

«Firma»	Our reference	FSCA C-126
«Straße» «Haus_Nr»	Message date	28.03.2023
«Plz» «Ort»	Edited by	Andy Ölsner
«Land»	Tel direct	+49 3671 5450 18
	Email	andy.oelsner@haag-streit.com

Field Safety Notice
Supplement to the labelling and instructions for use
Concerning the refraction units
Ecocentric
HS-810
Sinus

Addressee:

This Field Safety Notice is addressed to all HS Doms distributors and their customers.

Identification of the affected medical devices:

This corrective action affects the Ecocentric, Sinus and HS-810 refraction units, which are equipped with a 2-device table. Affected devices can be identified using the serial number on the nameplate. The nameplate is located on the back of the refraction unit, where the power supply cable is connected to the device. A list of affected serial numbers is attached.

Description of the problem including the determined cause:

At testing of the refraction unit, a non-compliance with the EN 60601-1 standard was determined. If the table is swivelled back in its extended position (position 2) without being pushed back to position 1 first, the refraction unit may tip over if you lean on the table in that state. If the refraction unit tips over, this can lead to serious injuries of the patient or user. The user is not informed sufficiently about this risk.

Which measures are to be taken by the addressee?

If you have used table instrument 2 and want to bring the table to its rest position, always first slide the table back to position 1 and only then swing it back into the rest position. Do not lean on or sit on the table.

With this letter you will receive a "No Sitting" sticker and a supplement to the instructions for use. Stick the sticker on the instruments table in a clearly visible place.

HS DOMS GmbH

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07318 Saalfeld, Germany
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Managing Director: Matthias Stahl
Commerzbank Saalfeld
IBAN: DE 16 8204 0000 0655 3259 00
SWIFT (BIC): COBADEFFXXX
VAT ID : DE298090449

The supplement to the instructions for use contains a safety notice for the further safe use of the refraction unit, which must be observed. Please add this supplement to your instructions for use and keep both together.

Please fill out the enclosed confirmation of receipt and send it to the address given there .

Disclosure of the information described here:

Please ensure in your organization that all users of the above products and other persons who need to be informed are aware of this **Field Safety Notice**. If you have given the products to a third party, please forward a copy of this information or inform the contact person given below.

Please keep this information at least until the action has been completed.

The Federal Institute for Drugs and Medical Devices has received a copy of this "urgent safety information".

Contact person:

If you have any questions about this corrective action, you can contact the following person:

Mr Andy Ölsner

Phone +49 3671 5450-18

Email: andy.oelsner@haag-streit.com

We regret any inconvenience caused and apologize for it.

Best regards

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Device serial numbers affected by the FSCA C-126

Ecocentric

HD00967	HD00970	HD00971	HD00976	HD00975	HD00980	HD00981	HD00983
HD00984	HD00985	HD00986	HD00987	HD00989	HD00990	HD00991	HD00992
HD00993	HD00994	HD00995	HD00997	HD00999	HD01000	HD01002	HD01005
HD01006	HD01007	HD01008	HD01011	HD01012	HD01013	HD01016	HD01017
HD01019	HD01020	HD01025	HD01029	HD01030	HD01031	HD01032	HD01033
HD01034	HD01035	HD01036	HD01037	HD01038	HD01039	HD01040	HD01041
HD01042	HD01043	HD01044	HD01047	HD01048	HD01049	HD01050	HD01051
HD01052	HD01053	HD01058	HD01061	HD01063	HD01069	HD01070	HD01071
HD01072	HD01074	HD01075	HD01076	HD01077	HD01078	HD01079	HD01080
HD01081	HD01082	HD01083	HD01084	HD01085	HD01086	HD01087	HD01091
HD01092	HD01093	HD01094	HD01095	HD01096	HD01097	HD01098	HD01102
HD01103	HD01104	HD01105	HD01106	HD01108	HD01109	HD01110	HD01111
HD01112	HD01113	HD01114	HD01115	HD01116	HD01117	HD01118	HD01119
HD01121	HD01122	HD01123	HD01124	HD01125	HD01126	HD01127	HD01128
HD01129	HD01130	HD01131	HD01132	HD01133	HD01134	HD01135	HD01136
HD01137	HD01139	HD01140	HD01145	HD01146	HD01150	HD01151	HD01152
HD01153	HD01154	HD01155	HD01156	HD01157	HD01158	HD01160	HD01161
HD01163	HD01167	HD01168	HD01169	HD01170	HD01171	HD01175	HD01176
HD01178	HD01179	HD01180	HD01181	HD01182	HD01183	HD01184	HD01185
HD01186	HD01191	HD01192	HD01198	HD01199	HD01201	HD01203	HD01204
HD01205	HD01206	HD01207	HD01208	HD01209	HD01210	HD01215	HD01220
HD01221	HD01222	HD01223	HD01225	HD01226	HD01227	HD01228	HD01231
HD01240	HD01241	HD01243	HD01250	HD01251	HD01253	HD01254	HD01255
HD01256	HD01259	HD01278	HD01280	HD01281	HD01282	HD01302	HD01304
HD01305	HD01306	HD01307	HD01308	HD01315	HD01331	HD01332	HD01333
HD01334	HD01335	HD01336	HD01339	HD01340	HD01341	HD01348	HD01349
HD01352	HD01367	HD01396	HD01398	HD01408	HD01410	HD01417	HD01418
HD01419	HD01420	HD01421	HD01422	HD01425	HD01426	HD01427	HD01437
HD01442	HD01443	HD01445	HD01446	HD01447	HD01448	HD01459	HD01460
HD01463	HD01465	HD01470	HD01474	HD01475	HD01482	HD01483	HD01484
HD01485							

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Sinus

ES00316	ES00317	ES00318	ES00319	ES00320	ES00321	ES00322	ES00323
ES00324	ES00325	ES00326	ES00327	ES00328	ES00329	ES00330	ES00331
ES00332	ES00333	ES00334	ES00335	ES00336	ES00337	ES00338	ES00339
ES00340	ES00341	ES00342	ES00343	ES00344	ES00345	ES00346	ES00347
ES00348	ES00349	ES00350	ES00351	ES00352	ES00353	ES00354	ES00355
ES00356	ES00357	ES00358	ES00359	ES00360	ES00361	ES00362	ES00363
ES00364	ES00366	ES00367	ES00369	ES00370	ES00371	ES00372	ES00373
ES00374	ES00375	ES00376	ES00377	ES00378	ES00379	ES00380	ES00381
ES00382	ES00383	ES00384	ES00385	ES00386	ES00387	ES00388	ES00389
ES00390	ES00391	ES00392	ES00393	ES00394	ES00395	ES00396	ES00397
ES00398	ES00399	ES00400	ES00401	ES00402	ES00403	ES00404	ES00405
ES00406	ES00407	ES00408	ES00409	ES00410	ES00411	ES00412	ES00413
ES00414	ES00415	ES00416	ES00417	ES00418	ES00419	ES00420	ES00421
ES00422	ES00423	ES00424	ES00425	ES00426	ES00427	ES00428	ES00429
ES00430	ES00431	ES00432	ES00433	ES00434	ES00435	ES00436	ES00437
ES00438	ES00439	ES00440	ES00441	ES00442	ES00443	ES00444	ES00445
ES00446	ES00447	ES00448	ES00449	ES00450	ES00451	ES00452	ES00453
ES00454	ES00455	ES00456	ES00457	ES00458	ES00459	ES00460	ES00461
ES00462	ES00463	ES00464	ES00465	ES00466	ES00467	ES00468	ES00469
ES00470	ES00471	ES00472	ES00473	ES00474	ES00475	ES00476	ES00477
ES00478	ES00479	ES00480	ES00481	ES00482	ES00483	ES00484	ES00485
ES00486	ES00487	ES00488	ES00489	ES00490	ES00491	ES00492	ES00493
ES00494	ES00495	ES00496	ES00497	ES00498	ES00499	ES00500	ES00501
ES00502	ES00503	ES00504	ES00505	ES00506	ES00507	ES00508	ES00509
ES00510	ES00511	ES00512	ES00513	ES00514	ES00515	ES00516	ES00517
ES00518	ES00519	ES00520	ES00521	ES00522	ES00523	ES00524	

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HS-810

HD00520	HD00521	HD00524	HD00525	HD00526	HD00527	HD00528	HD00529
HD00530	HD00531	HD00533	HD00534	HD00535	HD00536	HD00537	HD00538
HD00539	HD00540	HD00541	HD00542	HD00543	HD00544	HD00545	HD00547
HD00548	HD00549	HD00551	HD00552	HD00553	HD00554	HD00555	HD00556
HD00557	HD00558	HD00559	HD00560	HD00561	HD00562	HD00563	HD00564
HD00565	HD00566	HD00567	HD00568	HD00569	HD00570	HD00571	HD00572
HD00573	HD00574	HD00575	HD00576	HD00577	HD00578	HD00579	HD00580
HD00581	HD00582	HD00583	HD00584	HD00585	HD00586	HD00587	HD00588
HD00589	HD00590	HD00591	HD00592	HD00593	HD00594	HD00595	HD00596
HD00597	HD00598	HD00599	HD00600	HD00601	HD00602	HD00603	HD00604
HD00605	HD00606	HD00607	HD00608	HD00609	HD00610	HD00611	HD00612
HD00613	HD00614	HD00615	HD00616	HD00617	HD00618	HD00620	HD00621
HD00622	HD00623	HD00624	HD00625	HD00626	HD00627	HD00628	HD00629
HD00630	HD00631	HD00632	HD00633	HD00634	HD00635	HD00636	HD00637
HD00638	HD00640	HD00641	HD00642	HD00643	HD00644	HD00645	HD00646
HD00647	HD00648	HD00649	HD00650	HD00651	HD00652	HD00653	HD00654
HD00655	HD00656	HD00657	HD00658	HD00659	HD00660	HD00661	HD00662
HD00663	HD00664	HD00665	HD00666	HD00667	HD00668	HD00669	HD00670
HD00671	HD00672	HD00673	HD00674	HD00675	HD00676	HD00677	HD00678
HD00679	HD00680	HD00681	HD00682	HD00683	HD00684	HD00685	HD00686
HD00687	HD00688	HD00689	HD00690	HD00691	HD00692	HD00693	HD00694
HD00695	HD00696	HD00697	HD00698	HD00699	HD00700	HD00701	HD00702
HD00703	HD00704	HD00705	HD00706	HD00707	HD00708	HD00709	HD00710
HD00711	HD00712	HD00713	HD00714	HD00715	HD00716	HD00717	HD00718
HD00719	HD00720	HD00721	HD00722	HD00723	HD00724	HD00725	HD00726
HD00727	HD00728	HD00729	HD00730	HD00731	HD00732	HD00733	HD00734
HD00735	HD00736	HD00737	HD00738	HD00739	HD00740	HD00741	HD00742
HD00743	HD00744	HD00745	HD00746	HD00747	HD00748	HD00749	HD00750
HD00751	HD00752	HD00753	HD00754	HD00755	HD00756	HD00757	HD00758
HD00759	HD00760	HD00761	HD00762	HD00763	HD00764	HD00765	HD00766
HD00767	HD00768	HD00769	HD00770	HD00771	HD00772	HD00773	HD00774
HD00775	HD00776	HD00777	HD00778	HD00779	HD00780	HD00781	HD00782
HD00783	HD00785	HD00786	HD00787	HD00788	HD00789	HD00790	HD00791
HD00792	HD00793	HD00794	HD00795	HD00796	HD00797	HD00798	HD00799
HD00800	HD00801	HD00802	HD00804	HD20001	HD20003	HD20004	HD20005
HD20006	HD20007	HD20008	HD20009	HD20010			

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Supplement for instructions for use



Warning!

Do not lean on, sit on or climb on the instruments table. This is especially true when the table is extended (position 2). Do not swing the table back when it is extended. Failure to do so could result in the unit tipping over, which can lead to serious injuries.

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Acknowledgment of receipt

Corrective Action: C-126
Date: 24.04.2023
Affected Products: Ecocentric
Sinus
HS-810

I confirm that I have received this corrective action, FSCA number C-126, and that I have read and understood the information sent. I have forwarded the information to all relevant people and organizations.

Organization / Company: _____

Surname, first name: _____

Place, date: _____

Signature: _____

Please email the completed and signed form to andy.oelsner@haag-streit.com.