

MB ¹	Clause / subclause (e. g. 3.1)	Para-graph/ Figure/ Table (e. g. Table 1)	Type of comment ² (e. g. ed)	Comments: Justification for change	Proposed change	Observations of the secretariat on each comment submitted
FR	general		Ge	There have been so many discussions during the CEN/TC 102/WG5 meetings these years. The committee has recognised that the standard is not good enough and that its needs an immediate revision. It has approved to publish the standard EN 13060 as soon as possible in 2003 because of the lack of requirements and standard on the small steam sterilizers on the market (the standard EN 285 for the large steam sterilizers has been existing for years). The standard shall be consistent with the requirements and model of standards EN 285 and EN 554 ! There are many missed requirements (environment, service connections, insulating material, panelling, leak system, non condensable gases, ...), some mistakes about the values of temperatures and sensors, and the programme tests shall be revised.		
FR	introduction	Table 1	Te	No need to precise load A or B	Change to : "wrapped or non wrapped, solid, hollow load products and porous products"	
FR	3	definition	Te	Add the definition of non-condensable gas given in EN 285 clause 3.18	« non-condensable gas air and other gas which will not condense under the conditions of steam sterilization"	
FR	3		Te	Change the definition of saturated steam given in EN 285:1997 (not 200x)		
FR	4.3		Te	Add "Insulating material" as given in EN 285 clause 4.3.4	"Except where insulation would interfere with the function and operation of the sterilizer, external surfaces of the pressure vessel shall be insulated to reduce heat transmission to the environment."	
FR	4.3		Te	Add "panelling" as given in EN 285 clauses 4.4.1 and 4.4.2	"Where the sides of the sterilizer are visible from the operator area, they shall be enclosed with panelling. The	

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					<p>manufacturer shall provide instructions for the cleaning of the panelling.</p> <p>The panelling of the sterilizer shall allow access for maintenance work. Such panelling shall be demountable and the access shall not be obstructed.”</p>	
FR	4.3		Te	<p>Add leak system</p> <p>In the case of leak system, we need to propose a minimal value of the leak, as given in EN 285:1997 for the large steam sterilizers (it is so possible for the small ones)</p>	At least 70mBar	
FR	4.3.3.3		Te		Add “The filter shall be protected from any influence that may impair its proper function with a lid anti-return after the air filter ”	
FR	4.4.2.2	c	Te		Change 75°C to 50°C in accordance with 4.4.4.2.3	
FR	4.4.2.2	d	Te		Change 2°C to 1°C and 75°C to 50°C in accordance with 4.4.2.2. c) as proposed	
FR	4.4.2.2		Te		Add a point for the temperature sensors in accordance with 4.4.4.1.3	
FR	4.4.2.2	f	Te		The right resolution is 0.1°C and not 1°C ! it is an error (see EN 285)	
FR	4.4.2.2	g	Te		Change +/- 1,5°C to +/- 0,5°C (see EN 285)	
FR	4.4.2.3	g	Te		The right resolution is 1kPa and not 2kPa (see EN 285)	
FR	4.4.4.1.1		Te	Change “may” to “shall” (requirement, not a note)	“Recorders shall be either analogue or digital.”	

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FR	4.4.4.2.4	b	Te		Add "... (-1 bar to 3 bar) with respectively a reading of the zero in the atmospheric pressure and in the absolute vacuum"	
FR	4.4.4.3.3	Table 2	Te	It is not optional because it is the time of sterilization important to follow	Ts : time = x (not x ^a)	
FR	4.6.3	Time/temperature	Te		Add "... or national or regional regulations, for example, the Prion cycle 134°C – 18 min" (Taylor DM. Inactivation of transmissible degenerative encephalopathy agents : a review. Vet J 2000 ; 159 : 10-7)	
FR	4.7		Te	Add the description relative to the environment (as EN 285 clause 13.9) without the notion of humidity	"The sterilizer shall be designed to operate in an ambient temperature as specified in EN 61010-1."	
FR	4.7		Te	Add the description relative to the service connections (as EN 285 clause 13.10)	"The sterilizer shall be designed to operate with all service connections for fluids (e.g. water, steam, compressed air) provided with an isolating valve and terminating in accordance with the manufacturer's sterilizer specification."	
FR	4.7		Te	Add the requirements relative to non condensable gases (as EN 285 clauses 13.3.2, 13.3.3 and 13.3.4)	"The sterilizer shall be designed to operate with saturated steam containing up to 3,5 % V/V of non-condensable gases. Dryness value : The sterilizer shall be designed to operate with saturated steam with a dryness value down to 0,95 for metal loads and 0,90 for other types of load. Superheat : When the supplied steam is expanded to atmospheric pressure the superheat shall not exceed 25 °C."	
FR	4.7.3.2	a	Te		Add at the end of the sentence "For it, foresee any purge after the reservoir"	

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FR	4.7.3.2	g	Te		Add "g) the water shall not be recycled"	
FR	4.8.2.4	title	Te		Delete "on request"	
FR	5		Te		Add the description of Bowie-Dick (as EN 285 clause 8.3.2)	
FR	5		Te		Add the notion of acoustic power (as EN 285 clause 9)	
FR	5.3.2		Te		Add "hollow load A and B " and delete clause 5.3.3	
FR	5.3.2		Te	Consistence with EN 554 :	change the tolerance 4K to 3K	
FR	9	Table 4	Te		Add the tests of steam quality for the types B and S (type tests) as given in EN 285 table 4	
FR	9	Table 4	Te		Add the BD tests for the types B and S for all tests as given in EN285 table 4	
FR	9	Table 4	Te		Add the acoustic power for the types B, S and N (type tests) as given in EN285 table 4	
FR	9		Te		Add residual air test for type B (type tests) and see helix test	
FR	9		Te	Add work tests (documented) + BD or better helix test		
FR	Annex B	2sd para	Te		Change "... if due interpretation by operator..." to "...if needed interpretation by operator..."	

PROPOSED TESTS

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tests	STERILIZER TYPE B			
	TYPE	WORK	OQ	OP (performances)
Calibration of the equipment (recorder, supervision, controller of process Indicators)		X	X	A
Air leakage	X	X	X	A
Dynamic sterilizer chamber pressure	X			
Empty chamber	X	X	X	A
Test cycle of penetration of the steam for helix, BD...	X	X	X	A
Solid load, unwrapped	O	O		
Solid load, single wrapped	X	O		
Solid load, double wrapped	X	X3	X3	One load
Hollow load A	X	X3	X3	types (used
Hollow load B	O	O	O	and qualified OQ)
Small porous load, single wrapped	X	O		repeated 3 times
Small porous load, double wrapped	X	O		
Full porous load, single wrapped	O	O		
Full porous load, double wrapped	X	X3	X3	
Small porous items, single wrapped	X	O		
Small porous items, double wrapped	X	O	O	
Visual dryness non porous load/by weighed for porous load	X	X	X	Y

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Residual air (to discuss)	X	X			
micro-biological tests	X		O	O	
Y : yearly X : obligatory X3 obligatory repeatability (3 tests) O : optional					

tests	STERILZER TYPE S			
	TYPE	WORK	OQ	OP (performances)
Calibration of the equipment (recorder, supervision, controller of process Indicators)		X	X	A
Air leakage	X	X	X	A
Dynamic sterilizer chamber pressure	X			
Empty chamber	X	X	X	A
Test cycle of penetration of the steam for helix, BD...	X	X	X	A
Solid load, unwrapped	O	D X3	D X3	
Solid load, single wrapped	X	D X3	D X3	
Solid load, double wrapped	X	D X3	D X3	One load types (used and qualified OQ) repeated 3 times
Hollow load A	X	D X3	D X3	
Hollow load B	O	D X3	D X3	
Small porous load, single wrapped	X	D X3	D X3	
Small porous load, double wrapped	X	D X3	D X3	
Full porous load, single wrapped	O	D X3	D X3	
Full porous load, double wrapped	X	D X3	D X3	

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		Small porous items, single wrapped	X		D X3	D X3		
		Small porous items, double wrapped	X		D X3	D X3		
		Visual dryness non porous load/by weighed for porous load	X		D X3	D X3	A	
		Residual air (to discuss)	X		X			
		micro-biological tests	X			O	O	
Y : yearly X : obligatory X3 obligatory repeatability (3 tests) O : optional								

tests	STERILIZER TYPE N			
	TYPE	WORK	OQ	OP (performances)
Calibration of the equipment (recorder, supervision, Air leakage	X a	X a	X a	X a
Dynamic sterilizer chamber pressure Empty chamber	X	X	X	X
Test cycle of penetration of the steam for helix, BD...				
Solid load, unwrapped	X	X3	X3	X3
Solid load, single wrapped				
Solid load, double wrapped				
Hollow load A				
Hollow load B				
Small porous load, single wrapped				

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				Small porous load, double wrapped						
				Full porous load, single wrapped						
				Full porous load, double wrapped						
				Small porous items, single wrapped						
				Small porous items, double wrapped	X	X	X	X		
				Visual dryness non porous load/by weighed for porous						
				Residual air (to discuss)						
				^a IF AIR EXTRACTION BY UNDER VACUUM						

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