URGENT MEDICAL DEVICE CORRECTION
URGENT FIELD SAFETY NOTICE

Subject:	Additional Safeguards available to Users of Conical Collimator Accessories for Radiosurgery Treatments
Commercial Name of Affected Product:	Clinac, Trilogy, Trilogy Tx and Novalis Tx
Reference / FSCA Identifier:	CP-01891, 2011 release
Date of Notification:	**2011-08-2**
Type of Action:	Notification and Correction
Details on Affected Devices:	Refer to appendices pages.

Description of Problem:

In a warning dated in October 2009, Varian Medical Systems notified users of all C-Series Clinac, Trilogy, Trilogy Tx and Novalis Tx platforms, advising of risks when using conical collimator accessories with these platforms for Stereotactic Radiosurgery (SRS) treatments.

That notification was in response to Varian becoming aware of incidents in which SRS treatments had taken place with the intended conical collimator accessory not installed, or with the conical collimator accessory correctly mounted, but with a primary collimator field size setting which exceeded the outside diameter of the conical collimator.

Details:

<u>Previous Mitigations and Actions</u>

Varian previously advised users performing treatments using conical collimator accessories to establish Quality Assurance (QA) protocols which:

1. Ensured the correct conical collimator and conical collimator mount was in place prior to initiating treatment.

2. Ensured the field size setting was correctly within (smaller than) the outside diameter of the conical collimator accessory in use.

3. Verified that the treatment planning system and/or patient data system features intended to ensure correct prescription definition and transfer are enabled and operating correctly.

URGENT MEDICAL DEVICE CORRECTION
URGENT FIELD SAFETY NOTICE

Varian previously took the following actions:

1. Notified potentially affected customers of Varian products with the October 2009 letter.

2. Distributed a safety warning decal with CTB-ZM-783 in January 2011 to Varian C-Series customers that attaches to the conical collimator mount or Clinac Interface Mount to help reinforce the October 2009 warnings at the time of treatment.

3. Added a warning to the Clinac Safety Manual about checking the primary field size when using conical collimator accessories.

4. Continued to investigate technical means for improving verification of accessories.

New Mitigation and Actions

As a result of Varian's continued investigation of technical means for improving verification of accessories as described above, Varian has now developed a new system called Barcode Conical Collimator Verification (BCCV). It includes a wireless hand-held barcode scanner to be used inside the treatment room in conjunction with barcode decals that adhere directly to the conical collimators and conical collimator mount. BCCV allows facilities to configure their systems such that the conical collimator mount, the conical collimator(s) as defined in the treatment plan and the primary collimator jaws ("field size") are within user-defined limits.

BCCV is an add-on that will be provided at no additional charge to any institution meeting the configurations below. This add-on will require approximately four (4) hours to install. On-line user training and dedicated Instructions For Use (IFU) are also included at no additional charge.

Recommended User Action
Please contact your Varian Customer Support District or Regional Manager to request the BCCV add-on free of charge if:

1. The serial number of your Varian linear accelerator is in Appendix A

2. You are using Brainlab, Integra or other third-party conical collimators

3. Your accelerator is configured with 4D ITC (all versions)

4. You have ARIA v.8.0 or higher
   OR
   VARiS Vision v.6.5 or higher
   OR
   Elekta (IMPAC) MOSAIQ™ 1.6 or higher

Note that some configurations may have limitations.

URGENT MEDICAL DEVICE CORRECTION
URGENT FIELD SAFETY NOTICE

Please contact the Varian Oncology Help Desk using the information provided below, if you have any questions about this notification or would like additional information about your use of conical collimators or BCCV.

Varian Actions:

Customers of the linear accelerator serial numbers in Appendix B "LIST OF AFFECTED DEVICE SERIAL NUMBERS." will be contacted by Varian to install this BCCV add-on provided that the following minimum compatibility requirements are met and pending local National Regulatory clearance for product distribution:

1. Varian linear accelerators using Varian (Zmed) Conical Collimators
   OR
   Varian Trilogy, Trilogy Tx, or Novalis Tx platforms used with Brainlab Conical Collimators

2. 4D ITC (all versions)

3. ARIA v.8.0 or higher
   OR
   VARiS Vision v.6.5 or higher
   OR
   Elekta (IMPAC) MOSAIQ™ 1.6 or higher

Note that some configurations may have limitations.

MOSAIQ users should contact Elekta directly to apply the required configuration settings, or for related questions. If you do not meet the minimum compatibility requirements and wish to obtain further information about BCCV, contact the Varian Oncology Help Desk using the information provided below.

Please advise the appropriate personnel working in your radiotherapy department of the content of this letter.

We sincerely apologize for any inconvenience and thank you in advance for your cooperation. If you require further clarification, please feel free to contact your local Varian Customer Support District or Regional Manager.

The undersigned confirms that this notice has been provided to the appropriate Regulatory Agency.

[redacted] _____ ___2011-08-2___

[redacted] Manager Reporting and Corrections Date

URGENT MEDICAL DEVICE CORRECTION
URGENT FIELD SAFETY NOTICE

Varian Oncology Help Desk Contact Information:

Phone:	USA and Canada – 1-888-VARIAN5 (888- 827-4265) Europe **-** +41 41 749 8844
Email:	North America: support-americas@varian.com Australia/New Zealand: support-anz@varian.com Europe: support-emea@varian.com South East Asia: seasia.apps.helpdesk@varian.com China / Asia: china.apps.helpdesk@varian.com Japan: Japan.Apps.Helpdesk@varian.com Latin America: soporte.al@varian.com
Internet:	Oncology Systems customer site - www.myvarian.com Varian Medical Systems public site - www.varian.com

URGENT MEDICAL DEVICE CORRECTION
URGENT FIELD SAFETY NOTICE

APPENDIX A
LIST OF SERIAL NUMBERS OF VARIAN ACCELERATORS POTENTALLY USING Brainlab, INTEGRA OR OTHER THIRD-PARTY CONICAL COLLIMATORS.
The last four digits represent the serial number of the device.

H140001	H140070	H140133	H140710	H140792	H140869	H180004	H180167	H180272	H180440	H180520	H180587	H180660
H140002	H140072	H140134	H140711	H140793	H140870	H180007	H180168	H180273	H180441	H180521	H180588	H180661
H140003	H140073	H140135	H140712	H140794	H140871	H180008	H180170	H180275	H180442	H180522	H180590	H180662
H140005	H140074	H140136	H140713	H140795	H140872	H180017	H180171	H180283	H180443	H180524	H180591	H180663
H140007	H140075	H140137	H140714	H140796	H140873	H180019	H180173	H180284	H180444	H180525	H180592	H180664
H140008	H140076	H140138	H140715	H140798	H140874	H180025	H180178	H180285	H180445	H180527	H180593	H180665
H140009	H140077	H140139	H140717	H140800	H140875	H180026	H180179	H180287	H180446	H180528	H180595	H180667
H140010	H140078	H140140	H140718	H140801	H140876	H180028	H180181	H180289	H180447	H180529	H180596	H180668
H140011	H140079	H140141	H140720	H140802	H140877	H180040	H180182	H180291	H180449	H180530	H180597	H180669
H140012	H140080	H140142	H140722	H140803	H140878	H180043	H180185	H180292	H180450	H180531	H180598	H180670
H140014	H140082	H140143	H140724	H140804	H140879	H180044	H180186	H180293	H180451	H180532	H180599	H180671
H140015	H140083	H140144	H140726	H140805	H140881	H180045	H180188	H180294	H180452	H180533	H180600	H180672
H140017	H140084	H140145	H140728	H140807	H140884	H180048	H180192	H180295	H180453	H180534	H180601	H180676
H140019	H140085	H140146	H140729	H140810	H140885	H180049	H180193	H180296	H180454	H180535	H180603	H180678
H140021	H140086	H140147	H140730	H140811	H140886	H180050	H180195	H180298	H180455	H180538	H180604	H180679
H140022	H140087	H140148	H140731	H140812	H140887	H180053	H180197	H180299	H180456	H180539	H180605	H180680
H140024	H140088	H140149	H140732	H140813	H140888	H180056	H180199	H180303	H180457	H180540	H180606	H180681
H140025	H140089	H140150	H140734	H140814	H140890	H180058	H180201	H180304	H180459	H180541	H180607	H180682
H140026	H140090	H140151	H140736	H140815	H140892	H180059	H180203	H180305	H180460	H180542	H180608	H180683
H140027	H140091	H140153	H140738	H140816	H140893	H180065	H180204	H180307	H180461	H180543	H180613	H180684
H140028	H140092	H140154	H140739	H140818	H140895	H180066	H180206	H180309	H180463	H180544	H180614	H180685
H140029	H140093	H140201	H140740	H140819	H140897	H180073	H180208	H180310	H180467	H180545	H180616	H180687
H140030	H140094	H140203	H140744	H140821	H140898	H180075	H180209	H180311	H180468	H180548	H180618	H180690
H140031	H140095	H140205	H140745	H140822	H140899	H180079	H180214	H180312	H180469	H180549	H180619	H180691
H140032	H140096	H140206	H140747	H140823	H140900	H180080	H180215	H180314	H180471	H180550	H180620	H180692
H140033	H140097	H140207	H140748	H140825	H140901	H180082	H180217	H180318	H180472	H180551	H180621	H180693
H140034	H140099	H140208	H140749	H140826	H140902	H180083	H180218	H180319	H180473	H180552	H180622	H180694
H140035	H140100	H140211	H140750	H140827	H140903	H180087	H180220	H180321	H180474	H180553	H180624	H180695
H140036	H140101	H140212	H140751	H140828	H140904	H180088	H180221	H180322	H180475	H180554	H180625	H180696
H140037	H140102	H140215	H140752	H140831	H140906	H180093	H180222	H180323	H180476	H180555	H180626	H180697
H140038	H140103	H140216	H140754	H140832	H140907	H180098	H180225	H180324	H180477	H180556	H180627	H180703
H140039	H140105	H140219	H140755	H140833	H140908	H180102	H180226	H180325	H180478	H180557	H180628	H180704
H140040	H140106	H140220	H140758	H140834	H140909	H180106	H180228	H180326	H180479	H180559	H180629	H180705
H140041	H140107	H140222	H140759	H140835	H140912	H180107	H180229	H180327	H180480	H180560	H180630	H180706
H140042	H140108	H140224	H140761	H140838	H140913	H180108	H180230	H180328	H180482	H180561	H180631	H180707
H140043	H140109	H140225	H140762	H140839	H140916	H180115	H180235	H180329	H180484	H180562	H180632	H180709
H140044	H140110	H140226	H140763	H140841	H140917	H180117	H180236	H180401	H180485	H180563	H180633	H180710
H140045	H140111	H140227	H140764	H140842	H140918	H180119	H180237	H180402	H180486	H180564	H180634	H180715
H140047	H140112	H140228	H140767	H140843	H140920	H180122	H180238	H180404	H180487	H180565	H180635	H180716
H140048	H140113	H140229	H140768	H140845	H140921	H180124	H180240	H180405	H180489	H180566	H180636	H180718
H140049	H140114	H140230	H140769	H140846	H140923	H180128	H180242	H180407	H180490	H180567	H180639	H180719
H140051	H140115	H140231	H140770	H140847	H140925	H180129	H180243	H180410	H180491	H180569	H180640	H180720
H140052	H140116	H140232	H140771	H140848	H140926	H180131	H180245	H180411	H180493	H180570	H180641	H180721
H140053	H140117	H140233	H140772	H140850	H140927	H180132	H180246	H180412	H180494	H180571	H180642	H180722
H140054	H140118	H140234	H140774	H140851	H140929	H180133	H180249	H180413	H180495	H180572	H180643	H180723
H140055	H140119	H140235	H140775	H140852	H140930	H180135	H180250	H180414	H180496	H180573	H180644	H180724
H140056	H140120	H140236	H140776	H140853	H140931	H180143	H180251	H180417	H180498	H180574	H180645	H180725
H140057	H140121	H140238	H140778	H140858	H140932	H180144	H180254	H180419	H180499	H180575	H180646	H180726
H140058	H140122	H140239	H140779	H140859	H140933	H180147	H180255	H180420	H180501	H180576	H180647	H180728
H140059	H140123	H140240	H140782	H140860	H140935	H180148	H180256	H180422	H180505	H180577	H180649	H180731
H140060	H140125	H140700	H140784	H140861	H140938	H180151	H180257	H180424	H180507	H180578	H180650	H180733
H140061	H140126	H140701	H140785	H140862	H140940	H180154	H180258	H180425	H180508	H180579	H180651	H180734
H140062	H140127	H140703	H140786	H140863	H140941	H180157	H180260	H180426	H180510	H180580	H180652	H180735
H140063	H140128	H140704	H140787	H140864	H140944	H180158	H180262	H180427	H180511	H180581	H180653	H180736
H140064	H140129	H140705	H140788	H140865	H140945	H180159	H180264	H180432	H180513	H180583	H180654	H180737
H140065	H140130	H140707	H140789	H140866	H140947	H180161	H180267	H180433	H180514	H180584	H180655	H180738
H140068	H140131	H140708	H140790	H140867	H149999	H180164	H180268	H180436	H180515	H180585	H180657	H180739
H140069	H140132	H140709	H140791	H140868	H180003	H180166	H180271	H180437	H180519	H180586	H180659	H180741

URGENT MEDICAL DEVICE CORRECTION
URGENT FIELD SAFETY NOTICE

H180717	H180832	H181009	H181094	H181168	H260940	H270270	H270419	H270525	H270685	H270800	H270889	H271085
H180742	H180833	H181010	H181095	H181170	H260942	H270271	H270420	H270529	H270686	H270801	H270890	H271086
H180745	H180834	H181011	H181096	H181173	H260944	H270273	H270421	H270530	H270692	H270803	H270891	H271088
H180746	H180836	H181012	H181097	H181174	H260947	H270274	H270425	H270532	H270693	H270805	H270892	H271091
H180747	H180837	H181013	H181098	H181175	H260948	H270277	H270426	H270534	H270697	H270806	H270893	H271092
H180749	H180838	H181015	H181101	H181176	H260949	H270280	H270427	H270535	H270698	H270808	H270894	H271093
H180750	H180839	H181018	H181102	H181177	H260950	H270281	H270428	H270539	H270699	H270812	H270895	H271094
H180751	H180840	H181019	H181103	H181178	H260951	H270282	H270430	H270540	H270700	H270813	H270896	H271095
H180752	H180841	H181020	H181104	H181179	H260952	H270285	H270431	H270542	H270705	H270814	H270897	H271096
H180753	H180842	H181021	H181105	H181180	H260953	H270288	H270435	H270544	H270708	H270817	H270898	H271097
H180754	H180843	H181022	H181106	H181181	H270004	H270290	H270436	H270547	H270709	H270819	H270899	H271098
H180756	H180844	H181023	H181107	H181182	H270009	H270293	H270437	H270550	H270710	H270820	H271000	H271099
H180757	H180848	H181026	H181108	H181183	H270010	H270297	H270438	H270601	H270711	H270821	H271002	H271100
H180759	H180851	H181027	H181109	H181184	H270021	H270303	H270439	H270602	H270712	H270822	H271004	H271101
H180760	H180852	H181028	H181112	H181185	H270026	H270307	H270443	H270605	H270714	H270823	H271005	H271102
H180761	H180853	H181029	H181113	H181187	H270027	H270310	H270445	H270606	H270715	H270825	H271006	H271103
H180762	H180854	H181030	H181114	H181189	H270029	H270314	H270446	H270607	H270716	H270826	H271009	H271104
H180763	H180855	H181031	H181115	H181191	H270030	H270320	H270447	H270613	H270717	H270827	H271013	H271106
H180765	H180856	H181032	H181116	H181192	H270038	H270321	H270448	H270615	H270718	H270828	H271015	H271107
H180768	H180857	H181033	H181117	H181193	H270047	H270323	H270449	H270616	H270719	H270833	H271016	H271108
H180769	H180858	H181036	H181118	H181195	H270073	H270324	H270450	H270617	H270722	H270835	H271017	H271109
H180774	H180859	H181039	H181119	H181196	H270074	H270329	H270451	H270622	H270725	H270836	H271018	H271110
H180776	H180860	H181041	H181120	H181197	H270079	H270332	H270452	H270623	H270726	H270837	H271019	H271111
H180777	H180861	H181042	H181121	H181198	H270088	H270335	H270454	H270624	H270727	H270838	H271021	H271112
H180778	H180862	H181043	H181124	H181199	H270094	H270337	H270455	H270625	H270728	H270840	H271023	H271113
H180779	H180863	H181045	H181125	H181200	H270096	H270338	H270458	H270626	H270732	H270841	H271024	H271114
H180780	H180864	H181046	H181126	H181201	H270106	H270341	H270461	H270627	H270733	H270842	H271025	H271115
H180781	H180866	H181047	H181128	H181202	H270107	H270343	H270462	H270631	H270735	H270844	H271026	H271116
H180784	H180867	H181048	H181129	H181203	H270110	H270344	H270464	H270632	H270736	H270845	H271027	H271117
H180785	H180868	H181049	H181130	H181205	H270111	H270345	H270470	H270633	H270737	H270846	H271029	H271118
H180786	H180869	H181052	H181132	H181209	H270118	H270346	H270473	H270634	H270739	H270847	H271031	H271120
H180788	H180870	H181053	H181133	H181210	H270126	H270351	H270474	H270635	H270740	H270848	H271032	H271121
H180791	H180871	H181055	H181134	H181211	H270128	H270352	H270476	H270637	H270741	H270852	H271033	H271123
H180792	H180872	H181056	H181135	H182000	H270134	H270353	H270477	H270639	H270746	H270854	H271034	H271125
H180793	H180873	H181058	H181136	H182001	H270138	H270355	H270479	H270641	H270749	H270855	H271035	H271127
H180794	H180874	H181059	H181137	H182002	H270144	H270356	H270482	H270642	H270751	H270857	H271037	H271131
H180795	H180877	H181060	H181138	H182003	H270201	H270360	H270483	H270643	H270752	H270858	H271038	H271132
H180796	H180878	H181061	H181139	H182005	H270209	H270361	H270484	H270644	H270755	H270859	H271039	H271135
H180803	H180879	H181062	H181140	H182006	H270211	H270364	H270486	H270645	H270757	H270861	H271042	H271136
H180805	H180880	H181065	H181142	H182007	H270214	H270365	H270487	H270646	H270759	H270863	H271043	H271137
H180806	H180881	H181066	H181143	H182008	H270215	H270370	H270490	H270648	H270760	H270864	H271044	H271139
H180807	H180882	H181067	H181145	H182009	H270216	H270371	H270491	H270649	H270761	H270865	H271051	H271141
H180808	H180883	H181068	H181146	H182010	H270219	H270373	H270495	H270651	H270762	H270866	H271052	H271142
H180809	H180884	H181069	H181147	H182012	H270227	H270375	H270498	H270652	H270763	H270867	H271055	H271143
H180810	H180885	H181070	H181148	H182016	H270228	H270378	H270499	H270653	H270766	H270868	H271056	H271144
H180811	H180886	H181071	H181149	H182017	H270229	H270380	H270500	H270654	H270767	H270869	H271057	H271145
H180812	H180887	H181073	H181151	H260905	H270230	H270384	H270501	H270656	H270769	H270870	H271061	H271149
H180815	H180890	H181074	H181152	H260909	H270232	H270385	H270502	H270660	H270777	H270871	H271062	H271151
H180816	H180891	H181075	H181153	H260915	H270235	H270386	H270503	H270661	H270778	H270872	H271063	H271152
H180817	H180894	H181076	H181154	H260916	H270240	H270391	H270504	H270662	H270781	H270873	H271065	H271153
H180819	H180895	H181077	H181155	H260917	H270242	H270392	H270505	H270663	H270782	H270875	H271066	H271154
H180820	H180896	H181078	H181156	H260922	H270244	H270395	H270506	H270664	H270783	H270877	H271067	H271155
H180821	H180898	H181079	H181157	H260923	H270245	H270397	H270507	H270665	H270785	H270878	H271068	H271157
H180822	H180899	H181082	H181158	H260924	H270251	H270398	H270508	H270667	H270786	H270879	H271071	H271159
H180823	H180901	H181083	H181159	H260926	H270252	H270400	H270511	H270669	H270787	H270880	H271073	H271160
H180824	H180907	H181084	H181160	H260928	H270254	H270401	H270512	H270670	H270789	H270881	H271075	H271161
H180825	H181002	H181085	H181161	H260931	H270255	H270404	H270513	H270671	H270791	H270882	H271076	H271162
H180826	H181003	H181086	H181162	H260932	H270256	H270409	H270514	H270675	H270793	H270883	H271079	H271163
H180827	H181004	H181087	H181163	H260933	H270260	H270410	H270516	H270680	H270794	H270884	H271080	H271165
H180829	H181005	H181089	H181164	H260936	H270261	H270412	H270518	H270681	H270796	H270885	H271082	H271166
H180830	H181007	H181091	H181165	H260938	H270264	H270416	H270520	H270682	H270797	H270886	H271083	H271168
H180831	H181008	H181092	H181167	H260939	H270267	H270418	H270522	H270684	H270799	H270888	H271084	H271170

URGENT MEDICAL DEVICE CORRECTION
URGENT FIELD SAFETY NOTICE

H271171	H271249	H271321	H271392	H271463	H271536	H271603	H271674	H271739	H271808	H271871	H271944	H272010
H271172	H271250	H271322	H271393	H271464	H271537	H271604	H271675	H271740	H271809	H271872	H271945	H272011
H271174	H271251	H271323	H271394	H271465	H271538	H271605	H271676	H271741	H271810	H271873	H271946	H272012
H271175	H271253	H271324	H271395	H271466	H271539	H271607	H271677	H271742	H271811	H271874	H271947	H272013
H271176	H271256	H271325	H271397	H271467	H271540	H271608	H271678	H271743	H271812	H271875	H271948	H272014
H271177	H271257	H271327	H271398	H271468	H271541	H271609	H271679	H271744	H271813	H271876	H271949	H272015
H271178	H271258	H271328	H271399	H271470	H271542	H271610	H271680	H271746	H271814	H271877	H271950	H272016
H271179	H271259	H271329	H271401	H271472	H271543	H271611	H271681	H271747	H271815	H271878	H271951	H272017
H271182	H271260	H271330	H271402	H271473	H271544	H271612	H271682	H271748	H271816	H271879	H271952	H272018
H271183	H271263	H271331	H271403	H271474	H271545	H271613	H271683	H271749	H271817	H271880	H271953	H272019
H271184	H271264	H271332	H271404	H271475	H271546	H271614	H271684	H271750	H271818	H271881	H271954	H272020
H271185	H271265	H271333	H271406	H271476	H271547	H271615	H271685	H271751	H271819	H271882	H271955	H272021
H271186	H271266	H271334	H271407	H271477	H271548	H271617	H271686	H271752	H271820	H271883	H271956	H272022
H271188	H271267	H271335	H271408	H271478	H271549	H271618	H271687	H271755	H271821	H271885	H271957	H272023
H271189	H271268	H271336	H271410	H271479	H271550	H271619	H271688	H271756	H271822	H271886	H271958	H272024
H271190	H271269	H271337	H271411	H271480	H271551	H271620	H271689	H271757	H271823	H271887	H271959	H272025
H271191	H271270	H271338	H271412	H271481	H271552	H271622	H271691	H271758	H271824	H271888	H271960	H272026
H271193	H271271	H271339	H271413	H271483	H271553	H271624	H271692	H271759	H271825	H271889	H271961	H272027
H271194	H271272	H271340	H271414	H271484	H271554	H271625	H271693	H271760	H271826	H271890	H271962	H272028
H271195	H271273	H271342	H271415	H271486	H271555	H271626	H271695	H271761	H271827	H271891	H271963	H272029
H271196	H271274	H271343	H271416	H271487	H271557	H271627	H271696	H271762	H271828	H271894	H271964	H272030
H271197	H271275	H271344	H271417	H271488	H271559	H271628	H271697	H271763	H271829	H271895	H271965	H272031
H271198	H271276	H271345	H271418	H271490	H271560	H271629	H271698	H271764	H271830	H271897	H271966	H272032
H271199	H271277	H271347	H271419	H271492	H271561	H271630	H271699	H271765	H271831	H271898	H271967	H272033
H271200	H271278	H271349	H271420	H271493	H271562	H271631	H271700	H271766	H271832	H271899	H271968	H272034
H271201	H271280	H271350	H271421	H271494	H271563	H271632	H271701	H271767	H271833	H271901	H271969	H272035
H271202	H271281	H271351	H271422	H271495	H271564	H271633	H271702	H271768	H271834	H271902	H271970	H272036
H271204	H271282	H271353	H271423	H271497	H271565	H271634	H271703	H271769	H271835	H271903	H271971	H272039
H271205	H271283	H271355	H271424	H271498	H271566	H271635	H271704	H271770	H271836	H271904	H271972	H272040
H271206	H271284	H271356	H271425	H271499	H271567	H271636	H271705	H271771	H271837	H271905	H271973	H272041
H271207	H271285	H271357	H271426	H271500	H271568	H271637	H271706	H271772	H271838	H271907	H271974	H272043
H271208	H271286	H271358	H271427	H271501	H271569	H271638	H271707	H271773	H271839	H271908	H271975	H272046
H271209	H271287	H271359	H271428	H271502	H271570	H271640	H271708	H271775	H271840	H271909	H271976	H272047
H271210	H271288	H271360	H271429	H271503	H271571	H271641	H271709	H271778	H271841	H271910	H271977	H272048
H271211	H271289	H271361	H271430	H271504	H271572	H271642	H271710	H271779	H271842	H271912	H271978	H272049
H271212	H271290	H271362	H271431	H271505	H271573	H271643	H271711	H271780	H271843	H271913	H271980	H272050
H271216	H271291	H271363	H271432	H271506	H271574	H271644	H271712	H271781	H271845	H271914	H271981	H272051
H271217	H271292	H271364	H271433	H271507	H271575	H271645	H271713	H271782	H271846	H271915	H271982	H272052
H271218	H271293	H271365	H271434	H271508	H271576	H271646	H271714	H271783	H271847	H271916	H271983	H272053
H271219	H271294	H271367	H271435	H271509	H271577	H271647	H271715	H271784	H271848	H271917	H271984	H272055
H271223	H271295	H271369	H271436	H271510	H271578	H271648	H271716	H271785	H271849	H271919	H271985	H272056
H271224	H271297	H271370	H271438	H271511	H271580	H271649	H271717	H271786	H271850	H271920	H271986	H272057
H271225	H271298	H271371	H271439	H271512	H271581	H271650	H271718	H271787	H271851	H271922	H271987	H272058
H271226	H271299	H271372	H271440	H271513	H271582	H271652	H271719	H271788	H271852	H271923	H271988	H272059
H271227	H271300	H271373	H271441	H271514	H271583	H271653	H271720	H271789	H271853	H271924	H271989	H272060
H271228	H271301	H271374	H271442	H271516	H271586	H271654	H271721	H271790	H271854	H271925	H271991	H272061
H271229	H271302	H271375	H271443	H271517	H271587	H271655	H271722	H271791	H271855	H271926	H271992	H272062
H271230	H271304	H271376	H271444	H271518	H271588	H271656	H271723	H271792	H271856	H271927	H271993	H272064
H271231	H271305	H271377	H271445	H271519	H271589	H271657	H271724	H271793	H271857	H271928	H271995	H272065
H271232	H271306	H271378	H271447	H271521	H271590	H271658	H271725	H271794	H271858	H271929	H271996	H272066
H271233	H271307	H271379	H271448	H271522	H271591	H271659	H271726	H271795	H271859	H271930	H271997	H272067
H271234	H271308	H271380	H271449	H271523	H271592	H271660	H271727	H271796	H271860	H271931	H271998	H272069
H271235	H271309	H271381	H271450	H271525	H271593	H271662	H271728	H271797	H271861	H271932	H271999	H272071
H271236	H271311	H271382	H271451	H271526	H271594	H271663	H271729	H271798	H271862	H271933	H272000	H272072
H271238	H271312	H271383	H271453	H271527	H271595	H271664	H271730	H271799	H271863	H271934	H272001	H272073
H271239	H271314	H271384	H271454	H271528	H271596	H271666	H271731	H271800	H271864	H271935	H272002	H272074
H271241	H271315	H271385	H271456	H271529	H271597	H271667	H271732	H271801	H271865	H271938	H272003	H272076
H271242	H271316	H271386	H271458	H271530	H271598	H271669	H271733	H271802	H271866	H271939	H272004	H272077
H271243	H271317	H271387	H271459	H271531	H271599	H271670	H271734	H271804	H271867	H271940	H272005	H272078
H271245	H271318	H271388	H271460	H271533	H271600	H271671	H271735	H271805	H271868	H271941	H272006	H272079
H271247	H271319	H271389	H271461	H271534	H271601	H271672	H271736	H271806	H271869	H271942	H272007	H272080
H271248	H271320	H271391	H271462	H271535	H271602	H271673	H271738	H271807	H271870	H271943	H272009	H272081

URGENT MEDICAL DEVICE CORRECTION
URGENT FIELD SAFETY NOTICE

H272082	H272148	H272213	H272281	H272348	H272414	H272485	H272855	H272923	H272987	H273052	H273123	H273192
H272083	H272149	H272214	H272282	H272349	H272415	H272488	H272856	H272924	H272988	H273053	H273124	H273193
H272084	H272150	H272215	H272283	H272350	H272416	H272489	H272857	H272925	H272989	H273054	H273125	H273194
H272085	H272151	H272216	H272284	H272351	H272417	H272490	H272858	H272926	H272990	H273055	H273126	H273195
H272086	H272152	H272217	H272285	H272352	H272418	H272491	H272859	H272927	H272991	H273056	H273127	H273196
H272088	H272153	H272219	H272286	H272353	H272420	H272492	H272860	H272928	H272992	H273057	H273128	H273197
H272089	H272154	H272220	H272287	H272355	H272421	H272493	H272861	H272929	H272993	H273058	H273130	H273198
H272090	H272155	H272221	H272288	H272356	H272422	H272494	H272862	H272930	H272994	H273059	H273131	H273199
H272091	H272156	H272222	H272289	H272357	H272423	H272495	H272863	H272931	H272995	H273060	H273132	H273200
H272092	H272157	H272223	H272290	H272358	H272424	H272496	H272864	H272932	H272996	H273061	H273133	H273201
H272093	H272158	H272224	H272291	H272359	H272425	H272497	H272865	H272933	H272997	H273062	H273134	H273202
H272094	H272159	H272225	H272292	H272360	H272426	H272500	H272866	H272934	H272998	H273063	H273135	H273203
H272095	H272160	H272226	H272293	H272361	H272427	H272800	H272867	H272935	H272999	H273064	H273136	H273204
H272096	H272161	H272227	H272294	H272362	H272428	H272801	H272868	H272936	H273000	H273065	H273137	H273205
H272097	H272162	H272228	H272295	H272363	H272430	H272802	H272869	H272937	H273001	H273066	H273138	H273206
H272098	H272163	H272229	H272296	H272364	H272431	H272803	H272870	H272938	H273002	H273067	H273139	H273208
H272099	H272164	H272230	H272297	H272365	H272432	H272804	H272871	H272939	H273003	H273068	H273140	H273209
H272101	H272165	H272231	H272298	H272366	H272433	H272805	H272872	H272940	H273004	H273069	H273141	H273547
H272102	H272166	H272232	H272299	H272367	H272434	H272806	H272873	H272941	H273005	H273070	H273142	H273711
H272103	H272167	H272234	H272300	H272368	H272435	H272807	H272875	H272942	H273006	H273071	H273143	H273929
H272104	H272168	H272235	H272301	H272369	H272436	H272809	H272876	H272943	H273007	H273072	H273144	H280006
H272106	H272169	H272236	H272303	H272370	H272437	H272810	H272878	H272944	H273008	H273074	H273145	H290003
H272107	H272170	H272237	H272304	H272372	H272438	H272811	H272879	H272946	H273010	H273075	H273146	H290012
H272108	H272171	H272238	H272305	H272373	H272440	H272812	H272880	H272947	H273011	H273077	H273147	H290021
H272109	H272173	H272239	H272306	H272374	H272442	H272813	H272881	H272948	H273012	H273078	H273148	H290026
H272110	H272174	H272240	H272307	H272375	H272443	H272814	H272882	H272949	H273013	H273079	H273149	H290027
H272111	H272175	H272241	H272308	H272376	H272444	H272815	H272883	H272950	H273014	H273080	H273150	H290031
H272112	H272176	H272242	H272309	H272377	H272445	H272816	H272884	H272951	H273016	H273081	H273151	H290032
H272113	H272177	H272243	H272310	H272378	H272446	H272817	H272885	H272952	H273017	H273082	H273152	H290033
H272114	H272179	H272244	H272311	H272379	H272447	H272818	H272886	H272953	H273018	H273083	H273153	H290034
H272115	H272180	H272245	H272312	H272380	H272448	H272819	H272887	H272954	H273019	H273085	H273155	H290103
H272116	H272181	H272246	H272313	H272381	H272449	H272820	H272888	H272955	H273020	H273086	H273156	H290104
H272117	H272182	H272247	H272314	H272382	H272450	H272821	H272889	H272956	H273021	H273088	H273158	H290105
H272118	H272183	H272248	H272318	H272383	H272451	H272822	H272890	H272957	H273022	H273089	H273159	H290108
H272119	H272184	H272249	H272319	H272384	H272452	H272823	H272891	H272958	H273023	H273090	H273160	H290110
H272120	H272185	H272250	H272320	H272385	H272453	H272824	H272892	H272959	H273024	H273091	H273162	H290111
H272121	H272186	H272251	H272321	H272387	H272454	H272825	H272894	H272960	H273025	H273095	H273163	H290113
H272122	H272187	H272253	H272322	H272388	H272455	H272826	H272895	H272961	H273026	H273097	H273164	H290114
H272123	H272188	H272254	H272324	H272389	H272458	H272827	H272896	H272962	H273027	H273098	H273165	H290116
H272124	H272189	H272255	H272325	H272390	H272459	H272828	H272897	H272963	H273028	H273099	H273166	H290118
H272125	H272190	H272256	H272326	H272391	H272460	H272829	H272898	H272964	H273029	H273100	H273167	H290121
H272126	H272191	H272257	H272327	H272392	H272461	H272830	H272899	H272965	H273031	H273101	H273169	H290122
H272127	H272192	H272258	H272328	H272393	H272462	H272831	H272900	H272966	H273032	H273102	H273170	H290123
H272128	H272193	H272259	H272329	H272394	H272463	H272833	H272904	H272967	H273033	H273103	H273171	H290125
H272130	H272194	H272260	H272330	H272395	H272464	H272834	H272905	H272968	H273034	H273104	H273172	H290128
H272131	H272195	H272261	H272331	H272396	H272465	H272836	H272906	H272969	H273035	H273105	H273173	H290130
H272132	H272196	H272262	H272332	H272397	H272467	H272837	H272907	H272970	H273036	H273106	H273174	H290132
H272133	H272197	H272263	H272333	H272398	H272468	H272838	H272908	H272972	H273037	H273107	H273175	H290135
H272134	H272198	H272264	H272334	H272399	H272469	H272839	H272909	H272973	H273038	H273108	H273176	H290137
H272135	H272199	H272265	H272335	H272400	H272470	H272840	H272910	H272974	H273039	H273109	H273177	H290138
H272136	H272201	H272266	H272336	H272401	H272471	H272841	H272911	H272975	H273040	H273110	H273178	H290139
H272137	H272202	H272269	H272337	H272402	H272472	H272842	H272912	H272976	H273041	H273111	H273180	H290141
H272138	H272203	H272270	H272338	H272403	H272473	H272843	H272913	H272977	H273042	H273113	H273181	H290142
H272139	H272204	H272272	H272339	H272405	H272475	H272845	H272914	H272978	H273043	H273114	H273182	H290143
H272140	H272205	H272273	H272340	H272406	H272476	H272846	H272915	H272979	H273044	H273115	H273183	H290144
H272141	H272206	H272274	H272341	H272407	H272477	H272848	H272916	H272980	H273045	H273116	H273184	H290145
H272142	H272207	H272275	H272342	H272408	H272478	H272849	H272917	H272981	H273046	H273117	H273185	H290146
H272143	H272208	H272276	H272343	H272409	H272479	H272850	H272918	H272982	H273047	H273118	H273186	H290151
H272144	H272209	H272277	H272344	H272410	H272480	H272851	H272919	H272983	H273048	H273119	H273188	H290152
H272145	H272210	H272278	H272345	H272411	H272482	H272852	H272920	H272984	H273049	H273120	H273189	H290154
H272146	H272211	H272279	H272346	H272412	H272483	H272853	H272921	H272985	H273050	H273121	H273190	H290155
H272147	H272212	H272280	H272347	H272413	H272484	H272854	H272922	H272986	H273051	H273122	H273191	H290156

URGENT MEDICAL DEVICE CORRECTION
URGENT FIELD SAFETY NOTICE

H290157	H290241	H290312	H290382	H290527	H291043	H291137	H291220	H293317	H293388	H293467	H293559	H293641
H290158	H290242	H290313	H290383	H290528	H291044	H291138	H291221	H293318	H293389	H293468	H293561	H293643
H290159	H290243	H290314	H290384	H290529	H291045	H291139	H291222	H293320	H293390	H293469	H293563	H293644
H290160	H290244	H290315	H290385	H290530	H291048	H291141	H291223	H293321	H293391	H293471	H293564	H293645
H290162	H290246	H290316	H290386	H290531	H291049	H291142	H291224	H293322	H293393	H293472	H293566	H293646
H290164	H290247	H290317	H290387	H290532	H291051	H291143	H291225	H293323	H293394	H293473	H293568	H293648
H290165	H290248	H290318	H290388	H290534	H291052	H291144	H291226	H293324	H293395	H293474	H293569	H293649
H290166	H290249	H290319	H290390	H290535	H291054	H291145	H291227	H293325	H293396	H293482	H293570	H293651
H290168	H290250	H290320	H290392	H290537	H291055	H291146	H291228	H293326	H293399	H293485	H293573	H293652
H290171	H290253	H290321	H290393	H290538	H291057	H291147	H291229	H293327	H293401	H293486	H293574	H293653
H290173	H290254	H290322	H290394	H290539	H291063	H291148	H291230	H293328	H293402	H293487	H293575	H293654
H290175	H290255	H290323	H290395	H290540	H291064	H291151	H291231	H293329	H293403	H293488	H293576	H293655
H290176	H290256	H290324	H290396	H290541	H291065	H291152	H291232	H293330	H293407	H293489	H293577	H293656
H290180	H290257	H290325	H290397	H290542	H291066	H291153	H291233	H293331	H293408	H293491	H293578	H293657
H290181	H290258	H290326	H290398	H290543	H291067	H291154	H291234	H293332	H293409	H293492	H293579	H293659
H290182	H290259	H290327	H290399	H290544	H291068	H291155	H291235	H293333	H293410	H293493	H293581	H293660
H290183	H290260	H290328	H290400	H290545	H291072	H291156	H291236	H293334	H293411	H293494	H293582	H293661
H290185	H290261	H290329	H290401	H290546	H291073	H291157	H291237	H293336	H293412	H293496	H293583	H293662
H290186	H290262	H290330	H290402	H290547	H291074	H291159	H291238	H293337	H293413	H293497	H293584	H293663
H290189	H290263	H290331	H290403	H290548	H291075	H291160	H291239	H293338	H293414	H293498	H293586	H293665
H290191	H290264	H290332	H290404	H290549	H291076	H291161	H291240	H293340	H293415	H293499	H293587	H293666
H290193	H290265	H290333	H290405	H290550	H291077	H291162	H291242	H293343	H293416	H293500	H293588	H293667
H290194	H290266	H290334	H290406	H290551	H291078	H291167	H291243	H293344	H293417	H293501	H293589	H293668
H290195	H290267	H290335	H290408	H290552	H291080	H291168	H291244	H293345	H293418	H293503	H293590	H293669
H290196	H290268	H290336	H290409	H290553	H291081	H291169	H291245	H293347	H293419	H293504	H293591	H293670
H290197	H290269	H290337	H290410	H290554	H291082	H291170	H291246	H293348	H293420	H293506	H293592	H293671
H290198	H290271	H290339	H290411	H290555	H291083	H291171	H291249	H293349	H293421	H293508	H293593	H293672
H290201	H290272	H290340	H290412	H290556	H291085	H291172	H291250	H293350	H293422	H293509	H293594	H293673
H290202	H290273	H290341	H290413	H290557	H291087	H291175	H291252	H293351	H293423	H293510	H293595	H293674
H290203	H290274	H290342	H290414	H290558	H291088	H291176	H291253	H293352	H293424	H293511	H293598	H293675
H290205	H290276	H290343	H290415	H290559	H291090	H291177	H291257	H293354	H293427	H293512	H293600	H293676
H290206	H290277	H290344	H290416	H290560	H291092	H291178	H291258	H293356	H293428	H293513	H293601	H293678
H290208	H290278	H290345	H290417	H291003	H291093	H291179	H291259	H293357	H293429	H293514	H293602	H293679
H290209	H290279	H290346	H290422	H291004	H291097	H291180	H291260	H293358	H293430	H293519	H293603	H293681
H290210	H290280	H290347	H290423	H291006	H291098	H291182	H291261	H293359	H293432	H293520	H293604	H293682
H290211	H290281	H290348	H290424	H291007	H291099	H291183	H291262	H293360	H293433	H293521	H293606	H293687
H290212	H290282	H290349	H290425	H291009	H291101	H291184	H291263	H293361	H293434	H293522	H293608	H293688
H290213	H290283	H290350	H290426	H291010	H291102	H291186	H291264	H293362	H293435	H293523	H293609	H293689
H290214	H290284	H290351	H290427	H291011	H291103	H291187	H291266	H293363	H293436	H293524	H293610	H293690
H290215	H290285	H290353	H290501	H291013	H291104	H291188	H291267	H293364	H293437	H293525	H293612	H293692
H290216	H290286	H290354	H290502	H291015	H291105	H291189	H291268	H293365	H293440	H293527	H293613	H293693
H290217	H290287	H290355	H290503	H291016	H291106	H291190	H291271	H293366	H293441	H293528	H293615	H293694
H290219	H290288	H290356	H290504	H291018	H291107	H291191	H291272	H293367	H293442	H293529	H293616	H293697
H290220	H290289	H290357	H290505	H291019	H291108	H291192	H291273	H293368	H293443	H293530	H293617	H293698
H290221	H290290	H290358	H290506	H291020	H291111	H291194	H292832	H293369	H293444	H293531	H293619	H293699
H290222	H290291	H290359	H290507	H291021	H291114	H291195	H293009	H293370	H293445	H293533	H293620	H293704
H290223	H290292	H290360	H290508	H291022	H291115	H291197	H293207	H293371	H293446	H293535	H293621	H293705
H290224	H290293	H290363	H290509	H291024	H291116	H291198	H293300	H293372	H293448	H293536	H293622	H293706
H290225	H290295	H290364	H290510	H291026	H291118	H291199	H293301	H293373	H293451	H293538	H293623	H293707
H290226	H290296	H290365	H290511	H291027	H291120	H291202	H293302	H293374	H293452	H293539	H293624	H293710
H290227	H290297	H290366	H290513	H291028	H291122	H291204	H293304	H293375	H293453	H293540	H293625	H293712
H290228	H290299	H290368	H290514	H291029	H291123	H291205	H293305	H293377	H293454	H293543	H293626	H293713
H290229	H290301	H290370	H290515	H291030	H291124	H291207	H293306	H293378	H293455	H293545	H293628	H293714
H290230	H290302	H290371	H290517	H291031	H291125	H291208	H293307	H293379	H293456	H293548	H293629	H293715
H290231	H290304	H290372	H290518	H291032	H291126	H291210	H293308	H293380	H293458	H293549	H293630	H293716
H290232	H290305	H290373	H290519	H291035	H291127	H291211	H293309	H293381	H293459	H293550	H293631	H293717
H290233	H290306	H290374	H290520	H291036	H291128	H291212	H293310	H293382	H293460	H293551	H293632	H293718
H290234	H290307	H290377	H290521	H291037	H291130	H291213	H293311	H293383	H293461	H293552	H293633	H293719
H290235	H290308	H290378	H290522	H291038	H291131	H291215	H293312	H293384	H293462	H293553	H293634	H293720
H290237	H290309	H290379	H290523	H291040	H291132	H291216	H293314	H293385	H293463	H293555	H293637	H293721
H290239	H290310	H290380	H290525	H291041	H291134	H291217	H293315	H293386	H293464	H293556	H293639	H293722
H290240	H290311	H290381	H290526	H291042	H291136	H291219	H293316	H293387	H293466	H293557	H293640	H293723

URGENT MEDICAL DEVICE CORRECTION
URGENT FIELD SAFETY NOTICE

H293724	H293807	H293893	H293981	H294071	H294159	H294246	H294323	H294414	H294503	H294594	H294683	H294778
H293725	H293808	H293896	H293985	H294072	H294160	H294247	H294326	H294415	H294504	H294597	H294684	H294779
H293726	H293809	H293897	H293986	H294073	H294161	H294248	H294328	H294416	H294506	H294599	H294685	H294780
H293727	H293810	H293898	H293988	H294074	H294164	H294249	H294331	H294417	H294507	H294600	H294686	H294782
H293728	H293811	H293899	H293990	H294075	H294165	H294250	H294332	H294419	H294508	H294601	H294687	H294784
H293730	H293812	H293902	H293991	H294076	H294168	H294251	H294333	H294420	H294509	H294605	H294688	H294785
H293731	H293815	H293903	H293992	H294077	H294172	H294252	H294334	H294422	H294510	H294606	H294689	H294786
H293732	H293817	H293904	H293993	H294078	H294173	H294253	H294335	H294424	H294511	H294607	H294690	H294787
H293733	H293819	H293905	H293994	H294079	H294174	H294254	H294336	H294425	H294512	H294608	H294691	H294788
H293734	H293820	H293906	H293995	H294080	H294175	H294255	H294338	H294426	H294513	H294610	H294692	H294790
H293735	H293821	H293907	H293996	H294081	H294177	H294256	H294339	H294428	H294514	H294611	H294693	H294791
H293736	H293823	H293908	H293997	H294083	H294179	H294257	H294342	H294430	H294515	H294612	H294694	H294792
H293738	H293824	H293909	H293998	H294084	H294180	H294258	H294343	H294432	H294516	H294613	H294695	H294793
H293742	H293826	H293910	H293999	H294085	H294181	H294259	H294345	H294433	H294520	H294614	H294697	H294794
H293743	H293827	H293914	H294000	H294087	H294182	H294260	H294346	H294434	H294522	H294617	H294699	H294795
H293744	H293828	H293917	H294002	H294089	H294183	H294261	H294347	H294435	H294523	H294619	H294700	H294796
H293745	H293829	H293918	H294005	H294090	H294184	H294262	H294349	H294436	H294525	H294620	H294702	H294797
H293746	H293830	H293919	H294006	H294091	H294185	H294264	H294352	H294439	H294526	H294621	H294704	H294798
H293747	H293831	H293920	H294009	H294092	H294186	H294265	H294353	H294440	H294527	H294622	H294705	H294800
H293748	H293832	H293922	H294010	H294093	H294189	H294266	H294354	H294441	H294529	H294624	H294707	H294801
H293749	H293833	H293924	H294011	H294094	H294190	H294268	H294356	H294442	H294531	H294625	H294708	H294803
H293750	H293834	H293925	H294012	H294095	H294191	H294269	H294357	H294443	H294532	H294627	H294709	H294804
H293752	H293835	H293926	H294014	H294097	H294192	H294270	H294359	H294445	H294533	H294629	H294710	H294808
H293753	H293836	H293927	H294015	H294098	H294193	H294271	H294360	H294446	H294535	H294631	H294711	H294809
H293754	H293838	H293929	H294016	H294099	H294194	H294272	H294363	H294447	H294536	H294632	H294716	H294811
H293755	H293839	H293931	H294017	H294100	H294195	H294273	H294364	H294448	H294537	H294633	H294717	H294814
H293758	H293840	H293933	H294021	H294102	H294198	H294274	H294365	H294451	H294538	H294634	H294718	H294815
H293759	H293841	H293934	H294022	H294103	H294199	H294276	H294366	H294452	H294539	H294635	H294721	H294816
H293760	H293842	H293935	H294023	H294107	H294201	H294277	H294367	H294454	H294540	H294636	H294724	H294817
H293761	H293843	H293937	H294024	H294108	H294203	H294278	H294368	H294457	H294541	H294638	H294728	H294820
H293762	H293845	H293938	H294026	H294109	H294204	H294280	H294369	H294459	H294543	H294639	H294729	H294821
H293763	H293849	H293940	H294027	H294111	H294205	H294281	H294370	H294460	H294544	H294640	H294731	H294825
H293764	H293850	H293941	H294028	H294113	H294208	H294283	H294371	H294461	H294545	H294641	H294733	H294826
H293765	H293851	H293942	H294029	H294114	H294209	H294284	H294372	H294462	H294546	H294643	H294734	H294828
H293766	H293852	H293943	H294031	H294115	H294210	H294288	H294373	H294463	H294547	H294644	H294736	H294830
H293767	H293854	H293944	H294032	H294117	H294211	H294289	H294374	H294464	H294548	H294645	H294738	H294831
H293768	H293856	H293945	H294034	H294118	H294213	H294291	H294377	H294466	H294553	H294646	H294739	H294832
H293770	H293857	H293946	H294035	H294119	H294214	H294292	H294378	H294467	H294554	H294647	H294740	H294833
H293773	H293860	H293949	H294036	H294120	H294217	H294293	H294379	H294468	H294556	H294648	H294743	H294834
H293774	H293861	H293951	H294037	H294122	H294218	H294294	H294381	H294471	H294557	H294649	H294744	H294835
H293776	H293862	H293954	H294038	H294123	H294219	H294295	H294383	H294473	H294564	H294650	H294745	H294836
H293779	H293865	H293955	H294039	H294124	H294220	H294296	H294384	H294474	H294565	H294651	H294746	H294837
H293780	H293867	H293956	H294040	H294125	H294221	H294297	H294387	H294475	H294567	H294654	H294747	H294838
H293781	H293868	H293957	H294043	H294126	H294222	H294298	H294388	H294477	H294569	H294655	H294748	H294839
H293782	H293870	H293958	H294044	H294127	H294223	H294299	H294389	H294478	H294571	H294659	H294749	H294841
H293785	H293872	H293959	H294046	H294129	H294225	H294300	H294390	H294480	H294574	H294662	H294751	H294842
H293786	H293873	H293960	H294047	H294132	H294226	H294303	H294391	H294481	H294575	H294663	H294753	H294843
H293788	H293874	H293961	H294048	H294133	H294227	H294304	H294392	H294483	H294576	H294664	H294754	H294844
H293790	H293875	H293963	H294049	H294135	H294228	H294305	H294394	H294484	H294577	H294665	H294756	H294847
H293791	H293876	H293965	H294051	H294136	H294229	H294306	H294396	H294485	H294579	H294666	H294757	H294848
H293794	H293877	H293966	H294053	H294139	H294230	H294307	H294397	H294486	H294580	H294667	H294758	H294851
H293795	H293878	H293967	H294054	H294141	H294231	H294309	H294398	H294487	H294581	H294668	H294759	H294853
H293796	H293879	H293968	H294057	H294143	H294233	H294310	H294399	H294489	H294582	H294670	H294760	H294854
H293797	H293881	H293969	H294058	H294144	H294234	H294312	H294400	H294490	H294583	H294671	H294763	H294857
H293798	H293884	H293970	H294059	H294145	H294236	H294313	H294401	H294491	H294584	H294672	H294764	H294859
H293799	H293885	H293972	H294060	H294146	H294237	H294314	H294402	H294492	H294585	H294673	H294765	H294860
H293800	H293886	H293974	H294062	H294147	H294239	H294315	H294406	H294493	H294586	H294675	H294766	H294861
H293801	H293887	H293975	H294066	H294151	H294240	H294316	H294407	H294494	H294587	H294677	H294768	H294862
H293803	H293888	H293976	H294067	H294152	H294241	H294317	H294408	H294495	H294588	H294678	H294769	H294863
H293804	H293890	H293978	H294068	H294153	H294242	H294320	H294409	H294496	H294589	H294680	H294770	H294864
H293805	H293891	H293979	H294069	H294154	H294244	H294321	H294410	H294501	H294590	H294681	H294774	H294865
H293806	H293892	H293980	H294070	H294155	H294245	H294322	H294413	H294502	H294593	H294682	H294775	H294866

URGENT MEDICAL DEVICE CORRECTION
URGENT FIELD SAFETY NOTICE

H294867	H294890	H294920	H294954	H294984	H295019	H295047	H295076	H295116
H294868	H294891	H294922	H294956	H294986	H295021	H295048	H295077	H295117
H294869	H294892	H294923	H294957	H294987	H295022	H295049	H295078	H295118
H294870	H294893	H294925	H294958	H294988	H295023	H295050	H295082	H295119
H294871	H294896	H294926	H294959	H294992	H295024	H295051	H295084	H295122
H294872	H294897	H294930	H294962	H294995	H295025	H295053	H295085	H295126
H294874	H294898	H294932	H294963	H294996	H295026	H295054	H295087	H295129
H294875	H294899	H294933	H294965	H294997	H295027	H295056	H295090	H295131
H294876	H294900	H294935	H294967	H294998	H295028	H295058	H295094	H295132
H294877	H294901	H294936	H294969	H295002	H295029	H295059	H295096	H295134
H294878	H294903	H294937	H294971	H295003	H295030	H295060	H295097	H295144
H294879	H294904	H294938	H294972	H295004	H295031	H295062	H295100	
H294881	H294905	H294940	H294974	H295006	H295033	H295063	H295101	
H294882	H294907	H294941	H294976	H295008	H295034	H295064	H295102	
H294883	H294908	H294943	H294977	H295009	H295035	H295065	H295103	
H294884	H294910	H294946	H294978	H295014	H295037	H295066	H295105	
H294885	H294914	H294947	H294979	H295015	H295038	H295067	H295109	
H294886	H294916	H294950	H294980	H295016	H295044	H295070	H295111	
H294888	H294918	H294952	H294981	H295017	H295045	H295071	H295112	
H294889	H294919	H294953	H294982	H295018	H295046	H295075	H295114	

URGENT MEDICAL DEVICE CORRECTION
URGENT FIELD SAFETY NOTICE

APPENDIX B
LIST OF SERIAL NUMBERS OF THE AFFECTED SYSTEMS.
The last four digits represent the serial number of the device.

H140004	H140840	H270136	H272070	H290338	H291158	H293478	H293703	H293930	H294150	H294376	H294596	H294806
H140016	H140844	H270302	H272075	H290352	H291163	H293479	H293708	H293932	H294156	H294380	H294598	H294807
H140018	H140849	H270399	H272087	H290362	H291164	H293480	H293709	H293936	H294157	H294382	H294602	H294810
H140023	H140854	H270433	H272100	H290367	H291165	H293481	H293729	H293947	H294158	H294385	H294603	H294812
H140066	H140855	H270466	H272129	H290369	H291166	H293483	H293737	H293948	H294162	H294386	H294604	H294813
H140067	H140856	H270489	H272172	H290375	H291173	H293484	H293739	H293950	H294163	H294393	H294615	H294818
H140071	H140857	H270526	H272178	H290376	H291174	H293490	H293740	H293952	H294166	H294395	H294616	H294822
H140098	H140882	H270647	H272200	H290389	H291181	H293495	H293741	H293953	H294167	H294403	H294618	H294823
H140124	H140883	H270690	H272218	H290500	H291185	H293502	H293751	H293962	H294169	H294404	H294623	H294824
H140152	H140889	H270788	H272233	H290512	H291193	H293505	H293756	H293964	H294170	H294405	H294626	H294827
H140202	H140891	H270804	H272268	H290516	H291196	H293507	H293769	H293971	H294171	H294411	H294628	H294829
H140204	H140896	H270829	H272271	H290524	H291200	H293515	H293771	H293977	H294176	H294412	H294630	H294840
H140209	H140905	H271020	H272302	H290533	H291201	H293516	H293772	H293982	H294178	H294418	H294637	H294845
H140210	H140910	H271041	H272315	H290536	H291203	H293517	H293775	H293983	H294187	H294421	H294642	H294846
H140213	H140911	H271059	H272316	H290561	H291206	H293518	H293777	H293984	H294188	H294423	H294652	H294850
H140214	H140914	H271105	H272317	H290600	H291209	H293532	H293778	H293987	H294196	H294427	H294653	H294855
H140217	H140915	H271167	H272323	H291001	H291214	H293534	H293783	H293989	H294197	H294429	H294656	H294856
H140218	H140919	H271192	H272354	H291005	H291218	H293537	H293784	H294001	H294200	H294431	H294657	H294858
H140221	H140924	H271214	H272371	H291008	H291241	H293541	H293787	H294003	H294202	H294437	H294658	H294880
H140223	H140934	H271222	H272386	H291012	H291247	H293542	H293789	H294004	H294206	H294438	H294660	H294887
H140237	H140936	H271296	H272404	H291014	H291248	H293544	H293792	H294007	H294207	H294444	H294661	H294894
H140702	H180016	H271303	H272419	H291017	H291251	H293546	H293793	H294008	H294212	H294449	H294669	H294895
H140706	H180052	H271390	H272429	H291023	H291254	H293554	H293802	H294013	H294215	H294450	H294674	H294902
H140716	H180099	H271409	H272439	H291025	H291255	H293558	H293813	H294018	H294216	H294458	H294676	H294906
H140719	H180103	H271437	H272441	H291034	H291256	H293560	H293814	H294020	H294224	H294465	H294679	H294911
H140721	H180116	H271485	H272456	H291039	H291265	H293562	H293816	H294025	H294232	H294469	H294696	H294915
H140723	H180210	H271515	H272457	H291046	H291269	H293565	H293818	H294030	H294235	H294470	H294698	H294917
H140725	H180290	H271520	H272466	H291047	H291270	H293567	H293822	H294033	H294238	H294472	H294701	H294921
H140727	H180409	H271532	H272808	H291050	H293303	H293571	H293825	H294041	H294243	H294476	H294706	H294924
H140733	H180466	H271606	H272844	H291053	H293313	H293572	H293837	H294042	H294263	H294479	H294712	H294928
H140735	H180470	H271616	H272847	H291056	H293319	H293585	H293844	H294045	H294267	H294482	H294713	H294929
H140737	H180492	H271621	H272877	H291059	H293335	H293596	H293846	H294050	H294275	H294488	H294714	H294931
H140742	H180509	H271639	H272893	H291060	H293339	H293597	H293847	H294052	H294279	H294497	H294715	H294934
H140743	H180518	H271651	H272901	H291061	H293341	H293599	H293848	H294055	H294285	H294498	H294719	H294942
H140746	H180536	H271737	H272902	H291062	H293342	H293605	H293855	H294056	H294286	H294499	H294720	H294945
H140753	H180637	H271753	H272903	H291069	H293346	H293607	H293858	H294061	H294287	H294500	H294723	H294949
H140756	H180674	H271754	H272971	H291070	H293353	H293611	H293859	H294063	H294290	H294505	H294726	H294951
H140757	H180698	H271774	H273030	H291071	H293355	H293614	H293863	H294064	H294301	H294517	H294727	H294960
H140760	H180699	H271776	H273084	H291079	H293376	H293618	H293864	H294065	H294302	H294518	H294730	H294961
H140765	H180729	H271777	H273087	H291084	H293397	H293627	H293866	H294086	H294308	H294519	H294732	H294970
H140766	H180730	H271803	H273092	H291086	H293398	H293635	H293869	H294088	H294311	H294521	H294735	H294975
H140773	H180744	H271844	H273093	H291089	H293404	H293636	H293871	H294101	H294318	H294524	H294737	H294989
H140777	H180758	H271884	H273094	H291091	H293405	H293638	H293880	H294104	H294319	H294528	H294742	H294990
H140780	H180775	H271892	H273112	H291094	H293406	H293642	H293882	H294105	H294324	H294530	H294750	H294991
H140781	H180804	H271893	H273157	H291095	H293425	H293650	H293883	H294106	H294325	H294534	H294752	H294999
H140783	H180828	H271896	H273168	H291096	H293426	H293658	H293889	H294110	H294327	H294542	H294755	H295001
H140797	H180835	H271906	H273179	H291109	H293431	H293664	H293894	H294112	H294329	H294549	H294761	H295010
H140799	H180850	H271911	H273187	H291112	H293438	H293677	H293895	H294116	H294330	H294550	H294762	H295011
H140806	H180888	H271918	H273210	H291113	H293439	H293683	H293900	H294121	H294337	H294551	H294771	H295012
H140808	H181006	H271921	H280003	H291117	H293447	H293684	H293901	H294128	H294340	H294552	H294772	H295013
H140809	H181038	H271936	H290001	H291119	H293449	H293685	H293911	H294130	H294341	H294555	H294773	H295032
H140817	H181057	H271937	H290030	H291121	H293450	H293686	H293912	H294131	H294348	H294568	H294776	H295036
H140820	H181090	H271990	H290109	H291129	H293457	H293691	H293913	H294134	H294350	H294570	H294777	H295041
H140824	H181093	H271994	H290161	H291133	H293465	H293695	H293915	H294137	H294351	H294572	H294781	H295042
H140829	H181127	H272008	H290187	H291135	H293470	H293696	H293916	H294140	H294355	H294573	H294783	H295057
H140830	H181166	H272045	H290192	H291140	H293475	H293700	H293921	H294142	H294358	H294591	H294789	H295068
H140836	H260946	H272054	H290236	H291149	H293476	H293701	H293923	H294148	H294361	H294592	H294799	H295074
H140837	H270045	H272068	H290275	H291150	H293477	H293702	H293928	H294149	H294362	H294595	H294802	