



Gwendolyn Gemke

6.1 Reservation of Doctor's Rights in Accordance with the Requirements of the Heilpraktikergesetz (Law on Alternative Practitioners)

According to § 1 para. 2 Heilpraktikergesetz (HPG), all interventions that can be assigned to the field of medicine may only be performed by persons who either have a **license to practice medicine** or a **corresponding permission according to the Bundesärztleordnung (German Medical Code)** or via the **appointment as an alternative practitioner**.

According to the established case-law of the Federal Administrative Court, this applies to all interventions that require medical expertise and can cause damage to health, even if they are not carried out on the basis of medical indications but with the aim of improving the aesthetic appearance (BVerwG, judgment of 14.10.1958, Az. I C 25.54). For example, the removal of excess tissue and cartilage by expert use of a scalpel and other equipment requires considerable anatomical knowledge that a layman does not have, as does the handling of narcotics. These services are therefore subject to the reservation of permission according to § 1 para. 2 HPG even if they do not

pursue medical purposes (BVerwG, loc.cit.). Also the removal of pigment marks and warts by means of the cold cautery procedure requires the permission according to the HPG (BVerwG, judgment of 18.12.1972, Az. I C 2.69). According to the supreme court ruling cited above, an activity is subject to the reservation of medical knowledge if medical expertise is required in order to determine whether treatment may be started at all in an individual case. This applies in any case if a differential diagnosis must be carried out before the start of the treatment in order to rule out confusion between skin changes and malignant structures (melanoma or basal cell carcinoma), as otherwise the treatment can trigger the most serious health risks for the treated person (BVerwG, loc. Cit.).

These principles, established by the Federal Administrative Court on the demarcation between medicine and nonmedicine, naturally also apply to the user of lasers and IPL devices. Wherever the use of nonionizing radiation requires a differential diagnosis in order to avert dangers for the patient, the activity is subject to the reservation of permission according to § 1 para. 2 HPG and may not be carried out by persons who do not have a license to practice medicine according to the German Medical Code (Bundesärztleordnung). Persons who do not meet these requirements are therefore prohibited from using lasers and IPL devices. In case of infringement, they offend against the regulations of the Heilpraktikergesetz (HPG) and against the criminal offense according to § 5 HPG.

G. Gemke (✉)
HGA Law Firm, Munich, Germany
e-mail: gemke@med-recht.de

Further Qualification Requirements by the NiSG

According to § 2 para. 1 of the law for protection against nonionizing radiation in human applications (NiSG), the user of lasers and IPL devices in medicine must meet further qualification requirements. Thus, when operating installations that may emit nonionizing radiation in the exercise of medicine or dentistry on humans, only certain authorized persons may provide the justifying indication, namely, if the values specified in the statutory order to be issued in accordance with § 5 NiSG for certain types of application are exceeded. According to § 2 para. 1 NiSG, an entitled person is a person who is licensed as a doctor or dentist or who is otherwise entitled to practice medicine or dentistry and who has the necessary expertise to be able to assess the risks of the respective application of nonionizing radiation for humans. The appointment as a nonmedical practitioner is expressly not sufficient for this.

The Federal Government is authorized by the statutory order to be issued in accordance with § 5 NiSG not only to specify the values above which a justifiable indication is required for certain types of application but also to lay down further requirements for the required qualification of the authorized person and how this qualification is to be demonstrated to the competent authority. In view of the high and often underestimated risk potential, this regulation can be awaited with interest.

Because of the additional requirements in the law on the protection of nonionizing radiation (NiSG) and the medical device law, reference is made to the detailed description under Chap. 8.

What Does this Mean in Concrete Terms for Laser and IPL Technology? What Are the Decisive Parameters Here?

The question as to whether or not individual applications of lasers and IPL devices are subject to the medical reservation (medical science)

depends accordingly on the following parameters:

1. Does the application have to be preceded by a differential diagnosis in order to avoid endangering the patient? What knowledge is required to perform this differential diagnosis?
2. Does the implementation of the application require medical expertise or at least in-depth medical knowledge in particular knowledge of the anatomy of the skin or the ability to detect pathological changes in the skin organ? What biological, physical, and medical knowledge is required for the implementation?
3. What damage to health can the treatment cause if the practitioner does not have the necessary knowledge?
4. What health damage can the treatment cause even if it is performed *lege artis*? What are the basic treatment risks? Is it sufficiently likely that an improved level of training in the use of the equipment will reduce the risks?

For the typical areas of application of lasers and IPL devices listed below (Sect. 6.2), this means that the application is subject to the reservation of permission pursuant to § 1 para. 2 HPG and § 2 para.1 NiSG. These may therefore only be carried out by licensed physicians and persons who have a permit in accordance with the German Medical Code, but not by medical laypersons.

6.2 Typical Applications of Lasers and IPL Devices

Removal of Pigmented Marks

The removal of pigmented marks always requires a differential diagnosis in order to rule out the possibility of a malignant melanoma, lentigo maligna, or another malignoma (pigmented basal cell carcinoma, malignant vascular tumors). This is all the more true for the application of high-energy procedures, such as the laser or the IPL device, since the metastasis occurring in malig-

nant tumors can be hidden and misjudged and/or even the histological differential diagnosis after the energy input, with the devices in question, becomes impossible or at least more difficult.

When so-called moles (dysplastic nevi) are removed by laser, a histology must therefore be prepared beforehand.

A misdiagnosis in the treatment of pigmentation marks, e.g., a melanoma that is mistaken for an “age spot,” can have fatal consequences for the patient concerned.

Irrespective of whether it is done with the laser, an IPL device or a scalpel, the removal of pigment marks is therefore a **benefit subject to the doctor’s reservation**.

Removal of Warts

The removal of nonpigmented growths of the skin by laser or IPL device must also be preceded by a differential diagnosis. If a basal cell carcinoma, the most common type of cancer in humans, is confused with a benign tumor, treatment with laser/IPL may pose a serious health risk because it does not clear the source of the disease. In the majority of cases, the diagnosis is delayed; the growth of basal cell carcinoma can be accelerated, a basal cell carcinoma can break into all conceivable structures up to the bone as a proliferation and cause greater irreversible destruction there.

Removal of Dilated Skin Vessels

The dilation of skin vessels can have various causes. In almost all cases, this is a disease of the venous system in the lower legs with the consequence that before any treatment it must first be clarified by phlebological means whether there is a venous disease (e.g., chronic venous insufficiency with the consequence of *ulcus cruris venosum*, i.e., so-called open leg). Otherwise a relapse or aggravation of side effects is likely. The same applies to chronic inflammatory skin diseases, which lead to dilated vessels in the face. This can have hormonal causes but also infections of the follicular apparatus or autoimmuno-

logical diseases have to be considered differential diagnostically (e.g., lupus erythematosus).

Removal of Tattoos

The removal of tattoos by laser and IPL devices does not only involve the risk of burns due to incorrect dosage. Rather, tattoos often cover pigment marks or other pathological skin changes. This also applies to the so-called permanent make-up. According to prevailing opinion, the removal of pigmentation in the area of the eyebrow or mouth, i.e. the classic localization of permanent make-up, but also the removal of “real” decorative tattoos with the IPL device in general is obsolete. Laser treatment in the eye region requires special care and comprehensive knowledge of the user about the anatomy of the eye and the eye region as well as technical equipment knowledge, since incorrect treatment can lead to irreversible eye damage.

To make matters worse, the color pigments used for tattoos react very differently to the use of high-energy radiation from lasers and IPL devices, which can endanger the patients concerned. It is possible that during the laser removal of a tattoo toxic decomposition products are formed by the photolytic decomposition. The Federal Institute for Risk Assessment has recently detected **prussic acid** after laser treatment of tattoo pigments in a concentration high enough to cause cell damage in the skin (BfR, press release of 13.08.2015). With some pigments, the laser treatment does not lead to degradation but to **darkening**. Due to chemical-physical reactions, so-called permanent make-up often results in **color changes** that are disfiguring. A further undesirable effect is the destruction of melanocytes with the possible consequence of a **hypopigmentation**. Another problem with the laser treatment of tattoos is the emergence of **allergic reactions** to the pigment or its degradation products, which may go as far as anaphylactic shock (instructive statement of the Federal Institute for Risk Assessment, Requirements for Tattooing Agents, dated 28.08.2012 with further evidence).

Removal of Hair (Epilation)

It is controversial whether the removal of hair by laser or IPL device is subject to the reservation of permission according to § 1 para. 2 HPG. It is often overlooked that during epilation, the energy is not directed specifically at the hair follicle but is treated over an entire area of skin. Ideally, it is only the hair follicle that absorbs the energy more than the surrounding skin surface due to its pigmentation and is destroyed by the resulting heat. The energy absorption in the entire follicular apparatus is necessary for this, since the stem cells distributed in the follicle must also be destroyed. This destruction occurs through the transfer of energy from light into heat; the resulting heat unselectively boils the structures surrounding the follicle. However, this also means that as soon as a skin area shows pigment marks, these “pigment spots” also react to the energy emitted by the laser or the IPL device.

There are practically hardly any body surfaces that do not show any pigment marks.

The underlying vessels or other skin changes must also be subjected to a differential diagnosis prior to laser epilation. This also applies to the detection of endocrine diseases (polycystic ovaries) or drug side effects, which can be the cause of increased hair growth.

In contrast to this, the destruction of the follicle with the “electron needle” – desiccation – which is also permitted to medical laypersons only has a strictly local effect, so that an analogy cannot be drawn here.

6.3 Delegation to Nonmedical Staff

The above remarks do not exclude the possibility that the physician may delegate the technical performance of laser services to nonmedical employees in individual cases, although this is only possible to a very limited extent.

It goes without saying that the anamnesis, diagnosis, and indication for the laser must be made by the physician himself. However, other services which, because of their difficulty and danger for the patient and the unpredictability of

any reactions and the use of his specific expertise and experience, are to be provided by the physician himself may not be delegated from the outset. This includes the performance of operations, especially in outpatient care, since the surgeon bears full responsibility for each surgical step (publication of the German Medical Association and the National Association of Statutory Health Insurance Physicians, personal service provision – possibilities and limits of the delegation of medical services). Classic operations in the outpatient sector, such as the removal of skin changes, cannot therefore be delegated. It can make no difference whether these are carried out with the scalpel, the laser, or the IPL device.

The other applies to the technical performance of laser epilation according to the indication and the doctor’s instructions. This does not require specialist medical knowledge and can be delegated to trained staff under the supervision and control of the responsible physician. However, the doctor meets the so-called **selection obligation**. This means the delegate must ensure that the employee to whom he or she delegates is suitable for the performance of the delegated service on the basis of his or her professional qualifications or general skills and knowledge. He also has the **instruction obligation**. This means he must instruct him to independently carry out the service to be delegated. Finally he has the **duty of supervision**, which, depending on the intervention, includes the presence of the physician during the service provision, but in any case regular supervision of the execution (Federal Medical Association and Federal Association of Statutory Health Insurance Physicians, Personal Service Provision – Possibilities and Limits of the Delegation of Medical Services). Special care is required in the eye area, as anatomical knowledge and equipment knowledge must be coordinated in order to prevent the risk of irreversible eye damage.

6.4 State of the Case Law

In recent years, administrative courts have repeatedly dealt with the use of lasers by medical laypersons. The fact that the use of laser devices

requires medical expertise and that the treatment entails a potential hazard to human health to such an extent that the exercise of this activity is to be regarded as a medical science activity and is subject to the medical doctor's reservation pursuant to § 1 para. 2 HPG runs like a red thread through the case law.

The administrative court Gelsenkirchen has determined under the Az. 7 L 889/08 of 02.09.2008 that the ear acupuncture by means of a laser is subject to the doctor's reservation. The decision was confirmed by the Higher Administrative Court for the State of North Rhine-Westphalia with the decision of 13.11.2008, ref. 13 B 1488/08.

The Administrative Court of Gelsenkirchen ruled on 22/06/2011, file no. 7 K 2991/10, that the cosmetic use of a laser device classified according to EN 60825-1 in class 3b with a maximum power of 50 MB is not subject to approval. However, the decisive factor here was that the aforementioned soft laser excluded tissue or skin injury and only achieved a stimulating effect. Furthermore, it was expressly stated that the laser had 5 predefined laser programs which were explicitly not directed at the removal of pigmented skin changes, which is why the dangers feared in this respect were excluded.

The administrative court Arnsberg with the decision from 08/05/2012 under the ref.. 3 L 247/12 determined that the application of a laser device by a podologist represents medicine and is subject to the doctor's reservation, expressly also

for interventions in the body, which are carried out for aesthetic purposes. The decision concerned the application of the CoolTouch-VARIA laser technology.

6.5 Conclusion

Both the requirements of the Heilpraktikergesetz and the Gesetz zum Schutz vor nicht-ionisierender Strahlung codify requirements for the personal qualifications of users of lasers and IPL devices. They must be licensed to practice medicine or have a professional license in accordance with the German Medical Code (Bundesärztleordnung) and, if necessary, have additional specialist knowledge.

This does not exclude the delegation of the service by the responsible physician to a non-medical employee in every case, but the strict requirements which the case law places on the delegation of medical services must be observed. In particular, the physician is not only responsible for the diagnosis but also for the selection, instruction, and monitoring of his employee and the outcome of treatment.

Only applications of lasers or IPL devices which do not require medical expertise either with regard to a previous diagnosis or with regard to their technical implementation are permitted to be performed by persons who do not possess a medical license or a corresponding professional permit.