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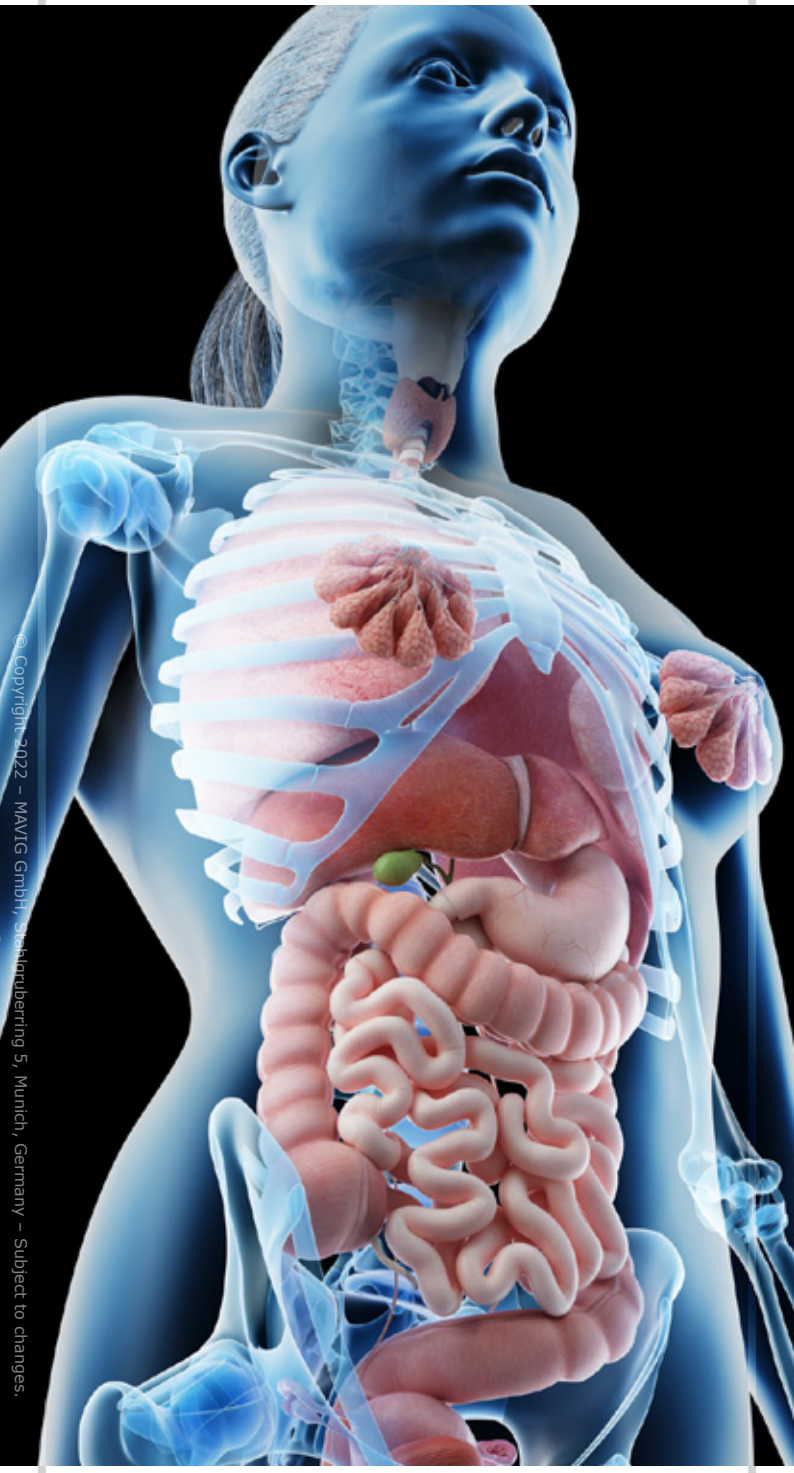
MAVIG Levio®

Increased protection of organs that are sensitive to radiation with lighter protective aprons

The new approach to X-ray protection



MAVIG

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Re-evaluation of the protective effect of X-ray protective clothing by considering the effective dose

Various studies are concerned with the physical stress caused by wearing X-ray protective clothing [1] – [3], especially at workplaces in interventional radiology.

X-ray protective clothing belongs to the category of personal protective equipment (PPE) and is an essential part of everyday work for users of radiation. Possible damage to the musculoskeletal system of the persons concerned is considered to be scientifically proven if the clothing is worn for long periods.

In this respect, the scientific literature recognises a considerable risk of orthopaedic damage in long-term users of radiation. However, personal protective equipment should not lead to irreversible physical impairments, even when worn for long periods!

Ultimately, there has been a lack of concepts and possibilities for significantly reducing the weight of protective equipment and providing substantial physical relief for people who are occupationally exposed to radiation.

Recent findings [4] – [6] now describe the need to rethink radiation protection.

The current approach of using the lead equivalent value alone to evaluate the protective effect of X-ray protective clothing is being critically examined in the latest publications. Instead, the actual distribution of the dose in the body and the radiation sensitivity of the primarily-exposed organs are used.

Consistent application of this concept, supported by computer simulations, leads to protective clothing with the same protection at lower weight or more protection at the same weight.

MAVIG is the first manufacturer to successfully implement these new findings with the Levio® concept.

Current regulatory requirements

Regulations

Due to the health-related function of X-ray protective clothing, it is subject to **regulations** that govern **shielding properties and design** throughout Europe and at national level.

These include first and foremost:

REGULATION (EU) 2016/425
of the European Parliament and of the Council of 9 March 2016 on personal protective equipment

DIN EN 61331-1:2016 / IEC 61331-1:2014
Protective devices against diagnostic medical X-radiation
Part 1: Determination of attenuation properties of materials

DIN EN 61331-3:2016 / IEC 61331-3:2014
Protective devices against diagnostic medical X-radiation
Part 3: Protective clothing, eyewear and protective patient shields

The current standards assume an even distribution of material on the body based on the lead equivalent value and leave no room for application-specific criteria. However, the lead equivalent value merely represents a material parameter and not a direct measure of health protection.

Thus, large parts of the body (from the neck to the knees) are covered with a uniform lead equivalent, without taking into account the examination-specific dose distributions on the one hand and the different radiation sensitivities of the organs on the other.

This blanket standardisation in the structure of protective clothing leads to an unnecessarily high weight load.

Protective clothing is heavy – with conventional protective material distribution

Lead equivalent and weight

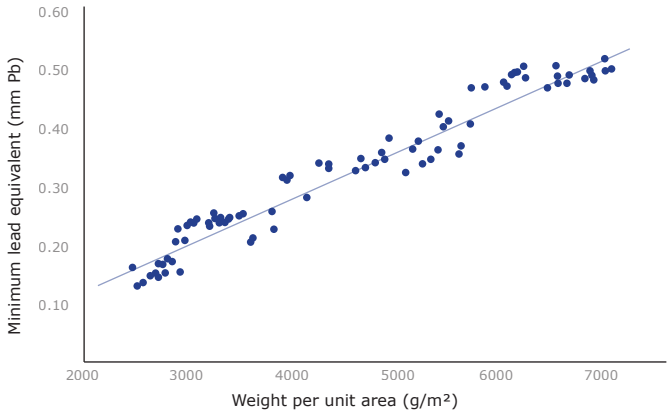
The last time it was possible to significantly reduce the weight of X-ray protective clothing was two decades ago with the introduction of lead-reduced protective materials. Since then, further alignment of the characteristics "high protective effect" and "low weight" has not been possible.

The graph below illustrates this relationship. For this purpose, MAVIG determined the lead equivalent value for various lead-free and lead-containing (solid lead and lead composites) protective materials and plotted this against the weight per unit area.

The graph clearly shows:

Exceptionally lightweight materials protect less against X-rays.

Weight comparison of various protective materials



Measured values ● minimum lead equivalent value of different serial materials from various manufacturers according to IEC 61331-1:2014, over the respective surface area weight.

Goal: Effective use of protective material

According to current knowledge, the correlation between lead equivalent value and weight per unit area does not permit any further reduction in the weight of the protective materials (see Chapter 1). Consequently, **new approaches** must be found. In their recent studies [4] – [6], the authors Dr Heinrich Eder and Dr Helmut Schlattl present a completely new approach for substantially optimising the weight of X-ray protective clothing while maintaining or increasing protection.

It is no longer just the lead equivalent that is considered but the protection factor of a radiation protective apron based on the effective dose.

The effective dose is a weighted whole-body dose measurement that takes into account the different radiation sensitivities of organs and tissues and thus best represents possible long-term damages such as radiation cancer and leukaemia. That is why the effective dose is specified in the Radiation Protection Act (Germany) as the basis for determining body doses and limits.

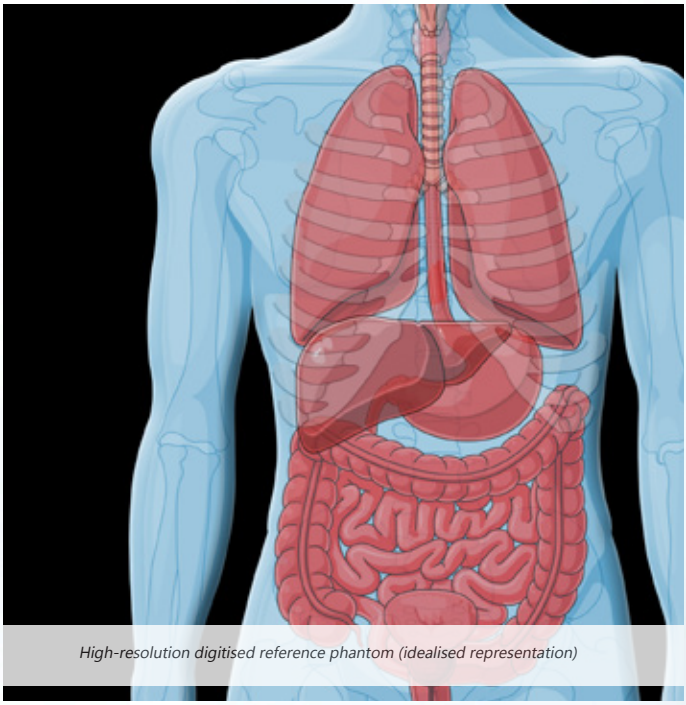
The protection factor (as known from sunscreen) tells you how long you can stay in a radiation field compared to without protection. *For example*, a protection factor of 50. This means that you can stay in the radiation environment in question 50 times as long as without protection before exceeding a given limit.

Instead of measuring X-ray protective clothing based on the lead equivalent value, as was previously the case, protection factors based on the effective dose now state the actual protective effect of the personal protective equipment.

The scientific basis

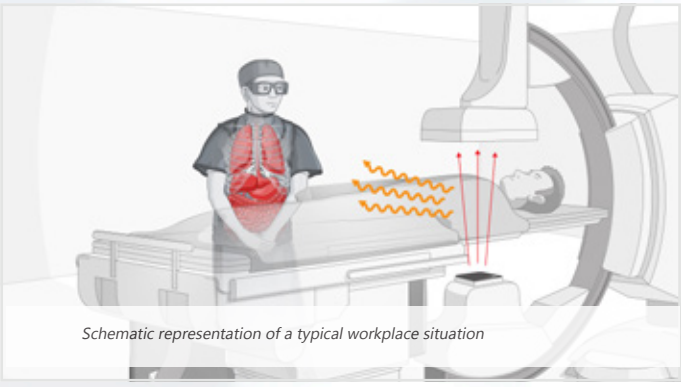
The radiobiological (effective dose-based) protection factor is calculated using a digitised phantom.

For this purpose, the International Commission on Radiological Protection (ICRP) has created a female and a male high-resolution digital reference phantom of the human body, including all organs and tissues. It is the basis for calculating body doses.



High-resolution digitised reference phantom (idealised representation)

In the publications [4] – [6], various Monte Carlo simulations were carried out on typical workplace situations (patient lying down, examiner looking at the monitor, etc.) with the aid of the aforementioned anthropomorphic ICRP reference model as well as extensive personal dose measurements at interventional workplaces.



Schematic representation of a typical workplace situation

It was shown that approx. 80% of the examiner's effective dose occurs in the area from the chest to below the gonads because this is where the organs that are particularly sensitive to radiation, such as the colon, stomach, urinary bladder, gonads and large parts of the active bone marrow are located.

Results:

To reduce the effective dose as much as possible, the radiation protective material must therefore be concentrated in the area from above the chest to below the gonads.

X-ray protective clothing with this optimised arrangement of protective material is significantly lighter than conventional radiation protective clothing while providing the same level of protection.

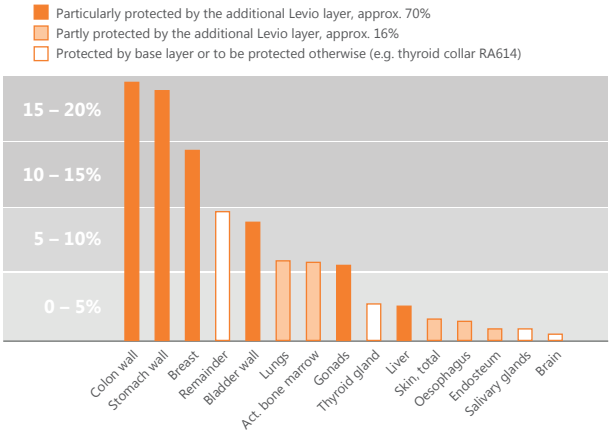
Likewise, the reinforced structure of the protective material in the area from the chest to the gonads makes a higher protection factor possible with the same weight.

Levio® Edition

MAVIG is the first manufacturer of radiation protective clothing (PPE) to develop a regulatory-approved and certified apron collection that implements the presented concept – the Levio Edition.

The protective clothing of the Levio Edition offers additional shielding for the most radiation-sensitive organs from the chest to the gonads resulting in an especially high dose reduction in those areas. The protective material is applied where it is most effective.

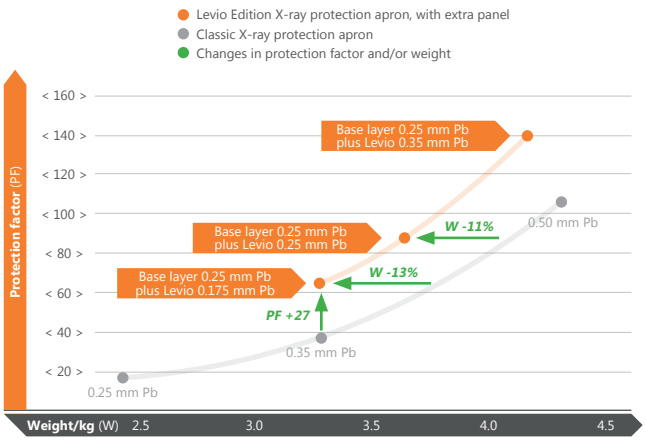
Contribution of the organ dose of the radiation user to the effective dose (%)



Reference: taken from [5] – Table 4 (patient lying down, examiner without radiation protection, 100 kV, doctor turned 30° to the right)

Thanks to this principle, protective clothing of the Levio Edition is lighter while maintaining the same shielding effect. On the other hand, protective clothing with a higher shielding effect can be produced while maintaining the weight.

Protection factor and weight comparison



Comparison of the Levio Edition with classic aprons: Protection factor – weight

Special design of the Levio Edition

The Levio Edition X-ray protective clothing consists of two layers of radiation protection material. The first, long protective layer, the basic protective layer, extends to the knee, as required in IEC 61331-3:2014 / DIN EN 61331-3:2016; chapter "5.2 Design". This basic radiation protective layer is designed in the minimum lead equivalent of a radiation protection apron of 0.25 mm Pb.

A shorter, second layer of radiation protective material, the Levio panel, is added in the area of the organs that are particularly sensitive to radiation, from above the chest to below the gonads, so that the complete mammary gland tissue is covered down to and including the gonads.

In order to achieve the greatest possible weight reduction, we manufacture the Levio panel specifically tailored to the individual body measurements. In this way, we produce individually suitable X-ray protective clothing for each user of radiation.

The concept presented and the resulting development of X-ray protective clothing can be implemented on a user specific basis for selected MAVIG models.

MAVIG all-round protective coat Levio Edition – opened front view

Instructions for dimensioning the Levio panel

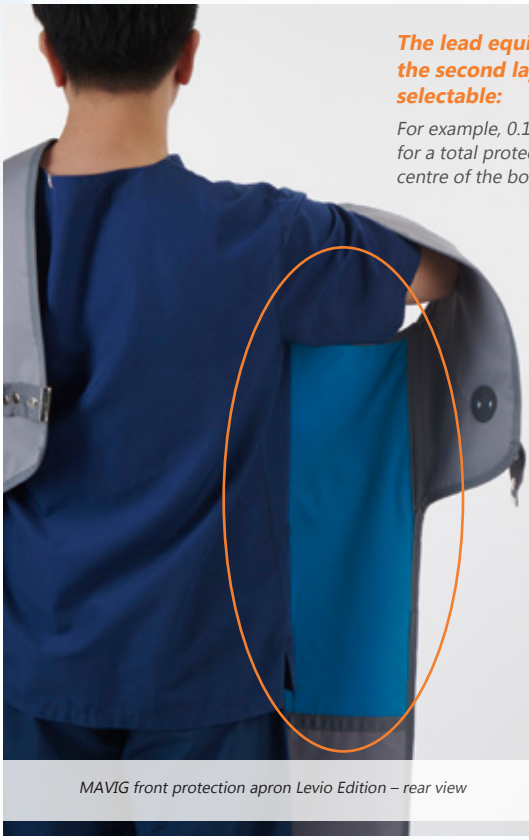
- ***Position from above***
  Measure from the middle of the shoulder to the start of the chest. Anatomically speaking, the chest begins at the second rib. This should be approximately midway between the collarbone and the mammary papilla.
- ***Length***
  Measure from the middle of the shoulder or from the waist (waist-band of the skirt) in the case of a skirt to below the gonads. In most cases, these should be covered if you measure to about 10 cm below the crotch.

In order to visualise the reinforced area at any time, it is highlighted in colour on the inside of the protective clothing.

The easy way to a new generation of X-ray protective clothing

As usual, you can choose the type, colour, radiation protective material and outer material. You can also select the lead equivalent value of the Levio panel yourself, for example, 0.175 mm Pb to achieve a total lead equivalent value of approx. 0.42 mm Pb (base protective layer 0.25 mm Pb + Levio panel 0.175 mm Pb).

In order to clearly state the lead equivalent value, both lead equivalent values of the front part are indicated on the label of the X-ray protective clothing separated by a slash, for example, 0.25 mm Pb / 0.42 mm Pb. The lead equivalent value in the back area of the RA631 (costume) and RA632 (coat) all-round protection in the Levio Edition remains 0.25 mm Pb, as required by the standard.



The lead equivalent of the second layer is freely selectable:

For example, 0.175 mm Pb for a total protection of the centre of the body of 0.42 mm Pb

MAVIG front protection apron Levio Edition – rear view

Of course, we have had the Levio Edition certified by an external notified body in accordance to all applicable standards.

All models received the well-known CE 0302 certification and fulfil all regulatory requirements.

Naturally it still applies, independently of the concept presented, that as much protection as possible should be provided by on-site radiation protection. This primarily includes lower body protection mounted on the table as well as ceiling-mounted radiation shields. If the specific intervention permits, radiation protection drapes positioned on the patient should also be used.

Future regulations

In their publications [4] – [6], the two authors Dr Heinrich Eder and Dr Helmut Schlattl even go one step further and call for a change of the current regulations.

According to their research, it would be possible to shorten the protective clothing altogether. This measure could of course save a considerable amount of weight.

The radiation protective aprons would then have a base layer of radiation protection material that would go from the neck to about 10 cm below the pubis (pubic bone). In addition, another, shorter layer would protect the area from above the chest to below the pubis.

According to the authors' calculations, the full implementation of the concept could even achieve a weight reduction of up to 40% compared to a current protective apron under the usual examination-specific conditions with a protection factor of 50.

At the time of writing though, this would not be compliant to the current standard IEC 61331-3:2014 / DIN EN 61331-3:2016.

However, perhaps it will be an impetus for rethinking.

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