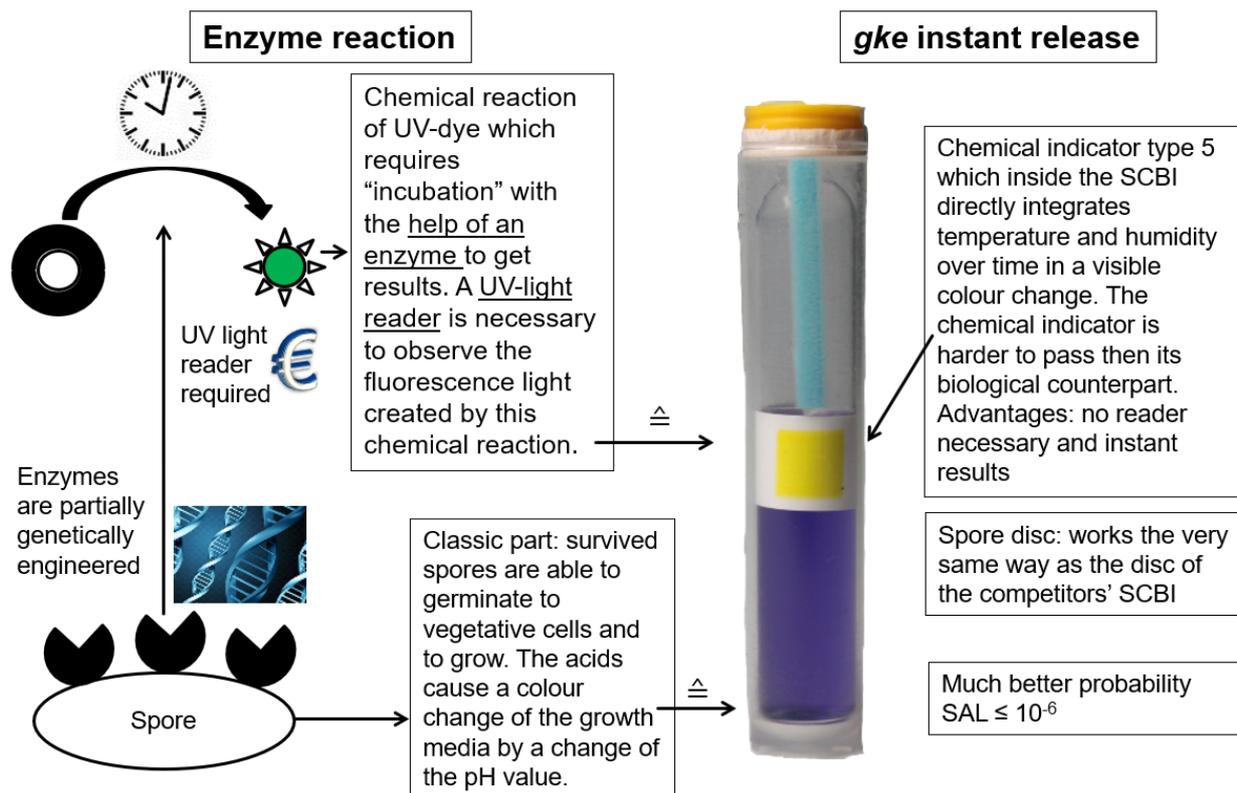


	Technical Information		730-165-EN	V03	
	Comparison of enzyme and chemical indicator based SCBIs		Created	14.11.2019	UK
			Changed	06.08.2021	KP
			Checked	06.08.2021	UK
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There are self-contained biological indicators (SCBI) for rapid or instant release on the market. The GKE Instant-SCBI is chemical indicator-based while competitors offer enzyme-based reading with the following differences:

- It will always take 30 – 180 min to incubate the enzymatic reaction of competitors' SCBI after sterilization. The chemical indicator of the GKE Instant-SCBI provides immediate information of the sterilization process without any incubation time.
- An expensive incubator with a UV-light and detector is required for competitive SCBI, because the enzymatic reaction generates fluorescence light, which is not visible with the human eyes.
- The cost of an enzymatic system is always higher than a chemical indicator which does the same but faster job.
- Some enzymatic SCBIs use genetic engineered organisms. Genetic engineered organisms in the environment are discussed, at least in Europe. This should be considered particularly for the use in hospitals and other medical facilities.
- The resistance of these genetically engineered organisms may be different than of the wild type organism found in nature.
- The sterility assurance level (SAL) of enzymatic SCBIs is only 10^{-2} while a pass based on chemical indicator is $\leq 10^{-6}$.



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Advantages of GKE Instant-SCBI in comparison to enzyme-based SCBI

1. Instant release, not waiting 0.5 or 3 h of enzyme-based SCBI
2. The probability of the GKE SCBI is $SAL = 10^{-6}$ while the enzyme-based SCBI provides only a probability of $SAL = 10^{-2}$ (between 1 and 3 SCBIs out of 100 grow after 24 h incubation) which provided before a full pass after 0.5 up to 3 h.
3. Enzyme-based SCBI require an expensive incubator with UV-light while GKE offers an inexpensive incubator. Alternatively the GKE SCBIs can be incubated in any other existing incubator.
4. The evaluation of GKE SCBIs is carried out by simple visual inspection without the necessity of transferring digital information to data files.
5. GKE can provide up to 10 different PCDs simulating the worst-case load configuration allowing to detect real sterility in hollow devices while the enzyme-based SCBI is used only a paper pack with a big hole of about 10 ml which provides no PCD characteristics not showing the required penetration characteristics of the load.
6. The GKE PCD system can provide sterility of complex MIS systems while the paper pack is even just good to demonstrate sterility for solid instruments only.