

New Field Safety Notice

Urgent Medical Device Correction – Potential Loose Instrument Carriage on da Vinci X and Xi Systems (ISIFA2022-14-C)

1- Introduction and Reason for Field Action

Dear Intuitive Customer,

This Field Safety Notice is to notify you that a population of the da Vinci X and Xi system instrument arms (USMs) have Instrument Carriages that may separate from the Insertion Axis Linear Rail during shipping, handling, or repositioning of the arms when the system is powered down. The Instrument Carriage would remain attached to the drive motor which prevents free-fall motion or complete detachment from the USM. However, the Instrument Carriage may feel like it is not tightly connected to the rail. This condition may also lead to increased friction along the insertion axis.

Instrument Carriages that are intact will function as intended and are expected to remain firmly attached throughout a surgical procedure.

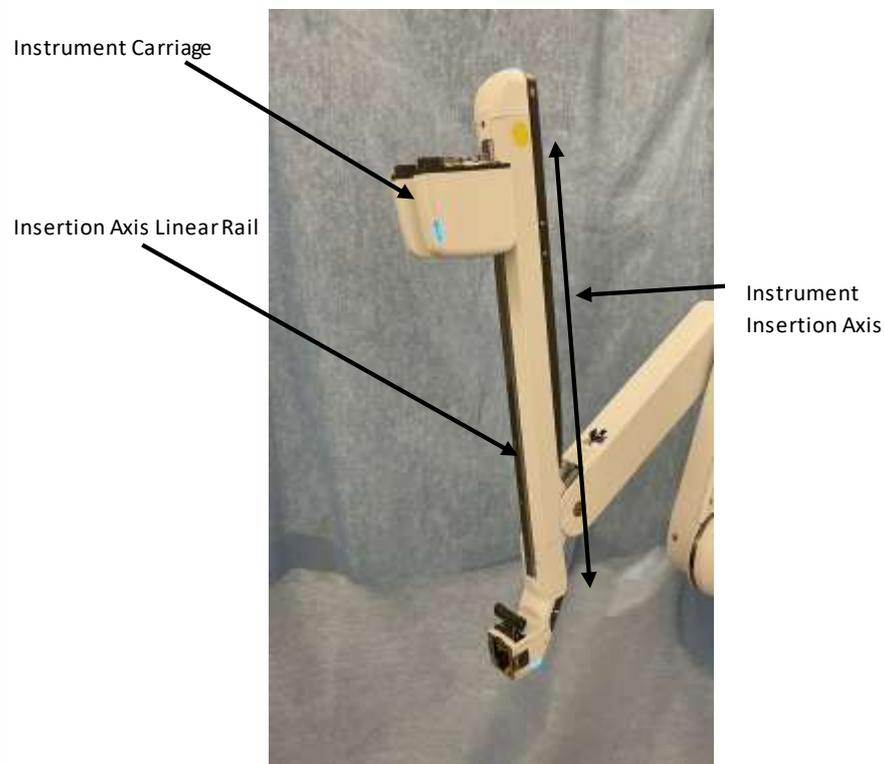


Figure 1: Instrument Carriage and Insertion Axis Rail on Instrument Arm

The Instrument Carriage slides on the Insertion Axis Linear Rail which ensures smooth motion along the Insertion Axis and maintains precise instrument alignment with the cannula. However, there is a population of USMs where the width of the insertion rail does not meet acceptance criteria. This puts the Instrument Carriage at risk of becoming separated from the linear rail when a large external force is applied to the side of the Instrument Carriage.

Examples of when such forces may be generated include but are not limited to:

- Shipping and handling of the USM or System

	<ul style="list-style-type: none"> • If the Instrument Carriage is grabbed to manually move the arm when the da Vinci X/Xi system is powered off • Other high impact forces, such as collisions while moving or stowing the arm cart <p>The function and performance of an Instrument Carriage along the insertion axis of the affected population of rails is not altered if the instrument carriage is properly attached to the rail. Forces resulting from standard instrument exchanges and/or internal/external instrument collisions are not likely to be large enough to separate the instrument carriage from the linear rail. It is highly unlikely for the Instrument Carriage to separate from the linear rail during normal use of the affected USM in a surgical procedure.</p>								
<p>2 - Risk to Health</p>	<p>To date, there have been no related Adverse Events*/Serious Incidents** for this issue.</p> <p>Risk to health is possible when a separated Instrument Carriage is used during a procedure. Instrument collisions both internal and external on an Instrument Carriage that is already separated from the linear rail may result in lateral displacement of the instrument tip. This lateral motion may result in unintended tissue contact.</p> <p>Additionally, unintended tissue interaction and/or injury may occur due to increased friction experienced while using an instrument installed on a separated Instrument Carriage. The degree of harm would depend on the tissue type and the degree of interaction, which could range from negligible to severe.</p> <p>An instrument installed on a separated carriage may not present any functional deficiencies due to increased friction during clinical use. In this case, no patient harm will occur. The separated instrument carriage may be noticed as being not tightly connected during use or it may be noticed outside of clinical use.</p> <p>During a procedure, instrument collisions both internal and external are not likely to separate the Instrument Carriage from the insertion linear rail.</p>								
<p>3- Affected Products</p>	<p>Within the affected population of USMs, two distinct sub-populations have been identified as Group 1 and Group 2. Please refer to the Affected Product Appendices B and C below for respective USM and associated Da Vinci X or Xi System Serial Numbers.</p> <p>While both groups are suspected to not meet acceptance criteria, the width of linear rails in Group 1 are thinner compared to the linear rails in Group 2.</p> <table border="1" data-bbox="466 1541 1445 1733"> <thead> <tr> <th>Part Number</th> <th>Product Name (if applicable)</th> <th>Unique Device Identifier</th> <th>Affected Serial Number</th> </tr> </thead> <tbody> <tr> <td>380647</td> <td>ASSY,USM,IS4000 da Vinci Xi Surgical System da Vinci X Surgical System</td> <td>00886874114216</td> <td>See Appendix B and Appendix C</td> </tr> </tbody> </table>	Part Number	Product Name (if applicable)	Unique Device Identifier	Affected Serial Number	380647	ASSY,USM,IS4000 da Vinci Xi Surgical System da Vinci X Surgical System	00886874114216	See Appendix B and Appendix C
Part Number	Product Name (if applicable)	Unique Device Identifier	Affected Serial Number						
380647	ASSY,USM,IS4000 da Vinci Xi Surgical System da Vinci X Surgical System	00886874114216	See Appendix B and Appendix C						
<p>4- Actions to be taken by the Customer/User</p>	<p>All affected systems remain safe for use if the following instructions are followed:</p> <ul style="list-style-type: none"> • Prior to each use, inspect all the Instrument Carriages on your affected da Vinci X and Xi systems using the 'Instrument Carriage Inspection Instructions' outlined in Appendix A below. If an Instrument Carriage fails the inspection or if there is any concern, do not use the USM and notify Intuitive. If 3 of the 4 USM Instrument Carriages pass the inspection, the da Vinci X or Xi system may be used per instructions in section Three-Arm procedure of the da Vinci X and Xi systems user manual. 								

	<ul style="list-style-type: none"> • Please continue to adhere to instructions in the da Vinci X and Xi User Manual and hold the USM/arm by its gray handle during manual moving and positioning of the arm. Do not use the Instrument Carriage to manually reposition the USM when the system is powered off or in a fault condition. If this is unavoidable in the event of an emergency, please Stop Using that USM and notify Intuitive. Intuitive representative will schedule a visit to perform inspection and necessary correction.  <p>Figure 2: Image showing how to properly hold the USM during manual positioning</p> <ul style="list-style-type: none"> • If instruments cannot be manipulated in a precise and controlled manner, contact Intuitive Technical Support immediately to prevent tissue injury. <p>As part of this communication, please take the following standard actions:</p> <ul style="list-style-type: none"> • This notice needs to be passed on to all those who need to be aware within your organization or functions where the potentially affected devices have been transferred. • Complete the attached Acknowledgement Form immediately and return it via fax or email to Intuitive as instructed on the form. • Please retain a copy of this letter, place a copy with your affected system, and keep the acknowledgement form for your files. • Please inform Intuitive of any Adverse Events */Serious Incidents** or quality problems concerning the use of the subject devices via the standard complaint process. • Additionally, if Adverse Events */Serious Incidents** or quality problems are experienced, please follow your standard reporting process to your health authority, if applicable.
<p>5- Actions to be taken by Intuitive Surgical</p>	<p>Affected Group 1 USM's An Intuitive Representative will schedule a site visit to perform replacement of the affected USMs.</p> <p>Affected Group 2 USM's An Intuitive Representative will schedule a site visit to inspect the insertion linear rail and replace the USM if found to not meet acceptance criteria.</p> <p>Please refer to the Affected Product Appendices B and C below for respective USM and associated da Vinci X or Xi System Serial Numbers.</p>
<p>6- Further Information & Support</p>	<p>If you need further information or support concerning this Medical Device Correction, please contact your Clinical Sales Representative or contact Intuitive Customer Service at the numbers listed below:</p> <ul style="list-style-type: none"> • Europe, Middle East, Asia, South America and Africa: +800 0821 2020 or +41 21 821 2020 (8 AM to 6 PM CET) or EUCS@intusurg.com



Please be informed that the appropriate Regulatory Authority for your region has been notified of this Field Safety Corrective Action.

Sincerely,

Intuitive Surgical SAS

11 avenue de Canteranne
33600 Pessac, France
+800 0821 20 20

Definitions:

* Adverse Event is defined as “an event or incident that led to a death, serious injury, or serious deterioration in the state of health of a patient, user, or other person; if the event or incident was wholly or partially caused by the device or by shortcomings in the information supplied with the device.”

**Serious Incident (EU MDR 2017/745) is defined as “any incident that directly or indirectly led, might have led or might lead to any of the following:

- a. the death of a patient, user or other person
- b. the temporary or permanent serious deterioration of a patient’s, user’s, or other person’s state of health,
- c. a serious public health threat”

ACKNOWLEDGMENT FORM

New Field Safety Notice

**Urgent Medical Device Correction – Potential Loose Instrument
Carriage on da Vinci X and Xi Systems (ISIFA2022-14-C)**

Ship-to:

Hospital Name: <mail merge>

Address: <mail merge>

City, State, Zip: <mail merge>

SFID: <mail merge>

ATTENTION: <mail merge>

PLEASE COMPLETE ALL REQUESTED INFORMATION AND RETURN IMMEDIATELY

1. I have received and read this notice.
2. I have ensured all appropriate personnel are fully informed of the contents of this notice.
3. I will contact Intuitive if I have any questions.

Hospital name: _____

Position:

Name (print): _____

- Robotics Coordinator
 Operating Room Director

Signature: _____

Risk Manager

Phone Number: _____

Surgeon

Other: _____

Email: _____

Date: _____

**PLEASE FAX OR EMAIL THIS ACKNOWLEDGEMENT FORM TO Intuitive
ATTN: REGULATORY COMPLIANCE FIELD ACTIONS
Subject line for email: Potential Loose USM's (ISIFA2022-014-C)
Scan and Email: EU.FSCA@intusurg.com or Fax: +800 0821 2021 / +41 21 821 2021**

Customer Service:

- Europe, Middle East, Asia, South America and Africa: +800 0821 2020 or +41 21 821 2020 (8 AM to 6 PM CET) or EUCS@intusurg.com

ISIFA2022-14-C Appendix A : Instrument Carriage Inspection
Instructions

From stowed position, orient all Patient Cart arms such that the instrument arms are in the vertical position (Figure 1). When facing the Patient Cart column, identify the right-hand side of the Instrument Carriage as designated by the arrow in Figure 1.



Position one Patient Cart arm such that it is pitched fully forward, and the instrument arm is parallel to the ground (Figure 2).



Using only two fingers, apply moderate pressure to the center of the Instrument Carriage on the right-hand side, as shown in Figure 3. **This must be done on the right-hand side of the Instrument Carriage, as defined in Figure 1.** The arm may move. If movement occurs, stabilize the arm to avoid collisions with user or other arms.



Figure 3

Closely inspect from all angles the interface between the Instrument Carriage and arm (inspection area in red box, Figure 4) and evaluate the interface using the below Pass/Fail criteria. **This must be done on the right-hand side of the Instrument Carriage, as defined in Figure 1.** Repeat all steps for all remaining arms.

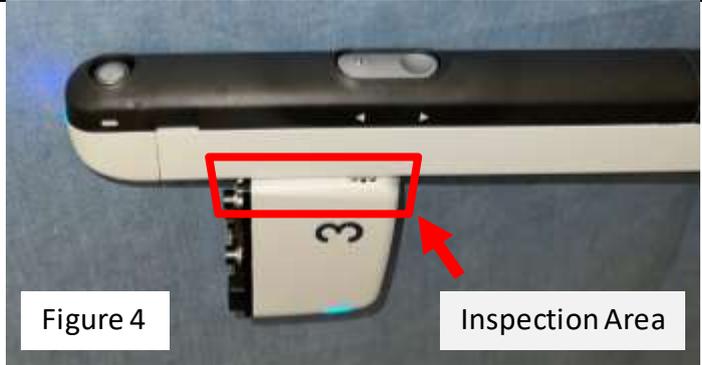


Figure 4

Inspection Area

PASS: Unable to see serial number and barcode (Figure 5).

Acceptable to use system.

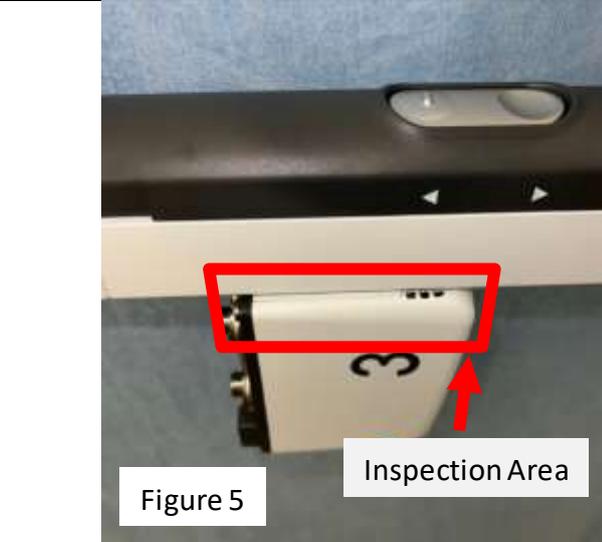
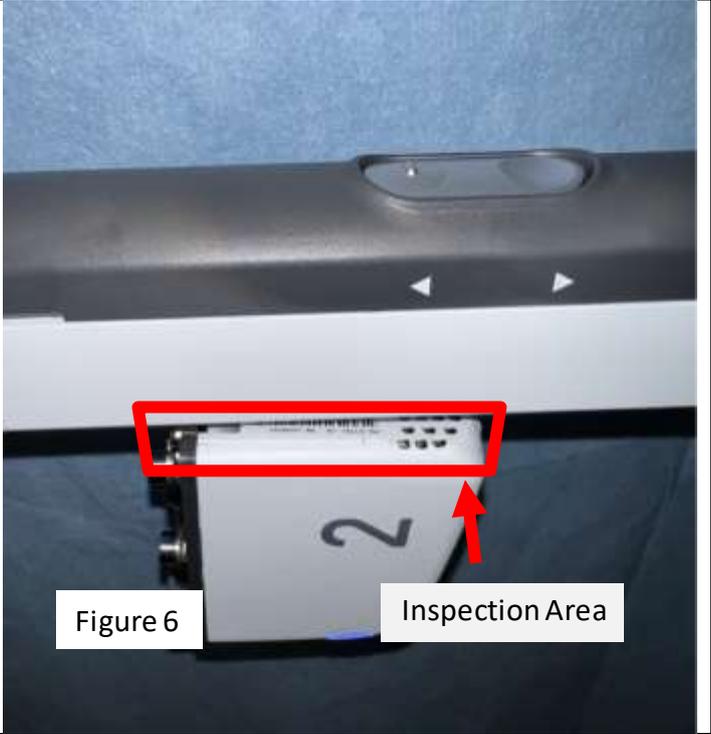


Figure 5

Inspection Area

FAIL: Able to see serial number **and** any section of barcode (Figure 6).

Do not use arm.



ISIFA2022-14-C Appendix B: Group 1 Affected System and USM Serial Numbers

Country	System Serial Number	USM Serial Number
Australia	SK1607	448553
Austria	SK5864	10156153
Austria	SK5864	10156581
Austria	SK5864	10158727
Austria	SK5924	10160468
Austria	SK5924	10160987
Austria	SK5924	10161574
Austria	SK5924	10161588
Belgium	SK5669	10161575
Brazil	SK5919	10160978
Canada	SK6243	10193039
China	SK5800	10156980
China	SK5800	10156986
China	SK5803	10156973
China	SK5803	10156982
China	SK5803	10157613
China	SK5803	10160467
China	SK5804	10156151
China	SK5804	10156968
China	SK5818	10156590
China	SK5818	10157619
China	SK5819	10156586
China	SK5819	10158179
China	SK5820	10156588
China	SK5820	10157621
China	SK5820	10158165
China	SK5820	10158176
China	SK5822	10156578
China	SK5822	10157627
Ecuador	SK5920	10158723
France	SK0912	418783
France	SK5814	10155497
France	SK5814	10156978
France	SK5861	10156149
France	SK5861	10156589
France	SL0354	449298

Country	System Serial Number	USM Serial Number
France	SL1016	10159440
Germany	SK0141	377227
Germany	SK2508	559374
Germany	SK3518	358921
Germany	SK5806	10161573
Germany	SK5865	10160453
Germany	SK5882	10156143
Germany	SK5882	10158180
Germany	SK5882	10158708
Germany	SK5882	10161592
Germany	SK6057	10156138
Germany	SL0940	10033447
Germany	SL1033	10155488
Germany	SL1033	10156587
Germany	SL1037	10156579
Germany	SL1037	10160476
Germany	SL1043	10156135
Hungary	SK5547	470860
Hungary	SK5547	552658
India	SK5961	10160993
India	SK6139	10192349
India	SK6139	10193050
India	SL1035	10157614
India	SL1044	10156972
India	SL1044	10160475
India	SL1054	10158709
India	SL1054	10158711
India	SL1054	10159419
India	SL1055	10158713
India	SL1055	10158731
Luxembourg	SK1118	376142
Mexico	SK5798	10156970
Mexico	SK5798	10156971
Netherlands	SK0957	462367
Norway	SK5897	10155491
Norway	SK5897	10156585

Country	System Serial Number	USM Serial Number
Norway	SK5897	10158729
Norway	SL1042	399715
Poland	SL0530	384054
Poland	SL1023	457384
Portugal	SK5884	10156161
Portugal	SK5884	10158732
Portugal	SK5884	10159416
Portugal	SK5884	10159431
Slovakia	SK5943	10156975
Slovakia	SK5943	10157620
Slovakia	SK5943	10157632
Slovakia	SK5943	10158177
South Korea	SK2538	384365
South Korea	SK5887	10158174
Spain	SK5869	10156152
Spain	SK5869	10158181
Spain	SK5869	10158715
Spain	SK5892	10156965
Spain	SK5892	10159429
Sweden	SK0540	707132
Sweden	SK2654	411325
Sweden	SL1032	10156976
Sweden	SL1032	10156983
Sweden	SL1047	832874
Taiwan	SK5894	10156144
Thailand	SK5866	10159438
Thailand	SK5866	10160474
Turkey	SK1651	10160464
Turkey	SK5942	10160981
United Kingdom	SK0213	922170
United Kingdom	SK5946	10161576
United Kingdom	SK6016	10194949

ISIFA2022-14-C Appendix C: Group 2 Affected System and USM Serial Numbers

Country	System Serial Number	USM Serial Number
Argentina	SK5850	10145831
Argentina	SK5850	10149905
Australia	SK0739	463501
Australia	SK1143	438554
Australia	SK1187	622709
Australia	SK2667	631715
Australia	SK5918	10178609
Australia	SK5918	10186167
Australia	SK5918	10186172
Australia	SL0015	419753
Austria	SK4674	438771
Austria	SK5864	10156596
Austria	SL1024	10122506
Belgium	SK5669	10145238
Belgium	SK5669	10145243
Belgium	SK5727	10141675
Belgium	SK5729	10124660
Brazil	SK1423	10137759
Brazil	SK5919	10179424
Brazil	SL1062	10125231
Canada	SK5646	10140839
Canada	SK5646	10140842
Canada	SK5646	10141670
Canada	SK5646	10143148
Canada	SK6111	10185264
Canada	SK6111	10186706
Canada	SK6243	10192345
Canada	SK6243	10192350
China	SK5554	10137748
China	SK5554	10137752
China	SK5555	10137754
China	SK5555	10137760
China	SK5561	10122498
China	SK5561	10125239
China	SK5586	10124669
China	SK5586	10142413

Country	System Serial Number	USM Serial Number
China	SK5586	10143144
China	SK5612	10137203
China	SK5704	10143143
China	SK5782	10144322
China	SK5782	10150522
China	SK5796	10153517
China	SK5796	10153798
China	SK5796	10153804
China	SK5796	10155082
China	SK5799	10153806
China	SK5804	10155059
China	SK5818	10156160
China	SK5822	10156594
China	SK5822	10156595
China	SK5885	10178605
China	SK5885	10186169
China	SK5885	10186174
Czech Republic	SK0329	462466
Denmark	SK0429	364479
Denmark	SK5693	10136558
Ecuador	SK5920	10186681
Ecuador	SK5920	10186687
Ecuador	SK5920	10187274
Finland	SK5832	10152296
Finland	SK5832	10153516
Finland	SK5832	10153784
Finland	SK5832	10154493
Finland	SL1029	10148489
Finland	SL1029	10153778
Finland	SL1029	10154490
France	SK5617	10124652
France	SK5814	10122978
France	SK5814	10155065
France	SK5861	10156592
France	SK5893	10146525
France	SK5893	10147268

Country	System Serial Number	USM Serial Number
France	SL0980	10122511
France	SL1010	10137211
France	SL1010	10138881
France	SL1010	10140216
France	SL1012	10137205
France	SL1012	10137778
France	SL1014	10148496
France	SL1014	10154477
France	SL1014	10154492
France	SL1016	10154498
France	SL1019	10142407
France	SL1019	10142410
France	SL1022	10144327
Germany	SK0128	433634
Germany	SK2274	10121698
Germany	SK2658	376345
Germany	SK5598	10122499
Germany	SK5598	10122503
Germany	SK5598	10142416
Germany	SK5598	10149894
Germany	SK5806	10137212
Germany	SK5865	10149540
Germany	SK5865	10154479
Germany	SK5865	10155077
Germany	SK5930	10178594
Germany	SK5930	10185241
Germany	SK5930	10186682
Germany	SK5947	10153522
Germany	SK5947	10153788
Germany	SK5947	10155061
Germany	SK5947	10155073
Germany	SL0116	596082
Germany	SL0905	411328
Germany	SL0912	10137761
Germany	SL1007	10137585
Germany	SL1013	10141679

Country	System Serial Number	USM Serial Number
Germany	SL1013	10142406
Germany	SL1017	10125235
Germany	SL1017	10142415
Germany	SL1028	10139723
Germany	SL1028	10141668
Germany	SL1037	10153796
Germany	SL1043	10156582
Greece	SK1322	10144866
Greece	SK5149	354562
Greece	SK5950	10185239
Hong Kong	SK0563	376016
India	SK4328	468796
India	SK4576	10143151
India	SK4576	10143702
India	SK5098	361795
India	SK5553	10121705
India	SK5582	10122987
India	SK5629	10148497
India	SK5629	10149901
India	SK6010	10187925
India	SK6010	10187929
India	SK6010	10187930
India	SK6139	10186696
India	SK6139	10187270
India	SL0984	10122497
India	SL0985	10122500
India	SL1035	10155475
India	SL1055	10153797
India	SL1095	10138882
Ireland	SL0205	410762
Italy	SK0395	396049
Italy	SK5447	471437
Italy	SK5649	10137746
Italy	SK5649	10146409
Italy	SK5649	10147248
Italy	SK5650	10144335

Country	System Serial Number	USM Serial Number
Italy	SK5650	10145823
Italy	SK5650	10147256
Italy	SK5650	10149898
Italy	SK5653	10144328
Italy	SK5653	10144334
Italy	SK5653	10145824
Italy	SK5654	10145826
Italy	SK5654	10146403
Italy	SK5662	10140322
Italy	SK5662	10145835
Italy	SK5663	656060
Italy	SK5663	10141683
Italy	SK5663	10142418
Italy	SK5663	10149553
Italy	SK5664	10137179
Italy	SK5664	10137757
Italy	SK5666	10140217
Italy	SK5668	10147240
Italy	SK5668	10149554
Italy	SK5668	10149904
Italy	SK5677	10122993
Italy	SK5677	10143140
Italy	SK5900	10178613
Italy	SK5900	10179426
Italy	SK5900	10180256
Italy	SK5901	10179423
Italy	SL0160	403044
Italy	SL0993	10124653
Italy	SL1030	10138888
Italy	SL1030	10140225
Italy	SL1031	10137170
Italy	SL1031	10137777
Mexico	SK5781	10154500
Netherlands	SK1436	716446
Netherlands	SK1784	10137749
Netherlands	SK2403	358073

Country	System Serial Number	USM Serial Number
New Zealand	SK5904	10186175
Norway	SL1042	592301
Poland	SK5689	10139732
Poland	SK5689	10139734
Poland	SL1006	10137772
Poland	SL1006	10137773
Poland	SL1006	10140307
Poland	SL1023	10148490
Portugal	SK0866	10137770
Portugal	SL1027	10143154
Portugal	SL1027	10149556
Portugal	SL1027	10149557
Portugal	SL1027	10149563
Romania	SK3504	353917
Romania	SK5609	10145234
Romania	SK5609	10145242
Romania	SK5609	10145257
Romania	SK5951	10185320
Romania	SK5951	10186690
Russia	SK4562	658459
San Marino	SK5665	10143695
San Marino	SK5665	10143698
San Marino	SK5665	10144325
San Marino	SK5665	10144326
South Africa	SK5753	10147253
South Africa	SK5753	10148492
South Korea	SK1450	576920
South Korea	SK2512	380947
South Korea	SK3182	576915
South Korea	SK5887	10147262
South Korea	SK5887	10185250
Spain	SK5667	10140228
Spain	SK5667	10140832
Spain	SK5667	10141669
Spain	SK5674	10138886
Spain	SK5674	10140843

Country	System Serial Number	USM Serial Number
Spain	SK5674	10142417
Spain	SK5675	10141663
Spain	SK5675	10143145
Spain	SK5676	10145145
Spain	SK5676	10145235
Spain	SK5676	10145240
Spain	SK5676	10145262
Spain	SK5692	10145233
Spain	SK5692	10145258
Spain	SK5692	10145259
Spain	SK5692	10145260
Spain	SL0996	10122501
Spain	SL0996	10122502
Spain	SL0996	10122510
Spain	SL1020	10121701
Spain	SL1020	10122505
Spain	SL1020	10137599
Spain	SL1021	10148503
Spain	SL1021	10149541
Spain	SL1021	10149559
Spain	SL1021	10151619
Sweden	SK5736	10137168
Sweden	SK5736	10137593
Sweden	SK5736	10138892
Switzerland	SK5599	10122504
Taiwan	SK5564	433824
Taiwan	SK5580	10125245
Taiwan	SK5894	10154504
Taiwan	SK5894	10155060
Turkey	SK0221	10121695
Turkey	SK5601	10124658
Turkey	SK5645	10137766
Turkey	SK5942	10156597
Turkey	SK5942	10156966
U.A.E.	SK3294	461315
United Kingdom	SK0751	10137765

Country	System Serial Number	USM Serial Number
United Kingdom	SK3893	10137745
United Kingdom	SK4400	414241
United Kingdom	SK5316	399674
United Kingdom	SK5673	10137781
United Kingdom	SK5673	10139729
United Kingdom	SK5673	10139736
United Kingdom	SK5853	10185252
United Kingdom	SK5853	10185324
United Kingdom	SK5853	10185329
United Kingdom	SK6015	10177847
United Kingdom	SK6016	10180278
United Kingdom	SK6016	10180279
United Kingdom	SK6016	10181073
United Kingdom	SK6018	10178612
United Kingdom	SL0974	473439
United Kingdom	SL1040	10148493
United Kingdom	SL1040	10150502
United Kingdom	SL1040	10154488