Hygiene Standarts for Tattooists

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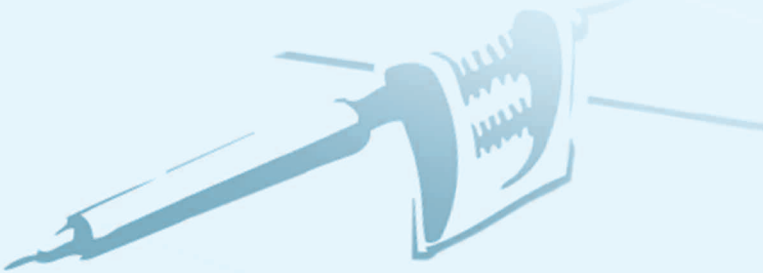

Foreword

Herewith, the United European Tattoo Artists e. V. (UETA) presents a fully revised brochure, "Hygiene Standards For Tattooists", which complies with current requirements.

This brochure represents the 'state-of-the-art', and is intended to provide professional assistance during day-to-day interactions with customers, public authorities and, of course, the tattooists concerned.

The detailed standards contained herein form a practicable set of instructions for the correct handling, in order to ensure an optimum protection of the customer as well as an optimum level of self-protection.

A detailed risk assessment is also included. Manufacturer-issued instructions regarding the use of disinfectants or devices should also be observed.

In the context of European Harmonization, these standards have already been submitted by us to the European Commission. Publication in other languages is planned.

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1. Preamble

A tattoo is a permanent artificial marking of the skin made by inserting pigments into the corium using needles. This layer of skin, located between the epidermis and the subcutaneous tissue, is agglutinated through the stratum papillare with the epidermis and features small and midsized blood vessels.

1.1 Health risks and infections during tattooing

Generally it is assumed that during the act of tattooing the needles in use may have contact with the bloodstream of the person to be tattooed; therefore a common risk of infection with viruses transmitted through blood is given. Dependent on the size of the tattoo a superficial skin wound of a greater or lesser extent is generated, so bacterial infections have to be taken into account as well.

The issue of health risks through tattooing is widely discussed, and the literature offers a great amount of data, which unfortunately, without exception, are not based on epidemiologic analysis.

The majority of data were collected in a time where there were no hygiene guidelines or originate from countries without health care directives for tattooing. As of now, there is no prospective study, in which sufficient data is analyzed to demonstrate the actual health complications due to infections. Also, none of the studies reported in the literature provides details if and which hygiene standards have been applied.

Hence, the process of tattooing poses a theoretical risk of infection with viruses transmittable through blood, although this risk is not verified with scientific data. Even a mathematical implication of the data at hand is inconclusive: According to literature, the prevalence of tattooing in the German population is 10%. Hence, approx. 8 million persons wear tattoos in Germany. Many do not wear only one tattoo and large tattoos require several sessions. If we multiply those 8 million tattoos by a factor 2.5 we are talking about 20 million tattoo sessions in Germany.

If only 1 percent of these sessions resulted in infectious complications, a total of 200,000 infections would have been amounted. Assuming those 20 million tattoo sessions took place during the last 10 years and assuming a 1% infection rate, in Germany alone 20,000 infections would have been contracted annually through tattooing. Even at a 0.1 % infection rate there would be still 2,000 cases per year.

Considering the magnitude of these numbers one may assume that it would have been noticed, or in other words it would have been identified as a major problem within the public health care system. Based on these calculations it can be assumed that the risk of infection through tattooing is less than 0.1 % or in other words less than 1 in a thousand tattoo sessions.

We don't show these calculations to downplay the issue, in our account every single infection caused by tattooing is one to many and must be avoided.

1.2 Allergic reactions

In addition to infectious complications, there are very rare cases of allergic reactions to the applied color. Again, no hard data exists in today's literature, which would allow a concrete risk evaluation.

1.3 Necessity for hygiene guidelines

Tattooing must not put the health of the customer or the tattoo artist at risk. Therefore, it is imperative to eliminate the eventualities of infection as much as possible. Since tattooing is a cosmetic procedure, working under aseptic conditions is not necessarily mandatory.
The following guidelines describe in detail which procedures are necessary before and during tattooing to ensure maximum safety for customers and tattoo artists.

2. Guidelines

2.1 Job specification: Tattoo Artist

2.1.1 Vocational training

Individuals who apply tattoos have to meet these requirements:

- they have to be reliable and master the technique of tattooing
- they have to be aware of the risks involved and have follow guidelines to minimize those risks and must deny a customer's request for a tattoo if special risks are foreseeable.

They must have basic knowledge in the following areas:

- general and specific microbiology, germinal sources and ways of transmission, causative organ isms of skin and wound infections, viruses transmitted by blood esp. hepatitis B and C as well as HIV.
- general hygiene (germinal sources and ways of transmission, possibilities and methods to break ways of transmission.

- specific hygiene (cleaning, disinfection and sterilization, treatment of instruments relevant to the transmission of pathogenic germs, hand disinfection, skin disinfection, surface disinfection, protection against re-contamination, handling of sterile materials, water requirements, handling disposables; waste disposal).
- personal protection (disposable medical gloves, protective gear, washing and desinfection of hands, clothing, prevention of environmental contamination)
- measures which support a fast healing of wounds sustained through tattooing

A mandatory catalog of educational objectives for corresponding courses is in preparation.

2.1.2 Personal hygiene

Tattoos are to be carried out only with disposable medical gloves (non-sterile, powder free, CE-labeled according to EN). Only instruments and objects are to be touched which are essential to the procedure of tattooing and which have been treated and prepared for this procedure as described above.

Clothes have to be protected against contamination; this can be done with an apron or a cloth. Contaminated cloths or aprons must be washed after use at 90 °C or at 60 °C using a disinfecting detergent. Contaminated laundry is only to be transported in closed plastic bags.

2.1.3 Vaccination

Vaccinations against hepatitis A and B are available. These vaccinations are recommended for tattoo artists and can be administered by any general practitioner.

2.1.4.1 Aftercare

Inadequate and insufficient care, strong direct sunlight, exposure or irritation of affected skin can cause complications during the healing process. The tattoo artist has to provide the customer with oral or written information material concerning tattoo aftercare. The most important factor of aftercare is a fast healing process without complications. The tattoo has to be protected from contamination. If despite all precautions swelling, redness or blistering occurs, the customer has to be referred to a physician.

2.1.4.2 First Aid

Every tattoo artist should provide documented evidence of being trained in first aid.

2.1.4.3 Injuries caused by used needles

In case of injury of the tattoo artist caused by a used needle, the wound must be bled dry followed by treatment with an appropriate disinfectant. Medical attention by a physician is recommended.

2.2 Customer requirements

2.2.1 Physical requirements

Only persons of legal age or who are at least fully grown should get a tattoo. Minors need written - permission by the legal guardian. Persons under the influence of medication, drugs or alcohol should not get a tattoo. Neither should pregnant women receive a tattoo. Skin areas which exhibit a pathological change or mutation must not be tattooed; the same applies for moles and birth marks. Tattooing scar tissue must be decided case by case.

2.2.2 Risk disclosure statement and consent form

Prior to receiving a tattoo, the customer must be furnished an oral or written risk disclosure statement.. It is strongly recommended to have the customer sign a consent form.

3. Facility

3.1 Work area

The work area not necessarily has to be structurally separated from the reception or showroom, but a functional separation (e. g. room-divider) is essential in order to avoid contamination of other areas.

Eating and drinking is prohibited in the tattoo work area. Smoking and animals are not allowed.

Work area has to be easily cleaned, well vented and adequately lit. Flooring and work surfaces must be smooth and water-repellent and/or easy to wipe and disinfect (e. g. tiles, PVC, linoleum, etc.).
A washstand should be close to the work area but in such manner, that contamination of the work area through splashing or aerosols may not take place.

Following equipment is needed:

- hand disinfectant dispenser
- liquid soap dispenser
- paper towels
- waste disposal container

Since washstand or faucets are only used before and after a tattoo session in compliance with hygiene guidelines cross-contamination through operating of faucets is excluded. Contactless armatures or elbow operated armatures are not required.

A smooth and easy to clean work space for setting down instruments is required. The work space should be covered with disposables (e. g. foil, paper towels). A change-over must be performed between customers.

All furniture and fixtures (tattoo chair / gurney, chairs) must have smooth and easy to clean and to disinfect surfaces. If necessary, liquid-repelling or impermeable disposable covers have to be used to cover chairs, gurney and chairs.

If disposable materials are not used exclusively, equipment must be available to prepare and treat instruments and objects (cleaning, disinfection, sterilization) on site.
Equipment has to offer a maximum in operability on one hand and ensure safety to the customer and artist on the other hand.

3.2 Sterilization and autoclaving

Sterilization is safer, the cleaner the material and the lower its level of contamination is. Through prior cleaning and disinfection the initial germ count should be reduced to low level. Manufacturer's specification concerning concentration and disinfection and sterilization times are calculated to inactivate or kill microorganisms on or inside the processed ware to eliminate their ability to infect, if the ware sustains a common grade of contamination.

To sterilize grips and needle holder dry heat sterilization is sufficient (see topic 6.3).

3.3 Ultrasonic cleaning

Ultrasonic cleaning systems are used to loosen particular matter like dried blood or ink from the needle. For each customer a fresh disposable container with a suitable cleaning agent has to be used. After the session this has to be poured down the drain and the container must be disposed of. Only the usage of disposable containers enables a fast and reliable treatment of instruments without cross contamination.

3.4 Used needle disposal

Standard commercial needle disposal containers for used needle disposal must be available. The container has to stay securely shut and once full must be disposed of.

3.5 Waste

Garbage bags must be used for waste disposal. Paper towels, ink cups, spatulas and all other waste which accumulate during a tattoo session have to be disposed of immediately into designated waste bin. Use either a closed waste bin, which can be opened by a foot pedal, or use an open waste bin, which has to be emptied after each tattoo session. If a closed bin is used daily emptying is sufficient. The waste bin may not be over-flowing. It is important, not to touch the waste bin during a tattoo session due to potential cross contamination.

4. Equipment

Only disinfectants of proven effectiveness may be used. This applies if corresponding certification / listing by VAH are available. (Exception: skin disinfectant)

4.1 Tattoo machines

Tattoo machines and clip cord have to be freshly bagged for each customer. Commercial plastic bags like freezer bags or plastic wrap are adequate. After tattooing, bags must be removed and instruments must be cleaned and disinfected with an appropriate agent. Disconnect instruments from power sources.

4.2 Materials and instruments needed

- for operator safety, disposable medical gloves (non-sterile) must be available in adequate quantity
- appropriate alcohol based hand disinfectant has to be in stock if possible as wall attached dispenser or as a pump bottle.
- for skin disinfection prior to tattooing alcohol based disinfectant must be used. (Note: This is use of an approved drug, therefore, make sure to strictly follow manufacturer's instructions.)
- disposable cleaning cloth / tissues for cleaning work space (work table, tattoo chair / gurney, chairs). Disposable paper towels can be used.
- alcohol based surface disinfectant for disinfection of small instruments
- surface disinfectant for flooring and appropriate towels
- disposable tattoo needles
- if necessary, disposable needle jig and grips

If disposable needles, needle jigs and grips are used exclusively, additional resources for treatment of instruments are not required.

- disposable bowls for ink (separate ones for each customer)
- ultrasonic cleaner to clean needle jig and grips
- disinfectant for instruments effective against HBV, HCV and HIV
- disinfectant pan
- running water to rinse instruments (of drinking water quality)
- if necessary, a sterilizer
- appropriate packaging material for sterilized needle jigs
- closed storage system (lockable drawers, cabinets) to prevent contamination of sterilized materials
- quality control to ensure efficiency of sterilization procedures

4.3 Colors

Ink bottles must be stored closed and protected against dust, to prevent micro-organisms from contaminating the contents. Colors have to comply with current tattoo guidelines.

The following information must be included on the ink bottle label:

- 'for tattoo purpose' or like 'tattoo ink' or 'tattoo color'
- lot number
- manufacturer information
- expiration date
- storage life after opening bottle
- list of ingredients

4.4 Lubrication, shaver, spatula and towels

Lubrication, shaver, spatula and towels should be stored outside the working area in locked containers. Shaver, color caps and spatula are removed from the container only with new disposable medical gloves and

are disposed of after usage. For lubrication use an unused spatula only. After removal, bottle must be closed immediately. Powder free gloves may be used only. Commercial disposable paper towels to be used during tattoo session must be stored in original packing outside the work area. Only the amount of paper towels needed per session should be in reach. Used paper towels have to be disposed of immediately into the available waste bin.

If bottles (ink, disinfectant) are used during the tattoo session, appropriate measurements must be in place to prevent contamination (change of gloves, bagging). Used ink cups may not be refilled. If needed, use a new cup.

5. Desinfection procedures

When using disinfectants, manufacturer's instructions must be followed.

5.1 Hands

In many cases pathogens are transmitted via hands, therefore hand contact in a tattoo studio should be limited as much as possible. Hand disinfection is supposed to inactivate germs which got there by contact with microbial contaminated surfaces. Hand disinfection is one of the most important measures to prevent infections. Washing hands should be reduced to a minimum. It only services cleansing.

Note: Skin irritation occurs are more due to washing hands than by proper hand disinfection.

In case of increased risk of infection or contamination, especially while handling customer's excretions or objects contaminated with blood or sputum, wearing disposable medical gloves to protect hands is mandatory. Contaminated hands may be washed with water and soap only after proper disinfection.

Hand disinfection is mandatory, for example:

- After contact with blood, secretions or excretions
- Before physical contact with customers or before touching the skin area to be tattooed
- After contact with contaminated surfaces or objects
- After taking off disposable gloves

Technique of hygienic hand disinfection

- Extraction of enough alcohol based disinfectant agent from pump- or elbow operated dispenser.

Palm has to be completely filled.

- Rub with both hands, make sure skin is completely covered. In case of contamination apply to fore arms as well. Exposure time for disinfectant to be effective is at least 30 seconds.

5.2 Skin

Objective: To attain an adequate reduction of germs on respective skin area with respect to the procedure. Large-area shaving of skin to be tattooed has to be done directly before beginning tattoo session and a suitable disinfectant has to be sprayed on with an exposure time of at least 15 seconds. Only original containers with manufactures labels may be used. Do not decant.

5.3 Surfaces (work area)

Cleaning:

Floors, working surfaces, gurney, chairs and sinks must be cleaned thoroughly at the end of each day. Surfaces which may have been in direct or indirect contact with costumer's blood must be disinfected (with appropriate surface disinfectant agent that is effective against HBV and HIV).

The surface to be disinfected must be wiped under light pressure with a cleaning cloth or sponge which is soaked in disinfectant. Hereby it is objective to disperse contaminants in the disinfectant. It is not sufficient to only spray disinfectant onto surfaces. Treated surfaces should be covered with a thin liquid film. It is not permitted to rub the surface dry shortly after applying the disinfectant. Only after the specified exposure time, treated surfaces are assumed to be disinfected.

Hands need to be protected from contact with the disinfection agent. Cloths and sponges used for disinfection procedure need to be disinfected and dried, they may not be kept wet. Heavy soiled surfaces must be cleaned first and disinfected subsequently.

5.4 Instruments

If possible, instruments should be cleaned and disinfected immediately after usage. Contamination should not dry onto instruments, since it complicates cleaning and disinfection. Chemical disinfection agents are used for instrument disinfection. Instruments are to be put into the disinfectant solution in such manner, that all surfaces of instrument are covered and access of disinfection agent is not hindered by air bubbles. Hollow objects must be flushed with disinfectant and filled with disinfectant avoiding any air bubbles.

6 Disinfection procedures

6.1 Preliminary note

Transfer of relevant micro-organisms during the process of tattooing is primarily a result of contaminated ink and used needles, secondary a result of needle jigs and other objects and materials used during the session.

Using the same colors for different customers and using reprocessed needles are the main risk in tattooing. Therefore, using new and disposable ink cups and new and disposable needles for each customer is the most important and effective hygienic measure.

Since needle jigs may be contaminated with blood, they may be contaminated with viruses transmitted through blood, and since under certain circumstances jigs may be in direct contact with the skin another

major risk of transferring relevant micro-organisms is related to the usage of reusable needle jigs. Additional increased safety can be achieved by using disposable needle jigs.

If disposable needle jigs are used exclusively, preparation and sterilization procedures are redundant (see preliminary not on sterilization).

Contamination of the tattoo machine during or because of its use cannot be ruled out. Therefore, a theoretical possibility of cross contamination exists. Disinfection of tattoo machines is limited and sterilization is not possible at all (refer to 4.1)

6.2 Preperation of needle jig and grips

6.2.1 Risk assessment

- no direct contact with blood, contamination with blood and ink are possible and likely
- effective cleaning and quality control of cleaning efficiency is possible
- only dismountable needle jigs and grips should be used, with components that do not have significant air pockets to impact sterilization
- treatments must follow proper and controlled procedures .

6.2.2 Measures

- Cleaning, disinfection and sterilization after each usage
- Locked storage in appropriate packaging (lockable cases, drawers, cabinet)
- Removal only immediately prior to use
- If necessary, assembly prior to use
- Place materials and instruments on disposable paper towels or foil

6.2.3 Preperation for treatment

After usage: temporary storage on disposable paper towels, **disassemble in to its parts** only while wearing non-sterile disposable gloves, place components into appropriate container (to disinfect or disposable).

6.2.4 Cleaning

Excellent cleaning is a precondition for a later effective disinfection and sterilization process. Adherent blood and ink residues may significantly impact disinfection and sterilization.

Not disinfected components, especially sharp and pointed objects bear the risk of injury and infection of personnel. Protective disposable gloves must be worn while handling contaminated objects.

Because of hard to remove pigment particles – particularly when mixed with blood - it is recommended to subject such contaminated objects to an ultra sonic cleaning procedure. Ultra sonic cleaning procedure should only be applied to the components. The Ultra sonic bath must be filled with disinfectant solution which provides effective inactivation of HBV/HCV/HIV.

The instrument disinfectant agent furthermore must be suitable for ultra sonic cleaning. Change of disinfectant agent must take place according to manufacturer's instructions (daily), or earlier depending on the level of contamination (longer periods only with a certificate of the manufacturer).

The ultra sonic bath is loaded to avoid sonic shadows. Temperatures above 40 °C should be avoided to prevent incrustation of blood. Alternatively, manual cleaning can be carried out. It is recommended to use cleaning and disinfection agents which inhibit incrustation of proteins.

The cleaning procedure is followed by extensive rinsing to remove cleaning and disinfection agent.

6.2.5 Disinfection

When performing the typical chemical disinfection, items are placed into a solution of the respective disinfectant. It is crucial to follow manufacturer's instructions with respect to dilution and exposure time. Only agents may be used which have been proven to be effective against HBV/HCV and HIV. After removing items from the disinfectant solution extensive rinsing with tab water is necessary. After this processing step there is no longer risk of infection for personnel so that the use of protective gloves is optional thereafter.

6.2.6 Drying

Rinsed components may be air-dried or may be dried using clean, lint-free tissue..

6.2.7 Inspection for residues

A thorough visual inspection with sufficient lighting and, if necessary, using a magnifying glass follows to ensure that the objects are free of residue (clean). Particular attention must be focused on hollow spaces, edges and corners. If needed, hollow spaces should be checked against the light. If necessary, repeat targeted cleaning and drying procedures, followed by inspection.

6.3 Sterilization

6.3.1 Preliminary note

Sterilization inactivates or kills micro-organisms including the most resistant spores.

All international standards address sterilization of health care products (DIN EN ISO 17665-1 and EN 13060). Since there are no applicable sterilization standards for other areas, these standards are - if applicable - relevant for sterilization of products related to tattooing.

Clean surfaces of the item in question are imperative for an effective sterilization, as well as a strict adherence to the specified temperature and duration of the sterilization process.

Although it is not yet clear if and how bacterial spores are relevant pathogens in tattooing, sterility is a mandatory prerequisite for all products or product components that come into direct contact with the epidermis

(see preamble) and the blood circulation. This applies - if no disposable products are being used – to all needles and needle jigs.

For sterilization, both physical or chemical procedures may be applied. Generally, physical procedures are used which include dry heat sterilization and steam sterilization.

If procedures are executed accurately, sterility of an item in question can be assumed.

6.3.2 Methods of sterilization

6.3.2.1 Dry heat sterilization

This method uses temperatures between 160 °C and 200 °C. The exposure time including safety margin at a temperature of 160 °C is 120 minutes, at a temperature of 180 °C exposure time is 30 minutes and at a temperature of 200 °C it is 15 minutes .

(Only prions - which are not relevant in tattooing - may not be inactivated sufficiently through dry heat sterilization).

One disadvantage of dry heat sterilization is the fact that heat distribution inside of the sterilizer is dependend on air circulation. In addition, dry heat reaches the interior of packages only with delay.

Appropriate packaging for dry heat sterilization include metal boxes, especially made of aluminum , since aluminum is an excellent heat conductor. Aluminum foil or other suitable foils may be used.

Notice:
In dry heat sterilization only the temperature must be controlled over time which makes handling relatively easy.

Dry heat sterilization is limited to materials which withstand high temperatures. For such materials like glass, metal, ceramics, etc.) dry heat sterilization in sterilizers with air circulation is still a safe and effective method of sterilization.

6.3.2.2 Steam sterilization

Steam sterilization distinguishes between flow procedures and pre-vacuum procedures. As a basic rule for steam sterilization, the lower temperature of 121 °C or 134 °C (compared to hot air sterilization) is effective only if sufficient steam saturation is achieved: i. e. the hot steam must be able to reach the surfaces of the items to be sterilized in order to be effective.

If packaged products are to be sterilized, these packages must be suitable for the respective sterilization process.

Long hollow systems (not dismountable needle holders / handles, which should not be used during tattoo-

ing) pose a problem during steam sterilization: only fractionated pre-vacuum processes are suitable for the sterilization of such systems.

Because tattooing instruments do typically not include such long hollow systems, a flow process is suitable during steam sterilization.

6.3.3 Packaging of products to be sterilized

If sterilized products are not used immediately after sterilizing or if they are sterilized and put in inventory, packaging must be suitable to maintain sterility.

Packaging must match the respective sterilization process (s. a.).

If the contents of the package cannot be determined from the outside due to the nature of the packaging material, the package must be labeled appropriately on the outside.

Furthermore, the sterilization date shall be documented on the packaging.

In the case of foil packages, the foil may not be written on; only the flap.

6.3.4 Procedures after sterilisation

After completion of the sterilization process, the packaged systems may be removed from the sterilization chamber. If these systems have not cooled down yet, suitable heat protective gloves must be worn to avoid burns.

Then, the sterilized goods must cool down for a sufficient period of time and are stored in closed storage systems (boxes, drawers, cabinets) - unless they are used immediately.

Before unpacking/using a sterile product, the user shall make sure that the packaging is not damaged. If the packaging is damaged or contains moisture, the content may no longer be considered sterile.

6.3.5 Inspections

Different inspections are required, depending on the method of sterilization.
If the products are packaged for sterilizing, a treatment indicator must be attached to every package. This treatment indicator only responds to the temperature level reached and is intended to avoid mix-ups of sterilized and non-sterilized products.

This treatment indicator does not give any indication if the overall conditions for sterilization were met; it is therefore not suitable to release a sterilization batch.

A steam penetration test and a vacuum test are required daily, if necessary, before commissioning steam sterilizers. Information in this regards may be found in the operating instructions of the sterilizing unit.

Further, batch inspections are necessary: depending on the sterilization process used, appropriate chemoindicators must be used. These indicators must be collected and read after a batch has been treated; the batch is only released if a passing result is obtained.

Note:
Because products for tattooing typically do not include hollow systems, batch control systems according to ISO 11140 Class 4 or Class 5 are sufficient.

So-called spore tests are required twice annually. These must be carried out by external service providers only.

However, the spore packs or bioindicators are inserted by the user; they must then be sent by mail to the respective provider for evaluation.

When using packages, spore packs or bioindicators must be inserted into the respective package. The number of spore packs depends on the chamber size. An untreated control is always required.

6.3.6 Release

As a rule, sterilized product or a batch is released only if the color change of the chemo-indicator for the batch passes.

Additionally, for hot air sterilizers the duration of sterilization must be documented; for steam sterilizers the temperature and pressure must be documented.

Modern steam sterilizers with fractionated vacuum procedures generate a print-out of the respective parameters.

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