



17 / 20 NOVEMBER 2021 CICG, GENEVA, SWITZERLAND





Schweizerische Gesellschaft für Sterilgutversorgung Société Suisse de Stérilisation Hospitalière Societă Svizzera di Sterilizzazione Ospedaliera

A new way for pre-cleaning surgical medical devices using a bicarbonate solution under pressure with a machine Safe Clean Box STK 103-113 of Bicarjet

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Why not look for a new MD pre-cleaning technology for decentralized STERs based on pressurized sodium bicarbonate?

7 WD with 18 baskets
2 large WD with 56 baskets
Operating time 6/7 days 24 hours a day, plus an extra shift on Sundays
50 employees
Turnover corresponds to approximately 120 sterile units

Long waiting time before reprocessing \rightarrow More focus on pre-cleaning

 \rightarrow High risk of corrosion

Requirement: better pre-cleaning \rightarrow significant reduction in MDs to be returned for cleaning Significant drop in no of MDs to be sent for repair







Schweiszefeche Gezellschaft für Sachgebermergun Sectivi Sotze de Statistica Logaistike Sectivi Sotzere il Stavilizzatione Oppelitione

The test should not only prove the quality and efficiency of the pre-cleaning process but also provide a better estimate of the various influences on our daily production and management.

We receive the MDs twice a day, at 7 a.m. and 5 p.m. The sterile MDs are returned at 2 p.m. and 5 a.m.
2 highlights in wet areas production.

Upstream, quality controls were carried out through laboratory analyzes which guarantee that additional contamination of the MD cannot take place and therefore cannot impact the final level of disinfection.





Lab checks



Schemissehade Genetischeit: Ne Startigetrearenzen Sectioù Setere de Seletischen Konsientike Sectioù Sekater al Starffanziore (genetichere

20 St.	SIMICON 🎯	No Campi Materiale
	ätszertifikat	
Bio-Indikatoren zur Validien	tor SIMICON EF ung und Routinekontrolle von Endoskope nach ISO 15883-5.	Controllo St. aureur Enteroco Ps. aerug Enterobal
Testkeim:	Enterococcus faecium ATCC 6057	No Campi Materiale
mittlere Keimzahl (KBE): ermittelt durch Agar-Oberfläche Proteingehalt (µg): ermittelt durch OPA-Methode	$1,4 \times 10^9$ enmethode (TSA) > 5000	, Controllo St. aureur Enteroco
Keimträger: Verpackung:	Edelstahlplättchen V4A Papier / Folie	Ps. aerug Enterobal
Organische Belastung:	Schafblut und Additive	
Charge:	521220	No Campi Materiale
Verwendbar bis Ende:	03.2021	
Bebrütung:	4 Tage bei 35 °C ± 2 K in Enterokokkenselektivbouillon	Controllo St. aureur
Lagerung:	bei + 4 °C bis + 8 °C	Enteroco
Nach Ablauf der Haltbarkei vor der Entsorgung desinfiz	it nicht mehr verwenden und zieren.	
Datum: 18.12.2020	Freigabe: H. Urbansky	Samplin
STATCON CMBH • Sigmun	d-Riefler-Bogen 19 • D - 81829 München 66 0 • Fax: +49 / (0)89 / 67 33 66 22	Analyse

No Campione	257739	84	Data prelievo	30.03.2021
Materiale	Bio-Indi	kator	1	
	STERI	BIASCA		
	SIMICO	N EF - 15 secondi		
Controllo endoscopi		risultati conformi ai req	uisiti richiesti	
St. aureus		non reperibile in 1 ml		
Enterococchi/Strepto	alfa	non reperibile in 1 ml		
Ps. aeruginosa/non fe		non reperibile in 1 ml		
Enterobatteriacee		non reperibile in 1 ml		
No Campione	257739	85	Data prelievo	30.03.2021
Materiale	Bio-Ind	kator	2	
	STERI	BIASCA		
	SIMICO	N EF - 30 secondi		
Controllo endoscopi		risultati conformi ai req	uisiti richiesti	
St. aureus		non reperibile in 1 ml		
Enterococchi/Strepto	alfa	non reperibile in 1 ml		
Ps. aeruginosa/non fe	rmen	non reperibile in 1 ml		
Enterobatteriacee		non reperibile in 1 ml		
No Campione	257739	86	Data prelievo	30.03.2021
Materiale	Bio-Ind	ikator	3	
	STERI	BIASCA		
	SIMICO	N EF - 45 secondi		
Controllo endoscopi		risultati conformi ai req	uisiti richiesti	
St. aureus		non reperibile in 1 ml		
Enterococchi/Strepto	alfa	non reperibile in 1 ml		
De serusinoes/non fe	man	non reperibile in 1 ml		

Sampling using biological indicators with a running time of 15 to 60 seconds. Analyses performed by an external laboratory with known indicators and degree of contamination.





Lab checks



Die Zuordnung der Proben erfolgt durch den Auftraggeber.

	Res	tproteinnach	veis					
Probe C210319-022-1	OPA- Assay	BCA- Assay**	Hb nach- weisbar	Bemerkungen SMP	Anmerkungen des Validieren			
	Рâ	99						
9433	139	26	nein		Probica 2			
13751	37							
11769	84	32	nein	-				
9786	83	58	ja					
11167	212	53	nein	2	-			
11753	46				US + LAV			
14070	67							
9358	9							
9409	25	-		-				
9648	12				24			
9324	13				Bica + Lav			
14143	19	-		-				
7073	74							
7800	32			2				
11912	10	-		-	1.0			
9271	24	-	2		Pre + US			
11292	26							
8874	17			2				
11075	27	-		-				
9408	22		1.1	-	-			
9239	14	· · · ·			Pre/bica			
8366	15							
13777	15			-				
8135	15							
10114	17							

Use of contaminated clamps analyzed by an external lab.

The results of pre-treatment with sodium bicarbonate and change to WD (cycle interrupted after cleaning) are consistent.

We had to redo the first pure pre-cleaning test... in case we had to learn how to use the device !!





Protein residue test



iverizzelezio Geneloziarit de Sartigoverengun; e1906 Setere do Solellendine Ecosieziare electi Setzatez di Scottizzzione Azoriziatoro

The MDs were stained with sheep blood and protamine sulfate and left to dry for 4 hours.







Protein residue test after precleaning with STK 103-113

Test results still negative





Staff planning

INSEL 1

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In the first phase of test planning, 3 work breakdown scenarios were defined

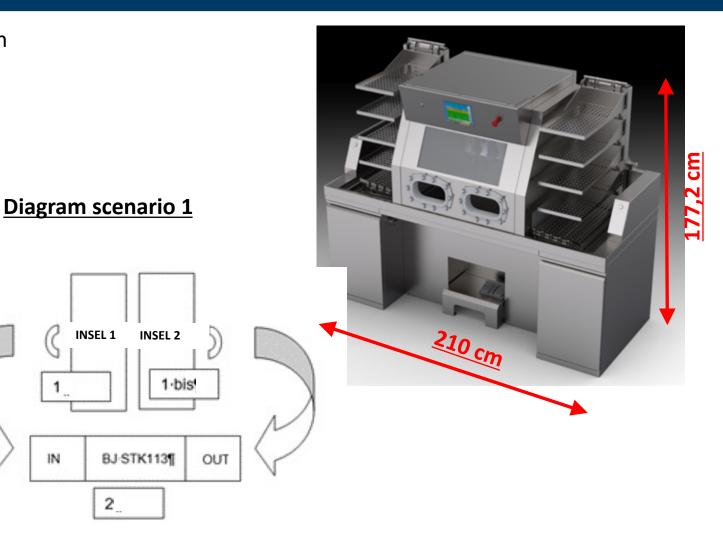
□ 1st scenario with 3 operators 1 operator preparing and loading the baskets 1 operator at STK 103-113 1 operator for STK 103-113 and emptying WD

2 2nd scenario with 4 operators

1 operator preparing and loading the baskets 1 operator at STK 103-113 1 operator emptying STK 103-113 1 person at the WD

□ 3nd scenario with 5 operators

1 operator in charge of receiving the MDs 1 operator preparing and loading the baskets 1 operator at STK 103-113 1 operator emptying STK 103-113 1 person at the WD









Schemizzeluche Casalischaft für Startigetwarnerper Section Setzen (10 Identification Receiveniller Societh Sekuten al Sco-Warnstown Agneticture

The following data were recorded during the test phase (daily and by shift):

- Number of employees involved
- Operation time
- □ Operation time STK 103-113
- Cleaning time STK 103-113
- □ Number of sets reprocessed per cycle
- □ Amount of sodium bicarbonate added
- Quantity of disinfectant used
- Number of individual protective measures

Feedback from the technical team monitoring the equipment and proposals from production staff







Process and description

SUSSV Scientizarizzie Genelischeit ihr Sertiger SUSSV Sectori Sriere de Hierlichten Konsteni SUSSV Sectori Srieren al Scriftanzione legend

Temporary installation for the test. The existing pre-cleaning area will of course be converted in the event of a purchase decision.



Images of sodium bicarbonate and disinfectant refills for the inside of the tank. Product approval by : <u>Dipartimento del territorio</u> <u>Divisione dell'ambiente</u> <u>Ufficio della gestione dei rischi ambientali e del suolo</u>









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Test of the 3 scenarios defined during the first days.

Result: scenarios 2 and 3 not applicable to our CSSD.

Too much unproductive time for employees at the start and end of the process: not efficient. For this reason we have focused on the scenario with 3 operators.

- 1 operator preparing and loading STK 103-113
 1 operator in charge of pre-cleaning with STK 103-113
- 1 operator in charge of emptying STK 103-113 and loading the WD holders



Successful integration of our 3 TDM apprentices in their 3rd year in this project.







chemisselecter Constituted für Startigebournerpung 1979) Setzer († 344-1834/184 Konstitut 1979) Setzer († Starförsstore Osperiktive

MDs divided into baskets as for the ultrasound tank, then positioned on the load support of the STK 103-113 and then introduced into the tank.







Remote control opens and closes doors and activates basket entry.

The water jet or rather the water jet combined with sodium bicarbonate and air is regulated with a foot pedal.



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Tweaking of the test for about 5 months.

□ Part 1 installation and training of the

technical staff

□ Laboratory tests

□ Training of shift supervisors

Training of operators

Production with the 3 scenarios

Programma lavori BicarMed STK113			-																									
			magg				glug	no				Lugi				Agos	ito					embre			Ottob			
ittività	Responsabile	Coinvolti	W18	W19	W20	W21	W22	W23	W24	W25	W26	W27	W28	W29	W30	W31	W32	W33	W34	W35	W36	W37	W38 1	W39	W40 V	V41 \	W42	N43
Indine macchina			1000											1	1.1.25		100											
reparazione istallazione macchina	Laloli	ST					1		1.1											1							1	
efinizione Superusers e gruppo operativo	Gruppo progetto			-											·													
Definizione DMX e test	Gruppo progetto																			-								
stallazione macchina	BicarJet	ST																										
ormazione manutenzione	BicarJet	ST																										
ormazione utilizzo ai "superusers"	BicarJet	Superusers																									_	
ormazione personale steri	Superusers	lista Balmelli									_																	
est a caldo modulística raccolta dati	Superusers	Operatori	-	-							-	-								-							_	_
est efficacia	BAT, SBT, VIA																										_	
nalisi test efficacia per definire processo da usare	Gruppo progetto																											
est compatibilità	BAT, SBT, VIA																											
nalisi test compatibilità per definire processo da usare																												
Itilizzo in produzione Modello 1	Superusers	lista Balmelli																										
Itilizzo in produzione Modello 2	Superusers	lista Balmelli			1	0.000																						
Itilizzo in produzione Modello 3	Superusers	lista Balmelli			-	100																						
Raccolta dati	Superusers	Gruppo progetto																										
a analisi dati raccolti e validazione processo	Gruppo progetto																											
inalisi dati e coerenza con il progetto	Gruppo progetto			1.		1.1			-											1		I						
ventuali richieste di modifica al fornitore	Gruppo progetto																		1.1									
ecisione acquisto o restituzione	Gruppo progetto			1.1																								
laborazione rapporto progetto x DG	Gruppo progetto																								0			
ecisione acquisto o restituzione	DG EOC	Gruppo progetto		-																-								
laborazione rapporto progetto finale	Gruppo progetto			1.		1.1														1								
laborazione rapporto x Bicarjet	Gruppo progetto																											

In production we ended up focusing only on the 3-person scenario that best suited our needs.







ineriaeleate Geoeffecteelt für Starthgeboernerpung 1990 Suites die Stiefflandene Konstentier 1996 Suites al Starifflandene Canadaithere

We work in CSSD with 3 levels of priority for the return of MDs to the OR

1 return for the next shift
2 return for the 2rd shift (24h)
3 return for the 3rd shift (36h)

OR requests 50% priority 1!

We decided to use STK 103-113 for priority 1 and compare the processing speed with the "traditional" process.

	ti in zona pulita lotti (05.10.21 0	9:54)			Totale ore ricomposizione: 19	D	Aggion
Priorità	Arrivo	Stato di produzione	ID set	Descrizione	Operatore	Clien	t RIC
Prioritario	05.10.21 06:34	IN ZONA PULITA	SET00376718	URETERORENOSCOPIO FLESSIBILE, IN PROVA OBV	Ingegneri G.	OBV	5
Prioritario	05.10.21 06:34	IN ZONA PULITA	SET00007533	POSA PIG TAIL + URS OBV	Dautaj L.	OBV	11
Prioritario	05.10.21 06:34	IN ZONA PULITA	SET00015711 •	VITI LCP 3,5, CORTICALI 2,7/3,5 - SPONGIOSE 4,0	Gandolfi L. A.	OBV	17
Prioritario	05.10.21 06:34	IN ZONA PULITA	SET00161147	PINZA PER CORPI ESTRANEI OBV	Aliti L.	OBV	3
Prioritario	05.10.21 06:34	IN ZONA PULITA	SET00170265	TRAPANO FISS. ESTERNO (3 PZ.) OBV	Aliti L.	OBV	3
rioritario	05.10.21 06:34	IN ZONA PULITA	SET00178657	TRAPANO A MANO OBV	Aliti L.	OBV	3
rioritario	05.10.21 06:34	IN ZONA PULITA	SET00019026	SET AMO OIL	Aliti L.	OIL	23
rioritario	05.10.21 06:34	IN ZONA PULITA	SET00145818	CUCCHIAIO PICCOLO CON DENTI	Aliti L.	OIL	3
rioritario	05.10.21 06:34	IN RICOMPOSIZIONE	SET00173302 •	COLIBRÌ II	Cairoli M.	OIL	27
rioritario	05.10.21 06:34	IN ZONA PULITA	SET00203831	COLIBRÌ II	Aliti L.	OIL	27
rioritario	05.10.21 06:34	IN ZONA PULITA	SET00409223	090 PICCOLA TRAUMA	Ingegneri G.	OIL	29
Prioritario	05.10.21 06:34	IN ZONA PULITA	SET00413052	090 PICCOLA TRAUMA	Ingegneri G.	OIL	29
rioritario	05.10.21 07:07	IN RICOMPOSIZIONE	SET00016553	BASE GINECOLOGIA OCL	Fazliu L.	OCL	26
rioritario	05.10.21 07:07	IN ZONA PULITA	SET00399613 •	SET EXPEDIUM KUHLEN COMPLETO OCL	Dautaj L.	OCL	18
Prioritario	05.10.21 07:24	IN ZONA PULITA	SET00000410	DIVARICATORE SPALLA ODL	Dautaj L.	ODL	5
Prioritario	05.10.21 07:24	IN ZONA PULITA	SET00013443 •	PLACCA PHILOS Ø 3,5	Dautaj L.	ODL	29
Prioritario	05.10.21 07:24	IN RICOMPOSIZIONE	SET00013746 •	PLACCHE METAFISARIE ODL	Lepore C.	ODL	36
Prioritario	05.10.21 07:24	IN ZONA PULITA	SET00400109	090 PICCOLA TRAUMA	Ingegneri G.	ODL	29
Prioritario	05.10.21 07:24	IN ZONA PULITA	SET00400164	090 PICCOLA TRAUMA	Ingegneri G.	ODL	29
rioritario	05.10.21 07:25	IN ZONA PULITA	SET00003234	PICCOLI INTERVENTI PEDIATRIA OSG	Dautaj L.	OSG	32
Rapido	04.10.21 12:11	IN ZONA PULITA	SET00414474	090 SET PICCOLO	Lepore C.	OCL	15
Rapido	04.10.21 16:27	IN ZONA PULITA	SET00000788	SENI PARANASALI OSG	Valente Veludo	OSG	28
Rapido	04.10.21 16:27	IN ZONA PULITA	SET00415348	090 SUPPLEMENTO SENO	Valente Veludo	ODL	8
Rapido	04.10.21 16:27	IN RICOMPOSIZIONE	SET00002541	SENI PARANASALI OSG	Travieso Cause	OSG	28
Rapido	04.10.21 16:27	IN ZONA PULITA	SET00214358	TROKAR 5.5 + MANDRINO OSG	Valente Veludo	OSG	4

At the same time, we were able to assess the effectiveness of STK 103!





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Comparison of processing times

Summary of MDs processed with STK-103-113										
KW	Anz. Set	Arb. Zeit	AnzMP	Zeit x MP						
28	106	17h30	3664	17.1"						
29	112	8h25	3447	8.8"						
30	125	17h73	4565	15.2"						
31	109	10h4	2660	14.0"						
32	63	5h4	1129	17.2"						
33	122	15h51	3662	15.2"						
34	61	11h	1255	31.5						
35	67	10h16	2914	18.6"						
Total	765		23296	17.2"						
2	÷									

Comparison with current process						
Anz. Set	Arb. Zeit	AnzMP	Tempo x MP "			
21	2h08	492	14.6"			
9	2h26	193	45.3"			
29	1h43	2074	2.9"			
10	2h11	373	20.3"			
22	2h58	1311	7.08"			
91	10h46	4443	8.4"			
	Anz. Set 21 9 29 10 22	Anz. Set Arb. Zeit 21 2h08 9 2h26 29 1h43 10 2h11 22 2h58	Anz. Set Arb. Zeit AnzMP 21 2h08 492 9 2h26 193 29 1h43 2074 10 2h11 373 22 2h58 1311			

In this case too, we recorded data using the same method.

From the opening of the sets to the loading in WD

1st finding ... with STK 103-113 it takes 2x as long!!but...

All MDs treated with STK 103-113 and processed in WD were perfectly clean. No MD had to be returned for cleaning.





SESV Schemissele SESV Schemissele SESV Sectors Set

civernizariacine Generalischen): Na Sizerligerbearmarpung artifoli Serten: die Siderligerdinan Kospilacitäre archeoli Serkennen al Sizerkiazarzioren Azpanistikare

Cost of consumables?

	Quantity	Price	Total costs
Sodium bicarbonate	64	36	2304
Disinfectant	2	270	540
Customs tax			342
Total costs of consumables			3186 €

			Cost	
	Total costs	Number o	f M B ser MD	
Costs per MD	3186	23296	0.14	€

Is it a lot? Is it low? For a final purchase decision the management also takes into account potential savings in terms of repair of MDs due to corrosion.

The next slides show images of MDs treated with STK 103-113.





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We immediately noticed that when using STK 103-113 the MDs were absolutely clean in the packaging area.

We encountered no problems with the cleaning of the MDs.

On the contrary, it was easier to identify MDs with significant corrosion problems.

These 3 DMx were processed with the STK 103-113 before being sent to the WD and showed no visible corrosion to the naked eye.

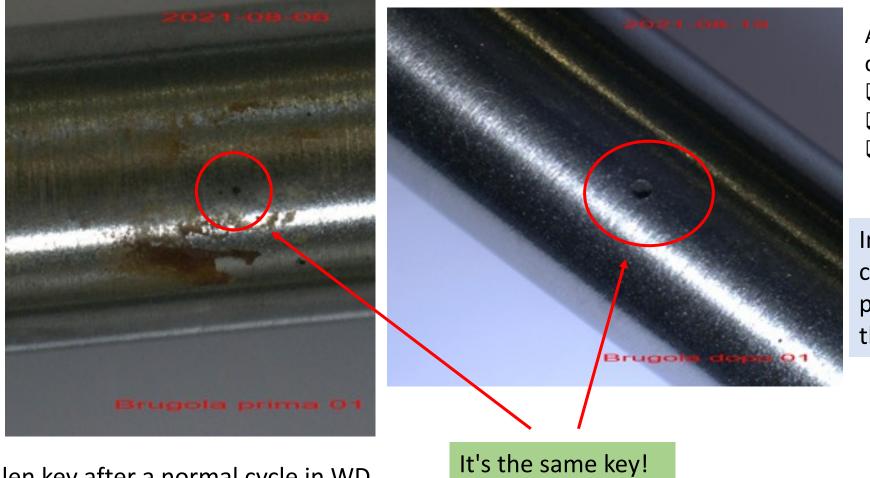
We were able to better detect problems thanks to STK 103-113







Serverizerlache Genelischeit die Start 2014 Section Server de Martinetten blau 2010 Section Setzen is Startizanione (m.



Allen key with precleaning
STK 103-113
Cycle in WD
Steam sterilization

In the case of surface or contact corrosion, it becomes possible to extend the life of the MD.



Allen key after a normal cycle in WD



SENV Scienciastasta (a SEN Scienciastasta (a SEN Science (b)







Example 2





Continuous testing

After 10 reprocessing cycles

STK 103-113 Standard program WD Steam sterilization

Needle holder after repair + normal cycle in WD. MD planned for the stock, but... look at the state of it...!



Again, the same MD!

Surfaces in much better condition



After 30 reprocessing cycles

STK 103-113 Standard program in WD Steam sterilization 134°C-18 min. (not used in OR)







iverviseriesine Geonifectuali für Startigerivernergung COVI Sertene die Nikellieurinen Konstitution cierie Serkuten al Startbizzasionen Deserktitere

2nd needle holder

Needle holder after repair + normal cycle in WD. MD planned for the stock, but... look at the state of it...!



After 10 reprocessing cycles

STK 103-113 Standard program in WD Steam sterilization



This test was conducted with 10 different instruments and the result was always convincing.



After 30 reprocessing cycles

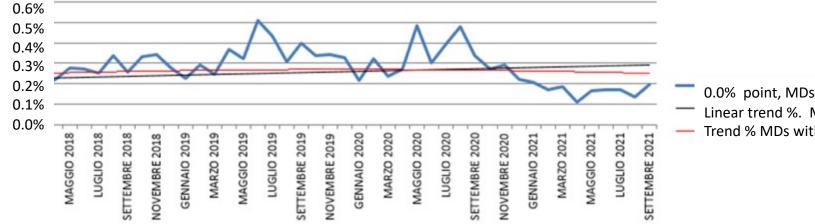
STK 103-113 WD standard program Steam sterilization 134°C-18 min. (not used in OR)





* 19 Schennisselecter Genetischeit: An Sierliger 19 Section Seiters die Statisticien Konsteinie 20 Section Sekenies of Statisticuscione Genetisch

Evidence of corrosion of MDs processed in CSSD



0.0% point, MDs with corrosion/MDs reprocessed Linear trend %. MDs with corrosion/MDs reprocessed Trend % MDs with corrosion/MDs reprocessed

Currently positive development in terms of corrosion... increasingly rare... certainly not only due to the use of STK 103-113... but we can affirm that the result was at least not negative.





Conclusion



From a technical point of view we can say that pre-cleaning with the STK 103-113 has improved the results!

Advantages

□ Better quality after cleaning in WD

- Better care of instrument surfaces
- □ Far fewer, if any, MDs requiring to be re-cleaned

Disadvantages

- □ Slightly higher costs of consumables
- □ Longer processing time
- □ New organization of the pre-cleaning process (staff must change their habits to some extend)
- Investment

Comments

- □ Longer processing time yes, but time is saved in repackaging without searching for clean MDs.
- □ Higher cost of consumables but less repair (a needle holder costs €20!)
- □ New organization, optimization will reduce time and costs





Thank you

chemischesise Gesellscheift Ale Starligebrennergung 1970) Suitze de Marillattine Konsientline 1979 Starlieu al Starlitzusione Ospeellichere

Thank you very much for your attention T. Balmelli Geneva 17-11-2021

In collaboration with Teresa Sbabo-Milano, shift manager Antonio Di Iorio, CSSD Manager



