you should stop taking your medication.

Aftercare:

Your vital functions will be monitored for a certain period of time after the procedure. Please inform your doctor immediately if you experience symptoms such as **pain when breathing, heart problems, fever, breathing or circulatory problems or paraesthesia**. These symptoms may appear days or even weeks after the procedure and must be examined immediately.

If the procedure is performed **on an out-patient basis**, it is necessary for an adult to come and collect you. Please also make sure there will be an adult at home to supervise you for the period of time recommended by your doctor. Since your reaction capacity will be impaired through the administration of analgesics and/

or sedatives, unless otherwise instructed, you must not actively participate in road traffic for **a period of 24 hours after the procedure** (not even as a pedestrian) nor participate in any risky activities. You should also refrain from drinking alcohol and from taking any important personal or economic decisions during this period.

Your **ability to drive** is usually impaired after the procedure for at least **one week**. Your doctor will let you know when it is safe for you to drive again.

With regard to additional **guidelines** regarding e.g. taking medication or physical activity, please follow the instructions of your doctor closely.

The first **check-up** will usually be scheduled between four and six weeks after the procedure. Further check-ups will then be scheduled, depending on the case, within two to twelve months. Please be conscientious in keeping those appointments.

RISKS, POSSIBLE COMPLICATIONS AND SIDE EFFECTS

It is well known that **any medical procedure is accompanied by certain risks**. If complications occur, they may sometimes require additional treatment or surgery and, in extreme cases, can sometimes even be **life-threatening** or lead to permanent damage – even after some time. Please understand that, for legal reasons, any possible risks associated with this procedure must be listed, even if some of these only occur in exceptional cases. During the interview, your doctor will inform you of any risks specific to your case. You may also choose to waive a detailed explanation. In that event, please pass over this section on risks and confirm your waiver with your signature in the final section of this form.

General risks

Infections can usually be treated with antibiotics. Surgical treatment is only necessary in rare cases. In extreme and exceptional cases, an infection that has spread beyond control can lead to **life-threatening blood poisoning** (toxaemia). Infections of the skin pouch carrying the generator may require the removal of the generator, the probes or the implantation of the generator on the other side of the chest.

Bruising (haematomata) sometimes occurs and may lead to firm, painful swelling. In most cases, they disappear after a few days or weeks without treatment.

Damage to the skin, soft tissue or nerves, - for instance through injections, bruising, syringe abscess, disinfectants or positioning - may occur. Numbness, paralysis and pain may then result. They are usually temporary. In some cases, permanent nerve damage, tissue death or scarring may occur.

Allergic reactions, for instance to medication or latex, can lead to skin rash, itching, swelling, nausea and coughing. Severe reactions such as shortness of breath, spasms, tachycardia or **life-threatening circulatory shock** are rare. They may then result in permanent organ damage, such as brain damage, paralyse or kidney failure requiring dialyses.

Special risks involved in probe replacement or system conversion

Replacing the probes may result in **cardiac arrhythmia** during the procedure. In extreme cases, dangerous tachycardia may occur, which will then have to be stopped with a power surge.

Sometimes **blood clots (thromboses)** may form through the insertion of the probe, causing obstruction of a blood vessel. Such blood clots may then travel to other parts of the body and block the vessels of other organs (**embolism**). This may then lead to e.g. **stroke, kidney failure requiring dialyses or lung em-**

bolism and result in permanent damage. If anticoagulant agents are administered to prevent formation of blood clots, the risk of bleeding or post-procedure bleeding is increased. If Heparin is administered, it may lead to a severe immune response (HIT) involving clotting of the platelets (thrombocytes) and obstruction of veins and of arteries.

The insertion of the probes may cause **injuries** or **perforation** of the **jugular vein, the wall of the heart** or the **cardiac vein**. If the artery below the collar bone (arteria subclavia) is wrongly punctured, it may lead to **vessel injury** and **impaired circulation of the arm** as a result. Post-procedure **bleeding** is usually noticed immediately and can then be stopped. Sometimes, bleeding may require additional measures; should severe blood loss occur, the use of donor blood/components (**transfusion**) may be required. This can lead to transmission of diseases, such as hepatitis in very rare cases (causing dangerous inflammation of the liver), HIV in extremely rare cases (causing AIDS), BSE (causing a form of Creutzfeldt-Jakob disease) or also of other dangerous – even unknown – diseases. Donation of your own blood usually isn't useful.

Post-procedure bleeding of the heart may lead to blood collecting inside the pericardium and impair the pumping function of the heart. A puncture or surgical opening of the pericardium will then be required.

If air enters through the vein during probe implantation, it may lead to dangerous **air embolism** requiring intensive medical care.

The procedure may lead to **injury of the lining of the lungs** (pleura) resulting in air entering into the chest and pushing aside the lungs (**pneumothorax**). In order to remove the air and improve breathing, a surgical drain may then have to be inserted.

Nerve injuries e.g. of vocal chord nerves, the phrenic nerve or the nerve bundle that supplies the arm, will lead to temporary, in rare cases to permanent speech impairments, hoarseness, shortness of breath or paralysis of the arm.

Breathing disturbances due, for instance, to diaphragmatic weakness may require respiration in intensive care for several days after the procedure. This may cause pneumonia.

With patients predisposed to delayed wound healing or **wound healing disorder**, painful scarring and abnormal proliferation of scar tissue (keloids) may occur. The area around the surgical scar may remain numb.

Important Questions for Outpatients

Wichtige Fragen für ambulante Eingriffe

Who will pick you up when you are discharged from the hospital/ clinic/surgeon's practise? Wer wird Sie abholen, sobald Sie aus Klinik/Praxis entlassen werden?

Name and age of the person picking you up: [Name und Alter des Abholers]

Where can you be reached within the 24 hours after surgery?
Wo sind Sie in den nächsten 24 Stunden nach dem Eingriff erreichbar?

Street, house number, postcode, place: [Straße, Hausnummer, PLZ, Ort]

Telephone: [Telefonnummer]

Name and age of person looking after you: [Name und Alter der Aufsichtsperson]

Especially in the beginning, the heartbeat itself or sudden jolting movements may lead to **slipping of the probes** inside the heart. The generator will then have to be reprogrammed or the probes will have to be fixed inside the heart again.

Alterations of the heart muscle through inflammation or impaired blood circulation may also lead to an **impairment of pacemaker/ICD function**, to an extent which will require a corrective procedure in which the probes inside the heart will have to be relocated.

Since the probes are highly flexible and thus move with every heartbeat, the mechanical wear and tear of several years may lead to a **probe fracture** or to a short circuit. The probe will then have to be replaced.

If an additional probe is inserted into the coronary vein, the iodine-containing contrast medium administered to the patient may lead to **thyroid hyperfunction**. This will result in **heart palpitations, restlessness, sweating, diarrhoea**, but can be treated with medication. An **impairment of kidney function** may occur in patients with pre-existing kidney damage or diabetes. Permanent kidney damage even requiring dialysis only occurs in rare cases.

Since the probe inserted into the coronary vein is very close to the diaphragm, an uncomfortable pulsating **spasm of the diaphragm** may occur. If reprogramming the generator does not remove this problem, the probe will have to be relocated in the heart.

Since the implantation procedure has to be carried out under X-ray control, the body is **exposed to radiation**. Acute damage such as skin alterations are rare. Long-term effects cannot be ruled out entirely.

Medical devices are subject to very high quality standards. Nevertheless, **malfunctioning** cannot be ruled out entirely even with a pacemaker/defibrillator. In that event, the pacemaker/defibrillator may have to be replaced.

Who is your physician (the one whose care you are in/who referred you/family surgeon)? Wer ist Ihr überweisender Arzt / Hausarzt / weiter betreuender Arzt?

Name: [Name]

Street, house number: [Straße, Hausnummer]

postcode, place: [PLZ, Ort]

Telephone: [Telefonnummer]



Questions about Your Medical History

Please fill in the following questionnaire carefully before your information talk. **Please tick the applicable box!** It goes without saying that your information will be treated confidentially. The information you provide will help the physician to better assess the risks in your particular case, to advise you on the complications that could occur, and to take any steps needed to prevent complications and side effects.

Information about medications: Do you regularly require blood thinning medications (anticoagulants) or have you taken any or have any been injected during the past 8 days? yes no

Aspirin® (ASS), Clopidogrel, Eliquis®, Heparin, Marcumar®, Plavix®, Pradaxa®, EfiEnt®, Brilique®, Ticlopidin, Xarelto®, Iscover®.

Angaben zur Medikamenteneinnahme: Benötigen Sie regelmäßig blutgerinnungshemmende Mittel oder haben Sie in der letzten Zeit (bis vor 8 Tagen) welche eingenommen bzw. gespritzt? Aspirin® (ASS), Clopidogrel, Eliquis®, Heparin, Marcumar®, Plavix®, Pradaxa®, EfiEnt®, Brilique®, Ticlopidin, Xarelto®, Iscover®.

Any other: _____
Sonstiges:

When did you take the last dose? _____
Wann war die letzte Einnahme?

Do you take any other medications? yes no
Werden andere Medikamente eingenommen?

If so, which ones: _____
Wenn ja, bitte auflisten:

(Please include non-prescription medications, herbal and other natural remedies, vitamins, etc.) (Auch rezeptfreie Medikamente, natürliche oder pflanzliche Heilmittel, Vitamine, etc.)

Have you ever had an operation in the chest area or on your heart? Do you have a breast implant? yes no

Wurden Sie schon einmal im Brustbereich oder am Herzen operiert oder haben Sie ein Brustimplantat?

Have you ever had a procedure done on the pacemaker? yes no

Wurde bei Ihnen schon einmal ein Eingriff am Herzschrittmacher durchgeführt?

If so, what? _____
Wenn ja, welcher?

Are you pregnant? not certain yes no
Sind Sie schwanger? nicht sicher

Do you smoke? yes no

If so, what and how much daily: _____
Rauchen Sie? Wenn ja, was und wie viel täglich:

Do you have or have you ever had any of the following diseases: Liegen oder lagen nachstehende Erkrankungen vor:

Blood diseases / blood clotting disorders? yes no

Increased bleeding tendency (e.g. frequent nose bleeds, increased post-operative bleeding, increased bleeding from minor injuries or after dentist treatment, stronger or longer menstrual bleeding), tendency to bruise (frequent bruising possibly for no particular reason).

Bluterkrankung/Blutgerinnungsstörung? Erhöhte Blutungsneigung (z.B. häufiges Nasenbluten, verstärkte Nachblutung nach Operationen, bei kleinen Verletzungen oder Zahnarztbehandlung, verstärkte oder verlängerte Regelblutung), Neigung zu Blutergüssen (häufig blaue Flecken auch ohne besonderen Anlass).

Do you have any blood relatives with signs of blood disease / clotting disorders? yes no

Gibt es bei Blutsverwandten Hinweise auf Bluterkrankungen/Blutgerinnungsstörungen?

Has a transfusion of blood or blood components ever been necessary? yes no

War jemals eine Übertragung von Blut/Blutbestandteilen notwendig?

If so, were there any complications? yes no
Wenn ja, kam es dabei zu Komplikationen?

Blood clot (thrombus) / blood vessel occlusion (embolism)? yes no

Blutgerinnsel (Thrombose)/Gefäßverschluss (Embolie)?

Allergies / Oversensitivity? yes no

Medications, foods, contrast media, iodine, sticking plaster, latex (e.g. rubber gloves, balloons), pollen (grass, trees), anaesthetics, metals (itching caused by metal spectacles frames, jewellery, jeans buttons).

Allergie/Überempfindlichkeit? Medikamente, Lebensmittel, Kontrastmittel, Jod, Pflaster, Latex (z.B. Gummihandschuhe, Luftballon), Pollen (Gräser, Bäume), Betäubungsmittel, Metalle (z. B. Juckreiz durch Metallbrillengestell, Modeschmuck oder Hosennieten).

Any other: _____
Sonstiges:

Diseases of the respiratory tract (breathing passages) or lungs? yes no

Asthma, chronic bronchitis, inflammation of the lungs, emphysema, sleep apnoea (intense snoring with breathing interruptions), vocal cord/diaphragm paralysis.

Erkrankung der Atemwege/Lungen? Asthma, chronische Bronchitis, Lungenentzündung, Lungenemphysem, Schlafapnoe (starkes Schnarchen mit Atemaussetzern), Stimmband-Zwerchfelllähmung.

Any other: _____
Sonstiges:

Metabolic diseases? yes no

Diabetes (sugar sickness), Gout.

Stoffwechsel-Erkrankungen? Diabetes (Zuckerkrankheit), Gicht.

Any other: _____
Sonstiges:

Thyroid diseases? yes no

Underactive thyroid, overactive thyroid.

Schilddrüsenerkrankungen? Unterfunktion, Überfunktion.

Any other: _____
Sonstiges:

Kidney diseases? yes no

kidney insufficiency, kidney inflammation.

Nierenerkrankungen? Nierenfunktionsstörung (Niereninsuffizienz), Nierenentzündung.

Any other: _____
Sonstiges:

Communicable (contagious) diseases? yes no

Hepatitis, tuberculosis, HIV.

Infektionskrankheiten? Hepatitis, Tuberkulose, HIV.

Any other: _____
Sonstiges:

Predisposition to impaired wound healing, abscesses, fistulas, excessive scar formation (keloids)? yes no

Neigung zu Wundheilungsstörungen, Abszessen, Fisteln, starker Narben-Bildung (Keloide)?

Any other acute or chronic diseases/illnesses? yes no

Nicht aufgeführte akute oder chronische Erkrankungen?

Please describe: _____
Bitte kurz beschreiben:

If certain answers are preselected, please correct them if anything has changed.)

Medical documentation for the informative interview

Ärztl. Dokumentation zum Aufklärungsgespräch

To be completed by the doctor Wird vom Arzt ausgefüllt

Über folgende Themen (z. B. mögliche Komplikationen, die sich aus den spezifischen Risiken beim Patienten ergeben können, nähere Informationen zu den Alternativmethoden, Erfolgsaussichten) habe ich den Patienten im Gespräch näher aufgeklärt:

planned procedure: geplanter Eingriff:
 Defibrillator **Pacemaker** Herzschrittmacher

 Removal Entfernung
 System conversion Systemumwandlung
Removal Austausch:
 Generator Aggregat **Probes** Sonden
Capability to give wilful consent:**Fähigkeit der eigenständigen Einwilligung:**
 The patient is **capable of making a decision** on the recommended procedure on his/her own and giving his/her consent for the procedure.

Der/Die Patient/in besitzt die Fähigkeit, eine **eigenständige Entscheidung** über die empfohlenen Maßnahme zu treffen und seine/ihre Einwilligung in den Eingriff zu erteilen.

 The patient is represented by a **custodian** with a custodian's card which states that he/she is also responsible for the patient's healthcare, or by a trusted person with a healthcare proxy. These persons are capable of making a decision in the best interest of the patient.

Die Patientin/Der Patient wird von einem **Betreuer** mit einem die Gesundheitsorge umfassenden Betreuerausweis oder einer Vertrauensperson mit einer Vorsorgevollmacht vertreten. Diese sind in der Lage, eine Entscheidung im Sinne des Patienten zu treffen.

 Custodian's card healthcare proxy advance healthcare directive has been submitted.

 Betreuerausweis Vorsorgevollmacht Patientenverfügung liegt vor.

Place, date, time [Ort, Datum, Uhrzeit]

Doctor's signature [Unterschrift der Ärztin/des Arztes]

Patient's refusal Ablehnung

The doctor _____ has provided me with detailed information regarding the procedure at hand and has also pointed out the disadvantages of rejecting it. I have understood the information provided to me and reject the procedure suggested to me.

Die Ärztin/der Arzt hat mich umfassend über die vorgeschlagene Maßnahme und über die sich aus meiner Ablehnung ergebenden Nachteile aufgeklärt. Ich habe die diesbezügliche Aufklärung verstanden und lehne die mir vorgeschlagene Maßnahme ab.

Place, date, time [Ort, Datum, Uhrzeit]

Refusal of patient / legal guardian / witness if applicable
[Ablehnung Patientin / Patient / Betreuer / ggf. des Zeugen]**DECLARATION OF CONSENT**

Please tick the appropriate boxes and confirm your statement with your signature below:

 I hereby confirm that I have understood all sections of this form. I have read the entire form (5 pages). During the pre-procedure interview with the doctor _____, I received detailed information regarding the course of the scheduled procedure, the risks, complications and side effects associated with it as they apply to my particular case as well as the advantages and disadvantages of any alternative methods. **Ich bestätige hiermit, dass ich alle Bestandteile der Patientenaufklärung verstanden habe.** Diesen Aufklärungsbogen (5 Seiten) habe ich vollständig gelesen. Im Aufklärungsgespräch mit der Ärztin/dem Arzt wurde ich über den Ablauf der geplanten Maßnahme, deren Risiken, Komplikationen und Nebenwirkungen in meinem speziellen Fall und über die Vor- und Nachteile der Alternativmethoden umfassend informiert.

 I deliberately refrain from obtaining a more detailed explanation. However, I hereby confirm that the doctor _____ instructed me regarding the necessity of the procedure, its type and scope as well as the fact that all medical procedures are accompanied by certain risks.

Ich verzichte bewusst auf eine ausführliche Aufklärung. Ich bestätige hiermit allerdings, dass ich von der Ärztin/dem Arzt über die Erforderlichkeit der Maßnahme, deren Art und Umfang sowie über den Umstand, dass alle medizinischen Maßnahmen Risiken bergen, informiert wurde.

 I hereby confirm that I do not have any additional questions and do not need more time for consideration. I consent to the procedure proposed. I have answered the questions regarding my medical history (anamnesis) fully to the best of my knowledge.

Ich versichere, dass ich keine weiteren Fragen habe und keine zusätzliche Bedenkzeit benötige. Ich stimme der vorgeschlagenen Maßnahme zu. Die Fragen zu meiner Krankengeschichte (Anamnese) habe ich nach bestem Wissen vollständig beantwortet.

My consent also applies to any necessary additional measures as well as to any required changes or additions to the procedure. Meine Einwilligung bezieht sich auch auf alle notwendigen Neben- und Folgemaßnahmen, sowie auf erforderliche Änderungen oder Erweiterungen des Maßnahme.

 I confirm that I am capable of following the instructions given to me by my doctor.

Ich versichere, dass ich in der Lage bin, die ärztlichen Verhaltenshinweise zu befolgen.

 I agree that my copy of this explanatory form may be sent to the following e-mail address: Ich bin damit einverstanden, dass meine Kopie dieses Aufklärungsbogens an folgende E-Mail-Adresse gesendet wird:

e-mail address [E-Mail-Adresse]

Place, Date, Time [Ort, Datum, Uhrzeit]

Signature of the patient / legal guardian(s) [Unterschrift Patientin / Patient / Betreuer]

Copy/Kopie:

 received/erhalten waived/verzichtetSignature Copy received/waived
Kopieerhalt/-verzichtet