English translation of the recommendation
from the German Robert-Koch-Institute (RKI)

Homepage-Link of the German version:
http://www.rki.de/cln_006/nn_226790/DE/Content/Infekt/Krankenhaushygiene/FAQ/Dampfsterilisation/faq__krankenhyg__dampf__ges.html

Appropriate use of chemical indicators

Which value do chemical indicators and PCDs have for the monitoring of steam sterilization processes?

Sterile goods cannot be distinguished from non sterile goods by simple visual inspection. Only expensive and time consuming microbiological test methods ensure sterility but cannot be performed during routine monitoring.
The validation of a steam sterilization process ensures that the implemented sterilization procedure sterilizes the load configuration tested during validation. A validated process alone however is no proof that during routine operation all critical parameters (sterilization conditions) are met. Routine monitoring has to ensure that each load is processed the same way as tested during the process validation. The conditions in steam sterilization processes may vary from batch to batch. Not only the modification of the load configuration, the packing or the goods change the process conditions, but also the process conditions may have changed without the user's notice or without identifying the problem because of the user's lack of knowledge. Temperature or pressure changes over time are relatively simple to monitor by built in recorders and their corresponding documentation. The use of chemical indicators enables direct and contemporary monitoring at the end of each cycle, while biological indicators have to be incubated before the results are known and the goods can be released. Class 2, 5 and 6 chemical indicators manufactured according to the specifications and requirements of ISO 11140 provide the same results as a biological indicator, subsequently many countries in Europe use chemical indicators for routine monitoring.

The holding time of most sterilization processes is longer than necessary for killing biological indicators. As well as the heat-up phase to reach the holding time the subsequent cooling phase over the temperature range above 100°C contributes to inactivation. The temperature-time-window printed on chemical indicators therefore does not refer to the holding time but to the so-called "temperature-time-integral", the F_0-value, which is solely responsible for an information about inactivating biological indicators. Chemical indicators according DIN EN ISO 11140-1 do not directly monitor the defined parameters during holding time but document the temperature and pressure over the time and the use of chemical indicators complement the physical parameter recording.
Besides above possible parameter changes, other steam process malfunctions may occur but are not detected by recording of the temperature-time-integral or by the use of either biological or chemical indicators. The presence of non condensable gases (NCGs) in steam cannot be detected by any of these monitoring methods. NCGs may be present in the sterilizer chamber because of poor air removal, leaks during the vacuum phase, leaks from pneumatically sealed doors, residual air remaining in steam pipes, temperature changes in the cooling water affecting the performance of the vacuum pump or NCGs generated in the steam generator not using demineralised water. To detect these potential problems at start up, a Bowie-Dick-Test or so called Bowie-Dick-Simulation-Test is carried out before the sterilizer is used for production. The Bowie-Dick-Test however is only a functional test checking the sterilizer during the start up phase and cannot prevent or detect possible malfunctions that may occur later during production.

To ensure the ongoing production of sterile goods, each batch must be monitored on a routine basis to detect possible malfunctions mentioned above. If NCGs entrained in the steam enter packs, steam will condense to water losing most of its volume and the NCGs will

accumulate in the packs as large “bubbles.” These “bubbles” can only be detected by an indicator strip, if the strip is inside one of those “bubbles”. NCGs will also be created inside of tubes and MIS instruments where indicators cannot be placed because of unavailable space. These problems remain undetected even though effective class 5 and 6 chemical indicators are used. These indicators can only monitor the sterility conditions at the location they are placed. Therefore they have to be placed inside each pack between the instruments with the disadvantage that in non-transparent packages the result of the sterilization process is not visible before the pack is opened. If class 5 or 6 indicators are placed at the surface of or between packs in the sterilizer chamber, they can only provide information about sterility at those places. They must not be placed outside of packs because false positive results may be indicated. During packing the containers and loading the sterilizer wrong positioning of indicators has to be prevented. This has to be secured by establishing requirements in SOPs. Helpful are examples of correct load configurations which are recommended in cooperation with hygienic organisations and manufacturers.

NCGs inside hollow lumen instruments (i.e. class B medical devices) will block entering steam to the inner surfaces of hollow instruments with the consequence that the sterilization process even though the correct temperature is achieved, will not occur correctly at those areas not getting wet.
The only way to effectively monitor steam penetration inside hollow lumens during routine sterilization is to simulate complex hollow instruments with a so-called Process Challenge Device (PCD). Those PCDs simulating the surgical instruments which are most difficult to sterilize are called Medical Device Simulators (MDS). Special indicators are placed in the worst penetration location inside the MDS. This combination of such a PCD with an indicator inside is referred to as an indicator system which is defined as a class 2 chemical indicator according to EN ISO 11140-1. The use of class 5 and class 6 chemical indicators inside a PCD is not sufficient, if the indicator has not been tested for that specific case, because those special indicators have to detect very small amounts of NCG, and PCD and indicator are forming a unit. Both the class 5 and class 6 indicators are not generally specified to detect small amounts of NCG.

If these PCDs can simulate not only an instrument but a full load inside a sterilizer, they may be used for batch monitoring. Such systems must be validated before use to ensure that they are more difficult to penetrate with steam than the most difficult part of the load. Monitoring systems are available for various applications. Manufacturers of sterilizers or instruments can help to select the right ones.

It is not easy to find out which instrument represents the most difficult air removal problem. For example air in tubes with both ends open is similarly difficult to remove as in tubes of half length with one open end. The belief that air is more difficult to remove from tubes with small diameter, than from tubes with larger diameter is not correct. An approximation is to compare the product of tube length and diameter of different hollow devices. This value is called hollow penetration resistance (HPR). The HPR of a BMS shall be always 30% above the HPR of the hollow instrument. Unfortunately besides the above mentioned geometrical factors also material characteristics, wall thickness, sealed surfaces etc. play an important role to determine the steam penetration characteristics. The monitoring system shall be selected only for a defined load. If a sterilizer is unable to remove air from an appropriate selected (see change of chemical indicators) monitoring system, the selected sterilizer or program is not appropriate for the sterilization of that load. Then either the air removal capability of the sterilizer has to be improved or the goods difficult to penetrate have to be removed of the load.

Currently different organizations try to defined standard load configurations for special purposes (e.g. for dentists) and batch monitoring systems are designed accordingly. If users sterilize such defined standard load configurations or less difficult loads, they can easily

monitor their load using the appropriate batch monitoring system. Also sterilizer manufacturers are asked to support the users.

It is important to place those systems at the bottom of the sterilizer close to the door. At this place there is the highest probability to find NCG and critical accumulations of NCG can be detected.

The benefit is, that the entire load can be released at the end of the sterilization process without checking indicators inside the packs, if the indicator inside the batch monitoring system has changed correctly. This way monitoring the successful sterilization of inner lumens in hollow devices and MIS instruments can be achieved. To allow backtracing, the relevant data of the process must be documented. Tracing is one of the requirements of EN ISO 13485 to conform with the standard for a quality management system for the production of medical devices.
All above considerations are valid for big and small sterilizers. There are no essential technological process differences inside big and small sterilizers. Big sterilizers and small sterilizers may be very different in their air removal characteristics, depending on air removal method used before the sterilization procedure is carried out.
The European standard for small sterilizers EN 13060 differentiates 3 sterilizer classes:

1. N-Type (cycle N)
   These sterilizers have no vacuum pump, the air is removed by gravity displacement with steam. These sterilizers should only be used for the sterilization of solid instruments without hollow lumens and without packaging and with adequate porous packaging materials. Monitoring shall be carried out with class 5 or 6 indicators positioned in the packs. (In this sterilizer type dental hand pieces cannot be sterilized.

2. B-Type (cycle B)
   These sterilizers have a fractionated vacuum for air removal and have to pass the Hollow A device test according to EN 867-5. In these sterilizers solid instruments, porous goods or complex hollow instruments can be sterilized. Monitoring for solid instruments can be carried out with class 5 or 6 indicator strips in the packs. For hollow devices a batch monitoring system has to be used.

3. S-Type (cycle S)
   These sterilizers have an air removal characteristic between N- and B-types, some have no vacuum pump and remove the air with overpressure cycles or other air removal combinations. They can sterilize solid instruments and porous goods safely. After validation they can also sterilize hollow devices of small length. Monitoring shall be carried out with class 5 or 6 indicators in each pack or with a simple batch monitoring system which has to be adapted to the used hollow instruments.

Appropriate use of chemical indicators:

1 On each pack a process indicator class 1 according to EN ISO 11140-1 (formerly class A in EN 867-1) is required to enable a differentiation between goods that already have been exposed to a sterilization process and those which are not sterilized yet. This indicator does not provide any information about the efficacy of the sterilizing process.

2. If vacuum sterilizers are used, a Bowie-Dick-Test shall be carried out at start up to show that the steam generator and pipes are correctly purged and the sterilizer is ready for use. (Tabletop sterilizers may not require a BD-Test as their steam is generated internally and there are no pipes to purge.)

3. If a recorder is installed, temperature and pressure over time shall be recorded. (Alternatively, the temperature-time-integral can be monitored with a class 2, 5 or 6 chemical indicator, provided that the specifications of the indicator match with the sterilization programme.)

4. To ensure the sterilization of solid instruments and porous loads, class 5 or class 6 chemical indicators have to be placed in each pack in the worst penetration location. Never place indicators outside of any packs or between packs. They may provide false positive results. (The use of chemical indicators inside packs is not necessary, if a batch monitoring system is used.)

5. If hollow devices (group B MDs) are sterilized, they can only be monitored inside their lumens using a validated MDS in the package or with a validated BMS for the whole batch. If BMS are used, they have to be placed at the bottom area near the door. At the end of the sterilization process the entire batch can be released when the indicator has changed successfully according to the instructions of the manufacturer. Additionally each pack has to be labelled (see point 6).

6. Each pack has to be labelled with a process indicator containing batch number, production and/or expiry date and the content of the pack to enable back-tracing of the packs to the process parameters documented in the CSSD.

7. All relevant data of the process (temperature- and pressure-time-window; chemical indicator test results; sterilizer number; batch number, BD-test reference information; product content of the batch; name of the person in charge and signed off with their signature) should be documented together for each batch in the CSSD.

Version: 2006-12-22