The international standard EN ISO 11140-1 describes the general requirements/ definitions for chemical indicators and divides them into different applications and colour change characteristics. The standard uses a classification of 6 different indicator **types** from 1 to 6. (In the former standard version the types were called classes.)

The number does not allow any conclusion about the quality, e.g. an indicator type "6" according to EN ISO 11140-1 is not "better" than an indicator type "2", but specifies different characteristics by application.

6 chemical indicator types are classified in EN ISO 11140-1:

1. **Process or "Exposure" indicators, Type 1**
   These indicators, e.g. autoclave tape, are fixed on the surface of the packages which are going to be sterilized. These indicators are not applicable to provide Information about the result of the sterilization process, but only document that the package has passed the sterilization process (logistic Information, no Information about sterility).

2. **Indicators for use in specific tests, Type 2 (indicator systems)**

   Those indicator systems have performance requirements, which are not described in the above Standard but in other Standards, e.g. the BD-test according to EN 285 or the helix test according to EN 867-5, which conforms to the GKE batch monitoring System. These tests have quite often higher requirements than indicators of type 3 to 6 described later on. Those specific tests consist of a PCD (process challenge device) with a chemical indicator inserted (see figure 1). Both components must be from the same manufacturer because the combination of PCD and indicator must be tested as one system. Their specifications are described in specific Standards. The test is carried out only in the combination using the indicator inside of the specified PCD. It does not make sense to determine the type of the indicator in the PCD since always the whole indicator system consisting of PCD and the indicator inside is tested for special characteristics. Their colour change has to be adapted to the humidity inside of the PCD when used in steam sterilization processes. Requirements specified in type 2 indicator systems describe the detection of NCG which are not specified in the requirements of type 3 to 6 indicators. They test air removal and steam penetration in hollow lumen instruments.

The following figure made with reference to a figure in EN ISO 11140-1 Annex E illustrates the different components of an indicator/indicator system.

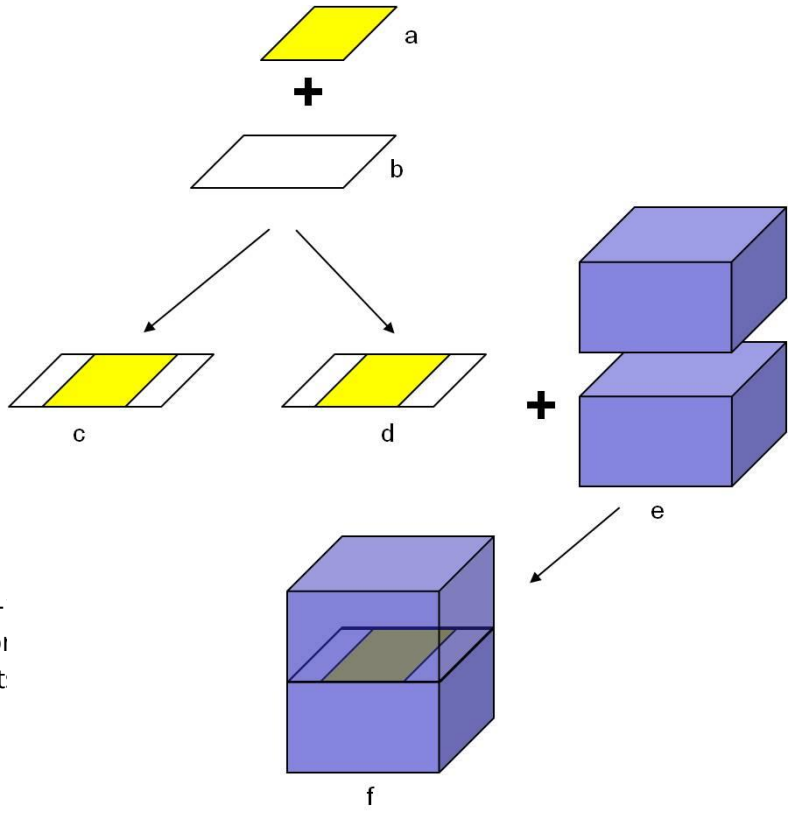
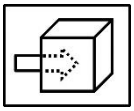


Fig. 1 according to EN ISO 11140-
Annex E: Relationship of indicato
and indicator system component
(by courtesy of DIN)

a = Indicator agent
b = Substrate
c = Indicator (to be used as such, e.g. process or package indicator **Type** 1, 3, 4, 5 or 6)
d = Indicator (to be used with a specific test load, e.g. inside a PCD)
e = Specific test load (PCD)
f = Indicator system (Type 2)

According to EN ISO 11140-1, clause 5.10 an indicator (d) for a specific test load (e) is marked to be used exclusively together with this test load with the following symbol:



Type 2 indicator systems manufactured by GKE for the Bowie-Dick-Simulation-Test and batch monitoring System consist of a PCD and an integrating chemical indicator inside. They can detect extreme small amounts of NCG and secure the penetration characteristics of steam into the most difficult internal lumens.

The chemical indicator strips used in GKE PCDs are consumables for those indicators (type 2) and have higher requirements than type 5 or 6 indicators. They do not have specific requirements to

NCG which are necessary for those indicators which are used inside of PCDs. The indicators in those PCD systems fulfil the specifications of type 5 or 6 but not vice versa.

3. **Single variable indicators, Type 3:**
   To monitor one parameter e.g., an achieved temperature. These indicators are only seldom used in sterilization processes.

4. **Multi-variable indicators, Type 4:**
   These indicators monitor two or more critical parameters relevant for the sterilization process, e.g., temperature over time. They are not sufficient to monitor the efficacy of most sterilization processes except dry heat and radiation sterilization processes because most other sterilization processes require monitoring the integral of all essential parameters.

5. **Integrating indicators, Type 5:**
   A multi-variable indicator should secure the whole sterilization process and provide the same information as standard biological indicators according to EN ISO 11138 series. All important physical and chemical specifications for the process have to be monitored. The temperature-time window (Stated Value at 121°C and 135°C and at one or more equally spaced temperature points in the range of 121° and 135°C) has to be described by the manufacturer. The fail conditions are -15 % (time) and -1°C (temperature) of the pass conditions.

   Note: Contrary to a common misunderstanding, the use of a type 5 indicator in PCDs is not possible. According to EN ISO 11140-1, a Type 2 indicator is a specified system where the PCD and detector must be tested together. If another indicator (as a detector) is used in the PCD, this changes the test characteristics dramatically. The Type 5 indicator may have different chemistry, carrier material, porosity, dimensions, etc., which greatly affects the test properties.

6. **Emulating indicators, Type 6:**
   Type 6 indicators have to monitor all critical parameters of the process and are used for special sterilization processes, e.g. shorter or longer sterilization times e.g. prion program of 18 min. The stated value for those indicators has to be described by the manufacturer. The fail conditions are -6% (time) and -1°C (temperature) of the pass conditions.

Especially in steam sterilization processes for type 5 and 6 indicators different opinions exist about which variables are critical and have to be monitored. The Standard describes in point 5.2 for steam sterilization processes that time, temperature and moisture are the critical variables while NCG as critical variables are not mentioned at all. Therefore type 5 and 6 indicators are not designed to monitor NCG. Indeed, homogenous mixtures of air and steam can sterilize solid instruments as long as air and steam are homogenously mixed and type 5 and 6 indicators will pass inside those steam/gas mixtures.
Because NCG as a critical variable is not mentioned in type 5 and 6 indicators for steam sterilization processes the general requirement that type 5 and 6 indicators should monitor all critical variable is only achieved exactly at the point they are located in the load. As a consequence, the use of type 5 and 6 indicators do not secure the sterilization efficacy of steam sterilization processes. Presently NCG can only be detected with indicator systems of type 2.

Accordingly, since type 5 and type 6 indicators are not designed to monitor NCG, but type 2 indicator systems have to monitor NCG, type 5 and type 6 indicators shall not be used as detectors inside of type 2 indicator systems which have to monitor NCG in addition.

Many users assume that type 5 and 6 indicators can successfully monitor the whole process. Due to their lack of detecting NCG, those indicators can only guarantee sterility at the location where the indicator is placed inside of a sterilization process but they cannot secure the whole load. The use of those indicators is historically justified with the wrong assumption that within a sterilization process homogenous conditions would exist within the whole sterilization chamber. Today we know that NCG accumulate in such places where no remix with steam can occur while steam during condensing to water is losing most of its volume. NCG volumes below 1 ml can lead already to an insufficient sterilization process in hollow devices like minimal invasive surgical (MIS) instruments.