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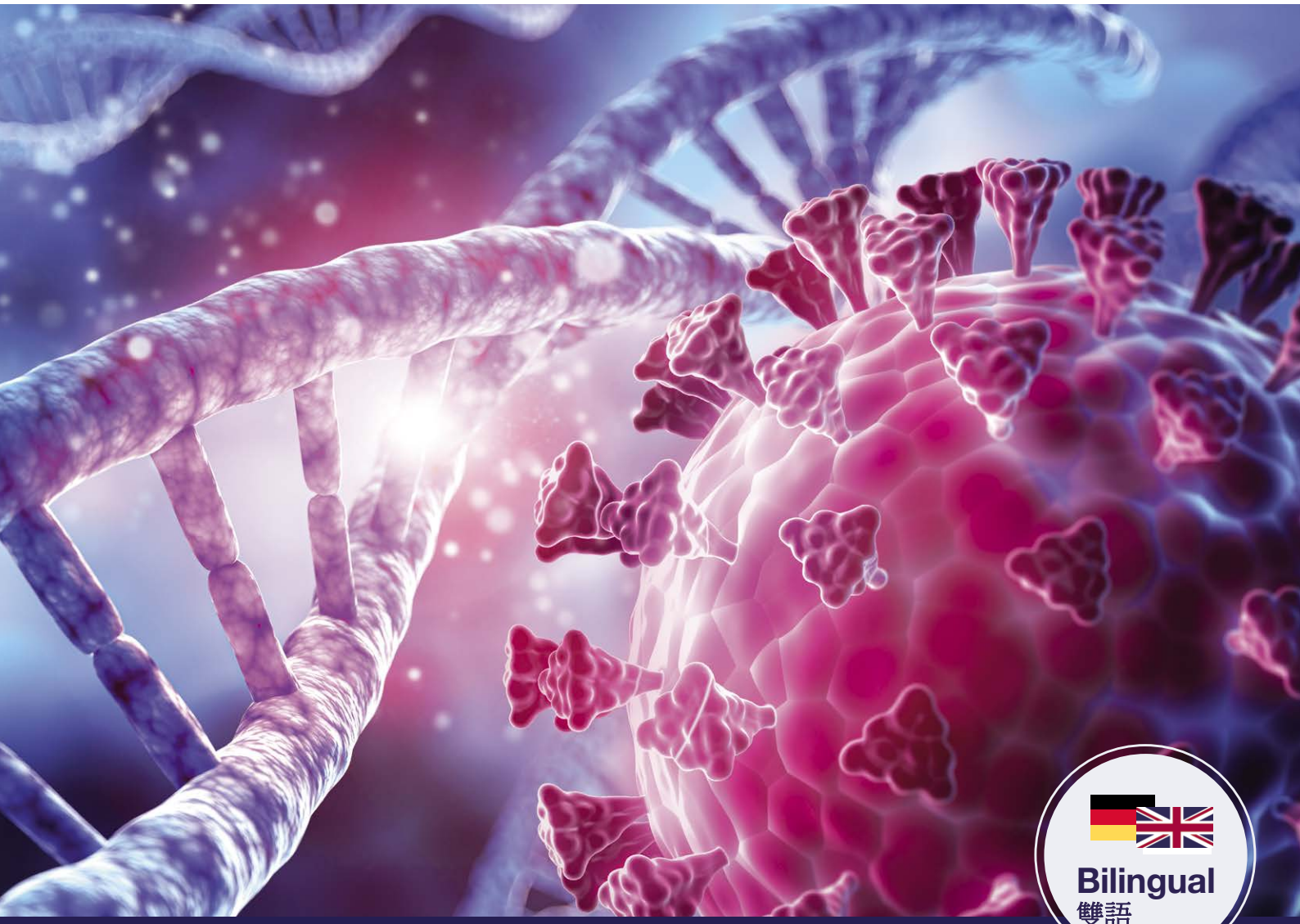

Bilingual
雙語

Stabilität von SARS-CoV-2 und anderen behüllten Viren auf Oberflächen Stability of SARS-CoV-2 and other enveloped viruses on surfaces

新型冠狀病毒SARS-CoV-2和其他包膜病毒在表面上的穩定性

Editorial 社論

Dear readers, 親愛的讀者

The Covid-19 pandemic has managed to retain its grip on the world into 2021, and Ger-many and many other countries across the globe are battling with a third lockdown. A great deal has changed over the past 12 months: in many cases, we are only able to pay virtual "visits" to the people we love, shops and restaurants are closed, and our profession-al lives have been relocated to home offices. 到2021年，Covid-19大流行已成功控制了全球，德國和全球許多其他國家正在與第三次封鎖進行鬥爭。在過去的12個月中，發生了很大的變化：在許多情況下，我們只能向我們愛的人進行虛擬的"拜訪"，商店和餐館都關門了，我們的職業生活已經轉移到了家庭辦公室。

But in spite of all these challenges, the vaccines from BioNtech, Moderna, AstraZeneca and other manufacturers have made us feel optimistic about the future. This latest issue of aseptic focuses on the virus, with topical articles on the "Stability of SARS-CoV-2 and other viruses on surfaces" and "Anti-viral surfaces – testing processes and practical rele-vance". What disinfection challenges are we facing? There are two ISO standards that we can use to measure how effective an anti-microbial surface is against viruses. 儘管存在所有這些挑戰，但BioNtech，Moderna，AstraZeneca和其他製造商生產的疫苗使我們對未來感到樂觀。最新一期的無菌關注於該病毒，主題文章為" SARS-CoV-2和表面上其他病毒的穩定性"和"抗病毒表面-測試過程和實際相關性"。我們面臨哪些消毒挑戰？我們可以使用兩個ISO標準來衡量抗菌表面對病毒的有效性。

For validators in particular, our article on "Parametric testing in the performance qual-ification of low-temperature sterilisation processes with hydrogen peroxide" will be of great interest. The field of parametric testing now has access to new pressure-temperature data loggers that operate in a pressure range of 0.1 to 1050 mbar (0.1 to 788 Torr) with 0.25 mbar precision, and in a temperature range of 0 °C to 85 °C with 0.1 °C precision. 特別是對於驗證者，我們的文章"用過氧化氫低溫滅菌過程的性能鑑定中的參數測試"將引起極大的興趣。現在，參數測試領域可以使用新的壓力溫度數據記錄器，這些記錄器可在0.1至1050 mbar（0.1至788Torr）的壓力範圍內以0.25 mbar的精度運行，並在0°C至85°C的溫度範圍內運行精度為0.1°C

I hope you enjoy reading this latest issue of aseptica.我希望您喜歡閱讀最新一期的無菌雜誌。

Stay healthy, 保持健康
Iven Kruse

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內容

Report 報導

Coronavirus reduces number of patent applications filed
冠狀病毒減少了專利申請的數量

During the coronavirus pandemic, many countries around the world have been forced into lockdown – with drastic consequences for some sectors of the economy. In addition to the threats of financial losses and insol-vency affecting many companies, coronavirus also seems to have had an impact on innovation and invention: in 2020, German inventors filed significantly fewer pat-ent applications compared to 2019 (56,778 compared to the previous year's 62,105), with the German Patent and Trade Mark Office reporting a decline of almost eight per cent. Other large industrial nations, including the USA and Japan, have observed a similar downward trend, which suggests that the automotive manufactur-ing, transport and mechanical engineering sectors have been particularly severely affected. Sectors such as med-ical technology and electromobility have benefited from the crisis, with some reporting an increase in patent ap-plications of as much as ten per cent.在冠狀病毒大流行期間，世界上許多國家被迫封鎖-對某些經濟部門造成了嚴重後果。除了影響許多公司的財務損失和資不抵債的威脅外，冠狀病毒似乎也對創新和發明產生了影響：2020年，德國發明人提交的專利申請數量明顯少於2019年（與以前相比，為56,778件）年的專利申請數量為62,105件），而德國專利商標局則下降了將近8%。其他大型工業國家，包括美國和日本，也觀察到了類似的下降趨勢，這表明汽車製造業，運輸業和機械工程業受到了特別嚴重的影響。醫療技術和電動汽車等行業已從這場危機中受益，一些行業報告專利申請量增長了多達10%。Source資訊來源: heise.de

Thoughts on virus tenacity
關於病毒堅韌性的思考

Friedrich v. Rheinbaben

The structure and environmental resist-ance of viruses 病毒的結構和環境抵抗力

In virus terms, tenacity describes the ability of a virus to maintain its infectiousness even when exposed to environmental conditions outside of its host. The term reflects the stability of the virus in the face of environ-mental factors and noxious chemicals. 用病毒術語來說，堅韌描述了病毒的能力保持其傳染性，即使暴露於宿主以外的環境條件。術語反映了面對環境病毒的穩定性因素和有害化學物質。

To better understand the tenacity of viruses, it is impor-tant that we first understand how they are structured. There are two categories of virus: non-enveloped (naked) and enveloped (Fig. 1). 為了更好地了解病毒的強度，重要的是我們首先要了解它們的結構。病毒分為兩類：非包膜（裸露）和包膜（圖1）。

If you want to assess the resistance of both of these groups to environmental conditions, these categories cannot be used to derive any general rules that can be universally applied to individual virus types. Influencing factors such as stability in dry and wet environments can vary sig-nificantly, even between individual types within a single familiy of viruses. In both the enveloped and non-en-veloped virus categories, it is possible to identify related viruses that retain their ability to multiply after years or even decades outside of the host organism or, conversely, that can only keep their stability for a few hours. 如果要評估這兩個組對環境條件的抵抗力，則不能使用這些類別來推導可普遍應用於單個病毒類型的任何常規規則。諸如在乾燥和潮濕環境中的穩定性等影響因素可能會發生巨大變化，即使在單個病毒家族中的各個類型之間也是如此。在包膜和非包膜病毒類別中，都有可能識別出在宿主生物體以外數年甚至數十年後仍保持繁殖能力的相關病毒，或者相反，它們只能保持其穩定性數小時。

As well as the differences in the outer capside, figure 1 also shows that there are differences in the genetic material in-side the particle. This allows us to draw conclusions about the sensitivity of the virus to influencing factors such as high-energy UV radiation. However, it is still not possible to derive general rules from this knowledge. This is even true of the effect of radioactive radiation, such as the gam-ma radiation emitted by a cobalt radiation source (^{60}Co).除了外層的差異之外，圖1還顯示了粒子內部的遺傳物質也存在差異。這使我們可以得出有關病毒對影響因素（例如高能紫外線輻射）的敏感性的結論。但是，仍然不可能從該知識中得出一般規則。甚至對於放射性輻射的影響，例如鈷輻射源（60Co）發射的伽瑪射線，也是如此。There is, however, one characteristic that all viruses share: they are all sensitive to direct sunlight. This is why sun, light and the colour white have long been associated with hygiene and a high level of protection against pathogens and virus infections; as it has clearly been derived from centuries of human experience. 但是，所有病毒都有一個共同的特徵：它們都對直射的陽光敏感。這就是為什麼太陽，光和白色長期以來一直與衛生和對病原體和病毒感染的高度防護相關聯的原因；因為它顯然源於數百年的人類經驗。

Resistance to chemical in lu-ences and European guide-lines on determining the e i-cacy of biocides 對化學影響的抵抗力以及確定殺生物劑功效的歐洲準則

Conversely, resistance to chemical in-fluences, disinfectants and disinfection procedures is easier to predict, and this is where categorising a virus as either enveloped or non-enveloped can prove useful. 相反的，對化學影響力，消毒劑和消毒程序的抵抗力更容易預測，這就是將病毒分類為包膜或非包膜的證明有效的地方。

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Enveloped viruses are all very sensitive to disinfection agents. Naked viruses, on the other hand, are affected usually by oxi-dising substances only, and sometimes need to be further increased by physical factors such as the application of heat.包膜病毒對消毒劑非常敏感。另一方面，裸病毒通常僅受氧化物質影響，有時需要通過物理因素（例如加熱）進一步增加。

For this reason, when determining the virucidal efficacy of biocides, disinfectants and disinfection processes, we use representative test viruses that allow us to assign one

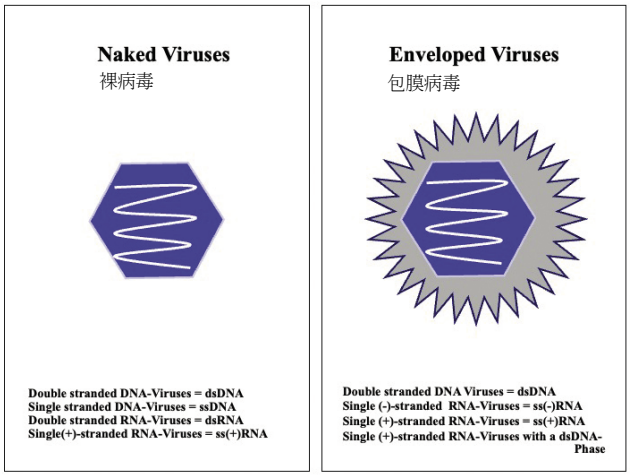

Fig. 圖1: Structure of viruses. 病毒的結構。

of three distinct virucidal efficacy gradations. The gradation "limited virucidal activity" is used for processes that have only been proven effective against enveloped viruses. An enveloped virus (Vaccinia virus) is used as the test virus.因此，在確定殺生物劑，消毒劑和消毒過程的殺滅病毒效力時，我們使用代表性的測試病毒，這些病毒可讓我們指定三個不同的殺滅病毒效力等級之一。"有限的殺病毒活性"等級用於僅被證明對包膜病毒有效的過程。包膜病毒（牛痘病毒）用作測試病毒。

The gradation "limited virucidal activity plus" is used for processes that have shown a significantly higher degree of efficacy and that have been tested on two non-envel-oped, relatively chemical-resistant viruses (Adenovirus and Murine Norovirus).“有限的殺病毒活性加級”等級用於顯示出明顯更高的功效水平並已在兩種非包膜的，相對耐化學性的病毒（腺病毒和鼠諾如病毒）上進行過測試的過程。

Finally, the gradation "virucidal activity" may only be used for biocides and processes that have shown ca-pacity to inactivate all viruses that are relevant to hu-man medicine. Therefore, only "virucidal disinfection processes" are capable of inactivating enveloped and naked, environment-resistant, heat-resistant and disin-fectant-resistant viruses and are stable when dried. The test virus that is most often used for such an expansive claim is the non-enveloped, highly temperature-resist-ant bovine parvovirus.最後，“殺病毒活性”等級僅可用於已證明具有滅活所有與人類醫學有關的病毒的能力的殺生物劑和過程。因此，只有“殺毒消毒過程”才能殺滅被包裹的裸露的，耐環境的，耐熱的和耐消毒的病毒，並且在乾燥時保持穩定。最常用於此類擴展聲明的測試病毒是無包膜的，耐高溫的牛細小病毒。

What information helps us to assess tenacity?哪些信息可以幫助我們評估韌性？

If the established enveloped and non-enveloped virus categories are helpful in assessing a virus' resistance to biocides, but do not allow us to draw any general con-clusions with regard to its stability in the environment, what other information can we use for this purpose?如果既定的包膜和非包膜病毒類別有助於評估病毒對殺生物劑的抗性，但不允許我們就其在環境中的穩定性得出任何一般性結論，那麼我們還可以使用哪些其他信息達到該目的？

In such cases, the biology of the virus can provide us with the key information that we need. The answers to the following questions are helpful: 在這種情況下，病毒的生物學特性可以為我們提供所需的關鍵信息。以下問題的答案很有幫助：

- How does the virus behave inside its host? Does it cause persistent infection or not?病毒在其宿主內部的行為如何？它會導致持續感染嗎？
- How and in what manner does the virus in question exit its host?有問題的病毒如何以及以何種方式退出其宿主？
- Which patient materials are linked within this process?在此過程中將哪些患者材料鏈接在一起？
- How high are the chances that the virus will rapidly reach and infect another susceptible host?該病毒迅速到達並感染另一名易感宿主的機會有多大？

The answers to all these questions are key to determining the tenacity of a virus. 所有這些問題的答案是確定病毒強度的關鍵。

Biology of virus infections 病毒感染生物學

How exactly does a virus behave inside its host? There are three main answers to this question. 病毒在其宿主內部的行為如何？這個問題有三個主要答案。

- The pathogen causes an acute infection and later leaves its host completely. Viruses that cause this type of infection must either possess a high level of tenacity or be capable of switching hosts rapidly, without remaining in the environment for too long. Which viruses belong in which group becomes evi-dent from their preferred transmission path, which in turn is connected to the manner in which they exit their host.該病原體引起急性感染，隨後完全離開其宿主。導致這種類型感染的病毒必須具有高強度，或者必須能夠快速切換宿主，而不能在環境中停留太長時間。從它們的首選傳播途徑中可以明顯看出哪種病毒屬於哪個組，而這些傳播途徑又與它們離開宿主的方式有關。

  Viruses like flu viruses, which get into their host's airways through cough aerosols in the environ-ment, have a limited level of tenacity (the Influenza A virus is one example). Infection via aerosols must occur quickly. Although discussions about the current coronavirus problems often suggest otherwise, remaining in the air for extended periods of time in-becomes a trap here.像流感病毒這樣的病毒通過環境中的咳嗽懸浮微粒進入宿主的氣道，其堅韌程度有限（A型流感病毒就是其中的一個例子）。通過懸浮微粒的感染必須迅速發生。儘管有關當前冠狀病毒問題的討論通常會提出其他建議，但在空氣中長時間保留會成為此處的陷阱。

  Viruses that exit the host via the stool are significantly more likely to remain in the environment for longer. These kinds of pathogens increase their likelihood of transmission if they have high tenacity. Often, other factors help the virus to find a new host, for example the (extremely) high number of particles with which these viruses are released into the environment. Nor-oviruses and rotaviruses are examples of these kinds of pathogens.通過糞便排出宿主的病毒更有可能在環境中保留更長時間。如果這些病原體具有很高的韌性，則增加了傳播的可能性。通常，其他因素也可以幫助病毒找到新的宿主，例如（極大量）將這些病毒釋放到環境中的顆粒。諾爾病毒和輪狀病毒就是這類病原體的例子。

  However, it is always a good idea to pay attention to gastrointestinal symptoms, even with respiratory virus infections. These symptoms indicate that the virus may be capable of surviving passage through the stomach and then finding a second target organ in the form of the intestine (examples: coxsackievi-ruses, ECHO viruses). In such cases, it is possible to determine whether a virus can survive the stomach by testing its sensitivity to a pH value of 2 to 3. Text-book examples of these kinds of pathogens include not only the aforementioned coxsackieviruses and ECHO viruses, but also representatives from the families of rhinoviruses and enteroviruses, corona-viruses and even some influenza viruses. Leaving the host via the intestine is always an indication of high tenacity and a faecal-oral transmission route for pathogens of this type. 但是，即使在呼吸道病毒感染的情況下，也要注意胃腸道症狀，這始終是一個好主意。這些症狀表明，該病毒可能能夠通過胃倖存下來，然後以腸的形式找到第二個目標器官（例如：柯薩奇病毒，ECHO病毒）。在這種情況下，可以通過測試其對2到3的pH值的敏感性來確定病毒是否可以在胃中存活。此類病原體的教科書示例不僅包括上述柯薩奇病毒和ECHO病毒，還包括來自鼻病毒和腸病毒，冠狀病毒，甚至是一些流感病毒家族的代表。經由腸道離開宿主總是表明這種病原體具有高強度和糞便-口腔傳播途徑。

- Pathogens that have the ability to cause persistent in-fections of various types are classed as possessing a low level of tenacity (HIV being one example). They often have the entire remaining lifespan of their pres-

ent host to transmit themselves to new hosts, and generally select less efficient routes of transmission, such as via sexual activity. As a result, they do not need to expose themselves to the selection pressures of environmental factors.能夠引起各種類型持續感染的病原體被歸類為具有低水平的堅韌性（愛滋病毒就是一個例子）。他們通常擁有當前宿主的整個剩餘壽命，以將自身傳播給新宿主，並且通常選擇效率較低的傳播途徑，例如通過性活動。結果，他們不需要暴露於環境因素的選擇壓力。

However, if sexual transmission is not available to these types of virus for any reason, they have to find another route. In this scenario, these kinds of virus-es can also show significant resistance to drying, as seen in the case of the herpes simplex virus type 1 (labialis). This virus causes an exanthema around the lips, as well as eye infections in some cases. It can also remainstable for some time on dry surfaces.但是，如果由於某種原因無法通過這些類型的病毒進行性傳播，則他們必須尋找其他途徑。在這種情況下，這些類型的病毒還可以表現出顯著的抗乾燥性，就像單純皰疹病毒1型（唇皰疹）一樣。這種病毒會引起嘴唇周圍的上皮發炎，在某些情況下還會引起眼部感染。它也可以在乾燥的表面上保持一段時間

Water and its influence on tenacity 水及其對韌性的影響

Viruses that can get into the environment and into surface water are usually expelled with faeces in natural conditions. Viruses that use this route of infection must almost always possess a very high level of tenacity (examples include poliovirus and hepatitis A virus). These kinds of viruses can sometimes be stable in the environment for decades, as demonstrated by incidental findings from the veterinary medicine sector in particular.可以進入環境和進入地表水中的病毒通常在自然條件下被糞便排出。使用這種感染途徑的病毒幾乎必須始終具有很高的堅韌性（例如脊髓灰質炎病毒和A型肝炎病毒）。這類病毒有時可以在環境中穩定數十年，特別是獸醫部門的偶然發現證明了這一點。

They can even persist for astonishing periods of time in biotopes such as aquatic sediments and sludge, even though these environments have high levels of microbial activity, which are characterised by high levels of aggressive metabolites produced by the microbiota present. The fact that these kinds of viruses also always show particularly high levels of tenacity against chemical substances is therefor not surprising. This continues to apply when they enter the digestive systems of humans or other organisms, such as mussels. In these cases, their tenacity opens up new routes of infection, such as transmission via food and drinking water.它們甚至可以在諸如水生沉積物和污泥的生物群落中持續驚人的時間，即使這些環境具有高水平的微生物活性，其特徵是存在的微生物群產生的侵蝕性代謝產物水平很高。因此，這些病毒對化學物質的抵抗力也始終很高，這一事實不足為奇。當它們進入人類或其他生物（例如貽貝）的消化系統時，這種情況繼續適用。在這些情況下，它們的堅韌性打開了新的感染途徑，例如通過食物和飲用水傳播。

Some of these viruses also show astonishingly high re-sistance to drying. This is particularly true of viruses that can use arthropods such as flies as a means of transport (vehicle) (like the coxsackieviruses, ECHO viruses and summer flu).這些病毒中的一些還顯示出驚人的高抗乾燥性。對於可以使用節肢動物（例如果蠅）作為運輸工具（車輛）的病毒（例如柯薩奇病毒，ECHO病毒和夏季流感）尤其如此。

However, viruses that rely on vectors (namely blood-sucking insects) for transmission must be capable of reproducing in multiple hosts (yellow fever viruses are one example) and these viruses are not subject to the se-lection pressure of needing to develop a particularly high level of tenacity. Vector-transmitted viruses are generally very sensitive to environmental influences.
但是，依靠載體傳播的病毒（即吸血昆蟲）必須能夠在多個宿主中繁殖（黃熱病病毒就是一個例子），這些病毒不受選擇壓力的影響。高韌性。媒介傳播的病毒通常對環境影響非常敏感。

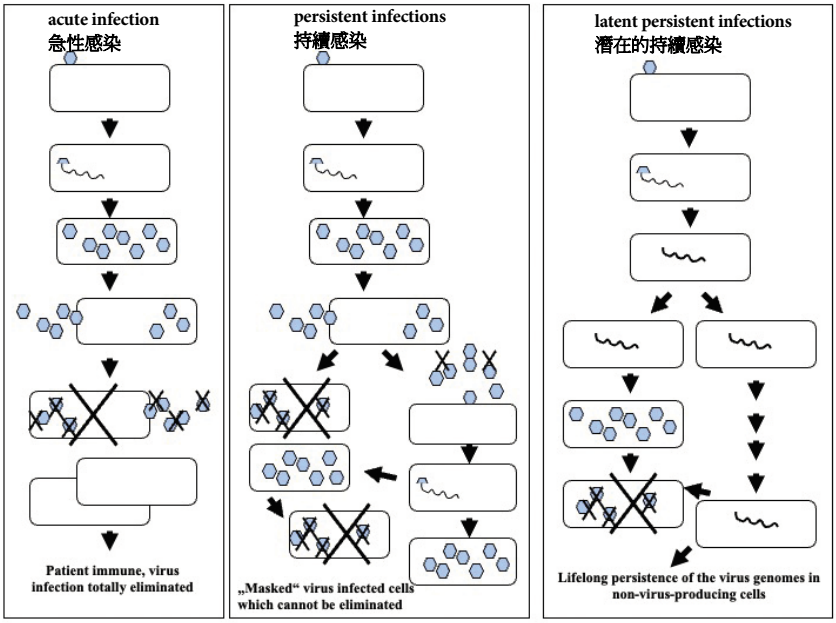

Fig. 2 Acute infection, persistent infection, latent persistent infection.急性感染，持續感染，潛在持續感染。

(The affected host is generally virus-free and immune by the end of the recovery period from an **acute infection**. With **persistent infections,** virus-infected cells are masked in delayed replication cycles and are only recognised as infected and destroyed when virus particles are released, leading to a sustained period of infection. In **latent persistent infections,** the replication cycle is completely interrupted and an infectious virus is formed only when the genetic material is activated and the replication cycle continues).（受影響的宿主通常在急性感染的恢復期結束之前是無病毒的，並且免疫。對於持續感染，受病毒感染的細胞會在延遲的複制週期中被掩蓋，並且只有在釋放病毒顆粒後才能被識別為已感染並被破壞在潛伏的持續感染中，複製週期被完全中斷，並且只有在遺傳物質被激活並且複制週期持續的情況下才形成感染性病毒。

Tenacity towards biocides: a special case 殺菌劑的堅韌性：特例

It is essential to have a precise understanding of how a virus responds to biocides to minimise the use of biocides and the environmental impact associated with them. This is why the parameters of disinfection processes must be determined through experimental testing in accordance with the defined European standards, which are EN 14476, EN 16777 and / or EN 17111 depending on their application in medical and institutional settings. 必須準確了解病毒對殺生物劑的反應，以最大程度地減少殺生物劑的使用以及與殺生物劑相關的環境影響。這就是為什麼必須根據定義的歐洲標準通過實驗測試確定消毒過程參數的原因，EN 14476, EN 16777 和/或EN 17111 ，具體取決於它們在醫療和機構環境中的應用。

The results of these tests apply to disinfection processes for surfaces, instruments, hands and laundry, and allows to determine whether a disinfection process is categorised as having “limited virucidal activity”, “limited virucidal activity plus”, or even “virucidal activity”. The top standard for a virucidal chemo-thermal disinfection process is demonstrating efficacy against parvovirus (non-enveloped and thermostable). The lowest hurdle is demonstrating efficacy against the (enveloped) Vaccinia virus.這些測試的結果適用於表面，儀器，手和衣物的消毒過程，並允許確定消毒過程是否被歸類為具有“有限的殺滅病毒活性”，“有限的殺滅病毒活性加級”或甚至是“殺病毒活性”。化學殺蟲熱化學消毒方法的最高標準是證明其對細小病毒（無包膜和熱穩定）的功效。最低的障礙是證明對（包膜的）牛痘病毒的功效。

Parvoviruses: tenacious extremists 細小病毒：頑強的極端分子

Murine parvovirus can survive temperatures of 80 °C for an hour; temperatures of 60 °C barely harm it at all. The dry stability of parvoviruses is generally very high and it can resist incubation at room temperature for periods of months to years with virtually no losses. Of the traditional disinfection agents, only active oxygen-releasing compounds, active chlorine and aldehyde tend to be successful. Oth-er active substances used in disinfectants generally have little to no effect. Parvovirus even displays a high level of resistance to gamma radiation from a radioactive cobalt source, and can survive doses of 30 kGy (^{60}Co).鼠細小病毒可以在80°C的溫度下存活一個小時。 60°C的溫度幾乎沒有危害。細小病毒的乾燥穩定性通常很高，並且可以抵抗在室溫下孵育數月至數年的時間，幾乎沒有損失。在傳統的消毒劑中，只有釋放活性氧的化合物，活性氯和醛才是成功的。消毒劑中使用的其他活性物質通常幾乎沒有作用。細小病毒甚至表現出對來自放射性鈷源的伽馬射線的高水平抵抗力，並且可以在30 kGy（60Co）的劑量下存活。

No enveloped human pathogenic virus even comes close to displaying this level of tenacity. This is also true of coronoviruses. These viruses are highly sensitive to virtually all disinfection agents and in many processes, exposure to a temperature of 60 °C can in itself pro-vide good protection. However, this information must never be used as the basis for sweeping generalisations. The virucidal activity of all disinfection and preparation processes must always be determined by experimental testing. 甚至沒有一種包膜的人類致病病毒能顯示出如此高的強度。冠狀病毒也是如此。這些病毒對幾乎所有消毒劑都高度敏感，在許多過程中，暴露於60°C的溫度本身可以提供良好的保護。但是，此信息絕不能用作全面概括的基礎。必須始終通過實驗測試確定所有消毒和製備過程的殺病毒活性。

“limited virucidal activity” and “virucidal activity” “有限殺病毒活性”和“殺病毒活性”

If a disinfection process is found to be active against enveloped virus-es, then its virucidal ability is limited to that category of virus. If it has been tested specifically against coronavirus, then the results should be used only as the basis for determining efficacy against corona-viruses, and never to draw general conclusions about its efficacy against all enveloped viruses.如果發現消毒過程對包膜病毒具有活性，則其殺病毒能力僅限於該類病毒。如果已針對冠狀病毒進行了專門測試，則結果應僅用作確定對冠狀病毒功效的基礎，而絕不能得出有關其對所有包膜病毒功效的一般性結論。

However, if a process has been proven effective against parvoviruses, it is deemed effective against all viruses that are relevant to human medicine: as long as the tested process conditions are met, it can be advertised as having full virucidal activity. 但是，如果已證明一種方法可有效抵抗細小病毒，則可以認為它對所有與人類醫學有關的病毒均有效：只要滿足所測試流程條件，就可以宣傳其具有完全的殺病毒活性。

The impact of accompanying materials 附帶材料的影響

There is a wealth of published information on the tenacity of individual viruses, but much of this material is confusing. Some of the conclusions drawn are based on experimental data. Unfortunately, in most studies, experiments are conducted on viruses obtained from cell culture lysates. For this reason alone, it is not possible to be completely certain that the virus type being studied has not been subject to a selection process, which would mean that its characteristics would not be anything like those of a wild virus. Furthermore, most of these studies do not take account of natural accompanying materials such as blood, stool and other secretions and excretions. However, these substances can have a significant impact on the tenacity of viruses, as incidental observations from clinical practice have proven time and time again. 關於單個病毒的強度，已經發布了很多信息，但是其中許多內容令人困惑。得出的某些結論是基於實驗數據的。不幸的是，在大多數研究中，對從細胞培養物裂解物中獲得的病毒進行了實驗。僅出於這個原因，不可能完全確定所研究的病毒類型尚未經過選擇過程，這意味著其特徵不會像野生病毒那樣。此外，這些研究大多數都沒有考慮到自然伴隨的物質，例如血液，糞便以及其他分泌物和排泄物。但是，這些物質可能會對病毒的強度產生重大影響，因為臨床實踐中的偶然發現已經一次又一次地證明了這一點。

Modern institutions determine routes of transmission 現代機構決定傳播途徑

Ultimately, the reason why we determine the tenacity of a virus is to develop prevention strategies. This is why we must never allow ourselves to be deceived by individual findings, however thorough or prominent they may be. This is particularly true when we need to break a chain of infection: in these cases, factors such as our everyday habits, home and public environments, mo-bility and the organisation of everyday life – in short, all aspects of our lifestyles and our behaviour – have an important role to play. In the institutions we have created – such as care homes, schools, kindergartens, professional kitchens, public transport and many others, and across the entire medical sector in particular – natural routes of transmission can change significantly based on the specific tenacity of a pathogen. One final example to conclude: the natural route of infection for HIV – which is widely acknowledged as a virus that is not particularly environmentally resistant – is sexual transmission. But in the medical environment we have created and during the behaviours we practice in this environment, even this highly sensitive pathogen can find new routes of transmission if we do not follow certain important rules.最終，我們確定病毒強度的原因是制定預防策略。這就是為什麼我們絕不能讓自己被個人發現所蒙蔽，無論這些發現可能是多麼徹底或突出。當我們需要打破感染鏈時，尤其如此：在這些情況下，諸如我們的日常習慣，家庭和公共環境，機動性和日常生活組織等因素–簡而言之，我們的生活方式和我們的所有方面行為–扮演重要角色。在我們創建的機構中（例如療養院，學校，幼兒園，專業廚房，公共交通等），尤其是整個醫療部門，自然傳播途徑會根據病原體的特定韌性而發生顯著變化。可以得出的最後一個例子是：愛滋病毒的自然傳播途徑-性傳播是愛滋病毒的自然傳播途徑，這種途徑被廣泛認為是一種對環境沒有特別抵抗力的病毒。但是在我們創造的醫學環境中以及在這種環境中我們的行為過程中，如果我們不遵循某些重要規則，即使是這種高度敏感的病原體也可以找到新的傳播途徑。

The stability of SARS-CoV-2 and other enveloped viruses on surfaces – new challenges for disinfection?

SARS-CoV-2和其他包膜病毒在表面上的穩定性–消毒的新挑戰？

Jochen Steinmann, Eike Steinmann, Florian H. H. Brill

Morphology-dependent virus stability形態學依據的病毒穩定性

The stability of human-pathogenic viruses on surfaces has always been a topic of special interest because with many virus infections, the respiratory pathogens can be transmitted not just through the air, but also via surfaces. In a previous overview published by Kramer et al, it has already been proven that the stability of human-pathogenic viruses on surfaces differs greatly.[1] In general, we can conclude that enveloped viruses with a lipid membrane are significantly less stable than non-enveloped viruses. Factors that are key to the stability of a virus in the environment include the potential addition of protein and blood, the temperature, air humidity and the type of surface. According to the overview by Kramer et al, enveloped viruses from the respiratory tract area and viruses that are transmitted via the blood (HIV, hepatitis viruses) are inactivated on surfaces in a matter of days, while non-enveloped viruses – which primarily come from the gastrointestinal tract – can survive for weeks and months.[1]人為致病性病毒在表面上的穩定性一直是人們特別關注的話題，因為在許多病毒感染中，呼吸道病原體不僅可以通過空氣傳播，還可以通過表面傳播。在Kramer等人先前發表的概述中，已經證明人致病性病毒在表面上的穩定性差異很大。總的來說，我們可以得出結論，帶有脂質膜的包膜病毒比未包膜的病毒穩定性要差得多。病毒。影響病毒在環境中穩定性的關鍵因素包括蛋白質和血液的潛在添加，溫度，空氣濕度和表面類型。根據Kramer等人的概述，呼吸道區域的包膜病毒和通過血液傳播的病毒（HIV，肝炎病毒）可在數天內被滅活，而非包膜病毒主要來自胃腸道–可以存活數周和數月。

Virus contamination in environments where infected SARS-CoV-2 patients are present病毒污染環境中被感染SARS-CoV-2的存在患者

There is now widespread agreement that many SARS-CoV-2 infections are transmitted via droplets and aer-osols. This is why it is important to maintain social distancing and wear masks to contain the pandemic. However, in addition to these measures, there are a number of other important hygiene rules that we must follow. Disinfection hands with an appropriate disin-fectant is one of the key pillars of our virus response. However, during the ongoing COVID-19 pandemic, scientists have (rightly) raised one question time and time again: where, how and to what extent could surfaces in the vicinity of a person who has received a positive nasal or throat swab for SARS-CoV-2 be contaminated? 現在，人們普遍同意，許多SARS-CoV-2感染是通過飛沫和懸浮粒子傳播的。這就是為什麼保持社會疏遠和戴口罩以遏制大流行很重要的原因。但是，除了這些措施之外，還必須遵循許多其他重要的衛生規則。用適當的消毒劑消毒雙手是我們病毒反應的關鍵支柱之一。但是，在正在進行的COVID-19大流行期間，科學家們（正確地）一次又一次地提出一個問題：一個人的鼻腔或咽喉擦拭檢測為SARS-CoV-2陽性後，其附近的表面，在哪裡，如何以及受到何種程度的污染？

The data collected from the surfaces is often based not on the detection of infectious virus particles, backed up by cell cultures, but on the presence of genetic material, which is detected using PCR. One study from Wuhan showed that with PCR, the virus could be detected in patient rooms for up to 28 days.[2] In another study, 52.3 % of the samples collected in a London hospital were found to contain genetic material.[3] A study in Singapore produced an un-clear picture with negative and positive findings; PCR was primarily successful at picking up signs of the virus in bathrooms.[4] However, because the positive genome evidence does not always correlate with evidence of the virus in cell culture, there has been much debate surrounding how relevant positive PCR findings are when determining the required level of surface disinfection and the potential for contamination in areas that have been frequented by a person who has tested positive.[5] An additional tool that could be useful in analysing positive samples could be the Ct (cycle threshold) value, which describes how many PCR cycles are required to generate a positive result. 從表面收集的數據通常不是基於細胞培養支持的傳染性病毒顆粒的檢測，而是基於使用PCR檢測的遺傳物質的存在。武漢的一項研究表明，使用PCR可以在患者病房中長達28天檢測到該病毒。在另一項研究中，發現在倫敦一家醫院收集的樣本中有52.3%含有遺傳物質.3在新加坡進行的一項研究產生了不清楚的圖片，帶有負面和正面的發現： PCR基本上可以成功地在浴室中發現病毒跡象。但是，由於基因組陽性證據並不總是與細胞培養物中的病毒證據相關，因此圍繞確定PCR陽性結果的相關性存在很多爭議。所需的表面消毒水平以及在經過檢測呈陽性的人經常去過的區域中可能造成污染的可能性。可以用於分析陽性樣品的其他工具可以是Ct（循環閾值）值，它描述了多少需要PCR循環才能產生陽性結果。

The stability of SARS-CoV2 SARS-CoV2的穩定性

During the ongoing pandemic, where there is potential for virus contamination in areas frequented by patients with SARS-CoV-2, the stability of the pathogen is very important because – as mentioned above – viruses have been shown to be present on surfaces. To describe the stability of the virus, we can look back at historic data that has been collected not based on SARS-CoV-2, but using other members of the Coronaviridae family. The Coronaviridae family is a large family of approximately 39 types. In recent, pre-COVID-19 history, we had already seen two members of this family – Severe Acute Respiratory Syndrome Coronavirus (SARS-CoV) and Middle East Respiratory Syndrome Coronavirus (MERS-CoV) – jump into humans. For this reason, the stability of coronaviruses on surfaces had already been tested before the current pandemic. 在持續的大流行期間，SARS-CoV-2患者經常光顧的地方可能存在病毒污染，病原體的穩定性非常重要，因為如上所述，已證明病毒存在於表面。為了描述病毒的穩定性，我們可以回顧一下不是基於SARS-CoV-2而是使用冠狀病毒科的其他成員收集的歷史數據。冠狀病毒科是大約39種類型的大家族。在最近的COVID-19以前的歷史中，我們已經看到該家族的兩個成員-重症急性呼吸綜合徵冠狀病毒（SARS-CoV）和中東呼吸綜合徵冠狀病毒（MERS-CoV）-跳入人類。因此，在當前大流行之前已經對冠狀病毒在表面上的穩定性進行了測試。

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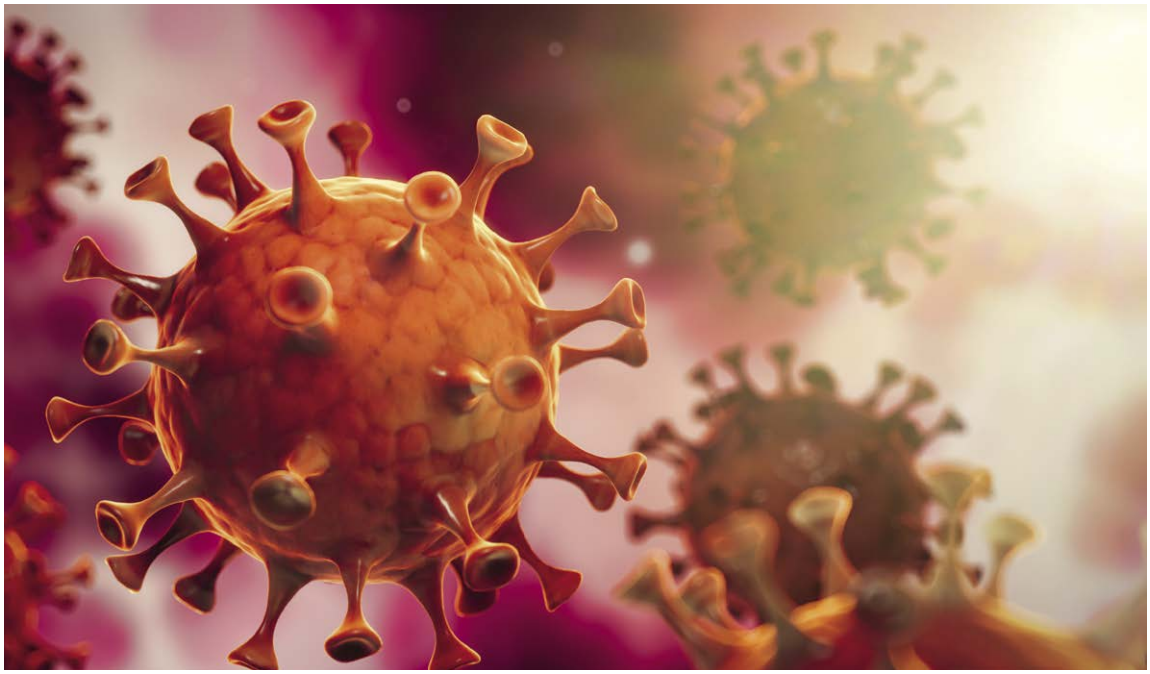

Fig. 1: Graphical model of a coronavirus from the large Coronaviridae family.來自大型冠狀病毒科的冠狀病毒的圖形模型。

Stability data collected on the human coronavirus (HCoV-) 229 E before the COVID-19 pandemic shows that the virus can remain infectious for periods from two hours up to nine days, depending on the material. Find-ings based on other members of this expansive family – including MERS-CoV, Transmissible Gastroenteritis Virus (TGEV), Mouse Hepatitis Virus (MHV) and rab-bit coronavirus – show residual infectiousness that can endure for up to ≥ 28 days in low temperatures. These studies were carried out on a number of different types of surfaces, primarily steel, aluminium, wood, glass and plastic.[6]

Recently, however, the ongoing pandemic has led to the execution of more targeted studies on the stability of SARS-CoV-2 on various surfaces, and to a reluctance to rely solely on the historic data from other members of the Coronaviridae family. An initial study showed that the virus remained infectious for up to four hours on copper, up to 24 hours on cardboard and up to two to three days on plastic and stainless steel.[7] 在COVID-19大流行之前在人類冠狀病毒（HCoV-）229 E上收集的穩定性數據表明，根據材料的不同，該病毒可以在2小時到9天的時間內保持感染性。基於該擴展家族其他成員的發現-包括MERS-CoV，傳染性胃腸炎病毒（TGEV），小鼠肝炎病毒（MHV）和阿拉伯病毒-冠狀病毒-顯示出殘留的傳染性，在低溫下可長達≥28天溫度。這些研究是在許多不同類型的表面上進行的，主要是鋼，鋁，木材，玻璃和塑料。

然而，最近，持續的大流行導致對SARS-CoV-2在各種表面上的穩定性進行了更有針對性的研究，並且不願僅依賴冠狀病毒科其他成員的歷史數據。初步研究表明，該病毒在銅上最多可感染四個小時，在紙板上最多可感染24小時，在塑料和不銹鋼上最多可感染2至3天。

A summary of previous data also showed that the virus was adequately inactivated on copper or copper oxide-coated surfaces within four hours or within one hour respectively. In another study, the virus was found to remain stable on hydrophilic substrates such as ordinary paper and tissues for three hours. On other surfaces, such as the fabric used for masks, it took up to seven days for all traces of the virus to disappear. All of these studies took temperature and air humidity into account. The studies were carried out at temperatures between 21–23 °C and at an air humidity level of 40 to 70 %.[8] Another, very recent comparative study carried out in Beijing in 2021 showed that, when an area measuring 1 x 1 cm was contaminated with 10^6 $TCID_{50}$/ml of virus sus-pension, the virus could still be detected on many surfaces at room temperature after seven days, with the exception of cotton cloths and paper.[9] 先前數據的摘要還顯示，該病毒分別在四個小時內或一小時內在銅或氧化銅塗層的表面上充分失活。在另一項研究中，發現該病毒在親水性基質（如普通紙和薄紙）上可保持穩定三小時。在其他表面（例如用於口罩的織物）上，該病毒的所有痕跡消失最多需要7天的時間。所有這些研究都考慮了溫度和空氣濕度。這項研究是在21-23°C的溫度和40％至70％的空氣濕度水平下進行的。另一項最新的比較研究是2021年在北京進行的一項研究表明，當面積為1 x 1公分時，被10^6 $TCID_{50}$ /ml的病毒懸浮液污染後，在7天后仍可在室溫下在許多表面上檢測到該病毒，但棉布和紙除外。

However, it is important to note that it is difficult to directly compare the data collected in the studies carried out to date, because the test conditions are too varied. 但是，重要的是要注意，由於測試條件變化太大，很難直接比較迄今為止進行的研究中收集的數據。

Chemical inactivation of SARS-CoV-2SARS-CoV-2的化學滅活

As is the case with the stability data, many of the studies used to draw conclusions about the inactivation of SARS-CoV-2 relate to other members of the large Coronavirus family. Although the members have not yet been directly compared, we can assume that each member of the Coronaviridae family will respond in a virtually identical way to chemical disinfectants. 與穩定性數據一樣，用於得出有關SARS-CoV-2滅活結論的許多研究都與大型冠狀病毒家族的其他成員有關。儘管尚未對成員進行直接比較，但我們可以假定冠狀病毒科的每個成員對化學消毒劑的反應幾乎相同。

New, more specific tests on surface disinfection agents will certainly only need to be carried out with SARS-CoV-2 in individual cases. When testing the virucides in chemical disinfectants, individual apathogenic and highly reproducible strains with high titre counts in cell cultures are generally used as test viruses in quantitative suspension testing and in practical testing under load conditions in accordance with German and European standards. As we know, the Vaccinia virus is used as a test virus for all enveloped viruses ("limited virucidal activity"), which means that it can also be used to draw conclusions about efficacy against SARS-CoV-2.[10] 當然，僅在個別情況下，才需要使用SARS-CoV-2對表面消毒劑進行新的，更具體的測試。在化學消毒劑中測試殺病毒劑時，在細胞培養物中具有高滴定濃度計數的單個無源性和高度可複制菌株，通常用作定量懸浮液測試和根據德國和歐洲標準在負載條件下的實際測試中的測試病毒。眾所周知，痘苗病毒被用作所有包膜病毒的測試病毒（"有限殺病毒活性"），這意味著它還可用於描繪出抗SARS-CoV-2功效的結論。

This means that the established German and European system of using surrogate viruses in disinfection testing, based on the Vaccinia virus, and the category of "limit-ed virucidal activity", remains valid. A quantitative sus-pension test performed on a chemical disinfectant on this basis, followed up with a practical surface test, is an objective procedure to ensure that tested and certified surface disinfectants are used to inactivate SARS-CoV-2 in the age of COVID-19. Surface disinfectants with great-er efficacy, such as "limited virucidal activity plus" and "virucidal activity", can also be used to inactivate SARS-CoV-2.
這意味著，基於痘苗病毒和"極限殺滅病毒活動"類別的德國和歐洲已建立的在替代病毒檢測中使用替代病毒進行消毒測試的系統仍然有效。在此基礎上對化學消毒劑進行的定量懸浮測試，然後進行實用的表面測試，是一項客觀程序，可確保使用經測試和認證的表面消毒劑在COVID-時代使用滅活SARS-CoV-2的方法。具有更高功效的表面消毒劑，例如"有限的殺病毒活性"和"殺病毒活性"，也可以用於滅活SARS-CoV-2。

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A report from change management: dispensing with inner liners in sterile containers 來自變更管理的報告：分配無菌容器中的內襯

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This report does not discuss the advantages and disadvantages of a particular ster-ile barrier system. Instead, it is intended to encourage readers to question existing processes and to decide, on clinical grounds, whether a change would be sensible and could even add value to the process. If you work in a central sterile services department (CSSD)本報告未討論特定無菌屏障系統的優缺點。相反，它旨在鼓勵讀者質疑現有流程，並根據臨床理由決定更改是否合理，甚至可以為流程增加價值。如果您在中央無菌服務部門（CSSD）工作

or in an operating theatre, you will know what a sterile barrier system is and what it is for. The container as a rigid sterile barrier system and the liner as a flexible sterile barrier system are both considered independent stable barrier systems. DIN EN ISO 11607 defines a sterile barrier system as the minimum packaging that can prevent the ingress of micro-organisms and that allows the product to be removed aseptically at its location of use.[1]或在手術室中，您將知道無菌屏障系統是什麼以及它的用途。作為剛性無菌屏障系統的容器和作為柔性無菌屏障系統的襯裡都被認為是獨立的穩定屏障系統。 DIN EN ISO 11607將無菌屏障系統定義為最小包裝，可以防止微生物侵入，並允許在使用位置以無菌方式去除產品。

At Saarbrücken hospital, in addition to soft-packaged sets, we primarily use sets packaged in containers. Previously, almost all medical devices were wrapped inside an additional liner inside the containers. This is a great example of continuing to do something just because "that's how we've always done it" – but there was potential to optimise the process, because inner packaging is not needed and is not required by any standard or guideline. Container manu-facturer Aesculap points out that, "in accordance with DIN EN ISO 11607, no inner packaging was used in any product testing and outside Germany, for example in the USA, Aesculap containers are always used without inner packaging in accordance with FDA approval".[2]在薩爾布呂肯醫院，除了軟包裝的餐具外，我們主要使用包裝在容器中的餐具。以前，幾乎所有醫療設備都被包裹在容器內的附加襯內裡。這是繼續做某事的一個很好的例子，僅僅是因為"這就是我們一直做的方式"，但是有可能優化流程，因為不需要內包裝，而且任何標准或準則都不需要內包裝。容器製造商Aesculap指出："根據DIN EN ISO 11607，在任何產品測試中均未使用內包裝，而在德國以外，例如在美國，根據FDA批准，Aesculap容器始終不使用內包裝而使用"。

When selecting appropriate packaging, the nature of the medical devices to be packed, the user's requirements and the transport logistics are all significant factors that must be taken into account. User-friendliness and safety are also equally important considerations. User-friendliness and safety play an important role during transitional periods; we must consider how the removal of the inner liner will affect the aseptic presentation of the medical devices in the operating theatre, and whether this change will have an impact on how the users handle the product. 選擇合適的包裝時，要包裝的醫療器械的性質，用戶的要求和運輸後勤都是必須考慮的重要因素。用戶友好性和安全性也是同等重要的考慮因素。在過渡期間，用戶友好性和安全性起著重要作用；我們必須考慮移除內襯會如何影響手術室中醫療器械的無菌外觀，以及這種變化是否會影響用戶使用產品的方式。

Involve and train employees when changes are made 進行變更時讓員工參與並進行培訓

In general, asking colleagues from other hospitals for advice and listening to their experiences is always an useful exercise. After all, there is no need to reinvent the wheel, and there are countless hospitals that have already embarked on the same journey. Feedback from this stage was consistently positive, which of course was very encouraging for us. However, our top priority was to involve col-leagues at our own hospital in the optimisation process and to explain the reasons why we were taking this step – not to seek unanimous approval for the change, but to promote acceptance and constructive criticism. Disman-tling existing structures requires a sensitive touch. But ul-timately, if you want to be able to assess the success of a change, you need to implement it. 通常，向其他醫院的同事徵求意見並聽取他們的經驗始終是有益的練習。畢竟，沒有必要重新發明輪子，並且已經有無數的醫院踏上了同樣的旅程。這個階段的反饋一直是積極的，這當然對我們來說是令人鼓舞的。但是，我們的首要任務是讓自己醫院的同事參與優化過程，並說明我們採取此步驟的原因-不是尋求一致同意的變更，而是要促進接受和建設性的批評。拆除現有結構需要靈敏的觸感。但最終，如果您希望能夠評估變更的成功，則需要實施它。

Other parties, such as the manufacturers of the containers, can also provide support during the change process. A set routine is essential to prevent uncertainty among staff, so specific user training is important. It is also helpful to critically study and assess the conditions and the existing sets. The sizes of the containers and the mesh baskets and trays they contain, and how this affects aseptic removal, are also important considerations. From this analysis, you can derive a set of recommendations for use that will help to facilitate and optimise the transition. If it is difficult to remove the device without a liner because there is very lit-tle space between the container shell and the mesh basket, or because the set is very heavy, it is a good idea to check whether it might be better to continue to use an inner liner for that specific application. Safety is the top priority.其他方，例如容器的製造商，也可以在更改過程中提供支持。設定常規對於防止員工之間的不確定性至關重要，因此特定的用戶培訓非常重要。批判性研究和評估條件以及現有設置也很有幫助。容器的尺寸以及容納的網籃和托盤的尺寸以及如何影響無菌去除也是重要的考慮因素。從此分析中，您可以得出一組使用建議，這些建議將有助於促進和優化過渡。如果由於容器外殼和網籃之間的縫隙很小，或者由於套件很重而很難在沒有襯套的情況下卸下設備，則最好檢查一下繼續操作是否會更好為該特定應用使用內襯。安全是重中之重。

All changes take time and need to become established. This is why it is all the more important to consult with the theatre team and doctors on a regular basis. For example, the managers of our orthopaedics and trauma surgery teams told us that they had to be very careful when opening the containers. The seal had to be fully removed from all sides of the sterile container before opening to prevent any part of the seal from falling into the set and rendering the medical device non-sterile. 所有更改都需要時間，並且需要確立。這就是為什麼定期向劇院團隊和醫生諮詢更為重要的原因。例如，我們的骨科和創傷外科團隊的經理告訴我們，打開容器時必須非常小心。在打開密封件之前，必須從無菌容器的所有側面完全取下密封件，以防止密封件的任何部分掉入套件中並導致醫療器械不無菌。

Doctors should also be involved in the change process, as they understand not only the chang-es in handling practices, but also the potential effects on the success of an operation. Could there be a higher risk of infections in patients if the inner liner is removed? These kinds of concerns must be taken seriously. 醫生還應該參與變更過程，因為他們不僅了解操作習慣的變化，而且還了解對手術成功的潛在影響。如果移除內襯，患者感染的風險會更高嗎？這些問題必須認真對待。

No change in infection rates感染率無變化

Users feel confident when a routine is established, and that takes a little while. At this point in the change process, we brought the hospital's hygiene team on board to check the post-implementation infection rates in the relevant operating theatres over a set period of time. After 18 months, there was no change in infection rates at Saarbrücken hos-pital that correlated with the removal of the inner liner. Based on these results, we do not anticipate any increase in infection rates with correct use.建立例程後，用戶會充滿信心，這會花費一些時間。在變更過程中的這一點上，我們召集了醫院的衛生團隊，以檢查在規定的時間段內相關手術室實施後的感染率。 18個月後，薩爾布呂肯醫院的感染率沒有發生與內襯去除相關的變化。根據這些結果，我們預計正確使用不會增加感染率。

Positive effects of process optimisation流程優化的積極影響

Leaving out the inner liner has made our process significantly leaner in a number of areas. The reduced number of inner liners has virtually eliminated an entire work step in the CSSD packing process. Working time is a valuable resource, particularly in chronically understaffed CSSDs, and the time saved can now be efficiently utilised else-where. The amount of space required in the CSSD store has been significantly reduced, and the operating theatre generates less waste: using inner liners generates a lot of waste, as we do not use the liners for any other purpose (e.g. as surgical covers). And less waste means lower waste disposal costs. In some cases, leaving out the liner even had a positive effect on the drying of the medical device in the container. After checking with our steriliser validators, we found that it was not necessary to revalidate the packaging process and the subsequent sterilisation process. 省略內襯使我們的流程在許多領域都變得更加精益。減少內襯的數量實際上消除了CSSD包裝過程中的整個工作步驟。工作時間是一種寶貴的資源，尤其是在人員長期短缺的CSSD中，節省的時間現在可以在其他地方得到有效利用。 CSSD商店中所需的空間已大大減少，並且手術室產生的廢物更少：使用內襯會產生大量廢物，因為我們不會將內襯用於任何其他目的（例如，用作外科手術蓋）。減少廢物意味著降低廢物處理成本。在某些情況下，省略襯裡甚至會對容器中醫療設備的干燥產生積極影響。在與我們的滅菌器驗證器核對之後，我們發現沒有必要重新驗證包裝過程和隨後的滅菌過程。

Without a doubt, the most significant knock-on effect of this change is the reduction in costs. Each year, we were spending approximately €20,000 on liners. The constantly rising cost pressure in hospitals – which has only worsened during the coronavirus pandemic that has affected the entire world – is challenging managers to identify potential savings and cut costs, but also to be flexible and come up with new ideas.毫無疑問，這種變化最顯著的連鎖效應就是降低了成本。每年，我們在內襯上的花費約為20,000歐元。醫院不斷增加的成本壓力（僅在影響整個世界的冠狀病毒大流行期間加劇了），正向管理人員提出挑戰，要求他們確定潛在的節省和削減成本的方法，同時也要靈活應對並提出新的想法。

Of course, eliminating a consumable from the process without replacing it will have a positive effect on costs. 當然，從流程中消除消耗品而不進行替換將對成本產生正面影響。

> 內襯支出在一年之內減少了一半。

Depending on the number of containers the organisation uses, there is potential for significant savings. At Saarbrücken hospital, we were able to reduce liner costs by more than half over the course of a year. 根據組織使用的容器數量，可能會節省大量資金。在薩爾布呂肯醫院，我們能夠在一年的時間內將內襯成本降低一半以上。

However, the drive to optimise must never come at the expense of the application or of safety. In this case, the operating theatre staff were asked to change a well-known process; a routine that had been established for years and that had always worked well. The users in theatre will barely notice the effects of the optimisation – which is why employee acceptance is all the more important with these kinds of change processes. 但是，永遠不要以犧牲應用或安全為代價來進行優化。在這種情況下，要求手術室工作人員更改眾所周知的流程：已經建立了多年並且一直運行良好的例程。影院中的用戶幾乎不會注意到優化的效果–這就是為什麼在這種類型的變更過程中，員工的接受度變得更加重要的原因。

Conclusion 結論

After working through some initial teething problems, the removal of the inner liner was well-received by the theatre and CSSD staff. The impact of the change has been exclusively positive for Saarbrücken hospital. 在解決了一些最初的磨牙問題之後，劇院和CSSD員工都非常滿意地去除了內襯。這一變化的影響對薩爾布呂肯醫院完全具有積極意義。

What has not changed for the CSSD and operating thea-tre team is that the containers must be regularly checked and maintained in accordance with the manufacturer's instructions. Only intact sterile containers guarantee that sterility is maintained, regardless of whether or not the container includes a liner. 對於CSSD和操作小組而言，不變的是必須按照製造商的說明定期檢查和維護容器。無論容器是否包含襯裡，只有完整的無菌容器才能確保保持無菌狀態。

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Anti-viral surfaces – testing processes and practical relevance 抗病毒表面–測試過程和實用性

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Virus transmission risks on con-taminated surfaces被污染表面上的病毒傳播風險

Alongside droplet infection and direct bod-ily contact, viruses that cause respiratory infection or diarrhoea are also often trans-mitted through contact with contaminated substances. If a patient is suffering from diarrhoea, vomiting, sneezing or coughing, surfaces in the environment may become contaminated with bodily secretions that contain the virus. The virus can then be transmitted via contact with these contam-inated surfaces and passed on indirectly to others. 除了飛沫感染和直接身體接觸外，引起呼吸道感染或腹瀉的病毒也經常通過與被污染物質接觸而傳播。如果患者腹瀉，嘔吐，打噴嚏或咳嗽，環境表面可能會被含有病毒的身體分泌物污染。然後，病毒可以通過與這些被污染的表面接觸而傳播，並間接傳遞給其他人。

The risk of a virus being transmitted via a contaminated surface depends on the virus itself, the environmental conditions, the virus load on the contaminated surface and how infectious the virus is. Infectiousness is measured based on various parameters, including the minimum number of virus particles required to induce an infection. In the human noroviruses (which cause se-vere vomiting and diarrhoea), the minimum infection dose is around 10 virus particles[1] and the virus remains infectious for days or even weeks on porous and non-porous sur-faces.[2] This means that there is a high risk of norovirus transmission via contaminated surfaces. 病毒通過受污染表面傳播的風險取決於病毒本身，環境條件，受污染表面上的病毒載量以及病毒的傳染性。可根據各種參數（包括誘導感染所需的最小病毒顆粒數）來衡量傳染性。在人類諾如病毒（引起嚴重的嘔吐和腹瀉）中，最小感染劑量約為10個病毒顆粒，並且該病毒在有孔和無孔的表面上仍可感染數天甚至數週。這意味著存在諾如病毒通過受污染表面傳播的風險很高。

In the case of the SARS-CoV-2 human coronavirus still circulating at a pandemic level, the minimum infection dose is estimated to be between a few hundred to around 1000 virus particles.[3] The number of virus particles required to cause infection is significantly higher than that of the noroviruses, which means that the risk of SARS-CoV-2 being transmitted via contact with contaminated surfaces is significantly lower. However, various studies – often using PCR as the detection system – have shown that SARS-CoV-2 can remain active on surfaces such as metal, glass, plastic and textiles for a number of days.[4,5,6] 對於SARS-CoV-2人類冠狀病毒仍處於大流行水平，估計最小感染劑量在幾百至約1000個病毒顆粒之間。3引起感染所需的病毒顆粒數量明顯高於諾如病毒。通過與受污染的表面接觸而傳播SARS-CoV-2的風險大大降低。但是，各種研究（通常使用PCR作為檢測系統）表明，SARS-CoV-2可以在金屬，玻璃，塑料和紡織品等表面上保持活性數天。

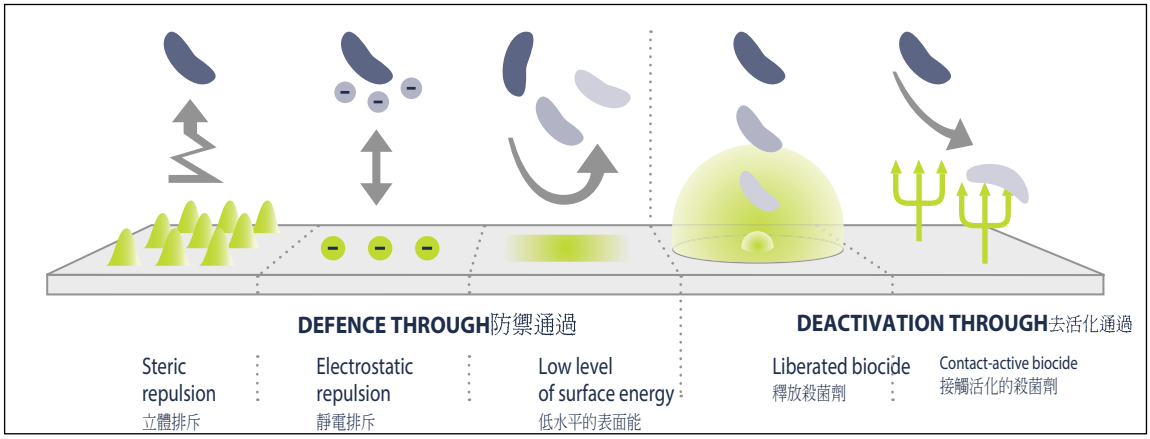
Alongside targeted disinfection measures, anti-microbial surfaces in public areas and healthcare environments could help to prevent the spread of viruses, which would be particularly useful during epidemics and pandemics. This idea is supported by a recent publication which proved that coating surfaces with cuprous oxide bound with polyurethane can reduce the virus titre of SARS-CoV-2 by around 99.9 % on a range of surfaces.[7] The United States Environmental Protection Agency (EPA), too, recently announced that anti-viral products could be used on an emergency ba-sis under certain circumstances during the COVID-19 pandemic (https://www.epa.gov/coronavirus/there-any-thing-i-can-do-make-surfaces-resistant-sars-cov-2-cov-id-19). 除了有針對性的消毒措施外，公共區域和醫療環境中的抗菌表面還可以幫助防止病毒傳播，這在流行病和大流行期間尤其有用。最近的出版物支持了這一想法，該出版物證明用聚氨酯結合的氧化亞銅塗層表面可以在一系列表面上將SARS-CoV-2的病毒滴度降低約99.9%.7美國環境保護署（EPA）同樣，最近也宣佈在COVID-19大流行期間的某些特定情況下，可以在緊急情況下使用抗病毒產品（https://www.epa.gov/coronavirus/there-any-thing-i-can-do-make-surfaces-resistant-sars-cov-2-cov-id-19）。

Anti-viral surfaces抗病毒表面

There is already a huge range of anti-viral surfaces avail-able, and the selection is growing all the time. The spec-trum ranges from intrinsic surfaces with anti-microbial properties from materials such as copper, silver or gold and functional surfaces with a modified micro-structure or nano-structure, to surfaces that contain an anti-mi-crobial substance (e.g. titanium oxide or copper oxide) or that are coated with an anti-microbial substance (e.g. peptides, organosilanols). The function of an anti-viral surface is based either on its ability to directly repel the relevant micro-organisms so that they cannot adhere to the surface, or to inactivate the pathogens as soon as they come into contact with the surface (see Fig. 1).已經有大量的抗病毒表面可用，並且選擇一直在增長。光譜範圍從具有抗微生物特性的本徵表面（例如銅，銀或金等材料）以及具有修飾的微結構或納米結構的功能性表面，到包含抗微生物成分（例如胜肽）的表面氧化物或銅氧化物）或塗有抗微生物物質（例如肽，有機矽烷醇）。抗病毒表面的功能是基於其直接排斥相關微生物以使其不能粘附在表面上的能力，或基於病原體與表面接觸後立即使其滅活的能力（見圖1）。

Test procedure to determine the anti-viral activity of surfaces 確定表面抗病毒活性的測試程序

There are currently two ISO standards that we can use to measure how effective an anti-microbial surface is against viruses. ISO 21702:2019-05 is used to measure the anti-viral activity of plastics and other non-porous surfaces[8] and ISO 18184:2019-06 is used to determine the anti-viral activity of textile products.[9] Both stand-ards use quantitative germ carrier testing in standardised conditions. 當前，我們可以使用兩個ISO標準來衡量抗菌表面對病毒的有效性。ISO 21702：2019-05用於測量塑料和其他無孔表面的抗病毒活性，ISO 18184：2019-06用於確定紡織品的抗病毒活性。在標準條件下進行細菌攜帶者測試。



Fig圖. 1: Active mechanisms of anti-viral surfaces (adapted from Felix Siedenbiedel and Joerg C. Tiller – Antimicrobial Polymers in Solution and on Surfaces: Overview and Functional Principles, Polymers 2012, 4, 46-71; https://www.mdpi.com/2073-4360/4/1/46/htm). 抗病毒表面的主動機制（改編自Felix Siedenbiedel和Joerg C. Tiller –溶液中和表面上的抗菌聚合物：概述和功能原理，《聚合物》 2012年第4期，第46-71頁：https://www.mdpi. com/2073-4360/4/1/46/htm).

The influenza A virus (H3N2): A/Hong Kong/8/68 (ATCC VR-1679) (enveloped) and the feline calicivirus, strain F-9 (ATCC VR-782) (non-enveloped) are listed as test viruses; other viruses may also be used for tests under these standards.

In tests carried out under ISO 21702, the anti-microbial, non-porous test sample surfaces are contaminated with a defined amount of virus suspension. The inoculated area is then covered with a film and the individual samples are incubated for a specified holding time (≤ 24 h) at a relative humidity (RH) of ≥ 90 % (see Fig. 2). With ISO 18184, a defined amount of virus suspension is applied to an anti-microbial textile product (woven and knitted fabrics, fibres, yarns, braids etc. => sample measuring 2 x 2 cm or 2 cm strands with a total weight of 0.4 g ± 0.05 g per sample). The samples are then incubated in a closed reaction vessel for a maximum of 24 hours at 25 °C. Once the appropriate holding time has elapsed, the residual infectiousness is determined by rinsing the surface with elution fluid (for ISO 21702) or immersing the textile in elution fluid (for ISO 18184). If there is a titre count reduction in the test sample compared to the virus control sample (untreated control sample), it is possible to draw direct conclusions on the anti-viral properties of the anti-microbial surfaces in the tested conditions. A型流感病毒（H3N2）：A / Hong Kong / 8/68（ATCC VR-1679）（被包裹）和貓杯狀病毒F-9株（ATCC VR-782）（未被包裹）被列為測試病毒;其他病毒也可用於根據這些標准進行測試。

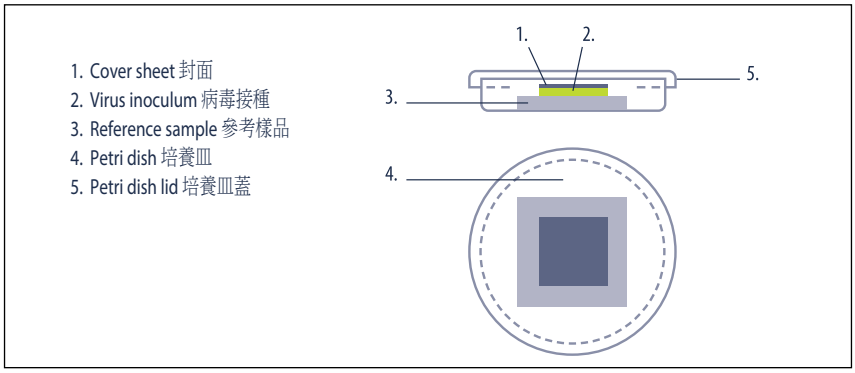
在根據ISO 21702進行的測試中，抗微生物，無孔的測試樣品表面被一定量的病毒懸浮液污染。然後用一層薄膜覆蓋接種區域，然後將單個樣品在≥90％的相對濕度（RH）下孵育指定的保持時間（≤24小時）（見圖2）。根據ISO 18184，將一定量的病毒懸浮液應用於抗微生物紡織品（機織和針織織物，纖維，紗線，辮子等）=>樣品尺寸為2 x 2公分或2公分股，總重量為0.4 g±0.05 g（每個樣品）。然後將樣品在密閉的反應容器中於25°C孵育最多24小時。一旦經過適當的保持時間，就可以通過用洗脫液沖洗表面（對於ISO 21702）或將紡織品浸入洗脫液中（對於ISO 18184）來確定殘留的傳染性。如果與病毒對照樣品（未處理的對照樣品）相比，測試樣品的滴定濃度降低，則可以得出在測試條件下抗微生物表面的抗病毒特性的直接結論。

According to ISO 18184, an anti-microbial surface has a good anti-viral effect if a titre count reduction of ≥ 2.0 to 3.0 $\log_{10}$ is achieved. If a titre count reduction of ≥ 3.0 $\log_{10}$ is achieved, the product is deemed to have excellent anti-viral properties. ISO 21702, on the other hand, does not define any thresholds for when a product can be categorised as anti-viral.根據ISO 18184，如果將滴定濃度計數降低≥2.0至3.0 log10，則抗菌表面具有良好的抗病毒作用。如果滴定濃度計數降低≥3.0log10，則認為該產品具有出色的抗病毒特性。另一方面，ISO 21702沒有定義何時可以將產品歸類為抗病毒藥物的任何閾值。

The practical relevance of testing processes測試過程的實際相關性

The advantages of ISO 21702 and ISO 18184 lie in the relatively simple methods of implementation, high level of standardisation and the associated high reproducibility of the results. ISO 21702和ISO 18184的優勢在於相對簡單的實現方法，高水平的標準化及其相關的高可重複性結果。

A disadvantage of both of the described methods is that both ISO 21702 and ISO 18184 rely on the creation of conditions – through the processes of inoculation and incubation of the samples contaminated with virus suspension – that would not generally occur in real life. Placing a film over the sample as prescribed by ISO 21702, for example, will cause the virus suspension to be evenly dis-tributed across the test surface to maximise exposure to the virus suspension. However, this kind of evenly distributed contamination is unlikely to occur outside of the laboratory. 上述兩種方法的缺點是，ISO 21702和ISO 18184都依賴於條件的產生-通過接種和孵育受病毒懸浮液污染的樣品-在現實生活中通常不會發生這種情況。例如，按照ISO 21702的規定在樣品上放一層膜將使病毒懸浮液均勻地分佈在整個測試表面上，以最大程度地暴露於病毒懸浮液。但是，這種均勻分佈的污染不太可能在實驗室外發生。



Fig圖. 2: Inoculation of a test sample in accordance with ISO 21702. 根據ISO 21702接種測試樣品。

Nor is the practice of incubating the samples
in a damp chamber (ISO 21702) or creating a damp environment by placing a cover on the container (ISO 18184)
to prevent or limit the drying of the virus suspension an accurate reflection of real-life conditions. It is also important to bear in mind that the test processes are generally carried out using samples produced on an unknown date
or on samples that were produced specifically for the test. The results generated in the laboratory can therefore only
be used to make observations about the levels of efficacy seen in the tests. They cannot be taken as confirmation of long-term efficacy after multiple uses, multiple washes or over extended periods of months or years. 孵化樣品的做法也沒有在潮濕的室內（ISO 21702）或通過在容器上蓋上蓋子來創建潮濕的環境（ISO 18184）以防止或限制病毒懸浮液的乾燥，準確反映現實生活條件。同樣重要的是要記住，測試過程通常是使用未知日期生產的樣品進行的或專門為該測試生產的樣品。因此，在實驗室中產生的結果只能用於觀察測試中觀察到的功效水平。在多次使用，多次清洗或數月或數年的長時間使用之後，不能將其視為長期療效的確認。

Conclusion 結論

Overall, both standards provide a good framework for generating data on the efficacy of anti-viral materials, even though the results achieved with the prescribed methods of investigation are not directly applicable to real-life practice. New and significantly more realistic procedures must be deployed, or existing methods must be further developed, to obtain directly applicable and highly relevant information on the efficacy of anti-viral surfaces in each application. 總體而言，儘管用規定的調查方法獲得的結果並不直接適用於現實生活中的實踐，但這兩個標準為生成有關抗病毒材料功效的數據提供了一個良好的框架。必須部署新的，更現實的程序，或者必須使用現有方法進一步開發，以獲得在每種應用中抗病毒表面功效的直接適用且高度相關的信息。

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Validation and routine control of processes in the H2O2 (hydrogen peroxide) steriliser

H2O2過氧化氫滅菌器中的流程驗證和重新認證

ebro
a xylem brand

During the validation and routine control of VH2O2 processes, target values specified by the manufacturer are measured, documented and assessed using inde-pendent measuring technology, such as pressure-temperature data loggers, in order to verify the sterilisation conditions. The new high-precision temperature and pressure logger from Xylem/ebro is ideal for recording the vacuum test and the sterilisation parameters of pres-sure, temperature and time. The data logger operates in a pressure measurement range from 0.1 to 1050 mbar (0.1 to 788 Torr) with an extremely high precision of +/- 0.25 mbar (0.1 mbar to 50 mbar measurement range), making it the perfect choice when measuring the vacuum in H2O2 sterilisers. The data logger also measures temperatures to within +/- 0.1 °C accuracy in a measurement range of 0 to 85 °C. 在汽化式過氧化氫VH2O2流程的驗證和常規控製過程中，使用獨立的測量技術（例如壓力溫度數據記錄器）對製造商指定的目標值進行測量，記錄和評估，以驗證滅菌條件。 Xylem / ebro的新型高精度溫度和壓力記錄儀非常適合記錄真空測試以及壓力，溫度和時間的消毒參數。數據記錄儀在0.1至1050 mbar（0.1至788Torr）的壓力測量範圍內運行，具有+/- 0.25 mbar（0.1 mbar至50 mbar的測量範圍）的極高精度，使其在H2O2滅菌器中成為測量真空度的理想選擇。數據記錄器還在0至85°C的測量範圍內測量溫度，精度在+/- 0.1°C之內。

Fig圖. 1: Independent testing using the EBI 12-TP290 pressure-temperature data logger in the VH2O2 process. 在汽化式過氧化氫VH2O2過程中使用EBI 12-TP290壓力溫度數據記錄器進行獨立測試。

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Low-temperature sterilisation with vaporised hydrogen peroxide (VH2O2) 汽化式過氧化氫的低溫滅菌

Parametric testing in routine controls and performance checks 日常控制和性能檢查中的參數測試

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In recent years, the number of manufacturers of VH2O2 sterilisers has steadily increased, and the technology is now supplied by var-ious European and American providers, as well as a large number of Asian companies. At the same time, acceptance of VH2O2 ster-ilisers and their use in German CSSDs has also risen.近年來，VH2O2消毒器的製造商數量穩步增長，該技術現在由各種歐洲和美國的供應商以及大量的亞洲公司提供。同時，VH2O2殺菌劑的接受程度及其在德國CSSD中的使用也有所增加。This varied manufacturer landscape is reflected in the amount of variation between the VH202 processes themselves.不同製造商格局反應在VH202流程自身之間的變化量。

Unlike LTSF (low-temperature steam and formaldehyde) processes, which are regulated in DIN EN ISO 25424[1], and EtO (ethylene oxide) processes, which are governed by DIN EN ISO 11135[2], there is no standard that sets out requirements for the development and validation of VH2O2 or for routine checks on its use as a sterilisation procedure for medical devices. Instead, the general requirements of DIN EN ISO 14937[3] and E-DIN EN 17180[4] are used as a framework. DIN EN ISO 254241中規定的LTSF（低溫蒸汽和甲醛）工藝與在DIN EN ISO 111352中規定的EtO（環氧乙烷）工藝不同，VH2O2沒有確認的標準規定開發和生產的要求或對其進行常規檢查以用作醫療器械的滅菌程序。反而，將DIN EN ISO 149373和E-DIN EN 171804的一般要求作為框架。

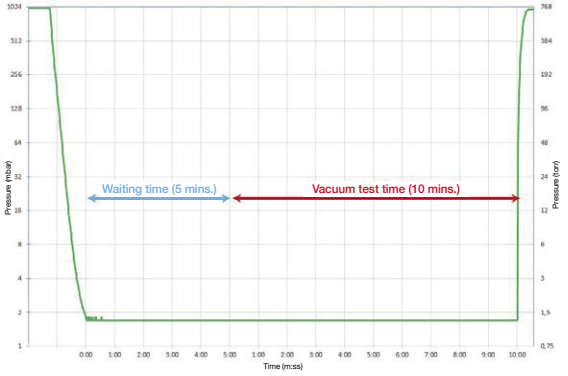
Technical Committee TC 198, working group WG 16 at ISO (the International Organisation for Standardisation) is currently working on a standard (ISO 22441). It is not expected to be published before 2022. Unlike the well-known steam-based processes, it is not possible to perform purely physical checks on low-temperature steriisation processes. To assess the performance of these pro-cesses, bio-indicators must be used – alongside process parameter checks – to demonstrate that the test organ-isms have been eliminated.
The physical parameters that must be achieved in the pro-cess are the basis for a sufficient level of germ elimination. ISO（國際標準化組織）的TC 198技術委員會WG 16工作組目前正在製定標準（ISO 22441）。預計不會在2022年之前發布。與眾所周知的基於蒸汽的過程不同，不可能對低溫滅菌過程進行純粹的物理檢查。為了評估這些過程的性能，必須使用生物指示劑以及過程參數檢查來證明已經消除了測試生物。

在此過程中必須達到的物理參數是消除細菌的足夠水平的基礎。

The cycles 週期

• *Vacuum test cycle* (based on manufacturer's specifica-tions)真空測試週期（根據製造商的規範）

E-DIN EN 17180[4] does not define a daily vacuum test, so the vacuum test must be used and performed in accord-ance with the manufacturer's instructions.E-DIN EN 171804沒有定義每日真空測試，因此必須按照製造商的說明使用和執行真空測試。



Fig圖. 1: Vacuum test with test pressure 測試壓力下的真空測試< 2 mbar abs. (1.5 Torr).

Fig圖. 2: Automatically generated vacuum test in accordance with E DIN EN 17180; appendix D 6.24, result with ebro Winlog.validation / Winlog.med analysis software.根據E DI E 17180自動生成真空測試：附錄D 6.24，使用ebro Winlog.validation / Winlog.med分析軟件得出的結果。

With VH2O2 sterilisers, a vacuum test cycle is performed, subject to manufacturer approval (Fig. 1). The vacuum test is a way to ensure that the machine is functioning correctly. Where available, it is carried out daily before work is commenced. The process is the same as for steam sterilisers.
However, with a vacuum of up to 1 mbar and a leak rate of < 10 % of the test pressure (e.g. 0.1 mbar/min), the parameters of the vacuum test differ significantly from the same test in the steam steriliser (Fig. 2).對於VH2O2滅菌器，要進行真空測試循環，但要得到製造商的認可（圖1）。真空測試是確保機器正常運行的一種方式。在可行的情況下，每天在工作開始之前進行檢查。該過程與蒸汽滅菌器的過程相同。
但是，在真空度高達1 mbar且洩漏率小於測試壓力的10%（例如0.1 mbar / min）時，真空測試的參數與蒸汽滅菌器中的同一測試有顯著差異（圖2）。

• *Sterilisation cycles滅菌週期*

Sterilisation cycles vary between different machines and manufacturers, with different numbers of process steps and varying durations of each step. Sterilisers must per-form a number of sterilisation cycles to satisfy the re-quirements for reprocessing medical devices. Figure 3 shows the structure of a typical sterilisation cycle with VH2O2.滅菌週期在不同的機器和製造商之間有所不同，其處理步驟的數量不同，並且每個步驟的持續時間也不同。消毒器必須執行多個消毒週期，以滿足對醫療器械進行再處理的要求。圖3顯示了使用VH2O2的典型滅菌循環的結構。

Cycle description 週期說明

1. Preparation (pre-conditioning) 準備（預處理）
In this part of the cycle, the air is removed from the steriliser chamber. Introduced moisture is vaporised and extracted via suction. The temperature is adjusted to the process condition. The defined preparations take place for the specific process.
在這一部分的循環中，空氣從消毒器腔室中排出。引入的水分汽化並通過抽吸提取。將溫度調節至流程條件。
對特定過程進行已定義的參數。

2. First vacuum step (conditioning) 第一真空步驟（調節）
The air is removed. The vacuum may drop as low as < 1 mbar. The duration of the vacuum depends on the process. During this stage, a "plasma" is generated, depending on the process and the manufacturer. This reduces foreign gases and moisture to prevent the gaseous H2O2 from being bound or degraded by other elements.空氣被清除。真空度可能會降低至<1 mbar。真空的持續時間取決於過程。在此階段，將根據過程和製造商生成"等離子體"。這減少了外來氣體和水分，以防止氣態H2O2被其他元素束縛或降解。

3. Vacuum steps 真空步驟
The air is removed. The vacuum may drop as low as < 1 mbar. The duration of the vacuum depends on the process.
空氣被清除。真空度可能會降低至<1 mbar。真空的持續時間取決於流程。

4. Sterilisation消毒
At the start of the sterilisation process, the H2O2 is va-porised and fed into the chamber. This action increases the pressure in the chamber (20 mbar). The duration of the step depends on the process.在滅菌過程開始時，將H2O2汽化並送入滅菌室。此操作會增加腔室（20 mbar）中的壓力。步驟的持續時間取決於流程。

5. Diffusion擴散
The pressure in the chamber rises and the H2O2 is diluted. This is when the H2O2 is split.
Three different processes may be used to split and re-move H2O2:
腔室內的壓力上升，H2O2被稀釋。這是將H2O2分開的時間。
可以使用三種不同的方法來分離和去除H2O2：

a. The simplest process is based on the assumption that H2O2 is not stable and will degrade by itself. These processes draw the H2O2 out of the chamber using suction and direct it into the drain.最簡單的過程基於H2O2不穩定並且會自行降解的假設。這些過程使用吸力將H2O2抽出腔室，然後將其引導到排水管中。

b. Another process involves using ozone (O3) as a ca- talyst. In this process, the H2O2 is split into water (H2O) and oxygen (O2); the additional catalyst in-creases the process costs. 另一個過程涉及使用臭氧（O3）作為催化劑。在此過程中，H2O2分解為水（H2O）和氧氣（O2）；額外的催化劑增加了流程成本。

c. The third process involves the use of plasma. In this process, strong electromagnetic waves (microwaves) are used to split the H2O2 into water (H2O) and oxygen (O2). There are two options for this process: the radiation can be generated in the chamber or, ideally, in the chamber drain. This second option protects sensitive instruments and allows metal sieves to be used. 第三個過程涉及等離子體的使用。在此過程中，使用強電磁波（微波）將H2O2分解為水（H2O）和氧氣（O2）。此過程有兩種選擇：可以在腔室內或理想情況下在腔室排水口中產生輻射。第二個選項可保護敏感儀器，並允許使用金屬篩。

6. Desorption 脫附
The final remaining residues of H2O2 are removed. 除去最後剩餘的H 2 O 2。

7. Ventilation通氣
Pressurised to ambient level and end of cycle.加壓至周圍環境水平並結束循環。

Pressure chart VH2O2 Flex programme in Steelco PL 130
VH2O2 Flex程序在Steelco PL 130的壓力表

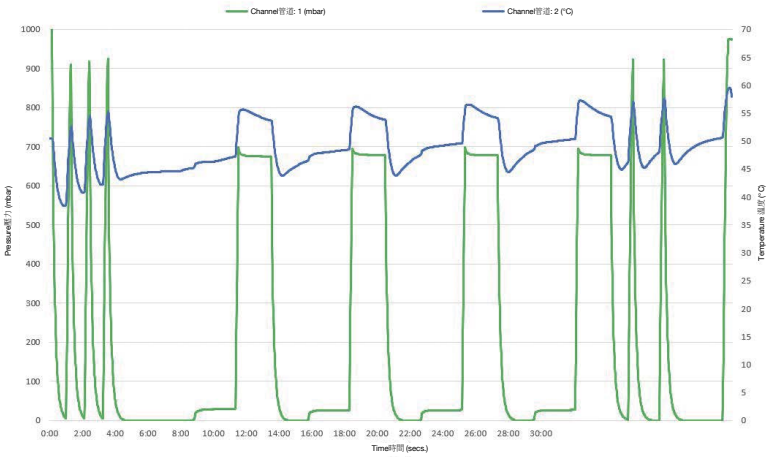
Fig圖. 3: Cycle description – process steps in the Steelco PL 130. 週期說明-在Steelco PL 130流程步驟

Note on cycle description: steps 3 to 5 are repeated multiple times, depending on the process.關於週期說明的注意事項：步驟3至5重複多次，具體取決於流程。

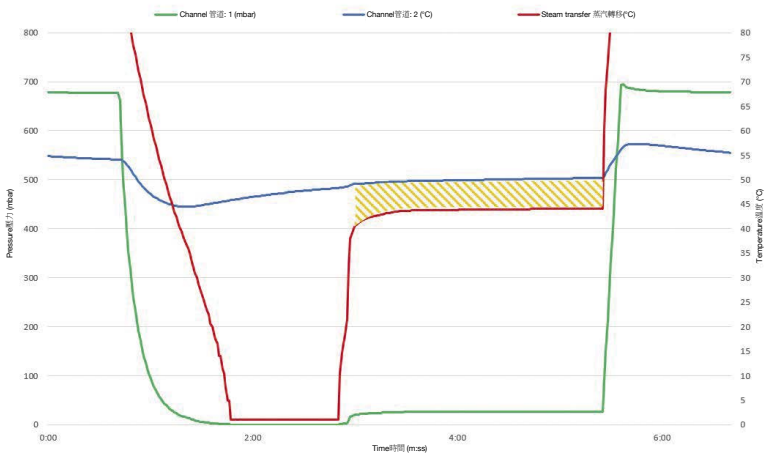
Parametric approval 參數批准

As is the case for all low-temperature processes (LTSF, EtO), sterility must be demonstrated through micro-biological and parametric testing. Parametric testing ensures that the machine also works within the spec-ified range. To conduct these tests, you need to know the process parameters (Fig. 4).
During parametric testing, the pressure, temperature and time are documented. From the pressure data, the Antoine equation can be used to verify that vaporised H2O2 is present in the chamber. 與所有低溫過程（LTSF，EtO）一樣，必須通過微生物和參數測試證明無菌性。參數測試可確保機器也能在指定範圍內工作。要進行這些測試，您需要了解過程參數（圖4）。在參數測試期間，應記錄壓力，溫度和時間。根據壓力數據，可以使用Antoine方程來驗證腔室內是否存在汽化的H2O2。

This equation applies to pure substances, but it can also be used as an ap-proximation to generate figures for the various concen-trations of H2O2 fluids. Many processes sterilise in a range of 9 to 10.5 mbar (7 to 8 Torr) and at temper-atures around 50 °C. In such cases, the vaporisation temperature is around 45 °C (Fig. 5). This ensures that there is VH2O2 in the chamber. As the fluids used are not pure H2O2, the flash point is reduced. If the item being sterilised is too cold (sink) or the material creates suction (e.g. silicone), the amount of free VH2O2 in the chamber is reduced. It is no longer possible to perform reliable sterilisation and the process will cause the chamber pressure to fall. If the pressure remains stable during the sterilisation phase, this is a sign that sterili-sation is taking place reliably. 該方程式適用於純物質，但也可以用作近似值來生成H2O2流體各種濃度的圖形。許多過程在9到10.5 mbar（7到8Torr）的範圍內以及大約50°C的溫度下滅菌。在這種情況下，汽化溫度約為45°C（圖5）。這樣可確保腔室內有VH2O2。由於使用的流體不是純H2O2，因此閃點降低了。如果要消毒的物品太冷（下沉）或材料產生吸力（例如矽樹脂），則腔室內的游離VH2O2量會減少。不再可能執行可靠的消毒，並且該過程將導致腔室壓力下降。如果在滅菌階段壓力保持穩定，則表明已可靠地進行了滅菌。



Fig圖. 4: Temperature and pressure in an H2O2 cycle. H2O2週期中的溫度和壓力。



Fig圖. 5: The shaded area is the steri-lisation range. It is important to note that the actual temperature (blue) is above the calculated vaporisation temperature of the H2O2 (red).陰影區域是滅菌範圍。重要的是要注意，實際溫度（藍色）高於計算出的H2O2（紅色）的汽化溫度。

Routine checks 例行檢查

The most important routine check is the daily vacuum test using independent measuring technology. For routine checks, low-pressure data loggers that operate in a range from 0.1 to 1050 mbar (0.1 to 788 Torr) with an accuracy of 0.25 mbar may be used. This measuring range and accuracy are required to allow the fine vacuum to be measured with the low limits of the process. Due to the required level of accuracy, it is not possible to use a standard pressure-temperature logger of the type used when performing routine checks and vali-dation on washer-disinfectors, endoscope washer-disinfectors, LTSF, EtO or vapour sterilisation processes. 最重要的例行檢查是使用獨立測量技術的每日真空測試。為了進行常規檢查，可以使用在0.1到1050 mbar毫巴（0.1到788Torr）範圍內，精度為0.25毫巴的低壓數據記錄器。需要此測量範圍和精度，才能以較低的過程極限來測量細真空。由於要求的精度水平，因此無法使用在清洗消毒器，內視鏡清洗消毒器，LTSF，EtO或蒸汽消毒中進行例行檢查和確認時使用的標準壓力溫度記錄器流程。

Process documentation流程文件

There are chemical indicators for monitoring the pro-cess in H2O2 sterilisers. Further information on the function and mode of action of these indicators can be found in the article by Brian Kirk published in Zentral-sterilisation – Central Service, issue 4/2020.[5] 有化學指示劑可監測H2O2滅菌器的過程。有關這些指標的功能和作用方式的更多信息，請參見Brian Kirk在“ Zentral-sterilisation – Central Service”第4/2020期中發表的文章中。

Fig. 6: EBI12-TP290 pressure-temperature logger for measuring fine vacuums.
圖6：用於測量高真空的EBI12-TP290壓力溫度記錄儀。

The process is documented using an appropriate indicator and the parametric testing is conducted using an EBI12-TP290 pressure-temperature data logger (Fig. 6).使用適當的指示劑記錄該過程，並使用EBI12-TP290壓力溫度數據記錄器進行參數測試（圖6）。

Performance validation 性能驗證

In the performance validation, the target values spec-ified by the manufacturer are measured, documented and assessed using independent measuring technology, such as pressure-temperature data loggers, in order to verify the sterilisation conditions. 在性能驗證中，使用獨立的測量技術（例如壓力溫度數據記錄器）對製造商指定的目標值進行測量，記錄和評估，以驗證滅菌條件。

· Basic process for a performance validation: 性能驗證的基本流程：

· Record and document vacuum test.記錄並記錄真空測試。
· Record and document the temperature-pressure profile of each process used. 記錄並記錄所使用的每個過程的溫度-壓力曲線。
· Compare the determined parameters of pressure, temperature and time with the cycle descriptions pro-vided by the manufacturer.
The compared measured values (Fig. 7) can be used as test criteria in the automatic parameter checks per-formed with the data logger during process control, for the purposes of parametric approval.將確定的壓力，溫度和時間參數與製造商提供的周期說明進行比較。
· 出於參數批准的目的，在過程控制期間，與數據記錄器一起執行的自動參數檢查中，比較的測量值（圖7）可用作測試標準。

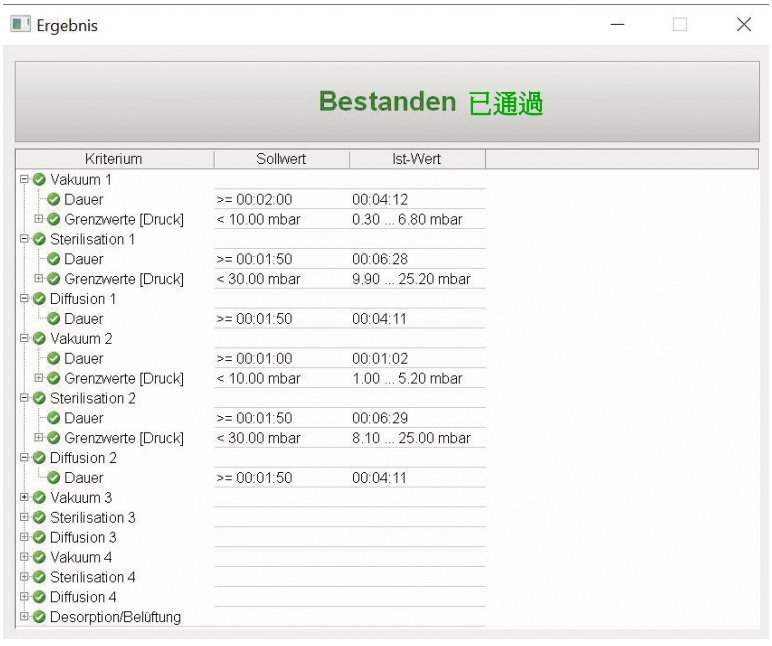
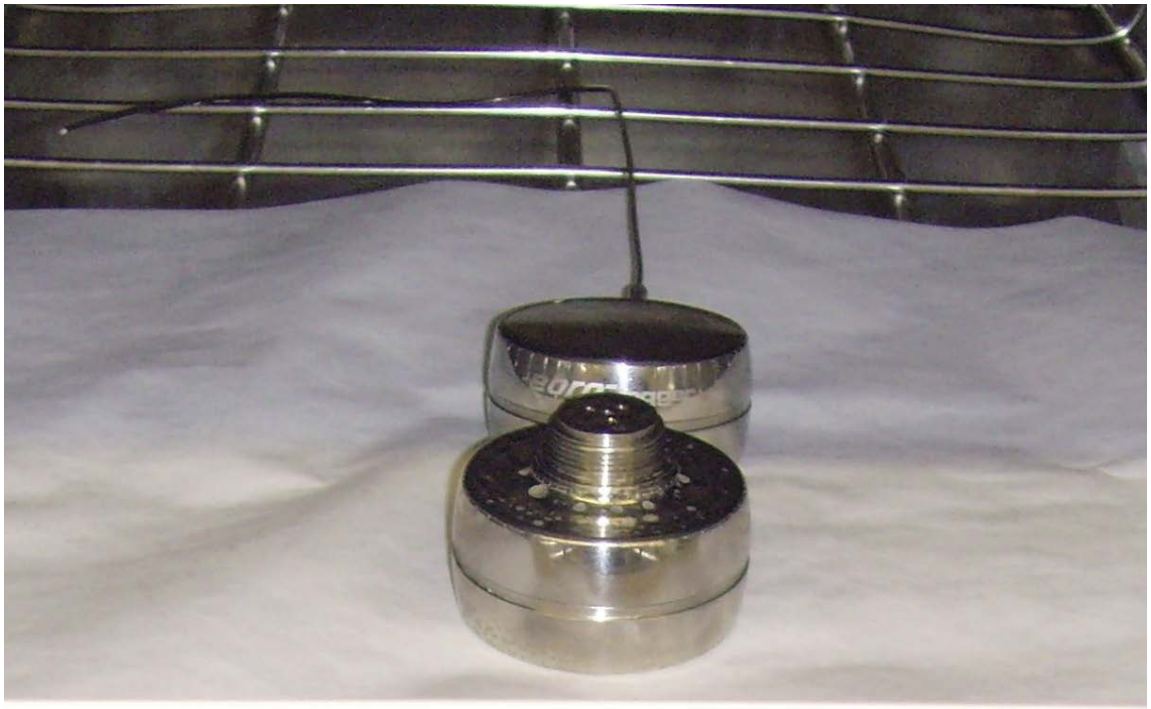


Fig. 7: Result of the automatic analysis with target and ac-tual values in the ebro analysis software Winlog.validation.
圖7：在ebro分析軟件Winlog.validation中使用目標值和實際值進行自動分析的結果。



Fig圖. 8: EBI12-TP290 and EBI12-T220 in an H2O2 steriliser. 在H2O2滅菌器中的EBI12-TP290和EBI12-T220。

For the routine checks: 對於例行檢查：

· Record and document the vacuum test each working day using the data logger.

· Use the data logger to perform regular parametric checks of the sterilisation processes used.

· Compare the values with the values determined in the performance validation.

· 在每個工作日使用數據記錄器記錄並記錄真空測試。

· 使用數據記錄器對使用的滅菌過程進行定期的參數檢查。

· 將這些值與性能驗證中確定的值進行比較。

Routine and validation measuring technology
例行和驗證測量技術

Due to the extremely low vacuum and the strong electromagnetic waves, the standard data loggers used in steam sterilisers or washer-disinfectors cannot be used in VH2O2 sterilisers. To achieve the extremely high levels of precision required in the fine vacuum, only special data loggers such as the EBI12-TP290 may be used. 由於極低的真空度和強電磁波，蒸汽滅菌器或清洗消毒器中使用的標準數據記錄器無法用於VH2O2滅菌器中。為了達到超高真空所需的極高精度，只能使用特殊的數據記錄儀，例如EBI12-TP290。

These special data loggers are not sensitive to electromagnetic radiation and boast a very high level of accuracy of ±0.18 Torr in the critical range (0.5 to 10 Torr) and beyond.這些特殊的數據記錄儀對電磁輻射不敏感，並且在臨界範圍（0.5至10Torr）及更高範圍內具有極高的±0.18Torr精度。

A pressure data logger designed for use in a steam steriliser, with a tolerance of ±20 mbar (±15 Torr), will produce errors of ±15 K if it is used to calculate the vaporisation temperature of H2O2 in a fine vacuum – if it can even measure to this degree of accuracy in this range, which is unlikely. A special pressure logger with an accuracy of ±0.18 Torr (±0.25 mbar) will be accurate to within ±0.3 K when calculating the vaporisation temperature. This corresponds roughly to the margin of error that can occur with steam sterilisation (±20 mbar= ±0.25 K at 134 °C). 如果設計用於蒸汽滅菌器的壓力數據記錄儀的公差為±20 mbar（±15 Torr），則用於計算H2O2在容器中的蒸發溫度時會產生±15 K的誤差。良好的真空度-如果它甚至可以在此範圍內達到這種精確度，那是不可能的。計算汽化溫度時，精度為±0.18托（±0.25 mbar）的特殊壓力記錄儀將精確到±0.3 K之內。這大致對應於蒸汽滅菌時可能發生的誤差範圍（在134°C下為±20 mbar =±0.25 K）。

Standard-compliant temperature loggers with flexible metal probes, such as EBI12-T220 (Fig. 8), may be used as additional temperature loggers during validation. The temperature sensors and elec-tronics are not sensitive to electromagnetic radiation. Significant temperature differences within the load can cause the pressure inside the chamber to fall. This is because too much VH2O2 condenses in these areas, which reduces the concentration process in the chamber and disturbs the sterilisation process. A further complicating factor is that in a fine vacuum, the medium required to distribute the temperature is almost completely absent, making it very difficult to balance the temperature. Overloading or the presence of materials that generate suction, such as silicone, can have the same effect. 驗證期間，帶有柔性金屬探頭的符合標準的溫度記錄器，例如EBI12-T220（圖8），可以用作其他溫度記錄器。溫度傳感器和電子設備對電磁輻射不敏感。負載內的明顯溫差可能導致腔室內的壓力下降。這是因為太多的VH2O2在這些區域中凝結，這減少了腔室中的濃縮過程並干擾了滅菌過程。另一個複雜的因素是，在高真空下，幾乎沒有溫度分佈所需的介質，因此很難平衡溫度。過載或存在產生吸力的材料（例如矽樹脂）可能具有相同的效果。

In conjunction with the automatic analysis software Winlog.Med / Validation, it is possible to reliably monitor parameters and compile documentation. 結合自動分析軟件Winlog.Med / Validation，可以可靠地監視參數並編譯文檔。

Conclusion結論

In order to demonstrate reliable and reproducible sterilisation results, it is essential to use independent pres-sure-temperature data loggers for parametric testing during routine controls and performance checks.為了證明可靠和可重複的滅菌結果，在常規控制和性能檢查過程中，必須使用獨立的壓力溫度數據記錄器進行參數測試。

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By Brian Kirk, Sterilization Consultancy Group Ltd.

Accurately assessing and analysing surface changes: residues from process chemicals 準確評估和分析表面變化：來自製程的化學品殘留物

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In clinical practice, the surfaces of medical devices may change over time as a result of mechanical, chemical and/or physical (e.g. thermal) influences. The causes of these surface changes can normally be traced back to the treatment process, provided they were not caused during use. Should surface changes occur, a systematic sequence of steps must be followed for rectification and prevention.在臨床實踐中，由於機械，化學和/或物理（例如熱）影響，醫療設備的表面可能會隨時間變化。這些表面變化的原因通常可以追溯到處理過程，只要它們不是在使用過程中引起的。如果發生表面變化，則必須按照系統的步驟順序進行糾正和預防。

- Locate the type, origin and cause 找到類型，起源和原因
- Assess the risks 評估風險
- If necessary, follow the manufacturer's recommendations for prevention 如有必要，請遵循製造商的建議進行預防
- Determine avoidance measures and conduct a new performance qualification if necessary 確定避免措施並在必要時進行新的性能鑑定

The example surface changes that most commonly affect metallic instruments made from stainless steel and/or products made from plastic or rubber are based on the system described above. 表面變化的示例最常影響由不銹鋼製成的金屬儀器和/或由塑料或橡膠製成的產品，是基於上述系統的。

Films on metals caused by process chemical residues 流程化學殘留物在金屬上形成的膜

Depending on the amount of residue, the instrument type and the surface properties, light to dark-grey films/discolouration may appear across the entire surface, in patches or in specific areas. The process of sterilisation may make these marks even more visible.根據殘留量，儀器類型和表面特性，淺色至深灰色膜/變色可能會出現在整個表面，斑點或特定區域。滅菌過程可能會使這些標記更加明顯。

Fig圖.1 Surface with visible residues.

Fig圖. 2 Suitable load carri-ers for cleaning and rinsing ophthalmic (Miele A207) instruments.

Fig圖. 3 Incorrect loading/kidney dishes that have toppled over. 不正確的裝載/ 腎臟盤倒塌了。

Type of surface changes
Origin and causes表面變化的類型起源與成因

Often, a failure to remove process chemicals properly during the interim and/or final rinse (due to areas being missed or the machine being loaded incorrectly) is what causes the surfaces changes mentioned above. 通常，在中期和/或最終沖洗過程中（由於漏掉區域或機器裝載不正確）未能正確去除流程化學品是導致上述表面發生變化的原因。

Recommendations for removal 移除建議

The surface changes can be wiped away with a lint-free cloth or removed by performing a deep clean using a special acidic cleaning agent recommended by the ma-nufacturer.

Preventive measures 預防措施

Preventive measures should be taken to avoid surface changes. Metallic instruments should be given a tho-rough intermediate and/or final rinse using demineralised water, and the load size and layout should be corrected where necessary. The manufacturer's instructions for disassembly and cleaning must also be strictly followed.應採取預防措施以避免表面變化。應使用軟化水對金屬儀器進行徹底的中間和/或最終沖洗，並在必要時校正負載大小和佈局。還必須嚴格遵守製造商的拆卸和清潔說明。

Assessment of potential risks 潛在風險評估

With ophthalmic instruments, alkali and/or tenside residues can put patients at risk of irritation or chemical burns.使用眼科儀器時，鹼和/或表面活性劑殘留物可能會使患者遭受刺激或化學灼傷的危險。

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"3 questions for ..."
3個問題...

Challenges in instrument reprocessing儀器後處理面臨的挑戰

Dr Ulrike Weber
Miele Professional business unit
Customer Segments & Solutions

1. Why is instrument reprocessing such a complex topic?1.儀器後處理為何如此復雜？

In instrument reprocessing, all of the parties involved (including the manufacturers of medical instruments, washer-disinfectors, sterilisers and process chemicals) are subject to specific requirements within the intended uses, legal regulations and categories. The reprocessing steps "overlap" between the parties.
This overlap only joins up with all the variables in the customer installation. At this point, everything needs to work together.
And of course, instrument reprocessing is also subject to the general chal-lenges of hygiene. When everything is working as it should, hygiene is taken for granted; there is no increase in infections and no surface changes to reprocessed products or reprocessing equipment – everything is great. If something isn't right, things can become unpleasant and, usually, very hectic. 在儀器後處理中，所有涉及的方面（包括醫療儀器製造商，清洗消毒器，消毒劑和過程化學品）都應符合預期用途，法律法規和類別中的特定要求。雙方之間的重複處理步驟"重疊"。

此重疊僅與客戶安裝中的所有變量結合在一起。在這一點上，一切都需要一起工作。當然，儀器的後處理也要受到衛生方面的普遍挑戰。當一切正常運行時，衛生是理所當然的：感染的數量沒有增加，後加工產品或後加工設備的表面也沒有變化——一切都很好。如果事情不對勁，事情可能會變得令人不快，而且通常會變得非常忙碌。

2. How does the way we do things in Germany dif-fer from the methods used in other European coun-tries? 我們在德國的做事方式與其他歐洲國家所採用的方式有何不同？

The criteria that apply to medical devices and their reprocessing are largely governed by European standards and regulations. Other countries also have a clear understanding of hygiene and infection prevention. 適用於醫療器械及其後處理的標准在很大程度上受歐洲標準和法規約束。其他國家也對衛生和預防感染有清晰的了解。

There are differences in some of the details, such as specific holding times or processes for removing prions, which are graded differently in different countries. However, there is a basic common understanding, which is promoted by a number of highly active international committees (e.g. the WFHSS and the Instrument Reprocessing Working Group AKI) and through dialogue between the parties. 在某些細節上存在差異，例如特定的保存時間或去除病毒的過程，在不同國家/地區分級不同。但是，存在著一些基本的共同理解，這是由一些活躍度很高的國際委員會（例如WFHSS和儀器後處理工作組AKI）和各方之間的對話所推動的。

3. What would you improve if you were able to? 如果可以的話，您會改進什麼？

That's an easy one to answer: I would reduce com-plexity. It would be great to be able to just put an in-strument down, wait a while, and that's it. But unfor-tunately it's not that easy. On the other hand, we can now structure reprocessing in a way that is flexible and adaptable, for example with a range of adapter solutions and modular combinations. I would like to move close to full process control with complete fulfilment of all of the requirements of the various parties, including water quality. As part of this, we need validated, reproducible processes and process indicators as a quality monitoring system. This means not only implementing end product controls (such as cleaning or sterilisation indicators) but also in-process controls for other relevant parameters, utilising the technical equipment available to us (e.g. 4D sensors) supported by modern digital solutions.這很容易回答：我會減少複雜性。能夠放下儀器，稍等片刻，這真是太好了。但不幸的是，這並不容易。另一方面，我們現在可以以靈活和適應性強的方式來構造後處理，例如使用一系列適配器解決方案和模塊化組合。我想接近全面過程控制，同時完全滿足各方的所有要求，包括水質。在此過程中，我們需要經過驗證的，可重複的流程和流程指標，作為質量監控系統。這意味著不僅要利用現代數位化解決方案支持的可用技術設備（例如4D傳感器）實施最終產品控制（例如清潔或消毒指示器），而且還要對其他相關參數進行過程中控制。

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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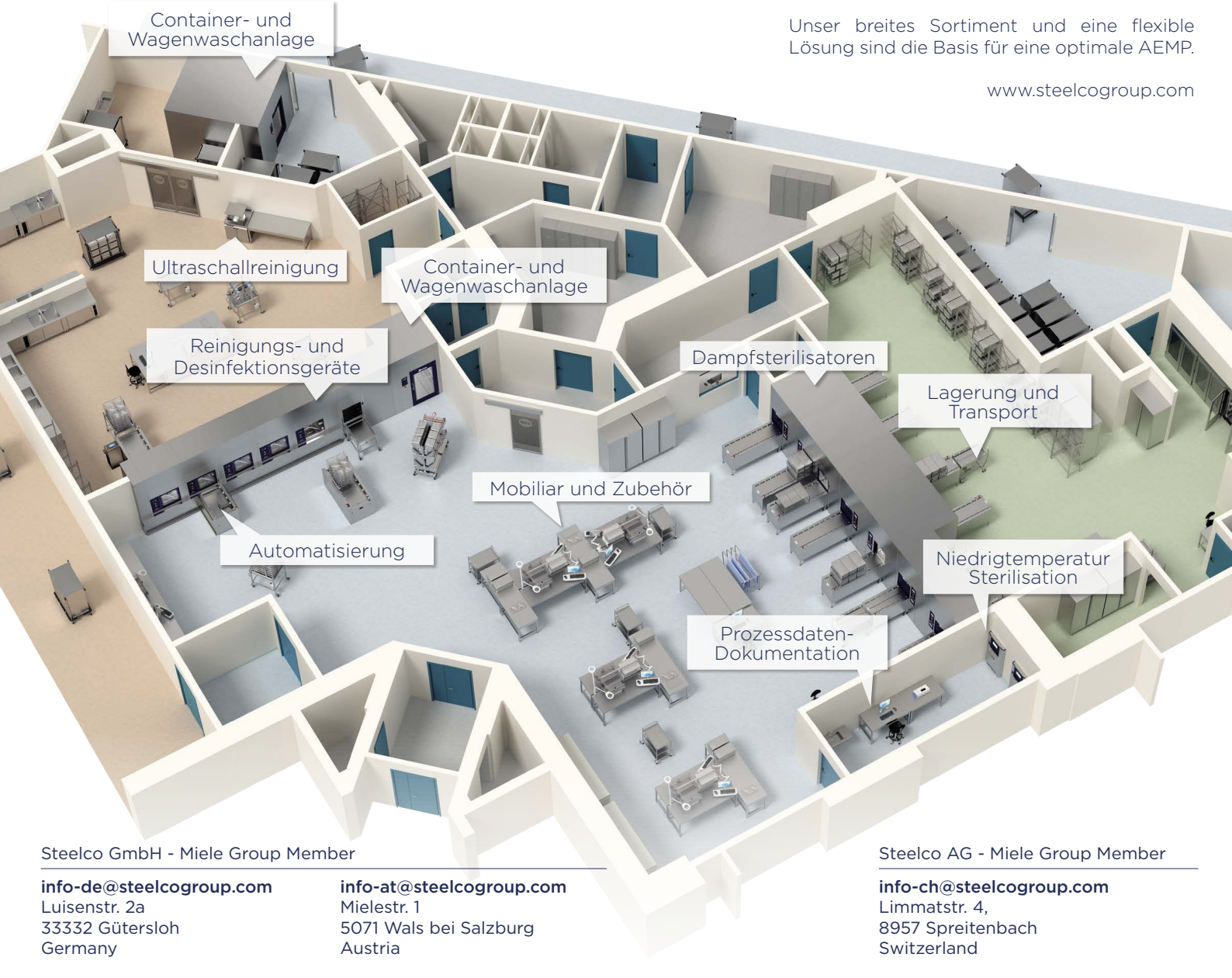

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