## MAVIG INFORMATIONAL FLYER ON RECOMMENDED RADIATION PROTECTION

based on the 3rd edition of the

#### "Guidelines to establish and operate catheterization laboratories and hybrid operating rooms/hybrid laboratories"

published in 2015

In order to help support hospitals to have a modern and state of the art layout and operation of their cardiac catheter laboratories and hybrid operating theatres, the German Cardiology Society (Deutsche Gesellschaft für Kardiologie – Herz- und Kreislaufforschung e.V. - DGK )published the 3rd edition of the Guideline in February 2015.

This guideline deals with organisational, technical, constructional, and legal requirements for the layout and operation of cardiac catheter laboratories and hybrid operating theatres.

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#### Introduction

With this informational brochure, MAVIG would like to offer you a guide to the latest technological stand and the variety of radiation protection options, taking into account the recommendations of the German Cardiology Society.

The guideline also considers the latest cardiological procedures such as invasive electrophysiology, the implantation of cardiac rhythm devices, and catheter-based valve treatment.

Section 3 of the society's guideline is devoted to radiation protection, which emphasises the high importance of radiation protection measures.

The radiation protection options are divided into

- Permanent protective equipment such as ceiling suspended radiation protective shields or mobile protective shields (classified in the guideline as "Site specific shields")
- Personal protective equipment (PPE) such as radiation protective clothing or safety glasses (classified in the guideline as "Individual measures for the examiner")
- Shields placed on or under the patient, e.g. radiation protective drapes (classified in the guideline as "Patient specific shields").

In this general overview, we would like to call your attention to the measures that can be used to meet the recommendations of the DGK guideline. For your guidance, we are using the classification of the radiation protection measures from the guideline. All radiation protection measures listed in the guideline are described and explained in this brochure.

Of course, we are happy to advise you on our products individually at any time.

#### Who we are:

MAVIG GmbH has been successful worldwide as an independent research and manufacturing company for over 90 years.

MAVIG products stand for quality and reliability, made in Germany. Our product range comprises above and below table devices to protect against scattered radiation, mobile protective shields, ceiling suspension systems for monitors and lights, radiation protective windows and curtains, as well as radiation protective clothing and accessories.

All MAVIG products are designed, manufactured, and distributed in strict observance of the international regulations and standards - in many cases, higher than internationally accepted minimal standards.

Our wide product portfolio covers all radiation protection measures described in the guideline to limit exposure to scattered radiation for the examiner and the patient. Thus, from one source, you are able to obtain all recommended products optimally designed to work with one another for their applications.

MAVIG GmbH, Munich (Publisher) (2015):

Informational flyer for the "Guidelines to establish and operate catheterization laboratories and hybrid operating rooms/hybrid laboratories".

Literaturnachweis:

 V. Schächinger, H. Nef, S. Achenbach et al. (2015) "Guidelines to establish and operate catheterization labo- ratories and hybrid operating rooms/hybrid laboratories", 3rd edition 2015, Kardiologe 2015 • 9:89–123

Further Literature:

 H. Eder, C. Seidenbusch, M. Treitl, P. Gilligan (2015) "A New Design of a Lead-Acrylic Shield for Staff Dose Reduced in Radial and Femoral Access Coronary Catheterization"
 Fortschr Röntgenstr 2015; 187:1-9

 P. Gilligan, J. Lynch, H. Eder, S. Maguire, E. Fox, B. Doyle, I. Casserly, H. Mc Cann, D. Foley. (2015) "Assessment of clinical occupational dose reduction effect of a new interventional cardiology shield for radial access combined with a scatter reducing drape."

Catheter Cardiovasc Interv. 2015 Jul 8. doi: 10.1002/ccd.26009

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## X-Ray Protection & System Solutions from One Source - MAVIG GmbH

Site and personal radiation protection offered by MAVIG includes all the recommendations of the guideline created by the German Cardiac Society.



An overview of radiation protection solutions and systems for cardiac catheterization labs and hybrid operating rooms from MAVIG's product portfolio

#### Depicted Above:

Radiation Protective Shield with Panel Curtain Protective Patient Covers Wrap Around Protective Clothing X-ray Protective Glasses Thyroid and Sternum Shield X-ray Protective Gloves X-ray Protective Head Wear Table Mounted Lower Body Protection Mobile X-ray Shields



On-Site consultation and advice from a team of experts.



#### Additional Protection:

Radiation Protective Windows X-ray Protective Curtains/Blinds

#### Ceiling Suspended Systems:

Ceiling Tracks and Stationary Columns Suspension Arms for Medical Grade Lamps and Monitors



## Ceiling Suspended, Protective Shield with Lead Strip Extension

For the first time in 1995, fixed radiation protective equipment, comprising of a ceiling suspended, protective shield and a lower body protection, became compulsory in interventional radiology workplaces in Germany, such as in cardiac catheter laboratories. This was due to the the Federal Guideline SV-RL (*Guideline for the technical testing of X-ray devices and stray radiation sources requiring approval*). These first protective shields without a panel curtain (Fig. 1), reduced the examiner's exposure to radiation 3 to 5 times.

The "Guidelines to establish and operate catheterization laboratories and hybrid operating rooms/hybrid laboratories" currently recommends using radiation protection shields with a panel curtain. The advantage is a distinctly higher protection compared to the shields without an additional panel curtain, as it screens off a considerable proportion of the scattered radiation emanating from the patient's body (underpassing radiation effect / Fig. 2).

A further refinement to this concept, MAVIG had already in 2014 designed a new radiation protective shield with a flexible panel with modified dimensions and shape to achieve the following goals:

- Elimination of the underpassing radiation
- Clear reduction of radiation exposure
- Optimal shielding for taller examiners
- Greater freedom of movement and enlarged protection zone for the examiner, co-examiner, and assistants
- Equal protection for femoral and radial approach

Using this new shield (series OT54/OT94) reduces the radiation exposure 6-fold at the examiner's and assistant's positions at a height of 160 cm when compared to using a shield without a paneled curtain.

If radiation protective drapes placed on the patient are additionally used, the protective zone is enlarged and the protective effect is increased 10-fold.

For further information, see page 27.



Condition for the examiner with the new protective shield with a panel curtain: The purple area indicates a significantly lower scattered radiation dose in the upper body area.



# Lower Body Protection with a Pivoting Side Part

Lower body protective systems are an integral part of every radiation protection concept in interventional radiology. In combination with a ceiling suspended, radiation protective shield, they represent the required basic protection in a cardiac catheter laboratory or hybrid theatre.

The recommendation of the "Guidelines to establish and operate catheterization laboratories and hybrid operating rooms/hybrid laboratories" describes a lower body protection against scattered radiation with a pivoting side part, a shield positioned parallel to the table, and appropriate upper shields to minimize the gap between upper and lower body protection.

The idea is a distinctly extended zone of protection for the examiner as well as the assistants. Based on proven solutions, MAVIG has developed new lower body protection designs that meet all requirements.

The generous dimensions of the systems provide an extensive zone of protection for the staff exposed to radiation on either side of the table (Fig. 3a, series UT70 and Fig. 3b, series UT6030).

Position the lower body protection exactly as you need it: Either parallel to the table or with a pivotable wide and/or narrow side part. These can be pivoted up to 90°. The narrow side part is also ideal to align the lower body protection with the side of the table in cases where accessory rails protrude out (see sketch, Fig. 3b).

Flexible, overlapping strips allow more comfort for the examiner and unhampered movement of the C-arm.

Removable upper shields create the indispensable bridge to the ceiling suspended protection against scattered radiation.

ca. 120 cm	
	Fig. 3b



## Mobile Radiation Protection, Mobile Lead Acrylic Shields

Mobile X-ray protective shields are a basic component in interventional workplaces, especially when a ceiling suspended radiation shield or lower body protection cannot be used or is not available during specific procedures. Thus, these are included in the recommendations of the guideline.

MAVIG manufactures mobile protective shields out of modern materials in various forms. In particular, leadacrylic is a material of choice for its outstanding properties.

We design mobile protective devices that can be kept close to the body to allow unrestricted access to the patient. The free-moving shields, which can be moved around the room effortlessly, are anatomically contoured and can thus be easily carried along with the body (Fig. 4, WD300). When not in use, the access openings can be covered with additional radiation protective strips.

The height-adjustable radiation protection shield (Fig. 5, WD261) allows direct access to the table and patient. Here, flexible radiation protective drapes, well known in protective clothing, are the material of choice.

Also part of our portfolio are radiation protective shields such as the shield series WD257 shown in Fig. 6, which is equipped with a height-adjustable upper panel made of lead acrylic, or large shields, like the WD306, Fig. 7.







## Radiation Protection for Foot Switches

The recommendation of the "Guidelines to establish and operate catheterization laboratories and hybrid operating rooms/hybrid laboratories" calls for a lead equivalent shield for the foot switch for situations in which it is not longer covered by the lead strips of the lower body protection.

Such shields are custom made by MAVIG specifically for the relevant foot switch from the different equipment manufacturers (Fig. 8).

An alternative solution with a distinct radiation protection advantage, which reaches up to the level of the armpits, is the mobile MAVIG radiation protective shield WD261 in Fig. 9. This anatomically adopted means of protection is kept close to the body and offers the user unhampered access to the patient with the highest possible flexibility and freedom of movement.

Thanks to the shield's specific design, foot switches can be continued to be used without restrictions while protection up to the user's foot dorsum is offered (Fig. 10 and 11).

The foot switch is simply positioned between the shield's two supports. Because of the flexibility of the radiation protective drape, the foot switch can either be brought inside the shield or the user can extend his/her foot slightly outwards, in which case the radiation protection drape still provides protection as far as the foot dorsum.





## X-Ray Protective Clothing, Wrap Around Coat or Two-Piece

Wrap around coats or two-piece garments, also known in some standards as "heavy closed aprons" (Front protection class II: lead equivalence Pb 0.35 mm, Back protection class I: lead equivalence Pb 0.25 mm), are also recommended in cardiac catheter examinations according to DIN 6815:2013-06.

The "Guidelines to establish and operate catheterization laboratories and hybrid operating rooms/hybrid laboratories" not only specifies a lead equivalence of Pb 0.35 mm (protection class II) for the front of the apron, but also gives an alternative front protection lead equivalence of Pb 0.50 mm for the front of the apron (protection class III).

A higher lead equivalent value though means a higher weight of the X-ray protective clothing. This is a physical burden on the radiation exposed staff, especially if they have to wear the clothing for prolonged periods of time. Therefore, when deciding about the protection class, it should be taken into consideration that in the range of X-ray tube voltages between 60 and 100 kV no meaningful higher X-ray absorption is achieved by the use of protective clothing with a lead equivalence of Pb 0.50 mm when compared to protective clothing with a lead equivalence of Pb 0.35 mm. This can been seen in Table 1, which shows a comparison of X-ray absorption rates of different lead equivalences in work like conditions.

The large weight distribution has made two-piece outfits the most popular type of wrap around protective clothing (Fig. page 16, series RA631). The shoulders are noticeably relieved, as a substantial proportion of the total weight is transfered to the hips. Another aspect is the greater freedom of movement compared to a one-piece garment (coat).





One piece, X-ray protective coats (series RA632) can also make sense, if they have suitable weight relieving systems such as stretch belts.

Particularly, when they are worn for short periods, some users prefer one-piece protective clothing because they take slightly less time to put on and take off.



Adding sleeves to the protective clothing reliably covers the otherwise unprotected part of the armhole and ensures proper radiation protection.

The radiation exposure from scattered radiation falling laterally over the armhole is distinctly reduced by such sleeves and the shoulder joint is also completely shielded.



The cover is made of a special microfibre material which meets the requirements of DIN EN 13795 for surgical textiles and offers the wearer a high degree of comfort.

#### **Thyroid Protection**

The thyroid is a very radiation sensitive organ of the human body and has a high protection need. Wearing an appropriate shield to protect the thyroid should be a necessity during dose intensive examinations.

The "Guidelines to establish and operate catheterization laboratories and hybrid operating rooms/hybrid laboratories" regards the use of a thyroid shield as mandatory in its recommendations.

In the publication "Optimising radiation protection for radiology staff on the basis of the effective dose", it has been proven that additionally wearing a thyroid shield reduces the effective dose 1.7 to 3.0 fold for the radiation user (H. von Boetticher, J. Lachmund, W. Hoffmann, G. Luska, Fortschr Röntgenstr 2006; 178:287-291; Georg Thieme Verlag KG Stuttgart). It was found that a thyroid shield not only ensures that the organ dose thresholds are complied with, but also contributes significantly to the reduction of the effective dose.

Also the standard DIN 6815: 2013-06 (Rules for testing radiation protection for medical X-ray equipment up to 300 kV), which deals with protective clothing for the staff, recommends the use of thyroid shields in the cardiac catheter laboratory.

MAVIG thyroid protection not only offers optimal protection for the thyroid, but additionally through a generously cut "bib", protects the upper sternal region. This added protection is also important as red bone marrow for blood production is present here, even in adulthood, and often this area is not adequetly covered due to low neckline cuts of protective aprons.

The anatomically optimised "bib" also ensures weightbalanced and secure positioning of the thyroid/sternum shield. This means the weight is distibuted and the burden is not kept solely on the neck.



A thyroid protection with a generously cut bib will securly cover the many different shapes of neckline cuts of radiation protective garments (series RA614).

Fig. 12: Glasses model BR126 are optimally suited to the facial form of the user and equipped with protective side shields.

## Eye Protection, Wrap Around Lead Glasses

The sensitivity of the human eye to radiation exposure is classified as very high. The lens of the eye is particularly at risk from radiation. It has long been known that radiation exposure when working with ionising radiation can lead to radiation-induced lens opacities (radiation cataracts). The radiation cataract was originally regarded as a deterministic effect, which means a certain damage that happens after a threshold value is exceeded.

However, it has been reported since 2009 that there is probably not a threshold dose, below which damage to the lens of the eye can be definitely ruled out and that stochastic radiation damage is therefore likely even in low dose ranges.

In their recommendations from April 2011, the ICRP (International Commission on Radiological Protection) included a dramatic reduction of eye dose limits. They advised that the annual dose to the lens of the eye should not to exceed 20 mSv, averaged over 5 years. They went even further and also stated that the dose in any one year should not be over 50 mSv.

The "Guidelines to establish and operate catheterization laboratories and hybrid operating rooms/hybrid laboratories" states that the exposure of the examiner's eye increases dramatically when a leaded acrylic shield (site specific lead equivalent shields) and lead glasses are not used. The logical consequence is the recommended use of lead glasses.

The effectiveness of X-ray protective glasses depends on how well the protective lenses fit closely to the cheeks and wraps around the sides. The direction from which the scattered radiation hits the lens of the eye must be taken into consideration. The direction or angle will usually vary during a procedure, depending on the position and head movements of the radiation-exposed person. In most applications, looking at the patient, the area of the wound or puncture, or the monitors are the most common actions and determine the angle of incidence. Knowing this, we can conclude that the secondary radiation emitted from the laying patient does not just hit the front of the eye lens, but also comes from below or the side. This needed, multi-angle protection is best demonstrated in Fig. 12.



Unsuitable protective glasses: The pictures above show two good examples of incorrectly fitting glasses that allow radiation to directly hit the lens of the eye undeterred.

MAVIG lenses are made of radiation protective glass in high optical quality. Excellent light transmission and perfect transparency are guaranteed. Precision processing and lens adjustment to the respective frame assures top quality.

The MAVIG collection offers a wide range of frame models in order to be able to match many different facial features and forms with correctly fitting protective glasses.



## Radiation Protective Head Wear, "Cap or Helmet"

An increased risk of brain tumours in medical staff due to radiation exposure while working in high-dose workplaces is currently under discussion. Particularly, in work areas in which the radiation dose is not reduced by a permanent radiation protective system, the skull is certainly exposed to high levels of scattered radiation.

In the "Guidelines to establish and operate catheterization laboratories and hybrid operating rooms/hybrid laboratories", caps or helmets are pointed out as an option for radiation protection for such work areas.

The publication *"Brain tumours among interventional cardiologists: A cause for alarm"* (Ariel Roguin, Jacob Goldstein, Olivier Bar; EuroIntervention 2012; 7:1081-1066) talks about incidences of brain tumours in interventional cardiologists, particularly tumors formed in the left half of the brain. Dr. Ariel Roguin presented a summary of further cases in a lecture at the SOLACI Congress in Argentina in 2014. (Link: caci.org.ar/docs/novedades/roguin-ariel.pdf)

For this increasingly discussed need, MAVIG offers three different radiation protective head coverings. To meet the users' individual needs, the head wear has varying protective and air permeable surface areas.

- Fig. 13: Radiation protective cap with breathable insert (series RA611)
- Fig. 14: Closed radiation protective cap (series RA612)
- Fig. 15: Radiation protective headband (series RA610)

The RöV - Ordinance on protection against damage from X-ray radiation (German X-ray Ordinance) - stipulates in section 21 that the protection of people occupationally exposed to radiation is to be ensured primarily by constructional and technical fixtures and equipment or by suitable working procedures.

Using an effective on-site radiation protection (site specific lead equivalent shields) such as:

- A ceiling suspended, scattered radiation protective shield with a panel curtain
- A lower body, scattered radiation protection with an upper shield to close the gap to the ceiling suspended shield
- Supplementary protective measures such as radiation protective drapes, which are placed on top of the sterile cover of the patient (with appropriate sterile disposable coverings or as a sterile disposable product)

can drastically reduce the staff's radiation exposure, especially in the cranial region.

If these site specific radiation protective measures have been correctly implemented, the protection class of the radiation protection worn by the medical staff (PPE = personal protective equipment) can be positively influenced. Meaning the protective clothing used does not need to be of the highest lead equivalence, but can be in a lower protection class and be noticeably lighter in weight.

The MAVIG gloves HS100 convince with their high touch sensitivity and dexterity.

Microtextured surfaces create a secure grip, even in a wet environment. The soft and highly elastic material and the anatomically well contoured fit prevent fatigue and ensure optimal ergonomic qualities.

#### **Radiation Protective Gloves**

The "Guidelines to establish and operate catheterization laboratories and hybrid operating rooms/hybrid laboratories" describes the wearing of X-ray protective gloves as another option for radiation protection.

The recommendations of DIN 6815:2013-06 (rules for testing radiation protection for medical X-ray equipment up to 300 kV) for protective clothing for the staff indicate the use of surgical gloves with a radiation shielding effect in the cardiac catheter laboratory.

MAVIG's sterile protective gloves, which absorb X-ray radiation, certainly make it possible to optimise the radiation protection measures for the medical staff (series HS100).

Remarkably, a protective factor of 2 is obtained when the gloves are worn in the scattered radiation zone (X-ray tube voltage 60 – 80 kV). This dose reduction of more than 50% effectively helps to reduce the risk (see Table 2).

Measured values		Average
Attenuation of the scattered radiation (skin dose reduction)	X-ray tube voltage 60 kV X-ray tube voltage 80 kV X-ray tube voltage 100 kV	63 % 53 % 46 %
Lead equivalence	Pb 0.03 – 0.04 mm	
Reduction of effective radiation	X-ray tube voltage 80 kV	20-25 %
Table 2: The attenuation properties were determined in the broad beam		

in compliance with IEC 61331-1 (EN 61331-1:2002). The values for the skin dose reduction refer to a nominal material thickness of 0.30 mm.

Additional measures, such as the use of radiation protective shields with panel curtains and supplementary radiation protective drapes, which are positioned on or under the patient, can further reduce the hand dose for the examiner.



The gloves are classified as a powder-free, surgical glove that in addition to the basic properties of material consistency, impermeability, dimensions, and protection against chemicals and microorganism, provide effective protection against secondary X-ray radiation.



#### **Radiation Protective Drapes**

The "Guidelines to establish and operate catheterization laboratories and hybrid operating rooms/hybrid laboratories" describes protective equipment to be placed on top of or underneath the patient in order to better protect the radiation exposed staff in the room.

MAVIG radiation protective drapes achieve outstanding results. They are specifically tailored to the procedure or to the access point and are positioned on the patient adjacent to the relevant puncture site. When used with the radiation protective shield with panel curtain (see Fig. 16, with femoral access), the drapes considerably enlarge the protective zone and extend the effect of the panel curtain.

Not only the examiner, but also the co-examiner and assistants in the room are better protected. The radiation exposure is reduced by another 30 - 40% when compared to the use of just the shield with the panel curtain.

If a radiation protective shield is used without a panel curtain, the examiner's exposure can also be reduced by the use of these drapes, although to a lesser extent. Also in workplaces without fixed protective equipment, the radiation protective drapes provide a basic measure for reducing the examiner's dose.

MAVIG offers reusable radiation protective drapes, as well as disposable radiation drapes in its portfolio. The reusable drapes are used with corresponding sterile disposable covers so that it is possible to position the drapes on top of the sterile patient cover. Thus, the radiation protective equipment is visable and can be quickly repositioned or removed as needed without problems.



The disposable drapes are supplied as a sterile product and are also positioned on top of the sterile patient cover. After use, these drapes can be simply disposed of, in adherence to local regulations.



The drapes are available in various forms and are designed for specific applications or procedures.

Fig. 19: Illustration of the use of our disposable radiation protective drape for pacemaker operation, defibrillator implantation, and RF ablation (series AS100).

Radiation protective drapes without cutouts are also very suitable for minimising the examiner's hand exposure, if they are placed on the patient's thighs.



Fig. 20/21 Radiation protective drapes which can be placed above or below the patient outside of the imaging field can further reduce the scattered radiation (for hygienic reasons, the patient's body should be covered with a sterile, disposable cover), series RP689.

The drapes are made of the same highly flexible protective material and textile outer cover, which is also used for personal protective clothing.



## Radiation Protective Drapes, on Top of or Underneath the Patient

The use of the radiation protective drapes described on page 27 largely remove the necessity of using unsterile and generally larger patient drapes.

The minimised size of the radiation protective drapes ensures maximum comfort for the patient, while providing excellent protection for the examiner. They are also benifical to the user as they have a reduced weight, are simple to place and use, and minimise the risk of the drape getting into the imaging field.

Even extensive covers with or without openings for the puncture site, as shown in Figures 20-22, do not provide an overall advantage over the radiation protective drapes specifically developed for use under sterile conditions (reusable shield with sterile disposable cover or sterile disposable product).



## Our Advantage: X-Ray Protection from One Source



vertable protection against scattered radiation

- Ceiling suspended, highly transparent, lead acrylic, radiation protective shield with flexible panel curtain Protective shields for other positions of the staff around the table, including anaesthesia or pacemaker



Undertable protection against scattered radiation

- Functional, table mounted, lower body protection systems in various configurations
  Removeable upper shields in order to close the gap to the overtable protection against scattered radiation



Mobile protection against scattered radiation

- Smooth running, mobile protective shieldsFor spatial protection or anatomically fitted for working on the patient • Height adjustable or at fixed height

 $\checkmark$ 

## The Advantages you Gain from Working with us:



Personal protective equipment PPE

- Ergonomically designed aprons, coats, and
- Ergonomically designed aprons, coats, and two-piece costumes
  Eye protection collection catering to different facial features and forms
- Sterile, radiation protective surgical glovesHead wear in various designs



#### Patient specific drapes

- disposable covers Disposable radiation protective drapes



Radiation protective windows and curtain systems

- to shield the control room or other areas Customized curtain systems, such as vertical blinds

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A free download of the "Guideline on the layout and operation of cardiac catheter laboratories and hybrid operating theatres/hybrid laboratories" 3rd edition 2015 as a PDF is available on the website of the German Cardiac Society - Cardiovascular Research (Deutsche Gesellschaft für Kardiologie – Herz- und Kreislaufforschung e.V. - DGK):

http://leitlinien.dgk.org/2015/leitlinie-zum-einrichten-und-betreiben-von-herzkatheterlaboren-und-hybridoperationssaelenhybridlaboren/

