

June 22, 2022

RISK MANAGER
 UNIVERSITY OF CALIFORNIA - BERKELEY
 2000 CARLETON ST
 BERKELEY, CA 94720

VIA FEDEX

URGENT FIELD ACTION NOTICE

Affected Products: ULTIMA washer/dryer series (1400LX, 1400LXP and 1600LXP)

Product Issue: Getinge Life Science has received complaints where the screed/cylinder link of the ULTIMA washer/dryer was broken, leaving the door no longer retained when opened which may result in an unreasonable risk of harm to the user.

Resolution: Getinge proposes to repair the affected unit at your facility to ensure that it is working effectively and safely.

Affected Serial No.: Refer to page 5 and 6 for your affected serial numbers.

PLEASE FORWARD THIS INFORMATION TO ALL RISK MANAGERS AND ALL USERS OF THE ULTIMA WASHER/DRYER SERIES (1400LX, 1400LXP AND 1600LXP) WITHIN YOUR INSTITUTION.

Dear Risk Manager:

Getinge Life Science is initiating an Urgent Field Action Notice for the ULTIMA washer/dryer series (1400LX & 1400LXP and 1600LXP) due to the potential malfunction of the hydraulic/pneumatic braking mechanism, shown in Figure 1, which may result in an unreasonable risk of harm to the user.

Our records indicate that you may have an ULTIMA washer/dryer series (1400LX & 1400LXP and 1600LXP) with a serial number that is affected by this recall.

This letter is to inform you of the corrective action being conducted by Getinge Life Science to prevent a potential malfunction with the ULTIMA washer/dryer series (1400LX & 1400LXP and 1600LXP). This corrective action will be performed to prevent any possible hazard to staff, goods, and equipment.

The issue found may cause the ULTIMA washer/dryer door not being latched and possibly falling onto the operator/individual. This malfunction has a potential to cause serious injuries such as blunt injury to the neck, shoulder, and upper back. Also, it could result in minor injury including a hematoma/bruise, a contusion/laceration, or permanent damage to the vertebrae, nerves, or the vasculature.

Important notes:

- This failure does not occur during a washing/drying cycle.
- The door cannot fall entirely as it is horizontally blocked by a mechanical stop, leaving the loading racks unaffected.

This potential for malfunction is caused by a failure of the screed/cylinder, shown in Figure 2, due to the part being too constrained resulting in a rupture of the screed/cylinder link, as shown in Figure 3.

This Urgent Field Action Notification is to inform customers with the affected product to remove from area(s). Subsequently, an upgrade kit will be provided to replace existing door fixating mechanism with a new one. The installation will be done by Getinge service technicians at no charge to the customer. You will be contacted by a Getinge Service Technician when the upgrade kit is ready for installation at your facility.

Only the the ULTIMA washer/dryer series (1400LX & 1400LXP and 1600LXP) serial numbers identified on page 5 and 6 are impacted by this field action.

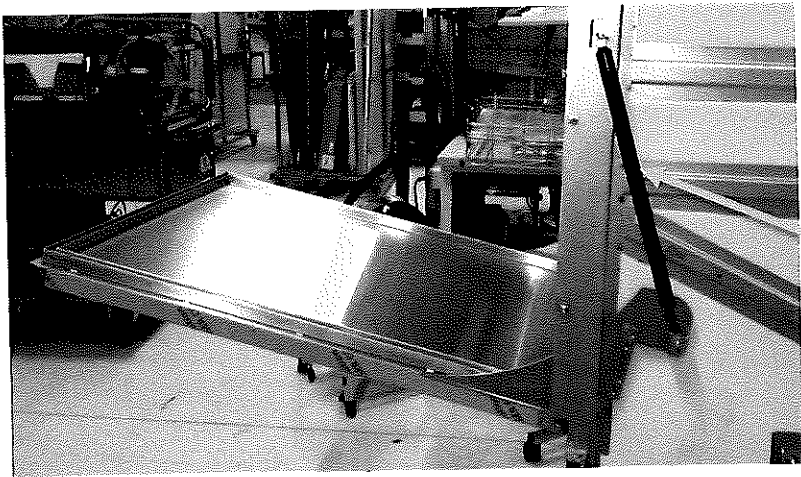


Figure 1: hydraulic/pneumatic braking mechanism

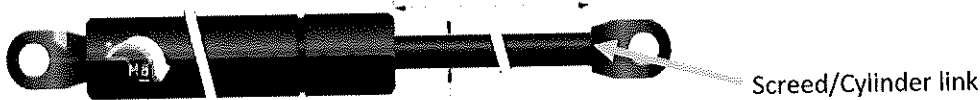


Figure 2: Screed / Cylinder link

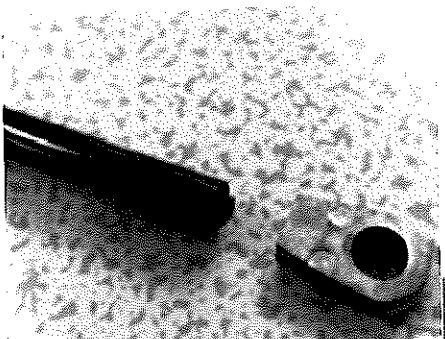


Figure 3: Screed/Cylinder link breaking

Next Steps:

1. Please examine your inventory immediately to determine if you have any ULTIMA washer/dryer series (1400LX, 1400LXP, 1600LXP) with the product codes/serial numbers listed in this notice.
2. Should you have any affected product, please remove from area(s) of use until a Getinge trained and authorized service technician replaces the new door fixating mechanism.
3. Whether or not you have affected product(s) with the serial numbers listed in this notice, please complete and sign the attached URGENT FIELD ACTION NOTICE - RESPONSE FORM (page 4) to acknowledge that you have received this notification. A Getinge Service Technician will contact the person you list on the Customer Response Form to schedule service for an inspection.

Return the completed form to Getinge by e-mailing a scanned copy to isultimawasher2022.us@getinge.com or by faxing the form to +1 (877) 457-1470.

4. You can also arrange a visit by a Getinge-trained or authorized service technician by contacting Getinge Tech Support at (888) 9GETUSA / (888) 943-8872 (select option 4, then option 2), between the hours of 8:00 a.m. and 6:00 p.m. Eastern Standard Time.
5. Please, forward this information to all current and potential ULTIMA washer/dryer series (1400LX & 1400LXP and 1600LXP) users within your hospital / facility

This Getinge Urgent Field Action Notice needs to be distributed to those individuals who need to be aware within your organization - or to any organization where the potentially affected products have been transferred.

If you are a distributor who has shipped any affected product to customers, please forward this document to your customers' attention for appropriate action.

Please maintain awareness of this notice and resulting action for the use period of the product to ensure effectiveness of the corrective action.

In cases where you as the customer choose not to proceed with completion of the corrective action requirements described above, Getinge cannot take any responsibility for safety related issues or legal liabilities caused by the failure to respond to this Urgent Field Action Notice.

We regret any inconvenience this field correction may have caused, but we greatly appreciate your understanding. If you have any further questions or require assistance, please do not hesitate to contact Getinge.

Sincerely,



Bryam Piedra
Specialist I, Regulatory Affairs and Field Action compliance

URGENT FIELD ACTION NOTICE
ULTIMA washer / dryer series (1400LX, 1400LXP and 1600LXP)
CUSTOMER RESPONSE FORM

June 22, 2022

UNIVERSITY OF CALIFORNIA - BERKELEY
2000 CARLETON ST
BERKELEY, CA 94720

Our records indicate that the Ultima washer/dryer series (1400LX, 1400LXP and 1600 LXP) indicated below were delivered to your location. Please verify that you have the listed sterilizer that is potentially affected and complete the information below.

List of Affected Cardiohelp-I Devices at Your Facility:

Part Number/REF Number(s)				
1400LXP <input type="checkbox"/> AA01260371 <input type="checkbox"/> 01260341	1400LX <input type="checkbox"/> 01260340	1600LXP <input type="checkbox"/> AA01260372 <input type="checkbox"/> 01260342		
Serial Number(s)				
2202355				

Please check the appropriate boxes below:

We have read the Urgent Field Action Notice and we understand the communication and the required actions. We will take action as soon as possible according to instructions.

We have read the Urgent Field Action Notice and we understand the communication and the required actions. We can not take action but are aware of the addressed problem.

If checked: please provide information where the affected equipment is physically located.

Field Action Notice Receipt and Customer Response Form Completion and Certification

Current Facility Name			
Contact Name / Title			
Address (no PO boxes,			
City, State, Zip			
Phone Number		Fax:	
E-Mail Address:			

We have sold/moved our equipment to another facility:

If checked: please provide new facility information below.

New Facility Name			
Contact Name / Title			
Address			
City, State, Zip		Phone Number	

FAX BACK TO: 1-877-457-1470 OR EMAIL TO: lsultimawasher2022.us@getinge.com

Product code/ Part number	Serial Number							
01260340: 1400LX	0E035346	8E065039	9E115279	9E035134	9E035135	9E065178	9E065179	9E065180
	9E065183	9E065184	9E065185	8E045001	8E055025	8E055026	8E055027	8E055028
	9E065181	9E065182	8E055029	8E055030				
01260341: 1400LXP	0E065377	9E075189	0E015310	9E035130	9E015113	9E015114	8E095078	8E095079
	8E075050	8E055020	8E055021	8E125098	9E115288	9E035128	0E055361	0E015312
	0E045355	8E075049	0E065382	0E045350	9E055171	9E055174	9E115285	9E055163
	8E125102	8E125103	9E105263	8E085063	9E025119	9E045151	9E075190	9E055162
	8E055033	9E075195	9E075196	0E035341	8E095074	0E015314	0E015305	8E065043
	9E035132	9E015110	0E045357	9E075192	9E075199	9E085222	9E085221	8E115091
	8E055031	0E015311	9E075193	9E125290	9E045143	9E115286	9E105266	9E045146
	0E065383	9E055160	8E095075	9E055172	0E045349	9E125301	0E035345	9E045144
	0E055363	8E055032	9E055161	9E105270	0E025321	8E044991	9E105277	9E085217
	0E035334	0E035335	0E035336	0E035337	9E085218	8E085061	9E105265	9E045142
	9E055169	9E055173	9E075194	8E125099	9E105264	9E055166	9E115280	8E065042
	9E125297	9E125298	9E125299	9E035136	9E035137	9E075200	9E015115	9E015116
	9E105267	9E085219	8E085062	9E045145	9E115283	0E035343	8E105085	8E065044
	8E085065	8E105089	8E085064	8E125101	9E085223	9E035139	8E085058	0E035342
	9E055158	0E055365	9E095245	9E095246	9E075197	0E035332	8E125097	0E015313
9E055165	9E055168	9E035138	9E115287	9E125291	9E095238			
01260342: 1600LXP	9G054253	9G104317	9G064260	0G044370	0G044371	9G114332	0G034362	8G124212
	9G114333	9G114330	9G084280	8G094192	9G084281	8G084175	9G104318	0G054376
	0G044366	0G044367	0G044368	0G044369	8G074171	8G124214	8G104195	8G104196
	8G104193	9G024235	0G054378	9G054254	8G054154	9G074266	8G124215	9G074269
	8G084176	9G104315	8G084177	0G064388	0G024355	0G024356	9G064258	8G104202
	8G064169	8G104197	8G064170	9G104329	9G104323	9G104324	0G064385	0G064386
	9G014230	9G014231	0G044372	9G094314	9G074268	9G104326	8G084178	9G044246
	9G114335	9G054251	9G064255	8G094187	0G044373	0G044374	9G084279	8G114205
	9G074267	8G104199	9G124336	9G124337	0G054375	9G044244	9G104316	8G044152
9G094290	8G064168	9G034238	9G034237	9G014228	9G114334	9G014232	8G104203	
	Continue next page.							

Product code/ Part number	Serial Number							
AA01260371: 1400LXP	1E045530	1E035522	0E075389	1E075574	1E015474	1E015475	0E105435	1E025490
	1E035508	1E035509	0E115455	0E095413	0E075388	0E095416	0E125466	0E075402
	0E105438	1E075581	0E095412	1E055539	1E085595	1E025486	1E065567	1E025492
	1E025506	1E055555	1E085599	1E055547	1E055548	1E075579	1E085587	1E055543
	0E085408	1E025496	0E115449	0E095411	0E095415	1E055554	1E075578	1E025491
	1E055552	1E055536	1E055537	1E065558	1E065559	1E065560	1E065561	1E065562
	1E065565	1E035523	1E055551	0E095414	0E095425	0E095426	0E095427	0E095428
	0E125463	0E125464	1E055538	1E055535	0E105432	0E105433	1E015480	1E015481
	1E045524	1E045525	1E045526	0E075385	0E075386	1E055542	0E075403	0E075395
	1E035521	1E025501	1E015485	1E085596	0E085407	0E125467	0E075397	0E105440
	1E085586	1E075580	1E065563	1E065564	0E105439	0E115450	1E045528	1E045529
	0E075391							
AA01260372: 1600LXP	0G094399	0G094402	1G084474	0G094400	1G054443	1G084471	1G084470	0G124414
	1G074461	0G124410	0G124411	1G054441	1G044434	1G044435	1G044436	1G024422
	0G074394	1G034431	1G054446	0G074395	0G104404	1G074457	1G044432	1G044433
	1G084469	1G054442	1G064450	1G024428	1G054445	1G014417	0G074391	0G074392
	1G024423	0G074393	0G094397	0G094398				