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雙語

Wissenskunde: Wasserführende Systeme in zahnärztlichen Behandlungseinheiten.

Insight: water leading systems in dental chairs
洞察：牙科椅中的導水系統

Editorial社論

Dear readers親愛的讀者們,

How does hygiene actually feel on the other side - as a patient? What does the patient see and does he feel more unsettled by the measures or is it reassuring when they are made transparent. I recently had to switch sides myself and was able to experience first-hand what it's like to be on the other side as a patient. As hygiene and reprocessing professionals, we know what is done in detail and how the measures should look and be carried out correctly. The "normal" patient, however, can easily become confused because measures look different than in the well-known doctor's series or because, due to the much helps much mentality during Corona in everyday life, the measures are supposedly too lax. Our task as professionals is also to pick up the patient for hygiene, to present all measures taken transparently and thus to take away some of the fear. Knowledge is extremely helpful in this regard, so that we can also appear confident to the patient and answer questions in a patient-friendly manner. 身為病患，另一邊對衛生的實際感受如何？患者看到了什麼？這些措施是否讓他感到更加不安，或者當這些措施變得透明時，他是否感到更加安心。我最近不得不自己換邊，並且能夠親身體驗作為患者站在另一邊的感覺。作為衛生和再處理專業人士，我們知道具體做了什麼，以及這些措施應該如何正確實施。然而，"正常"患者很容易感到困惑，因為措施看起來與知名醫生系列中的措施不同，或者因為在日常生活中，由於新冠期間的心態，措施被認為過於寬鬆。作為專業人員，我們的任務還包括接送病人進行衛生保健，透明地展示所採取的所有措施，從而消除一些恐懼。知識在這方面非常有幫助，這樣我們也可以對患者表現出自信並以患者友好的方式回答問題。
Refresh your knowledge and read about current trends in hygiene and reprocessing in the latest issue of aseptica. 在最新一期的《無菌》中刷新您的知識並了解衛生和再處理的當前趨勢。

I hope you enjoy reading and reading this issue of aseptica.希望您享受閱讀並讀讀本期《無菌》。

Stay healthy保持健康,

Stella Nehr-Werner

Report報導

New hygiene quick check app 新的衛生快速檢查應用程式

As the world's first clinic, Asklepios Klinik Nord at the Heidberg site has pre-sented an innovative hygiene quick check developed by Hamburg-based startup Darvis Healthcare. The principle: A "virtual airlock" consisting of optical sensors and artificial intelligence (AI) checks the correct donning of personal protective clothing such as mouth-nose protection, gloves, safety goggles, protective gowns or headgear among staff. The doctors, nurses and functional service staff use the new technology only on a voluntary basis and they are digitally anonymized in the process; all images and objects are "translated" by the software into 3D sche-matics. The correct or incorrect donning of protective clothing is displayed on monitors with corresponding indications (green/red light). 位於海德堡的 Asklepios Klinik Nord 作為世界上第一家診所，推出了由位在漢堡初創公司 Darvis Healthcare 開發的創新衛生快速檢查。其原理是：由光學傳感器和人工智能（AI）組成的"虛擬氣閘"檢查工作人員是否正確穿戴個人防護服，例如口鼻防護裝置、手套、護目鏡、防護服或頭盔。醫生、護士和職能服務人員僅在自願的基礎上使用新技術，並且在此過程中他們是數字匿名的；所有圖像和物體都被軟件"翻譯"成 3D 示意圖。防護服的正確或不正確穿戴會顯示在監視器上並帶有相應的指示（綠燈/紅燈）。

"The digital hygiene quick check using optical sensors replaces the need to look in the mirror or the time-consuming check by a colleague when putting on per-sonal protective clothing - and can thus increase safety for our employees and the patients," says Prof. Dr. Klaus Herrlinger, Medical Director of the Asklepios Clin-ic North - Heidberg and Head Physician of the Department of Internal Medicine. The digital quick check verifies in seconds whether everything has been thought of when putting on the personal protective clothing, for example whether the mouth-nose protection fits correctly and whether both gloves have been put on. The system then immediately provides visual feedback as to whether everything is correct. Klaus Herrlinger 博士教授，Asklepios Clinic North - Heidberg 醫療主任兼內科主任醫師說："使用光學傳感器進行數位衛生快速檢查，取代了照鏡子的需要，也不需要同事在穿上個人防護服時進行耗時的檢查，從而可以提高我們員工和患者的安全。"。數位快速檢查可在幾秒鐘內驗證穿戴個人防護服時是否考慮到所有事項，例如口鼻防護裝置是否正確貼合以及兩隻手套是否都已戴好。然後系統立即提供視覺反饋以判斷一切是否正確。

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Insight: Sterile barrier systems - part 2
洞察：無菌屏障系統 - 第 2 部分

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he article is divided into two parts – this is the 2nd part. Part 1 can be found in the previous issue.本文分為兩部分—這是第二部分。第 1 部分可以在上一期中找到。

The process of sealing 密封過程

A heat seal seam is intended to protect the sterile goods in the packaging from germs until they are used. The surfaces of two materials are joined together irreversibly by the action of heat, pressure and time (process parameters). The process parameters must be monitored regularly and should be laid down in the QMS by means of instructions and checklists. According to DIN 58953-7, the process of heat sealing must be carried out according to a validated procedure. 熱封接縫旨在保護包裝中的無菌物品在使用前免受細菌侵害。兩種材料的表面通過熱、壓力和時間（流程參數）的作用不可逆地連接在一起。必須定期監控流程參數，並通過說明和檢查表的方式將其記錄在質量管理體系中。根據 DIN 58953-7，熱封過程必須按照經過驗證的程序進行。

A validatable heat sealing device must be used for this purpose. Depending on the application, different sealing seams can be produced. The requirements for the heat sealing device can be found in DIN 58953-7 and in the RKI/KRINKO recommendation, Annex 4 (monitoring of process parameters, alarm in case of deviation, process interruption).[2] 為此必須使用可驗證的熱封裝置。根據應用，可以生產不同的密封接縫。熱封裝置的要求可在 DIN 58953-7 和 RKI/KRINKO 建議附錄 4 中找到（流程參數監控、偏差報警、過程中斷）

Reusable containers 可重複使用的容器

Containers are prefabricated rigid sterile barrier systems (DIN EN ISO 11607). Containers are classified as non-critical medical devices, but should preferably be reprocessed by machine (disinfection A0 600). The manufacturer's instructions (DIN EN ISO 17664) must always be observed during reprocessing. 容器是預製的剛性無菌屏障系統（DIN EN ISO 11607）。容器被歸類為非關鍵醫療器械，但最好通過機器進行再處理（消毒 A0 600）。在再處理過程中必須始終遵守製造商的說明 (DIN EN ISO 17664)

The containers must be checked for quality after each reprocessing and before the contents are used. Only a fully intact container is a recontamination-safe package and can preserve the sterility of the medical devices inside. The container tray and container lid must match and be from the same manufacturer. 每次再處理後和使用內容物前必須檢查容器的質量。只有完整的容器才是防再污染的包裝，並且可以保持內部醫療器械的無菌狀態。容器托盤和容器蓋必須匹配且來自同一製造商。

Container packaging exists in various sizes, which are selected depending on the contents to be packaged. The medical devices can be packed in the container with or without fleece. Inner packaging is not necessary and is not required by any standard, law or guideline, but it can facilitate the removal of the trays and aseptic presentation. The loading weight must be observed (recommendation max. 10 kg), because containers are only approved for a certain weight. The maximum stacking pressure according to EN 868 Part 8 is approx. 70 kg (0.5 N/cm2, minimum 100N).容器包裝有多種尺寸，根據所包裝的內容物來選擇。醫療器械可以用或不用絨布包裝在容器中。內包裝不是必需的，也不是任何標準、法律或指南所要求的，但它可以方便托盤的取出和無菌展示。必須遵守裝載重量（建議最大 10 公斤），因為集裝箱僅批准特定重量。根據 EN 868 第 8 部分，最大堆疊壓力約為70 公斤（0.5 N/cm2，最小 100N）。

Different loadings must be taken into account during validation (worst case loading; maximum loading; minimum loading, etc.). In case of overloading, success-ful sterilization is not guaranteed. In addition, containers should not be too heavy for reasons of occupational safety. 驗證期間必須考慮不同的負載（最壞情況負載：最大負載；最小負載等）。如果超載，則不能保證滅菌成功。此外，出於職業安全考慮，容器不應太重。

Sterilization containers must be checked before each reuse. Without effective control, there is a real risk that the sterile barrier effect and thus the sterility of the medical device are not guaranteed. Defective containers or container lids must be replaced. However, most containers are maintenance-free (observe manufacturer's instructions). 每次重複使用前必須檢查滅菌容器。如果沒有有效的控制，就存在無法保證無菌屏障效果和醫療器械無菌性的現實風險。有缺陷的容器或容器蓋必須更換。然而，大多數容器都是免維護的（請遵守製造商的說明）。

Sterilization containers can be stacked in the sterilizer and during transport and storage, which is a clear advantage over soft packaging in general. 滅菌容器可以在滅菌器內以及運輸和儲存過程中堆疊，這比一般軟包裝具有明顯的優勢。

Marking of the sterile barrier systems 滅菌容器可以在滅菌器內以及運輸和儲存過程中堆疊，這比一般軟包裝具有明顯的優勢。

The following information must be indicated on the packaging in accordance with DIN 58953-7根據 DIN 58953-7，必須在包裝上標明以下信息:

- Responsible employee who packaged the medical device負責包裝醫療器械的員工
- Designation of the medical device醫療器械的名稱
- Marking of the batch/number批次/編號標記
- Shelf life of the sterile product (expiry date)無菌產品的保質期（有效日期）
- Possibly information about storage• 可能有關儲存的資訊
- Process indicator流程指示劑
- Marking "sterile" 標記“無菌的”
- Date of sterilization.滅菌日期

Type of packaging包裝類型	Storage unprotected倉藏不受保護	Storage protected 倉儲受保護
Sterile barrier system無菌屏障系統	To be made available for consumption within 48 h **可在48小時內使用。**	6 month, but not longer than expiring date **6個月，但不超過有效期**
Packaging system包裝系統 Sterile barrier system無菌屏障系統+ protective packaging保護性包裝	5 years, unless a different expiry date is specified by the manufacturer. **5 年，除非製造商指定了不同的有效期。**	

Tab表. 3: Storage times儲藏時間.

Storage and storage duration儲存及儲存期限

The acceptable storage period for sterile medical devices depends largely on external influences and impacts during storage, transport and handling. The loss of integrity of the sterile packaging (EN 868-1) or the loss of sterility (DIN 58953-9) are usually considered to be event-related and not time-related, i.e. they depend less on the storage period and more on the circumstances of storage. 無菌醫療器械的可接受儲存期很大程度上取決於儲存、運輸和處理過程中的外部影響和影響。無菌包裝完整性的喪失(EN 868-1) 或無菌性的喪失(DIN 58953-9) 通常被認為與事件相關而不是與時間相關，即它們較少依賴於儲存期，而更多地依賴於儲存情況。

Released medical devices must be stored in closed containers. This can be done in closed transport trolleys (temporary), cabinets, shelves and drawers. Open storage must be avoided at all costs, as it is imperative that sterile goods are protected from dust (particle-bound contamination) and UV light.放行的醫療器械必須存放在密閉容器中。這可以在封閉的運輸手推車（臨時）、櫥櫃、架子和抽屜中完成。必須不惜一切代價避免開放式存儲，因為必須保護無菌物品免受灰塵（顆粒結合污染）和紫外線的影響。

The maximum storage period in a sterile barrier system is 6 months. The responsibility for the storage period and the storage conditions lies with the operator of the facility.無菌屏障系統中的最長儲存期為 6 個月。儲存期限和儲存條件由設施經營者負責。

Quality assurance 質量保證

Routine inspections must be an integral part of functional qualification according to DIN EN ISO 11607-2. The quality properties of a particular packaging material must be checked and documented by visual inspection. Visual inspection for integrity must be performed routinely during each packaging process (e.g. container check) and before each batch release after sterilization. For the combinations specified in the validation plan, a defined number of sterile barrier systems of the same material must be packaged (samples) and checked for the predefined quality properties.[3] This ensures that changes are detected in good time before a sterile barrier system no longer meets the requirements. 根據 DIN EN ISO 11607-2，例行檢查必須是功能鑑定的一個組成部分。特定包裝材料的質量特性必須通過目視檢查進行檢查和記錄。在每個包裝過程（例如容器檢查）期間以及滅菌後每批放行之前，必須定期進行完整性目視檢查。對於驗證計劃中指定的組合，必須包裝規定數量的相同材料的無菌屏障系統（樣品）並檢查預定的質量。這可確保在無菌屏障系統不再滿足要求之前及時檢測到變化。

For further routine checks, the intervals (daily, weekly, monthly) must be defined, including the procedure to be followed if a check is not passed. The results of routine checks must be documented.[3]對於進一步的例行檢查，必須定義間隔（每日、每週、每月），包括檢查未通過時應遵循的程序。例行檢查的結果必須記錄在案。

Documented orientation of new staff and documented training are also components of quality assurance. Staff must be trained in such a way that any visible impairments to the sterile barrier system during daily handling are identified before use.[3] All aspects to be checked and special features of the sterile barrier systems to be used must be formulated in a procedural instruction and must already be communicated as part of the initial training.記錄的新員工入職培訓和記錄的培訓也是質量保證的組成部分。於使用前確定日常處理期間，工作人員必須接受培訓，以確保無菌屏障系統在操作過程中出現任何明顯的損傷。所有要檢查的方面和要使用的無菌屏障系統的特殊功能必須在程序說明中製定，並且必須作為初始培訓的一部分進行溝通。

The sterile barrier system also has a significant influence on the drying success in the steam sterilization process. Even before a decision is made in favor of a particular sterile barrier system, it should be tested and ensured that the packaging system and medical devices are compatible and that drying is successful. If drying does not succeed, the process, packaging and/or loading must be optimized and confirmed as part of the process validation of steam sterilization. Insufficient drying results can, not least, be an exclusion criterion for a particular sterile barrier system.無菌屏障系統對蒸汽滅菌過程中的乾燥成功也有重大影響。即使在決定使用特定的無菌屏障系統之前，也應該對其進行測試並確保包裝系統和醫療器械兼容並且乾燥成功。如果乾燥不成功，則必須優化並確認流程、包裝和/或裝載，作為蒸汽滅菌流程驗證的一部分。乾燥結果不足尤其可以成為特定無菌屏障系統的排除標準。

Example: Routine checks on heat sealers 範例：熱封機的例行檢查

Integrity of the sealing seam 密封接縫的完整性

The tightness of sealing seam on the heat-sealing device must be checked regularly. The RKI/KRINKO recommendation suggests the seal check or ink test for this purpose.[2] The ink test can be used especially for packaging with side gussets. The seal seams should have the following quality characteristics: 必須定期檢查熱封裝置上的密封縫的密封性。 RKI/KRINKO 建議為此目的進行密封檢查或墨水測試。墨水測試尤其適用於帶有側面角撐板的包裝。密封接縫應具有以下質量特徵：

- intact sealing at a specified sealing width在指定的密封寬度下完好的密封。
- no channel formation or open sealing seams無通道形成或開放的密封接縫。
- no punctures or tears無刺穿或撕裂。
- no delamination or detachment of materials.材料無分層或脫落。

With the seal check, an indicator strip can be used to show whether the quality characteristics are met. If a process parameter deviates, this can be made visible on the indicator strip. 透過密封檢查，可以使用指示條來顯示是否符合品質特性。如果過程參數出現偏差，可以在指示條上看到。

Fig. 2 : Ink test
墨水測試.

In the ink test, approx. 2 ml of suitable test ink is pou-red into the bag just above the seal seam using a pipette. After a short time, you can see whether the sealed seam is tight. 在墨水測試中，大約使用移液管將 2 毫升合適的測試墨水倒入袋子中密封接縫上方。稍等片刻後，即可觀察密封接縫處是否嚴密。

If the sealing seam is defective, the test ink penetrates the bag. These tests should be performed and documented every working day如果密封接縫有缺陷，則測試墨水會滲入袋子。這些測試應在每個工作日進行並記錄。.

Peelability 剝離性

When opening a sterile package, care must be taken to ensure that the paper can be easily opened from the film and vice versa and does not "peel off ". There is a standardized test for this peel procedure in accordance with DIN EN 868-5 ("Method for determining the peel characteristics of paper/plastic composite materials"). The peel test can be performed as follows: 打開無菌包裝時，必須小心確保紙張可以輕鬆地從薄膜上打開，反之亦然，並且不會「剝離」。根據 DIN EN 868-5（「測定紙/塑膠複合材料剝離特性的方法」），有針對此剝離程序的標準化測試。剝離試驗可依下列方式進行：10

- Seal a section of the sterilization tubing on the peel side and add it to a sterilization process在剝離側密封一段滅菌管並將其添加到滅菌過程中
- after removal from the sterilizer, carefully and slowly pull apart the sealed seams with both hands along the peel direction• 從滅菌器中取出后，用雙手沿著剝離方向小心緩慢地拉開密封的接縫
- a visual check is made to see whether the seal seam is continuous and whether the paper can be separated from the film without fraying 目視檢查密封接縫是否連續以及紙張是否可以與薄膜分離而不會磨損
- The results of the peel test must be documented必須記錄剝離測試的結果.

Fig. 3: peel test剝離測試.

Example例如:
Routine checks on containers 容器的例行檢查

- Visual inspection of the container for damage目視檢查容器是否有損壞
- Residues of process chemicals?流程化學品的殘留物？
- Filter and filter holder (rubber lip intact?)過濾器和過濾器支架（橡膠唇完好嗎？）
- Filter gasket (porous? cracked? contaminated?)過濾器墊片（多孔？破裂？污染？）
- Lid (fit warped? contaminated? manufacturer?)蓋子（變形？污染？製造商？）
- Lid gasket (porous? cracked? contaminated?rusty?)蓋子墊圈（多孔？破裂？污染？生鏽？）
- Tub rim (fit warped? contaminated? rusty?manufacturer?)木盒邊緣（安裝變形？污染？生鏽？製造商？）
- Paper filter intact? (pay attention to container manufacturer!)濾紙是否完好？（注意容器製造商！）
- Paper filter inserted? (pay attention to container manufacturer!) 已插入濾紙？（注意容器製造商！）
- Round filter holder engaged? (audible "click")圓形過濾器支架已接合嗎？（聽到「咔噠」聲）
- Closure functional and undamaged? (Oil closure hinges occasionally, e.g. with Sterilit)閉合功能是否正常且未損壞？（油封偶爾會鉸鏈，例如使用 Sterilit）
- Closure flaps engaged? ("click")關閉鉸鏈板已接合？（“點擊”）
- Seal in place? (pay attention to container manufacturer!) 密封到位嗎？（注意容器製造商！）
- Carrying handles intact and undamaged?提把是否完好無損？

Risk assessment 風險評估

The use of any packaging material involves individual risks. The advantages and disadvantages of the different sterile barrier systems must be weighed up against each other, taking into account the in-house situation, before a decision is made.[3] Maintaining sterility until use or until the expiration date is reached is an absolute priority. In addition to costs, the nature of the medical devices to be packaged, user requirements, user-friendliness, safety aspects and transport logistics play a decisive role in selecting the right packaging.任何包裝材料的使用都涉及個人風險。在做出決定之前，必須權衡不同無菌屏障系統的優點和缺點，同時考慮內部情況。3 保持無菌直到使用或達到有效期是絕對優先事項。除了成本之外，要包裝的醫療器材的性質、使用者要求、使用者友善性、安全性和運輸物流在選擇正確的包裝方面也起著決定性作用。

There are also risks involved in changing a sterile barrier system for the user or handling. There will inevitably be effects on the working methods of the OR nurses or assistants. For this reason, all users must be involved in the decision-making process. User safety is achieved through sound familiarization, continuous training and ultimately only through a routine. 為使用者或操作更換無菌屏障系統也存在風險。這將不可避免地影響手術室護理師或助理的工作方法。因此，所有使用者都必須參與決策過程。使用者安全是透過充分熟悉、持續培訓以及最終只能透過例行公事來實現的。

Costs 成本

With the current continuous increase in consumption and energy costs, a business assessment of the sterile barrier systems, the associated consumables and investment costs is essential. After all, most CSSD affiliated with a hospital are exclusively cost centers that do not generate a profit. But even in the private practice sec-tor, hygiene costs account for a not inconsiderable share and must therefore be kept in mind. 隨著當前消耗和能源成本的不斷增加，對無菌屏障系統、相關消耗品和投資成本進行業務評估至關重要。畢竟，大多數附屬於醫院的 CSSD 都是專門的成本中心，不產生利潤。但即使在私人診所，衛生成本也佔不小的份額，因此必須牢記在心。

In principle, standardization should always take place and as few different sterile barrier systems as possible should be used. In this way, warehousing and ordering costs can also be minimized. 原則上，應始終進行標準化，並應使用盡可能少的不同無菌屏障系統。這樣，倉儲和訂購成本也可以最小化。

There are some cost factors which must be taken into account. Investment costs for containers and the associated consumption costs (filters, labels, etc.) must be compared with the consumption costs for soft packaging (nonwoven, paper-foil packaging, adhesive tape, labels, protective packaging, etc.). The time requi-red for the actual packaging process and handling must also be critically examined. The type of packaging significantly determines the requirements for storage and transport. Thus, it must be checked whether the existing cabinet systems, storage systems as well as transport systems are suitable. Maintenance and repair costs, especially for containers (filter holder, tub, lid, closure), must also be considered. The reprocessing costs for the containers must also be considered. In con-trast, when soft packaging is used, the disposal effort and the resulting costs must be calculated.有一些必須考慮的成本因素。容器的投資成本和相關的消耗成本（過濾器、標籤等）必須與軟包裝（不織布、紙箔包裝、膠帶、標籤、保護性包裝等）的消耗成本進行比較。還必須嚴格檢查實際包裝過程和處理所需的時間。包裝類型很大程度上決定了儲存和運輸的要求。因此，必須檢查現有的櫥櫃系統、儲存系統以及運輸系統是否合適。還必須考慮維護和維修成本，特別是容器（過濾器支架、浴缸、蓋子、封閉件）的成本。還必須考慮容器的後處理成本。相反，當使用軟包裝時，必須計算處理工作量和由此產生的成本。

Environmental aspects 環境方面

The fact that more waste is generated when using non-wovens than when using container systems does not require further explanation. Nevertheless, even when using containers, there are consumables such as filters and seals or even an inner and/or drying fleece. An additional fleece in the container should always be critically questioned if it is not absolutely obligatory for user safety or the steam sterilization process. Not only is there more waste, but an additional fleece also means additional costs and additional work. The rule here is that less is more. 使用不織布比使用容器系統產生更多廢物這一事實不需要進一步解釋。然而，即使在使用容器時，也存在諸如過濾器和密封件甚至內部和/或乾燥羊毛之類的消耗品。如果容器中的附加絨布對於使用者安全或蒸氣滅菌過程不是絕對必要的，則應始終嚴格質疑。不僅浪費更多，而且額外的羊毛也意味著額外的成本和額外的工作。這裡的規則是少即是多。

When processing containers, it must again be considered that there is a higher consumption of media, of course, water and chemicals are used. In the newer generations of equipment, however, there is the possibility of deionized water recycling. This means that the deionized water from the last rinsing step of the disinfection in the WD can be used for the first rinsing step in the container and trolley washer. This means that no fresh water is required for this first step and the water does not have to be heated. 在處理容器時，必須再次考慮到介質的消耗量較高，當然會使用水和化學品。然而，在新一代設備中，可以進行去離子水回收。這意味著 WD 消毒最後一個沖洗步驟中的去離子水可用於容器和推車清洗機的第一個沖洗步驟。這意味著第一步不需要新鮮水，也不需要加熱水。

Conclusion結論

Selecting the appropriate sterile barrier system is not an easy decision. It depends on various factors and is ideally decided by a team. If it fits the workflows in the OR, in the CSSD or in the practice, it helps to optimize the processes and is an essential part of the reprocessing process. Clear, familiar procedures, uniform packaging systems and adherence to the minimum principle not only help to prevent errors, they also speed up the overall process and thus save money. 選擇合適的無菌屏障系統並不是一個容易的決定。這取決於多種因素，最好由團隊決定。如果它適合 OR、CSSD 或實踐中的工作流程，則有助於優化流程，並且是再處理流程的重要組成部分。清晰、熟悉的程序、統一的包裝系統以及遵守最低限度原則不僅有助於防止錯誤，還可以加快整個流程，從而節省成本。

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Processing of cleaning textiles - DIN 13063 Hospital cleaning 清潔紡織品的處理- DIN 13063 醫院清潔

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DIN 13063 (2021) Hospital cleaning at a glance DIN 13063 (2021) 醫院清潔概況

DIN 13063 specifies the requirements for the cleaning of hospitals and other medical facilities (facilities for outpatient surgery, preventive or rehabilitation facilities, dialysis facilities and day clinics). DIN 13063 規定了醫院和其他醫療設施（門診手術設施、預防或復健設施、透析設施和日間診所）的清潔要求。

More than 50 experts from science and research, hygiene institutes, service societies and industry as well as the supplier industry participated. In addition, the expertise of the Robert Koch Institute, the German Hospital Association, the German Society for Hygiene and Microbiology, the German Society for Hospital Hygiene and the Federal Environment Agency as well as the DIN Consumer Council were available. 來自科研、衛生機構、服務協會和工業界以及供應商行業的50多位專家參加了會議。此外，還可以獲得羅伯特• 科赫研究所、德國醫院協會、德國衛生和微生物學協會、德國醫院衛生協會、聯邦環境局以及 DIN 消費者委員會的專業知識。

The purpose of this standard is to ensure consistent quality and effectiveness of cleaning services to ensure a hygienic environment for patients, visitors, and medical staff. Another important concern is to describe the permissibility of cleaning processes, especially if further standards are binding. For this reason, the chapter "Scope of application" deals with the inventory and equipment in the patient's room. These can be disinfectant cleaned according to the standard, even if they are classified as a medical device. 該標準的目的是確保清潔服務的品質和有效性始終如一，以確保患者、訪客和醫務人員的衛生環境。另一個重要的問題是描述清潔過程的允許性，特別是在進一步的標準具有約束力的情況下。因此，「適用範圍」一章涉及病房內的庫存和設備。即使它們被歸類為醫療器械，也可以按照標準進行消毒清潔。

The structure of the standard is based on the three dimensions of quality management in the healthcare sector: structural quality – process quality – quality of results. In particular, in the chapter on structural quality, requirements for both the client and the contractor are described. Thus, this standard is aimed at all parties involved in the cleaning process. 此標準的結構是基於醫療保健產業品質管理的三個維度：結構品質-流程品質-結果品質。特別是，在結構品質章節中，描述了對客戶和承包商的要求。因此，該標準針對參與清潔過程的所有各方。

Requirements for cleaning textiles for disinfectant cleaning 消毒清潔紡織品的要求

Cleaning textiles are all textiles that are used for the (disinfecting) cleaning of surfaces and objects. The essential functions of the cleaning textile are the delivery and distribution of detergent/disinfectant solution, transfer of sufficient mechanics to achieve wipe disinfection, mobilization of dirt, absorption of dirt and excess detergent/disinfectant solution. The characteristics of the cleaning textiles are, on the one hand, the structure of the textile, the durability and the compatibility in use with disinfectants.清潔紡織品是用於表面和物體清潔（消毒）的所有紡織品。清潔紡織品的基本功能是輸送和分配洗滌劑/消毒劑溶液、傳遞足夠的機械以實現擦拭消毒、移動污垢、吸收污垢和多餘的洗滌劑/消毒劑溶液。清潔紡織品的特點一方面是紡織品的結構、耐用性以及與消毒劑使用的相容性。

Nowadays, cleaning textiles are therefore technical products that have to withstand a high load in the application and in the washing processes (including drying). Unsuitable materials have too high a depletion of active ingredients and falsify the result. 如今，清潔紡織品已成為必須在應用和洗潔過程（包括乾燥）中承受高負荷的技術產品。不合適的材料會導致活性成分消耗過高，導致結果失真。

Here are some important aspects to consider: 以下是需要考慮的一些重要面向：

- **Cleanliness清潔度:** Cleaning textiles should be clean before they are used. They should be washed regularly, disinfected and, if necessary, sterilized to prevent the transmission of germs.傾斜的紡織品在使用前應清潔。應定期清洗、消毒，必要時進行滅菌，以防止細菌傳播。
- **Material材料:** The cleaning textiles used should be made of materials that are suitable for their intended purpose. They should be durable, tear-resistant, and chemical-resistant to meet hospital cleaning needs.所使用的清潔紡織品應由適合其預期用途的材料製成。它們應該耐用、抗撕裂、耐化學腐蝕，以滿足醫院的清潔需求。
- **Color coding顏色編碼:** It is recommended to use different color codes for cleaning textiles in different areas of the hospital to avoid cross-contamination. For example, specific colors can be set for cleaning patient rooms, bathrooms, operating rooms, etc.建議在醫院不同區域使用不同顏色代碼清潔紡織品，以避免交叉污染。例如，可以設定特定顏色來清潔病房、浴室、手術室等。

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Fig圖. 1: Example of a cleaning textile with color coding帶有顏色編碼的清潔紡織品範例 (Ecolab).

- **Intended use預期用途:** Cleaning textiles should be used according to their intended use. It is important to use separate textiles for cleaning floors, surfaces, toilets, etc., to minimize the transmission of germs.清潔紡織品應根據其預期用途使用。使用單獨的紡織品清潔地板、表面、廁所等非常重要，以盡量減少細菌的傳播。
-

In addition to economic factors, the properties and quality of the cleaning textiles should be at the forefront of procurement. Once used, cleaning textiles, such as dis-posable wipes, must be disposed of properly after use. Recyclable textiles must be subjected to a proper and professional reprocessing process before reuse. 除了經濟因素外，清潔紡織品的性能和品質也應該是採購的首要考慮因素。使用後，清潔紡織品（例如一次性抹布）必須在使用後妥善處理。可回收紡織品在重新使用之前必須經過適當和專業的再處理過程。

Components of the reprocessing process of reusable cleaning textiles 可重複使用的清潔紡織品再處理流程的組成部分

When preparing the cleaning textiles, the complete process must be considered from a hygienic point of view. The process begins with the intermediate storage of the cleaning textiles after their application, followed by the washing and disinfection process, the downstream process steps, such as mechanical drying or pre-impregnation, as well as the storage and transport of the textiles to the place of use. This process and the resulting re-quirements for processing apply both to internal processing, i.e. in the object itself, as well as to processing outside the object as well as to the outsourcing of processing to third parties. For internal processing, the necessary structural requirements for the client are named, this is the only way to ensure proper processing. 在準備清潔紡織品時，必須從衛生角度考慮整個流程。該流程從清潔紡織品使用後的中間儲存開始，然後是洗滌和消毒過程，下游流程步驟，例如機械乾燥或預浸漬，以及紡織品的儲存和運輸到指定地點使用。該流程和由此產生的處理要求既適用於內部處理，即對象本身，也適用於對像外部的處理以及將處理外包給第三方。對於內部處理，客戶必須提出必要的結構要求，這是確保正確處理的唯一方法。

Regardless of the place of reprocessing, the organization of the logistical processes must be evaluated from a hygiene point of view. Here, particular attention must be paid to the separation of soiled cleaning textiles and textiles that have already been processed. This separation is important to avoid unwanted recontamination. In addition to the textiles, however, the containers for transporting the textiles must also be separated into un-clean and clean containers and, if necessary, disinfected. 無論再處理地點為何，都必須從衛生角度評估物流流程的組織。在這裡，必須特別注意將髒污的清潔紡織品和已經處理過的紡織品分開。這種分離對於避免不必要的再污染很重要。然而，除了紡織品之外，運送紡織品的容器也必須分為不潔淨容器和潔淨容器，並在必要時進行消毒。

Preparation methods製備方法

For the first time, three different treatment methods are described in detail 首次詳細描述三種不同的治療方法

1. Disinfectant wash cycle with subsequent drying of the cleaning textiles消毒洗滌週期，隨後乾燥清潔紡織品
2. Disinfectant wash cycle with machine pre-soaking機器預浸泡的消毒清洗週期
3. Disinfectant wash cycle with manual pre-soaking手動預浸泡的消毒清洗週期

Common to all reprocessing methods is the disinfectant washing process. This is derived from the fact that a separation of the cleaning textiles before reprocessing according to 所有再處理方法的共同點是消毒清洗過程。這是因為在再處理之前根據以下標準對清潔紡織品進行了分離：

- Only used for cleaning僅用於清潔
- Used for disinfectant cleaning is not safe to comply with in practice.用於消毒清潔在實務上並不安全。

In the case of disinfectant washing processes, a distinction is made between thermal, chemo-thermal and chemical disinfection washing processes. In order to ensure the disinfecting effect of this process, compliance with the parameters of disinfection temperature, temperature holding time and liquor ratio must be reliably maintained. For all chemo-thermal and chemical disinfection washing processes, compliance with the dosing quantities and the dosing time are an important part of this process. 在消毒清洗過程中，可分為熱消毒清洗過程、化學熱消毒清洗過程及化學消毒清洗過程。為了確保此製程的消毒效果，必須可靠地保持消毒溫度、保溫時間和浴比等參數的符合性。對於所有化學熱和化學消毒清洗過程，遵守劑量和劑量時間是該流程的重要組成部分。

Tested chemo-thermal disinfection processes are listed, for example, in the list of the "Verbund für Angewandte Hygiene e.V." (VAH - Association for Applied Hygiene). Specifications for a thermal disinfection washing process, on the other hand, are listed in the disinfectant list of the Robert Koch Institute (RKI). 例如，「Verbund für Angewandte Hygiene e.V.應用衛生協會」清單中列出了經過測試的化學熱消毒過程。 （VAH - 應用衛生協會）。另一方面，羅伯特•科赫研究所 (RKI) 的消毒劑清單中列出了熱消毒清洗過程的規範。

Certain commercial washer have such disinfectant washing procedures. Proof is provided by validation. This is also accompanied by the equipment ofsafety functions, such as the fact that these procedures cannot be aborted. Various processes can be added downstream of the disinfecting washing process. From a hygienic point of view, drying the cleaning textiles is a safe method that does not include any restrictions on storage. However, this requires complete drying. This standard describes for the first time how proper drying can be demonstrated, namely by measuring the so-called a_W value. 某些商用清洗機有這樣的消毒洗滌程序。證明是透過驗證提供的。這也伴隨著安全功能的配備，例如這些程序無法中止。可以在消毒清洗過程的下游添加各種過程。從衛生的角度來看，乾燥清潔紡織品是一種安全的方法，不包括任何儲存限制。然而，這需要完全乾燥。該標準首次描述如何證明適當的乾燥，即透過測量所謂的 a_w 值。

Another method described is mechanical pre-soaking. In this process, the cleaning agents or surface disinfectants are added in the last treatment step of the disin-fecting washing process. To ensure this procedure, the manufacturer's instructions must be observed. In the absence of manufacturer's information, the test inter-vals with regard to the effectiveness of this method must be determined as part of a risk analysis. 所描述的另一種方法是機械預浸泡。在此過程中，清潔劑或表面消毒劑是在消毒清洗過程的最後處理步驟中添加的。為了確保此過程，必須遵守製造商的說明。在沒有製造商資訊的情況下，必須確定與該方法有效性相關的測試間隔作為風險分析的一部分。

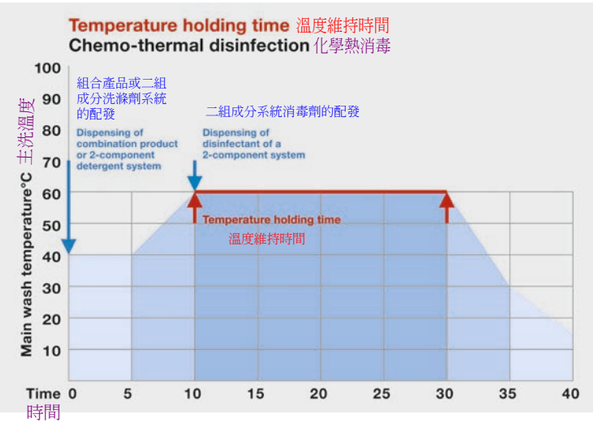
The third variant is wet storage with subsequent manual pre-impregnation. In the case of pre-impregnation, the maximum service life must be determined. At the end of the maximum service life, the cleaning textiles must meet the specified microbiological guideline values. The most important criterion for quality assessment is effectiveness on the surface. 第三種變化法是濕儲存並隨後進行手動預浸漬。如果是預浸漬，則必須確定最大使用壽命。在最長使用壽命結束時，清潔紡織品必須符合指定的微生物指南值。品質評估最重要的標準是表面上的有效性。

Quality tests for the functionality of the cleaning textile 清潔紡織品功能的品質測試

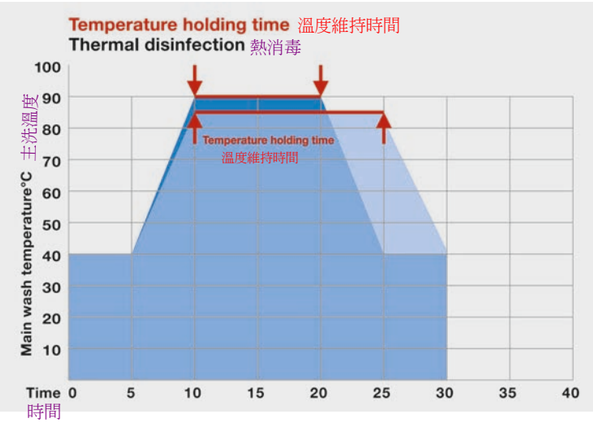
In general, functional tests of cleaning textiles are an important part of quality management in hospital cleaning. Specific testing procedures and criteria may vary from facility to facility, depending on internal policies and requirements. Here are some typical aspects that are considered when functional testing of cleaning textiles in hospital cleaning: 一般來說，清潔紡織品的功能測試是醫院清潔品質管理的重要組成部分。具體測試程序和標準可能因設施而異，具體取決於內部政策和要求。以下是在醫院清潔中對清潔紡織品進行功能測試時需要考慮的一些典型方面：

Cleanliness清潔度: The cleaning textiles should be clean and have no visible dirt or contamination. 清潔紡織品應乾淨，沒有可見的污垢或污染物。

Integrity完整性: The cleaning textiles should be in good condition, with no tears, holes or other damage that could affect the cleaning performance.



Fig圖. 2: Schematic representation of the disinfection phase in a chemothermal disinfection washing process化學熱消毒清洗流程中消毒階段的示意圖. Source來源: Miele



Fig圖. 3: Schematic representation of the disinfection phase in a thermal disinfection process.熱消毒流程中消毒階段的示意圖 Source來源: Miele

Washability耐洗性: The cleaning textiles should be washable and able to retain their shape and properties after washing.清潔紡織品應該是可清洗的並且能夠在清洗後保持其形狀和性能。

Disinfectant suitability消毒劑適用性: The cleaning textiles should be suitable for disinfection and should not contain any materials that could impair the effectiveness of disinfectants. 清潔紡織品應適合消毒，且不應含有任何可能損害消毒劑有效性的材料。

Low residues低殘留: The cleaning textiles should be low in residues and leave no fibers or residues on the cleaned surfaces. 清潔紡織品的殘留物應該很少，並且在清潔的表面上不留下纖維或殘留物。

A first indication that the functionality is no longer given is the increase or decrease in weight of the cleaning textile. 不再提供功能的第一個指示是清潔紡織品重量的增加或減少。

Summary總結

DIN 13063 is a comprehensive document that describes the requirements for cleaning and disinfectant cleaning in hospitals and other medical facilities. With the clearly structured structure in terms of structure, process and result quality, the requirements for preparation, implementation and quality controls are also listed. DIN 13063 是一份綜合文件，描述了醫院和其他醫療機構的清潔和消毒清潔要求。在結構、流程和結果品質方面結構清晰，也列出了準備、實施和品質控制的要求。

Cleaning textiles must meet many requirements for hygienic cleaning performance. Only reusable cleaning textiles advertised by the manufacturer can be properly reprocessed. The organizational and logistical procedures for reprocessing are dealt with in this standard from a hygienic point of view. 清潔紡織品必須滿足衛生清潔性能的許多要求。只有製造商宣傳的可重複使用的清潔紡織品才能進行適當的再處理。本標準從衛生角度闡述了再處理之組織的和後勤的程序。

To ensure that the cleaning textiles fulfill their functionality on the surface after processing, the disinfecting washing process, processes downstream of the washing process and their inspection are described in detail in DIN 13063 Hospital cleaning.為了確保清潔紡織品在處理後在表面上發揮其功能，DIN 13063 醫院清潔中詳細描述了消毒洗滌過程、洗滌過程的下游過程及其檢查。

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Dentsply Sirona

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With the increasing hygiene requirements, the requirements for the disinfectant increase as well for the waterlines in the treatment center. The new Dentosept Clean has a faster onset of action* and an improved effectiveness**. With its new active combination based on hydrogen peroxide, it thus ensures, within a very short time, the inactivation of the germs in the water lines of your treatment center – which, thanks to the improved depot effect, also provides long-lasting protection. Of course, Dentosept Clean is just as safe and gentle on material as its predecessor Dentosept S.

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* Comparison of the microbiological kinetics of action of the disinfectants Dentosept S and Dentosept Clean, HygCen Germany GmbH, 2021.

** Comparison of the microbiological effect of the disinfectants Dentosept S and Dentosept Clean on biofilm coatings in dental hoses, IWW Rheinisch-Westfälisches Institut für Wasser Beratungs- und Entwicklungsgesellschaft mbH, 2022.

Steelco positions its brand with new NCG sensor

Steelco
Miele Group Member

As the first hospital in Germany, the St. Maria Hospital in Hamm is trialling a new way to monitor sterilisation processes. The new NCG sensor from Steelco, a Miele subsidiary, is in use at the clinic on all three large steam sterilisers – processing around 35,000 sterile supply units per year.

NCG sensors record the quantity of air and other non-condensable gases in real time – in each individual cycle. The underlying principle: Each sensor auto-fills after the beginning of each process with a blend of steam and air from the sterilisation chamber. Steam condenses on the internal walls of the sensor, liberating heat which dissipates. The sensor monitors this heat at intervals of one second: If the condensate reaches the tip of the sensor, the rate of temperature rise is fast and the proportion of non-condensable gases is below the threshold value. If, on the other hand, condensate fails to reach the tip, this is an indication that there are more NCGs and hence air in the chamber. The sensor comes in response to the DIN EN ISO 17665-1 (2006) standard, which demands the use of the Bowie-Dick test on a regular basis. The NCG sensor furnishes proof that steam sterilisers and the associated process are compliant with the requirements of the DIN EN 285 standard.

Abb. 1: Satisfied with the performance of the NCG sensor at the St. Maria hospital in Hamm: CSSD manager Cornelia Plutz and Thorsten Fersch, Technical Manager for Validation, Digitalisation and Training in the DACH sales region at Miele. (Photo: Miele).

Specific inspection of lumened instruments in CSSD at MKM 對 MKM CSSD(中央消毒供應部)中的帶腔室儀器進行具體檢查

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The reprocessing of lumened instruments places great demands on washer-disinfectors and on CSSD personnel. A visual inspection of lumens is not possible or only to a limited extent. In the face of this, the MKM introduced a quarterly and additional inspection of lumened instruments several years ago. To this end, reprocessing is interrupted in the washer-disinfector to allow lumened instruments to be inspected by a hygiene specialist. 內腔器械的再處理對清洗消毒員和 CSSD 人員提出了很高的要求。管腔的目視檢查是不可能的或只能在有限的範圍內進行。面對這種情況，MKM 幾年前就對發光儀器進行了季度和額外的檢查。為此，清洗消毒器中的再處理中斷，以便衛生專家對內腔器械進行檢查。

Method方法

1)
A swab soaked in isotonic sodium chloride solution is introduced to the lumens, cones and valves and the inner surfaces swabbed intensively. This is followed by wiping the swab on a casein soya peptone agar plate (25 cm^2). The plates are then incubated for 3 days at 36°C. A first inspection of the plates takes place after 24, 48 and finally after 72 h. 將浸泡在等滲氯化鈉溶液中的拭子引入管腔、錐體和閥門，並集中擦拭內表面。然後將拭子擦拭在酪蛋白大豆蛋白胰瓊脂平板（25 cm^2）上。然後將板在 36°C 下孵育 3 天。對板進行第一次檢查是在 24 小時、48 小時後進行，最後是在 72 小時後進行。

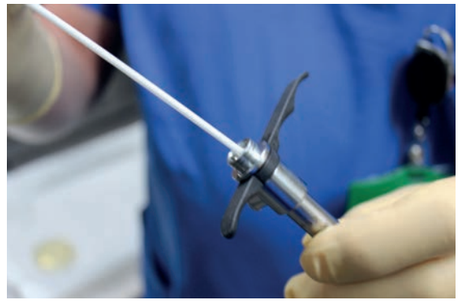
2)
Irrigation of lumened instruments using a sterile syringe, filled with sterile isotonic sodium chloride solution. Complete wetting of a sterile swab with the fluid (in the event of conspicuous findings, also examination of elu-ate), followed by wiping out the swab on a casein soya peptone agar plate (25 cm^2). The plates are then incubated for 3 days at 36°C. A first inspection of the plates takes place after 24, 48 and finally after 72 h. 使用裝有無菌等滲氯化鈉溶液的無菌注射器沖洗內腔器械。用液體完全潤濕無菌拭子（如果有明顯發現，也檢查洗出液），然後在酪蛋白大豆蛋白胰瓊脂平板（25 cm^2）上擦拭拭子。然後將板在 36°C 下孵育 3 天。對板進行第一次檢查是在 24 小時、48 小時後進行，最後是在 72 小時後進行。

Conclusion結論

As part of validated processes in a CSSD, it makes sound sense to carry out random internal quality control inspections. High product quality can be assured at an early stage in the interests of quality management through process monitoring, in this case on a complex medical product. 作為 CSSD 驗證流程的一部分，進行隨機內部品質控制檢查是很有意義的。透過製程監控（在本例中是複雜的醫療產品），可以在早期階段確保高產品質量，以實現品質管理。

Fig圖. 1: Swabbing of laparoscopic cannula腹腔鏡插管的擦拭.

Fig圖. 2: Swabbing of bi-polar sleeve擦拭雙極套管.



This affords an additional level of security before instruments are used again on patients. To secure this standard of quality, a quarterly microbiological inspection was introduced alongside the routine validation of processes. These inspections have so far produced favourable results throughout. 這在儀器再次用於患者之前提供了額外的安全等級。為了確保這項品質標準，除了流程的常規驗證之外，還引入了季度微生物檢查。迄今為止，這些檢查取得了良好的結果。

Our evaluations have so far not produced any negative results and no additional measures were ever necessary. It can be confirmed that the CSSD team performs highly diligent reprocessing work, even on complex medical products. 迄今為止，我們的評估尚未產生任何負面結果，也無需採取額外措施。可以確認的是，即使是複雜的醫療產品，CSSD團隊也進行了高度勤奮的再處理工作。

Fig圖. 3: Irrigation of trocar套管針的沖洗.

No.	Sampling point 採樣點	Agar 瓊脂	Testresult 測驗結果	Target 目標值	Evaluation 評估
1.	Sleeve Bipolar 雙極套筒 8384.974 Hose connection 軟管連接	Bacteria 細菌	0 CFU/24 cm^2	0 CFU/24 cm^2	inconspicuous 不明顯的
		Fungi 真菌	0 CFU/24 cm^2		
2.	Trocar EK 5248 Gas connection 套管針氣體連接	Bacteria 細菌	0 CFU/24 cm^2	0 CFU/24 cm^2	inconspicuous 不明顯的
		Fungi 真菌	0 CFU/24 cm^2		
3.	Trocar sleeve EK 090R Inner lumen 套管針內腔	Bacteria 細菌	0 CFU/24 cm^2	0 CFU/24 cm^2	inconspicuous 不明顯的
		Fungi 真菌	0 CFU/24 cm^2		
4.	Sleeve Grasping forceps distal end 套筒抓鉗遠端	Bacteria 細菌	0 CFU/24 cm^2	0 CFU/24 cm^2	inconspicuous 不明顯的
		Fungi 真菌	0 CFU/24 cm^2		
5.	LSK Suction cup 吸杯 8383.71 Connection hose 軟管連接	Bacteria 細菌	0 CFU/24 cm^2	0 CFU/24 cm^2	inconspicuous 不明顯的
		Fungi 真菌	0 CFU/24 cm^2		

Fig圖. 4: Assessment of findings.對調查結果的評估

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Insight洞察: water leading systems in dental chairs 牙科椅中的導水系統

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Water plays an important role in dental treatment. The dental chair is connected to the drinking water and supplies both the motors and the multifunction syringe with water for safe and pleasant treatment. Likewise, the patient is supplied with fresh water via the tumbler filler for rinsing during and after treatment. But who ensures that the water in the dental chairs is always fresh and reaches the patient hygienically uncontaminated? Are there design and construction measures that influence water hygiene? And how do I, as the operator, notice that something in my dental chair is no longer in order? 水在牙科治療中扮演重要角色。牙科椅與飲用水相連，為馬達和多功能注射器供水，以實現安全、愉快的治療。同樣，在治療期間和治療後，透過滾筒填料為患者提供新鮮水以進行沖洗。但誰能確保牙科椅中的水始終是新鮮的並且到達患者時衛生且不受污染？是否有影響水衛生的設計和施工措施？作為操作員，我如何注意到牙科椅上的某些東西不再正常？

What role does water play in dental treatment? 水在牙科治療中扮演什麼角色？

Water in the dental treatment unit is used at various points during patient treatment. Classically, a mixture of air and water is used to cool the rotating instru-ment during tooth preparation. In this case, the dentist and assistant as well as the patient come into contact with the water from the unit. Furthermore, dental chairs have a multifunctional syringe which enables the dentist to use air and/or water to rinse the area to be prepared, for example. 牙科治療設備中的水在患者治療過程中的不同點被使用。通常，在牙齒預備期間使用空氣和水的混合物來冷卻旋轉器械。在這種情況下，牙醫、助理以及患者都會接觸設備中的水。此外，牙科椅具有多功能注射器，使牙醫能夠使用例如空氣和/或水沖洗待準備的區域。

Fig圖. 1: spray of a turbine 渦輪機的噴霧.

Some units also have ultrasonic or sonic instruments, which offer water cooling to minimize heat build-up on the tooth and to directly rinse off any concrements that may accumulate. Not to forget the tumbler filler, through which the patient receives water to rinse the oral cavity during or after the treatment. The use of water from the dental chair is therefore manifold and indispensable during treatment. 有些裝置還配有超音波或聲波儀器，它們提供水冷卻功能，以最大限度地減少牙齒上的熱量積聚，並直接沖洗掉可能積聚的任何結石。不要忘記滾筒填充器，患者在治療期間或治療後透過它接收水來沖洗口腔。因此，在治療過程中，牙科椅中的水的使用是多方面且不可或缺的。

Legal classification of water 水的法定分類

In Germany, drinking water is subject to the Drinking Water Ordinance (TrinkwV), which regulates how drinking water must be treated, especially regarding its microbiological composition. It also specifies how drinking water must be protected from contaminated water being fed into the system, e.g. with a so-called free fall section that prevents contaminated water from flow-ing back into the drinking water circuit. What this me-chanical protection looks like is declared in EN 1717. Depending on the type of potential contamination, it must meet certain requirements. Therefore, it is speci-fied exactly how the dental chair must be structurally separated from the pipe network.在德國，飲用水須遵守《飲用水條例》(TrinkwV)，該條例規定了飲用水的處理方式，特別是其微生物成分。它還規定瞭如何保護飲用水免受注入系統的污染水的影響，例如：具有所謂的自由落體部分，可防止受污染的水流回飲用水迴路。 EN 1717 中聲明了這種機械保護的外觀。根據潛在污染的類型，它必須滿足某些要求。因此，明確規定了牙科椅必須如何在結構上與管網絡分離。

The dental chair itself is a medical device, which means that it needs to be approved and CE declared while fulfilling the requirements of medical device law (now MDR or MDD). It must meet all the necessities of these legal conditions and the manufacturer must provide information regarding care, maintenance, and hygiene measures. Evidence must be provided for these details, i.e. the manufacturer must prove that these measures actually work. A medical device as well as the water used must not pose any risk to the patient or user. 牙科椅本身是一種醫療器械，這意味著它需要獲得批准和CE聲明，同時滿足醫療器械法（現在的MDR或MDD）的要求。它必須滿足這些法律條件的所有要求，並且製造商必須提供有關保養、維護和衛生措施的資訊。必須提供這些細節的證據，即製造商必須證明這些措施確實有效。醫療設備以及所使用的水不得對患者或使用者造成任何風險。

Since the RKI guidelines for dentistry ("Requirements for hygiene in dentistry" 2006) are no longer being revised, reference is made to the recommendations of professional societies for special areas. Thus, information about water in dental chairs can be found in the current DAHZ Hygiene Guide.1由於RKI牙科指南（「牙科衛生要求」2006）不再修訂，特殊領域參考專業協會的建議。因此，有關牙科椅中水的資訊可以在最新的 DAHZ 衛生指南中找到。1

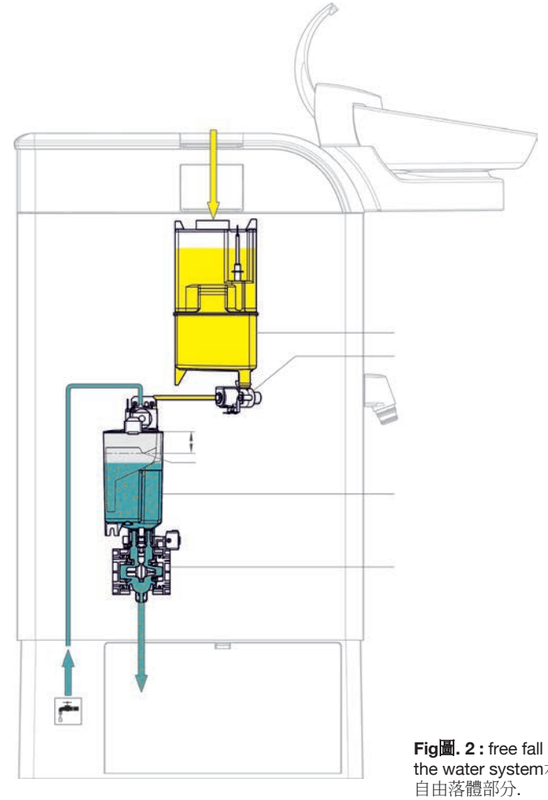
What does this mean for the practice? 這對實踐意味著什麼？

Although the water in the dental chair is not considered drinking water according to the German Drinking Water Ordinance (TrinkwV), the water quality must of course be equivalent to drinking water. The practice team must therefore ensure that the water quality is always consistently good so as not to endanger either patients or its own team. Initially, it must be ensured that the piping network and the domestic installation in the practice are in order and thus do not supply contaminated water. The challenge here is that many factors affecting water quality are building-related. For example, inadequate house inlet filters, dead sections in the piping system or old pipes can reduce the quality of the water and cause permanent difficulties. But poor home insulation or underfloor heating next to the supply line to the units can also promote fouling in the lines. Therefore, even before installation, the water lines should be sampled to ensure that good water quality prevails before connecting a new treatment unit to the mains. 雖然根據德國飲用水條例（TrinkwV），牙科椅中的水不被視為飲用水，但水質當然必須等同於飲用水。因此，實踐團隊必須確保水質始終保持良好，以免危及患者或自己的團隊。首先，必須確保實務上的管網和生活設施完好，從不供應受污染的水。這裡的挑戰是影響水質的許多因素都與建築有關。例如，房屋入口過濾器不足、管道系統死角或舊管道會降低水質並造成永久性困難。但是，不良的家庭隔熱或靠近設備供應管線的地暖也會導致管線結垢。因此，即使在安裝之前，也應該對水管進行採樣，以確保在將新的處理裝置連接到總管之前水質良好。

If everything is in order at the time of installation, hygiene measures taken by the practice team and regular routine checks ensure that the quality of the service water remains consistent. It is important that the measures recommended by the manufacturer are carried out meticulously. It is also worthwhile to have the house installation regularly inspected by experts and to monitor the quality with routine water samples. 如果安裝時一切正常，實踐團隊採取的衛生措施和定期例行檢查可確保供水品質保持一致。認真執行製造商建議的措施非常重要。由專家定期檢查房屋安裝並透過常規水樣本監測品質也是值得的。

What is biofilm什麼是生物膜?

In general, biofilms are communities of microorganisms. Optimally adapted to their environment and living conditions, their survival probabilities are higher in a group than alone and thus it is advantageous for these living organisms to form colonies. To the human eye, this colonization only becomes visible when a large biofilm has already formed and thus an exorbitant colonization has already taken place. Drinking water, which also feeds the waterways of dental chairs, also contains microorganisms that can potentially build up biofilms on the surfaces of water-bearing systems.一般來說，生物膜是微生物群落。它們能夠最佳地適應環境和生活條件，在群體中生存的機率比單獨生存的機率更高，因此有利於這些生物體形成群體。對於人眼來說，只有當大的生物膜已經形成並且因此已經發生了過度的拓殖時，這種拓殖才變得可見。飲用水也為牙科椅的水道提供水源，也含有可能在含水系統表面形成生物膜的微生物。



Fig圖. 2 : free fall section in the water system水系統中的自由落體部分.

Drinking water is never free of microorganisms, but certain limits must be observed with regard to microbiological quality. Once microorganisms have attached themselves to the surfaces, they form a slime layer that not only serves to absorb nutrients and thus feed this colony, but also to protect it from chemical and physical environmental influences. Particularly good biofilm formers are microorganisms such as P. aeruginosa, which are especially critical because of their hygienic relevance. 飲用水永遠不會沒有微生物，但在微生物品質方面必須遵守一定的限制。一旦微生物附著在表面，它們就會形成黏液層，不僅可以吸收營養物質並為該菌落提供食物，還可以保護其免受化學和物理環境的影響。特別好的生物膜形成劑是銅綠假單胞菌等微生物，它們由於其衛生相關性而特別重要。

Conversely, this means that preventing biofilm is much more effective than combating it. This is because an already formed and firmly anchored slime layer (microorganisms protected by the so-called extracellular matrix) can hardly be removed with simple measures such as vigorous rinsing or disinfectants. Already existing bio-films, which have negative hygienic effects, must be eliminated with elaborate measures such as a so-called biofilm removing. This usually involves dissolving the biofilm from the surface by treating it with special products. 相反地，這意味著預防生物膜比對抗生物膜更有效。這是因為已經形成並牢固固定的黏液層（受所謂的細胞外基質保護的微生物）很難透過簡單的措施（例如強力沖洗或消毒劑）來去除。已經存在的生物膜具有負面的衛生影響，必須透過所謂的生物膜去除等複雜措施來消除。這通常涉及透過用特殊產品處理來溶解表面的生物膜。

This results in downtime and additional costs. The selection of materials as well as the nature of the water (nutrient supply, temperature, and flow behavior) also influence the formation of biofilms 這會導致停機和額外成本。材料的選擇以及水的性質（養分供應、溫度和流動行為）也會影響生物膜的形成.[2]

How good should the water in the dental chairs be牙科椅裡的水應該要多好?

The water quality must always meet the national requirements for drinking water. In Germany, the Drinking Water Ordinance (TrinkwV) applies, according to which a maximum of 100 CFU (colony-forming units) per milliliter of water may be measured, of which a maximum of one CFU of Legionella per milliliter is allowed水質必須始終滿足國家生活飲用水的要求。在德國，適用《飲用水條例》(TrinkwV)，根據該條例，每毫升水最多可測量 100 CFU（菌落形成單位），其中每毫升水中最多允許測量 1 CFU 軍團菌.[3]

Fig. 3: dental chair from Dentsply Sirona登士柏西諾德牙科椅 – Axano.

What are the options for biofilm prevention and what is a bottle system預防生物膜的選項有哪些？什麼是瓶子系統？?

Manufacturer offer various systems and processes to ensure the water quality in the unit and to prevent the formation of biofilm. A common variant is a hygiene system installed in the unit, where chemicals are permanently added to the water in the dental chair to prevent the formation of biofilm and thus achieve consistent water quality. The practice staff has to regularly maintain these systems with chemicals. Modern dental chairs monitor the measures and report inadequacies directly to the user. In some units, it is also possible to view the condition of the units centrally in the practice via a monitoring system. It shows which measures have been carried out on which unit and indicates the current level of chemicals. With these hygiene systems, it is important that the practice team adheres precisely to the manufacturer's instructions, especially when selecting the chemicals and adhering to the routine measures. 製造商提供各種系統和工藝來確保裝置中的水質並防止生物膜的形成。一種常見的變體是在設備中安裝衛生系統，將化學物質永久添加到牙科椅中的水中，以防止生物膜的形成，從而實現一致的水質。實踐人員必須定期使用化學品來維護這些系統。現代牙科椅會監控措施並直接向使用者報告不足之處。在某些單位中，也可以透過監控系統在實務上集中查看單位的狀況。它顯示了哪個單位採取了哪些措施，並指示了當前的化學品水平。對於這些衛生系統，實踐團隊必須嚴格遵守製造商的說明，特別是在選擇化學品和遵守常規措施時。

This is the only way to ensure that the units survive the process and that the material is not damaged. 這是確保單元在整個過程中倖存且材料不被損壞的唯一方法。

Another measure usually offered by manufacturers to ensure water quality is the so-called bottle system. Here, the operator has the possibility to use the unit independently of the normal pipeline network. This measure becomes particularly necessary if the supplied drinking water (city water) is contaminated. Then the responsible health office publishes a notice stating that the water must be boiled before consumption. Again, for legal reasons, only the solutions offered by the manufacturer should be used.製造商通常提供的另一種確保水質的措施是所謂的瓶裝系統。在這裡，操作員可以獨立於正常管道網路使用該裝置。如果供應的飲用水（城市水）受到污染，這項措施就顯得格外必要。然後，負責的衛生部門發布通知，指出水必須在飲用前煮沸。同樣，出於法律原因，只能使用製造商提供的解決方案。

Fig. 4: Bottle-System瓶子系統.

Another necessity for the use of external cooling water is the treatment of immunosuppressed patients or extensive surgical procedures. Here, one should use the sterile saline solution and an external pump installed on the unit. 使用外部冷卻水的另一個必要條件是治療免疫抑制患者或進行大量外科手術。在這裡，應該使用無菌鹽水溶液和安裝在設備上的外部幫浦。

How important are routine checks and maintenance日常檢查和維護有多重要?

Routine checks ensure that the user can monitor his processes in daily operation and quickly detect inadequacies. This applies on the one hand to water quality, but also on the other hand, for example, when using chemicals for correct dosing. Regular water sampling can certainly help to monitor water quality optimally. Inadequacies can also be detected and remedied immediately during daily, weekly, or monthly care and maintenance work specified by the manufacturer for the dental chair. Maintenance and replacement of filters and strainers, as well as many other measures, belong to these care intervals. 例行檢查確保使用者可以在日常操作中監控其流程並快速發現不足之處。這一方面適用於水質，另一方面也適用於例如使用化學品進行正確劑量的情況。定期進行水採樣無疑有助於最佳地監測水質。在製造商為牙科椅指定的每日、每週或每月的護理和維護工作中，還可以立即檢測到缺陷並進行補救。過濾器和濾網的維護和更換以及許多其他措施都屬於這些保養間隔。

How can the manufacturer support廠商如何支持?

Construction and design施工與設計
Manufacturers support hygiene processes in the dental chair with an appropriate design of the waterways. Few stagnation elements, waterways aligned to flow velocities and the avoidance of dead stretches are just a few selected design measures. Furthermore, hygiene already plays a significant role in the planning of new treatment units and is reflected seamlessly in all elements of the unit from the very first design. 製造商透過適當的水道設計來支援牙科椅的衛生流程。很少的停滯組成、與流速一致的水道以及避免死角只是一些選定的設計措施。此外，衛生在新治療裝置的規劃中已經發揮著重要作用，並且從最初的設計開始就無縫地體現在裝置的所有組成中。

Materials 材料
Hygiene is also considered in the selection of materials for the waterways. In addition to the general suitability of the materials for water-bearing systems intended for human use, the materials should at least make coloni-zation by biofilm difficult. Thus, the right material in combination with routine hygiene measures is a critical component in maintaining water quality. 在選擇水道材料時也考慮了衛生問題。除了這些材料對於人類使用的含水系統的一般適用性之外，這些材料應該至少使生物膜的拓殖變得困難。因此，正確的材料與常規衛生措施相結合是維持水質的關鍵組成部分。

Manufacturer information 製造商資訊
Manufacturers evaluate all hygiene measures of their medical devices for effectiveness and material compatibility. The used agents (cleaners, auxiliaries, disinfectants, etc.) are validated in connection with the method described in the instructions for use. This gives the user the assurance that the agents described are effective and harmless to the materials. 製造商評估其醫療器材的所有衛生措施的有效性和材料相容性。使用的試劑（清潔劑、助劑、消毒劑等）根據使用說明中所述的方法進行驗證。這使用戶確信所描述的試劑是有效的並且對材料無害。

Conclusion 結論

The water paths in the dental chairs are complex. Keeping them hygienically stable is no easy task, as various influencing factors can affect the quality of the water. In addition to regular monitoring of the on-site water installations, the water in the units must also be monitored. It is worthwhile to carry out the measures specified by the manufacturer in order to take preventive action and not to react only when the values deteri-orate. This not only serves to protect patients and staff, but also helps to avoid expensive remediation measures such as biofilm removing. 牙科椅內的水路很複雜。要維持它們的衛生穩定並非易事，因為各種影響因素都會影響水質。除了對現場供水裝置進行定期監測外，還必須對單位內的水進行監測。值得執行製造商指定的措施，以便採取預防措施，而不是僅在數值惡化時才做出反應。這不僅可以保護患者和工作人員，還有助於避免昂貴的補救措施，例如去除生物膜。

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Validation of automated cleaning and disinfection processes for the reprocessing of thermolabile endoscopes according to the DGSV framework curriculum 根據 DGSV(德國無菌供應協會)架構課程，驗證不耐熱內視鏡再處理的自動清潔和消毒流程

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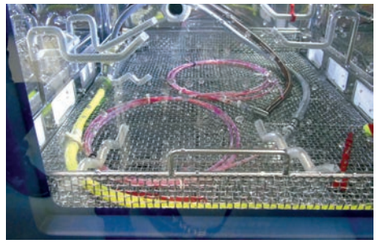
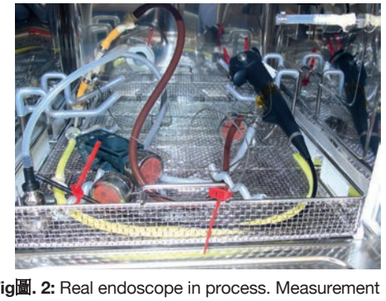


Fig圖. 1: Test tube for testing the cleaning performance.
用於測試清潔性能的試管



Fig圖. 2: Real endoscope in process. Measurement of temperature and conductivity of the rinsing liquor and the rinsing pressure在流程中真正的內視鏡。測量沖洗液的溫度和電導度以及沖洗壓力。.

In recent years, the validation of automated cleaning and disinfection processes for reprocessing thermolabile endoscopes has gained significantly in importance.
German hospitals are for the most part equipped with modern washer-disinfectors for thermolabile endoscopes (WD-E), whose reprocessing processes have been validated for many years近年來，用於再處理不耐熱內窺鏡的自動清潔和消毒過程的驗證變得越來越重要。德國醫院大部分配備了用於不耐熱內窺鏡的現代化清洗消毒機 (WD-E)，其後處理工藝已經過多年驗證。.

In private practice, there is a constant change from manual to mechanical reprocessing. However, gastroenterologists, who generally work with mechanical reprocessing processes, do not make up the majority of those who switch from manual to mechanical reprocessing. Rather, there are other medical specialties that work with thermolabile endoscopes, such as urologists in private practice, regardless of whether they are larger group practices or smaller individual practices. The demand for machine reprocessing of thermolabile endoscopes has steadily increased in these areas 在私人診所中，從手工再處理到機械再處理不斷發生變化。然而，通常從事機械再處理過程的胃腸病學家在從手動再處理轉向機械再處理的人中並非佔大多數。相反，還有其他醫療專業人士使用不耐熱內視鏡，例如私人診所的泌尿科醫生，無論他們是較大的團體診所還是較小的個人診所。這些領域對不耐熱內視鏡機器再處理的需求穩定增加。.

One reason for the increasing number of validated processes as well as the steadily increasing demand for certified training courses are the relevant paragraphs of the MPBetreibV [1] = Medical Devices Operator Regulations, such as §8 (1) "The reprocessing of medical devices intended for use aseptic or sterile must be carried out with suitable validated procedures, taking into account the manufacturer's specifications, in such a way that the success of these procedures is traceably guaranteed and the safety and health of patients驗證流程數量不斷增加以及對認證培訓課程的需求穩步增長的原因之一是 MPBetreibV 1 = 醫療器械運營商法規的相關段落，例如第8(1)分節"預期使用的醫療器械的再處理無菌或無菌必須採用適當的經過驗證的程序進行，並考慮製造商的規格，以確保這些程序的成功以及患者的安全和健康，

users or third parties is not endangered." and § 5 (2) Requirements for the validator: "Compliance with these specific requirements may be demonstrated by the presentation of a certificate issued by a body recognized by the authority responsible for notified bodies in the scope of this legal regulation (Article 35 (1) (EU) 2017/745) [2] or (Article 31 (1) (EU) 2017/746) [3] "用戶或第三方不會受到威脅。"以及第 5 (2) 分節證驗證者的要求："可以通過出示由負責範圍內公告機構的機構認可的機構頒發的證書來證明符合這些具體要求本法律法規的規定（第35 (1) (EU) 2017/745 條）[2]或（第31 (1) (EU) 2017/746 條）[3]

In this context, there was an increase in demand from validation companies for specific training courses especially in the area of performance qualification of automated cleaning and chemo-thermal disinfection processes在此情況下，驗證公司對特定培訓課程的需求增加，特別是在自動清潔和化學熱消毒過程的性能鑑定領域.

Since 2022, the DGSV[4] has therefore been offering a new uniform framework curriculum and a separate module on the topic of "Validation of automated cleaning and disinfection processes for the reprocessing of thermolabile endoscopes". This helps to further improve and optimize validations in this segment 因此，自 2022 年以來，DGSV[4] 一直提供新的統一架構課程和一個單獨的模組，主題為"耐熱內視鏡後處理的自動清潔和消毒過程的驗證"。這有助於進一步改進和優化該部分的驗證. The framework curriculum designed by DGSV[4] comprises 4 modules DGSV[4] 設計的架構課程包括4個模組：

Framework curriculum - parts 架構課程-部分

Vali A Basics of medical device reprocessing醫療器械再處理知識基礎(24TU)

Vali B Basics of performance qualification of reprocessing processes再處理流程性能驗證的知識基礎 (24TU)

Vali C Performance qualification of cleaning and disinfection processes清潔和消毒流程的性能驗證 (24TU)

Vali E Performance qualification of steam sterilization processes蒸汽滅菌流程的性能驗證 (16TU)

The Vali-C module includes two courses, C1 and C2. Each part has 24 teaching units (1TU = 45min)Vali-C 模組包括兩門課程：C1 和 C2。每個部分有24個教學單元（1TU=45分鐘）.

Fig圖. 3: Spypach „Classic" endoscope dummy with EBI12 data logger for measuring pressures and temperatures in the simulated endoscope. Spypach„ 經典 "內視鏡模型配有 EBI12 數據記錄器，用於測量模擬內視鏡中的壓力和溫度。

The module Vali-C2 is specially designed for the needs of performance qualification of automated cleaning and chemo-thermal disinfection processes and consists of the following components Vali-C2 模組專為滿足自動清潔和化學熱消毒過程的性能鑑定需求而設計，由以下單元組成：

- Welcome歡迎/Introduction介紹 1 TU
- Risk management in the performance qualification of automated cleaning and chemo-thermal disinfection processes 自動清潔和化學熱消毒過程性能鑑定中的風險管理 2 TU
- Sequence plans 序列計劃 1 TU
- Validation of cleaning and disinfection processes清潔和消毒過程的驗證 16 TU
- Tasks after performed process validation執行流程驗證後的任務 4 TU
- Knowledge review 知識回顧

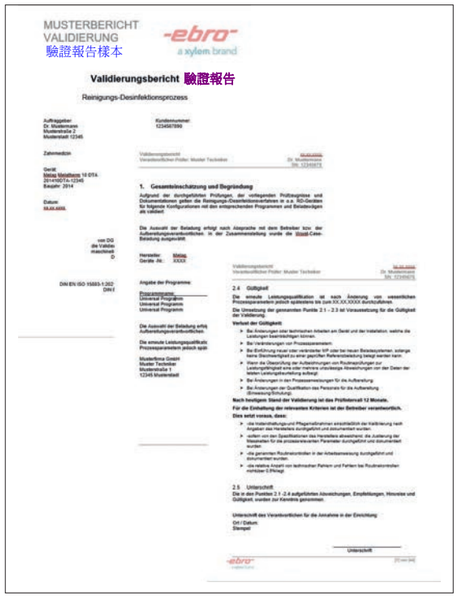
The course begins with a round of introductions of the participants and speakers, after which the contents, objectives and focal points of the validation course are explained by the course leader. 課程首先對參與者和演講者進行一輪介紹，然後由課程負責人解釋驗證課程的內容、目標和重點。

In the following part "Risk management" the connection of the risk management with the performance qualification according to the standard DIN EN ISO 14971[5] and the guideline VDI 5700-1[6] is taught在接下來的"風險管理"部分中，將介紹根據 DIN EN ISO 149715 標準和 VDI 5700-16 指南將風險管理與績效鑑定聯繫起來.

The topic "Sequence plans" deals with the general process of a performance qualification. Points such as important contact persons during performance and possible incidents that could prevent performance qualification are also discussed"順列計劃"主題涉及性能鑑定的一般過程。還討論了表演期間的重要聯繫人以及可能妨礙表演資格的可能事件等要點。.

The part "Validation of cleaning and disinfection processes" refers mainly to the performance qualification and requalification. It also briefly discusses the other components of validation, installation and operational qualification. The topic of routine inspections is also a brief part of the module. Reference is made to the most important standards and laws. The performance qualification is covered on the basis of the current WD-E guideline 7 and the most important standards for this area, DIN EN ISO 15883-1 [8], DIN EN ISO 15883-4 [9], DIN EN ISO 15883-5 [10] and DIN 58341 [11]. "清潔和消毒過程的驗證"部分主要指性能鑑定和再鑑定。它還簡要討論了驗證、安裝和操作資格的其他組成部分。例行檢查的主題也是該模組的簡短部分。參考了最重要的標準和法律。性能鑑定基於當前 WD-E 準則 7 以及該領域最重要的標準 DIN EN ISO 15883-1 8、DIN EN ISO 15883-4 9、DIN EN ISO 15883-5 10和 DIN 58341 11。

For this module, we recommend conducting the per-formance qualification in a practical part on the WD-E 對於此模組，我們建議在 WD-E 的實際部分中進行性能鑑定.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Validierungsbericht 驗證報告
Reinigungs-Desinfektionsprozess

Fig圖. 4: A report summarizing the results is required.總結結果的報告是必需的

Overview of the most important compo-nents最重要單元的概觀

Decision making of the processes to be validated, breakdown of the thermolabile endoscopes to be reprocessed into endoscope families as well as the configuration/equipment in the individual reprocessing programs. 決策要驗證的流程、將要再處理的不耐熱內視鏡分解為內視鏡系列以及各個再處理程序中的配置/設備。

- Prerequisites先決條件 / preparations of the process validation流程驗證的準備工作
- Significance of different influences on the respective result of process validation各自流程驗證結果不同影響的顯著性
- Components of the process validation過程驗證的組成單元 (IQ/OQ/PQ)安裝驗證(IQ)、操作驗證(OQ)、性能驗證(PQ)
- Sequence of the different reprocessing processes and their characteristics不同再處理過程的序列及其特點

- Determination of the components of performance qualification to be carried out and the number of test runs確定要進行的性能鑑定的單元和測試運行的次數
- Components of requalification without special cause as well as for special cause無特殊原因和有特殊原因的重新鑑定的組成單元
- Theoretical and practical performance qualification based on the following steps基於以下步驟的理論和實踐性能鑑定:

- Testing of the cleaning performance on the basis of test specimens and indicators根據測試樣本和指示劑測試清潔性能
- Testing of the overall process on the basis of test specimens and really soiled endoscopes- 根據測試樣本和真正臟器的內視鏡對整個過程進行測試
- Testing of process-relevant parameters (temperature, rinsing pressure, dosing quantity, etc.)- 測試流程相關參數（溫度、沖洗壓力、加藥量等）
- Testing of the rinse water for process chemical residues測試沖洗水的流程化學殘留物
- Microbiological condition of the rinse water沖洗水的微生物狀況
- Testing of the drying process乾燥流程測試

- Handling of test specimens as well as requirements for test specimens and test laboratories 測試樣本的處理以及測試樣本和測試實驗室的要求
- Handling of measuring equipment and evaluation software測量設備和評估軟件的處理
- Determination of routine checks例行檢查的確定

After the practical part, the exercises will be taught after the process validation has been performed. 實踐部分結束後，將在進行流程驗證後教授演練。

This includes 這包括:

- Content and form of the validation report驗證報告的內容和形式
- Contents of the follow-up discussion後續討論內容
- Release of the validation report發佈驗證報告
- Dealing with defects reporting處理缺陷報告.

A written examination follows after all components of the Vali-C2 module have been completed. Participants who pass the exam receive a DGSV [4] certificateVali-C2 模組的所有單元完成後，將進行筆試。通過考試的參與者將獲得 DGSV[4] 證書.

More information can be found at更多信息請參見:
www.fht-dsm.com/kurse/sterilisation-validierungs-lehrgang-für-validierer

Conclusion結論

The DGSV course Vali C2 is an important prerequisite for being able to perform validations of machine-based WD-E processes. This certificate enables the validator to meet the qualification requirements of [Medical Devices Operator Regulations 1, §5 (2)]. This ensures legal and process safety for the user as well as for the patients' protection DGSV 課程 Vali C2 是能夠對基於機器的 WD-E 流程進行驗證的重要先決條件。該證書使驗證者能夠滿足[醫療器械運營商條例 1, §5 (2)] 的資格要求。這確保了用戶以及患者的法律和流程安全。.

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Reprocessing of single-use products in endoscopy 內視鏡檢查中一次性產品的再處理

Birgit Kampf, Annette Rittich, Helmi Henn

The increasing use of disposable products is a current trend in endoscopy. This not only applies to endoscopic accessories and components, but also increasingly to the endoscopes themselves. By definition (according to Commission Implementing Regulation (EU) 2017/745, also known as Medical Device Regulation, MDR, article 2, point 8), single-use products should only be used once on a single patient.[1] Therefore, the instructions for use for single-use products do not contain any information on safe reprocessing practices or functional checks after reprocessing. To ensure these devices are utilized only once, some manufacturers have designed their sin-gle-use products in such a way that reprocessing is not possible after use ("single-use by design" principle). 越來越多地使用一次性產品是內視鏡檢查的當前趨勢。這不僅適用於內視鏡配件和組件，也越來越多地適用於內視鏡本身。根據定義（根據委員會實施法規 (EU) 2017/745，也稱為醫療器械法規，MDR，第 2 條第 8 點），一次性產品只能在單一患者身上使用一次。1 因此，說明用於一次性產品不包含任何有關安全再處理實務或再處理後功能檢查的資訊。為了確保這些設備僅使用一次，一些製造商將其一次性產品設計為使用後無法再處理（「設計一次性使用」原則）。

Surprisingly, reprocessing of single-use products is generally not prohibited even if it contradicts the intended use as defined by the manufacturer. §17 MDR regulates the reprocessing of single-use products, but national regulations must be used as a prerequisite for the permissibility of this practice. In these cases, the reprocessing entity becomes the "new manufacturer" and must assume the responsibility of the original manufacturer according to §17 MDR. This includes pre-paration of the technical documentation. For example, required risk management practices must include an evaluation of the following product characteristics:令人驚訝的是，即使與製造商定義的預期用途相矛盾，一次性產品的再處理通常也不被禁止。 §17 MDR 規定了一次性產品的再處理，但必須以國家法規作為允許這種做法的先決條件。在這些情況下，再處理實體成為"新製造商"，並且必須根據 MDR §17 承擔原始製造商的責任。這包括技術文件的準備。例如，所需的風險管理實務必須包括對以下產品特性的評估：

- materials材料
- design設計
- properties特性 and以及
- intended us預期的我們

In this context, the reprocessability must also be considered. This should include assessments of: 在這種情況下，也必須考慮可再處理性。這應包括以下方面的評估：

- the microbiological contamination to be expected during normal use of the product,產品正常使用過程中預期的微生物污染
- how reprocessing may affect the material changing of the product, in particular regarding the soluble or chemically reactive components of these materials, and再加工如何影響產品的材料變化，特別是這些材料的可溶性或化學反應性成分，以及
- remnants of reprocessing, that may cause pyrogenic, allergic, or toxic reactions.可能引起熱原、過敏或毒性反應的再處理殘留物

The Commission Implementing Regu-lation (EU) 2020-1207 [2] further explains that single-use products must not be reprocessed where severe incidents have occurred, such as patient infections related to improper reprocessing. If successful reprocessing of a single-use device seems possible through risk management, then all steps of the reprocessing process, including initial treat-ment at the point of use, must be validated. This also includes a determination of the maximum possible reprocessing cycles. Furthermore, procedures for performance testing and product lot releases must be defined and included in a quality management system.委員會實施條例 (歐盟 EU) 2020-1207 2 進一步解釋說，在發生嚴重事件（例如與不當再處理相關的患者感染）的情況下，不得對一次性產品進行再處理。如果透過風險管理成功地再處理一次性設備似乎是可能的，那麼再處理過程的所有步驟，包括使用時的初始處理，都必須得到驗證。這也包括確定最大可能的再處理週期。此外，必須定義效能測試和產品批次放行的程序並將其包含在品質管理系統中。

The manufacturer's responsibility does not end with the product release but extends to the obligation to report incidents and to ensure the traceability of all disposable products that have been reprocessed and brought into use. 製造商的責任不僅限於產品發布，還包括報告事件並確保所有經過再處理和投入使用的一次性產品的可追溯性的義務。

In summary, from the point of view of the Instrument Reprocessing Working Group (AKI), the only endoscopes, accessories and components that should be reprocessed are those intended to be reprocessed by the respective manufacturer and for which there are corresponding instructions for use. 總之，從儀器再處理工作組（AKI）的角度來看，唯一應該再加工的內窺鏡，附件和元件是那些打算由相應製造商進行再加工的內視鏡，附件和元件，並且有相應的使用說明。

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Dr. Sabine Kaufmann
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3 questions for 3個問題...

Dr. Sabine Kaufmann

1. What makes the job in the CSSD so exciting是什麼讓 CSSD(中央消毒物料供應部) 的工作如此令人興奮?

Working in an CSSD is very varied and demanding. No two days are the same. I like the close cooperation and communication with the OR and the surgeons, but also with the many other interface departments such as hygiene, quality management, human resources, the business department or the technical department. CSSD is a small company within a company. Therefore, business management thinking and meeting qualitative specifications and requirements are also absolutely necessary.在 CSSD 工作是非常多樣化且要求很高的。沒有兩天是相同的。我喜歡與手術室和外科醫生的密切合作和溝通，也喜歡與許多其他介面部門的密切合作和溝通，例如衛生、品質管理、人力資源、業務部門或技術部門。CSSD是一家公司中的小公司。因此，企業管理思維和滿足定性的規範和要求也是絕對必要的。

Especially the instrument management is very exciting. As a result, the CSSD has a direct influence on the design and quality of medical devices and sets, which has a direct added value for the users and ultimately a positive impact on the care of our patients. 尤其是儀器管理非常令人興奮。因此，CSSD 對醫療設備和套件的設計和品質有直接影響，這為使用者帶來直接的附加價值，並最終對患者的護理產生積極影響。

2.What doyou despair offrom timetotime, even inyour job?即使在工作中，您時而也會對什麼感到絕望？

Sentences like "It's always been like this" make me despair. There is always a possibility to become better and to optimize processes. You shouldn't lose sight of this, even in your stressful day-to-day business. 「一直都是這樣」這樣的句子讓我感到絕望。總是有可能變得更好並優化流程。即使在充滿壓力的日常商務中，您也不應該忽視這一點。

It is exhausting, but essential. The ever-increasing demands on CSSD, but also the current problems, such as the shortage of skilled workers, the omnipresent supply bottlenecks and the energy crisis, even make it inevitable to question and optimize processes. Only through continuous further development can an CSSD exist and work both qualitatively and economically. 這很累，但很重要。對CSSD不斷增加的需求，以及當前的問題，例如熟練工人的短缺、無處不在的供應瓶頸和能源危機，甚至使質疑和優化流程變得不可避免。只有透過不斷的進一步發展，CSSD 才能存在並在品質和經濟上發揮作用。

The shortage of personnel is actually also something that gives me many sleepless nights. Unfortunately, even as a manager, you have only limited influence and possibilities to find and keep employees. There is nothing worse than a high turnover in an existing and actually functioning team. 人員短缺其實也是給我很多個不眠之夜的原因。不幸的是，即使身為經理，你在尋找和留住員工方面的影響力和可能性也有限。沒有什麼比現有且實際運作的團隊的高流動率更糟糕的了。

3. The shortage of skilled workers is felt in many professions, including CSSD. How can the profession of medical device reprocessing specialist be brought to the attention of young people? 包括CSSD在內的許多行業都感受到技術工人的短缺。如何讓醫療器材再處理專家這個職業引起年輕人的注意？

The shortage of skilled workers is indeed a cause for concern. Of course, the work in CSSD must be adequately remunerated, especially because the demands on employees are constantly increasing, but that is certainly not the only adjustment screw that can be turned to make the job more attractive overall. It is important to provide detailed information about the content and challenges of the job. 技術工人的短缺確實令人擔憂。當然，CSSD的工作必須得到足夠的報酬，特別是因為對員工的要求不斷增加，但這肯定不是唯一可以使工作整體更具吸引力的調整螺絲。提供有關工作內容和挑戰的詳細資訊非常重要。

That's why our Corporate Communications department uses social media such as Facebook and Instagram to appeal to the younger generation in particular and to make the job more popular and raise awareness. Our work takes place "behind the scenes," but it is still a pivotal point. I think it is important to reflect this to the existing team, but also to potential new colleagues. Because new blood is often in short supply in CSSD, but it's really good for an existing team because it opens up new perspectives and gets us away from "we've always done it that way". 這就是為什麼我們的企業傳播部門使用 Facebook 和 Instagram 等社交媒體來吸引特別是年輕一代，並使這項工作更受歡迎並提高意識。我們的工作發生在“幕後”，但這仍然是一個關鍵點。我認為向現有團隊以及潛在的新同事反映這一點很重要。因為 CSSD 經常缺乏新鮮血液，但這對現有團隊來說確實有好處，因為它開闢了新的視角，讓我們遠離「我們一直都是這樣做的」。

Our job advertisements are also publicized in various ways in order to reach as many people and professional groups as possible. After all, career changers are always welcome. Thanks to the support provided by a special IT system/batch documentation system or digitalization, even employees with no previous knowledge can quickly find their way around the job. 我們的招聘廣告也透過各種方式進行宣傳，以便盡可能多地接觸到更多的人和專業群體。畢竟，轉行者總是受歡迎的。由於特殊 IT 系統/批次文件系統或數位化提供的支持，即使沒有任何知識的員工也可以快速找到工作的方法。

Another cornerstone is the sound training of employees in the CSSD. We attach great importance to induction training at our CSSD and have a comprehensive induction concept. Only those who are well trained can take on responsibility and develop further. 另一個基石是 CSSD 員工的良好培訓。 CSSD非常重視入職培訓，並有全面的入職理念。只有受過良好訓練的人才能承擔責任並進一步發展。

In order to give new colleagues a perspective, opportunities for further development in the CSSD are essential. Since last year, we have been working with the provider of an e-learning portal to offer the opportunity for continuous internal online training and to complete the Specialty Course I online with only one week of classroom instruction at our facility. This format is particularly attractive for people who are unable to be away for three weeks or who are not mobile. 為了給新同事一個新的視角，在 CSSD 進一步發展的機會至關重要。自去年以來，我們一直與電子學習入口網站提供者合作，提供持續內部線上培訓的機會，並在我們的工廠僅進行一周的課堂教學即可在線上完成專業課程 I。這種形式對於那些無法離開三週或行動不便的人來說特別有吸引力。

The term appreciation sounds trite, but it is a recurring theme among my employees. Often located in the low-wage sector, the importance of the CSSD in a hospital is not infrequently misjudged and not sufficiently appreciated, especially in terms of external perception. However, the "steri" of 20 years ago has nothing to do with the CSSD of today. The work is not only physically demanding, but also requires a high level of concentration, initiative and commitment from the employees. 「感激」這個詞聽起來很老套，但它是我的員工中反覆出現的主題。CSSD 通常位於低薪部門，醫院中 CSSD 的重要性經常被誤判且未被充分認識，尤其是在外部認知方面。然而，20年前的「steri」與今天的CSSD毫無關係。這項工作不僅需要體力勞動，還需要員工高度的專注力、主動性和奉獻精神。

For young people today, the work-life balance is playing an increasingly important role. We therefore offer, among other things, a wide variety of shift models tailored to life situations and reliable duty rosters and working hours. These times call for a rethink and new ways of doing things. 對於現今的年輕人來說，工作與生活的平衡發揮著越來越重要的作用。因此，我們提供多種適合生活情況的輪班模式以及可靠的值班表和工作時間。這些時代需要重新思考和新的做事方式。

Note: 此新聞稿中文翻譯的部分若有進一步疑問，請參考原文或洽詢大久生物科技。

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* Comparison of the microbiological kinetics of action of the disinfectants Dentosept S and Dentosept Clean, HygCen Germany GmbH, 2021.
** Comparison of the microbiological effect of the disinfectants Dentosept S and Dentosept Clean on biofilm coatings in dental hoses, IWW Rheinisch-Westfälisches Institut für Wasser Beratungs- und Entwicklungsgesellschaft mbH, 2022

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