

URGENT - Medical Device Correction - FA-009

Tempus Pro (with Trizeps 7 Hardware)

Date: 07-May-2021

Dear Valued Customer,

A problem has been detected with the Tempus Pro (with Trizeps 7 (TR7) Hardware) when used with the Video Laryngoscope, product name: C-MAC® S USB IMAGER WITH USB 2.0 PORT, which if it were to re-occur, could pose a potential risk for patients. This Field Safety Notice is intended to inform you about:

- what the problem is and under what circumstances it can occur
- the actions that should be taken by the customer / user in order to prevent risks for patients or users
- the actions planned by RDT to correct the problem.

This document contains important information for the continued safe and proper use of your equipment

Please review the following information with all members of your staff who need to be aware of the contents of this communication. It is important to understand the implications of this communication.

Please retain a copy with the equipment Instruction for Use.

We have reviewed our records and identified that you have been provided devices which are affected by the enclosed Field Safety Notice. We kindly ask that you read this notice carefully and send us written acknowledgement by **15 July 2021** that you have read and understood the contents of this notice.

If you need any further information or support concerning this issue, please contact:

RDT Recall contact:

- Email: RDT.Recall.Response@Philips.com
- Phone: +44 (0) 1256 362400

This notice will be reported to the appropriate Regulatory Agencies.

RDT apologises for any inconvenience caused by this problem



Remote Diagnostic Technologies Ltd.

Ascent 1, Farnborough Aerospace Centre, Aerospace Boulevard, Farnborough GU14 6XW, UK, www.philips.com, Tel +44 1256 362 400.

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FIELD SAFETY NOTICE

AFFECTED PRODUCTS	<p>Product Name: Tempus Pro</p> <p>Part Numbers with the Unique Device Identifier (UDI) numbers:</p> <table border="1" data-bbox="472 472 1273 710"> <thead> <tr> <th>Part No.</th> <th>UDI No.</th> <th>12NC No</th> </tr> </thead> <tbody> <tr> <td>00-1004-R</td> <td>05060472440020</td> <td>989706002081</td> </tr> <tr> <td>00-1007-R</td> <td>05060472440013</td> <td>989706000001</td> </tr> <tr> <td>00-1024-R</td> <td>05060472441027</td> <td>989706000051</td> </tr> <tr> <td>00-1026-R</td> <td>05060472441058</td> <td>989706000101</td> </tr> </tbody> </table>	Part No.	UDI No.	12NC No	00-1004-R	05060472440020	989706002081	00-1007-R	05060472440013	989706000001	00-1024-R	05060472441027	989706000051	00-1026-R	05060472441058	989706000101
Part No.	UDI No.	12NC No														
00-1004-R	05060472440020	989706002081														
00-1007-R	05060472440013	989706000001														
00-1024-R	05060472441027	989706000051														
00-1026-R	05060472441058	989706000101														
PROBLEM DESCRIPTION	<p>An inadvertent software error has been detected as part of an internal production control activity for the Tempus Pro. The defect initially identified was traced by investigation and found to relate to an intermittent software error which can occur immediately after unplugging the Video Laryngoscope (Part Number: 8403XSB) from the USB port.</p> <p>The software error can then impact the ability of Tempus Pro to continue monitoring the patient after unplugging the Video Laryngoscope.</p> <p>The software error is only present on Tempus Pro devices with Trizeps 7 Hardware.</p> <p>On review of our post market data, only one complaint has been identified which is linked to this issue. There have been no reports of patient harm as a result of this issue.</p>															
HAZARD INVOLVED	<p>Hazard associated with performance issue:</p> <p>If the mentioned failure occurs after unplugging the Video Laryngoscope, there is a possibility of one of the following failures:</p> <ul style="list-style-type: none"> • Cellular 3G/4G connection is lost until device has been rebooted • A frozen Video Laryngoscope image as the unplugging from the USB has not been detected • USB communications are frozen until power reset • Power reset could take up to 3 minutes to resume normal operation 															



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HOW TO IDENTIFY AFFECTED PRODUCTS

A list of affected Tempus Pro device serial numbers is provided in Attachment 1 of this Field Safety Notice.

The serial number of the Tempus Pro can be found on the rear labelling of the device. Devices using TR7 Hardware can be identified by a serial number beginning 61XXXX

- Tempus Pro with RapidPak Variants 00-1004-R and 00-1007-R.

The serial number (SN) label of the Tempus Pro with RapidPak is located on the top right hand corner of the device.



- Tempus Pro with Printer Variants 00-1024-R and 00-1026-R.

The serial number (SN) label of the Tempus Pro with Printer is located on the bottom left hand corner of the device.



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ACTION TO BE TAKEN BY CUSTOMER / USER	<ul style="list-style-type: none">- The information in this notice should be provided to all the users of the Tempus Pro (with Trizeps 7 (TR7) Hardware).- Notify all users of the potential risk of loss of monitoring when unplugging the Video Laryngoscope causing the device to reboot.- If you are using the Video Laryngoscope on a patient, we recommend completion of any critical interventions before unplugging the Video Laryngoscope from the USB port.- Should the Video Laryngoscope image become frozen on the screen, re-start (turn off and turn back on) the Tempus Pro device.
ACTIONS PLANNED BY RDT	RDT is developing a software update to resolve this potential issue which will be provided via a downloadable link and updated in the field as soon as it is available.
FURTHER INFORMATION AND SUPPORT	If you need any further information or support concerning this issue, please contact RDT Recall contact: <ul style="list-style-type: none">• Email: RDT.Recall.Response@Philips.com• Phone: +44 (0) 1256 362400



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FIELD SAFETY NOTICE

Customer Reply form

Tempus Pro - FA 009

Please complete, sign, and return this form at your earliest convenience,
and no later than 15 July 2021.

Customer Name:	
Contact Name:	
Telephone Number:	
Email Address:	
Facility Name:	
Street Address:	
City, State, Postal Code:	
Country:	

CUSTOMER ACKNOWLEDGEMENT

I acknowledge that I have read and understood the Field Safety Notice.

Signature: _____ Date: _____

Please return your completed form at your earliest convenience to the email address below:

- Email completed and signed form to: RDT.Recall.Response@Philips.com



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FIELD SAFETY NOTICE

Attachment 1

Purpose: This attachment is a listing of all global products in the scope of this Field Safety Notice.

Serial No	Serial No	Serial No	Serial No	Serial No	Serial No
614214	614303	614632	614699	614789	614858
614224	614325	614634	614703	614794	614859
614235	614326	614635	614704	614795	614860
614236	614328	614636	614705	614796	614861
614240	614330	614638	614706	614797	614862
614241	614335	614643	614707	614799	614863
614242	614369	614644	614730	614804	614864
614243	614388	614645	614734	614809	614865
614244	614396	614646	614736	614811	614866
614246	614421	614647	614737	614813	614867
614247	614451	614648	614743	614814	614868
614249	614452	614649	614744	614818	614869
614250	614455	614651	614745	614824	614870
614255	614456	614652	614747	614825	614871
614257	614464	614653	614748	614827	614872
614258	614477	614674	614749	614828	614873
614260	614494	614678	614751	614829	614874
614262	614508	614679	614753	614833	614875
614267	614523	614680	614759	614834	614876
614276	614528	614681	614761	614837	614877
614279	614531	614682	614762	614840	614878
614280	614547	614683	614767	614841	614883.
614283	614558	614686	614769	614844	614884.
614285	614588	614687	614773	614845	614885.
614287	614601	614688	614775	614849	614886.
614288	614604	614689	614776	614851	614887.
614289	614609	614690	614780	614852	614889.
614292	614610	614691	614782	614853	614890.
614295	614629	614692	614783	614855	614891
614300	614630	614693	614788	614856	614893



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Serial No	Serial No	Serial No	Serial No	Serial No	Serial No
614894	614958	615090	615122	615259	615309
614895	614964	615091	615123	615260	615311
614896	614966	615092	615124	615261	615312
614897	614967	615093	615125	615262	615313
614898	614974	615094	615126	615263	615315
614901	614975	615095	615127	615265	615316
614902	614976	615096	615128	615266	615317
614903	614977	615097	615130	615268	615318
614904	615032	615098	615131	615269	615320
614905	615034	615099	615133	615270	615321
614906	615036	615100	615236	615271	615323
614907	615037	615101	615237	615272	615326
614908	615038	615102	615238	615274	615327
614909	615039	615103	615241	615275	615329
614910	615040	615104	615242	615276	615330
614916	615047	615105	615243	615278	615331
614917	615048	615106	615244	615279	615332
614918	615049	615107	615245	615280	615335
614919	615050	615108	615246	615282	615336
614920	615051	615109	615247	615283	615338
614921	615052	615110	615248	615284	615342
614922	615053	615111	615249	615290	615343
614924	615055	615112	615250	615292	615344
614925	615056	615113	615251	615293	615345
614926	615060	615115	615252	615295	615346
614928	615061	615117	615253	615297	615347
614929	615084	615118	615255	615298	615348
614940	615085	615119	615256	615302	615349
614941	615088	615120	615257	615306	615351
614944	615089	615121	615258	615308	615352



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Serial No	Serial No	Serial No	Serial No	Serial No	Serial No
615353	615408	615461	615565	615635	615671
615355	615409	615463	615568	615636	615674
615358	615410	615465	615569	615638	615677
615359	615411	615467	615572	615640	615683
615360	615412	615468	615573	615642	615687
615361	615413	615470	615575	615643	615689
615362	615415	615472	615576	615644	615690
615363	615418	615473	615577	615646	615693
615364	615420	615476	615578	615647	615700
615369	615432	615477	615579	615648	615702
615370	615433	615481	615581	615649	615705
615381	615434	615498	615583	615652	615706
615383	615435	615513	615585	615653	615709
615385	615436	615522	615599	615654	615717
615386	615438	615525	615608	615655	615718
615388	615442	615526	615609	615656	615719
615389	615443	615541	615611	615657	615720
615393	615444	615542	615613	615659	615725
615395	615449	615543	615620	615661	615726
615396	615450	615545	615624	615663	615728
615399	615451	615547	615628	615664	615729
615401	615456	615554	615629	615665	615735
615402	615457	615560	615630	615667	615742
615403	615459	615561	615632	615669	615743
615405	615460	615563	615633	615670	615745



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