

26<sup>th</sup> June 2012

## URGENT - FIELD SAFETY NOTICE

COMMERCIAL NAME OF AFFECTED PRODUCTS:		CONCHATHERM® NEPTUNE™ HEATED HUMIDIFIER	
TELEFLEX REFERENCE	40002945	TYPE OF ACTION	SPEAKER REPAIR
AFFECTED PRODUCT CODES	425-00 425-10 425-30	REFER TO APPENDIX 1 FOR SERIAL NUMBERS IMPACTED	

Dear Customer,

### 1. Details of affected devices

Teleflex has issued a voluntary field safety corrective action for the specific product codes and serial numbers of the ConchaTherm Neptune Heated Humidifiers as identified in the above table and in appendix 1.

### 2. Description of the problem

Teleflex Medical has received complaints of speaker failures for ConchaTherm Neptune Heated Humidifier units (Product Codes 425-00, 425-10 and 425-30) manufactured prior to November 2010. If the speaker fails and an event occurs which would generate an audio alarm, the alarm will not sound and could cause a potential delay in patient treatment. No illnesses or injuries have been reported as a result of these complaints and a speaker failure has no effect on the Neptune's ability to detect an abnormality and take corrective action via its software. In the event of an alarm condition, the unit will detect it and continue to operate according to the product specifications.



### 3. FIELD SAFETY CORRECTIVE ACTION INSTRUCTIONS:

#### Advice on action to be taken by Medical Staff

To ensure reliability and uninterrupted use of the units in the field over their useful life, **Teleflex Medical will replace the existing speakers on affected product codes and serial numbers as referred to in the above table and appendix I with new speakers.**

1. We request that you check your inventory for product within the scope of this field action.
2. If you have stock from the affected product codes and serial numbers as referred to in the above table and appendix 1 then mark the according checkbox on the Acknowledgement Form (Appendix 2).
  - Check for the presence of an audio alarm simply by turning the unit on.
  - If the unit emits a sound during power up the speaker has passed, please mark the 'Pass' check box on the Acknowledgement Form (Appendix 2).
  - If the unit does not emit a sound during power-up the speaker has failed, please mark the 'Fail' check box on the Acknowledgement Form (Appendix 2).
  - Until the units are replaced, all units are to be checked prior to each use.
  - For units that are currently in use, be aware that the unit may not provide an audible alarm. Increased awareness/monitoring for observation of the visual alarm indicator is required.

**In the event that you find a unit with a defective speaker, please complete and return the Acknowledgment Form (Appendix 2) as instructed below and contact Customer Service immediately by calling the phone number mentioned in section 6 to organise for a replacement.**

3. Complete the Acknowledgment Form (Appendix 2) for all products in your possession and send this information immediately to the following fax number: **+353 (0)1 4370773** or email: **[orders.intl@teleflex.com](mailto:orders.intl@teleflex.com)**. This helps us to confirm your notification and to register the amount of products under your control.

4. On receipt of the completed Acknowledgment Form (Appendix 2) a Teleflex representative will contact you to organise for a trained technician to replace the affected unit(s) at no cost to you.
5. If you do not have stock from the affected product codes and serial numbers as referred to in the above table and appendix 1 then mark the according checkbox on the Acknowledgement Form (Appendix 2) and send the form to the fax number or email address mentioned there.

#### **Instruction for Distributors of affected product**

If you are a distributor, provide this Field Safety Notice to all of your customers who have received product/serial numbers as detailed in Appendix 1. Send the customers the following documents:

- A copy of this Field Safety Notice
- A copy of the affected product/serial numbers (Appendix 1)
- A copy of the Acknowledgement Form (Appendix 2)

The Acknowledgement Form (Appendix 2) has to be filled in completely by your customer and returned to you.

As a Distributor you are required to confirm to Teleflex that you have completed the instructed activity for all of your customers affected by this Field Action. Please forward the completed Acknowledgement Form (Appendix 2) to the following fax number: **+353 (0)1 4370773** or email: [orders.intl@teleflex.com](mailto:orders.intl@teleflex.com)

Please be aware that all European Economic Area/Switzerland (EEA/CH) and Turkey Member State Competent Authorities in which Teleflex distribute directly will be notified by Teleflex.

If you are a distributor and/or have a reporting responsibility within or outside the EEA/CH and Turkey area, please notify your local Competent Authority of this action. Please forward the notification and all communication with your local competent authority to Teleflex [emearecalls@teleflex.com](mailto:emearecalls@teleflex.com)

#### **4. Teleflex**

Teleflex informs all customers, employees of Teleflex and distributors on this Field Action.

#### **5. Transmission of this Field Safety Notice**

This notice should be passed on all persons who need to be aware within your organization or to any organization where the potentially affected devices have been transferred. Please consider end users, clinicians, risk managers, supply chain/distribution centres etc. in the circulation of this notice.

Maintain awareness of this notice until all required actions have been completed in your organisation.

#### **6. Contact reference person**

Should you require any further information or support concerning this issue, please contact:

<b>For Customer Service:</b>	<b>For Product Specific Queries:</b>
<b>Contact:</b> Shane Kenny <b>Telephone:</b> +353 (0)90 6460869 <b>FAX:</b> +353 (0)1 4370773 <b>E-mail:</b> <a href="mailto:orders.intl@teleflex.com">orders.intl@teleflex.com</a>	<b>Contact:</b> Vladimir Vasek <b>Telephone:</b> +420 602 791 683 <b>E-mail:</b> <a href="mailto:vvasek@teleflex.com">vvasek@teleflex.com</a>

Please be advised that all European Economic Area/Switzerland (EEA/CH) and Turkey Member State Competent Authorities to which Teleflex distribute directly will be notified by Teleflex.

Teleflex is committed to providing high quality, safe and effective products. We sincerely apologize for any inconvenience this action may cause your operations.

If you have any other questions, feel free to contact your local sales representative or Customer Service at [orders.intl@teleflex.com](mailto:orders.intl@teleflex.com)

*For and on behalf of Teleflex,*

**Padraig Hegarty**  
**Senior Director of Quality, EMEA**

PRODUCT CODE	SERIAL NUMBER	SERIAL NUMBER	SERIAL NUMBER	SERIAL NUMBER	SERIAL NUMBER	SERIAL NUMBER	SERIAL NUMBER	SERIAL NUMBER	SERIAL NUMBER	SERIAL NUMBER
425-00	607090220									
425-10	607120001	607120054	607120131	607120179	608010044	608010099	608010152	608050029	609060024	609060072
	607120003	607120056	607120132	607120180	608010045	608010100	608010153	608050030	609060025	609060073
	607120004	607120057	607120133	607120181	608010046	608010102	608010154	608050032	609060029	609060075
	607120005	607120058	607120136	607120183	608010048	608010103	608010156	608050033	609060031	609060076
	607120006	607120059	607120137	607120184	608010050	608010104	608010157	609050001	609060032	609060077
	607120008	607120060	607120138	607120185	608010051	608010105	608010159	609050002	609060033	609060078
	607120009	607120061	607120139	607120186	608010052	608010107	608010160	609050003	609060034	609060080
	607120011	607120062	607120140	607120187	608010054	608010108	608010162	609050004	609060035	609060081
	607120013	607120063	607120142	607120189	608010059	608010109	608010163	609050008	609060036	609060082
	607120015	607120064	607120143	607120190	608010060	608010110	608010166	609050010	609060037	609060083
	607120016	607120065	607120144	607120191	608010063	608010111	608010168	609050011	609060038	609060084
	607120017	607120069	607120145	607120192	608010064	608010112	608010170	609050012	609060040	609060086
	607120018	607120071	607120146	607120193	608010065	608010113	608010171	609050014	609060041	609060087
	607120019	607120073	607120147	607120194	608010066	608010115	608010172	609050015	609060042	609060088
	607120020	607120076	607120148	607120195	608010068	608010117	608010174	609050016	609060043	609060089
	607120021	607120087	607120150	607120197	608010069	608010118	608010178	609050017	609060044	609060090
	607120022	607120090	607120152	607120199	608010070	608010119	608050001	609050018	609060045	609060091
	607120023	607120092	607120153	607120200	608010071	608010120	608050002	609050019	609060046	609060092
	607120024	607120093	607120154	608010006	608010073	608010122	608050003	609050020	609060047	609060093
	607120025	607120100	607120157	608010007	608010074	608010123	608050004	609050021	609060048	609060094
	607120026	607120103	607120158	608010008	608010075	608010124	608050005	609050022	609060049	609060095
	607120027	607120104	607120159	608010010	608010076	608010125	608050006	609050023	609060050	609060096
	607120030	607120105	607120160	608010011	608010077	608010126	608050008	609050025	609060051	609060097
	607120031	607120106	607120161	608010012	608010078	608010127	608050009	609060002	609060052	609060098
	607120032	607120107	607120162	608010015	608010079	608010128	608050010	609060003	609060053	609060099
	607120033	607120108	607120163	608010016	608010080	608010130	608050012	609060005	609060054	609060100
	607120038	607120109	607120164	608010018	608010081	608010131	608050013	609060008	609060055	609060101
	607120039	607120110	607120165	608010019	608010083	608010134	608050014	609060009	609060056	609060102
	607120040	607120112	607120166	608010020	608010084	608010135	608050015	609060010	609060057	609060104
	607120042	607120113	607120167	608010021	608010085	608010137	608050017	609060011	609060058	609060105
	607120044	607120116	607120168	608010022	608010086	608010139	608050018	609060012	609060059	609060106
	607120045	607120118	607120170	608010025	608010087	608010140	608050019	609060013	609060061	609060107
607120046	607120119	607120171	608010028	608010088	608010141	608050020	609060014	609060062	609060108	
607120048	607120120	607120172	608010033	608010089	608010144	608050021	609060015	609060064	609060109	
607120049	607120121	607120173	608010035	608010093	608010146	608050022	609060017	609060065	609060110	
607120050	607120122	607120174	608010039	608010094	608010147	608050023	609060018	609060066	609060111	
607120051	607120124	607120175	608010040	608010095	608010149	608050024	609060020	609060067	609060112	
607120052	607120126	607120176	608010042	608010096	608010150	608050026	609060021	609060068	609060113	
607120053	607120128	607120178	608010043	608010098	608010151	608050028	609060022	609060070	609060114	

PRODUCT CODE	SERIAL NUMBER	SERIAL NUMBER	SERIAL NUMBER	SERIAL NUMBER	SERIAL NUMBER	SERIAL NUMBER	SERIAL NUMBER	SERIAL NUMBER	SERIAL NUMBER	SERIAL NUMBER
425-10	609060115	609080054	610010010	610020030	610030040	610040010	610040050	610040091	610050030	610050133
	609080001	609080056	610010011	610020031	610030041	610040011	610040051	610040093	610050031	610050135
	609080002	609080066	610010012	610020032	610030042	610040012	610040052	610040094	610050032	610050138
	609080003	609100007	610010013	610020033	610030043	610040013	610040053	610040095	610050033	610050140
	609080004	609100008	610010014	610020034	610030044	610040014	610040054	610040096	610050034	610050146
	609080006	609100009	610010015	610020035	610030045	610040015	610040055	610040097	610050038	610070001
	609080007	609100010	610010016	610020036	610030046	610040016	610040056	610040098	610050043	610070003
	609080008	609100011	610010017	610020037	610030047	610040017	610040057	610040100	610050045	610070004
	609080009	609100012	610010018	610030001	610030048	610040018	610040058	610040101	610050046	610070005
	609080010	609100013	610010020	610030002	610030049	610040019	610040059	610040102	610050057	610070006
	609080011	609100014	610020001	610030003	610030050	610040020	610040060	610040103	610050065	610070007
	609080012	609100015	610020002	610030004	610030051	610040021	610040061	610040104	610050066	610070008
	609080013	609100017	610020003	610030005	610030052	610040022	610040062	610040105	610050067	610070009
	609080014	609100018	610020004	610030007	610030053	610040023	610040063	610040106	610050069	610070012
	609080015	609100019	610020005	610030012	610030054	610040024	610040065	610040107	610050071	610070013
	609080016	609100021	610020006	610030013	610030055	610040025	610040066	610040108	610050074	610070015
	609080017	609100022	610020007	610030014	610030057	610040026	610040067	610040109	610050084	610070016
	609080018	609100024	610020008	610030016	610030058	610040027	610040068	610040110	610050086	610070017
	609080019	609100025	610020009	610030019	610030059	610040028	610040069	610040111	610050087	610070018
	609080020	609100026	610020010	610030020	610030060	610040029	610040070	610040112	610050091	610070019
	609080021	609120001	610020011	610030021	610030061	610040030	610040071	610040113	610050092	610070020
	609080022	609120002	610020012	610030022	610030062	610040031	610040072	610040114	610050093	610070021
	609080024	609120003	610020013	610030023	610030063	610040032	610040073	610040118	610050098	610070023
	609080025	609120004	610020014	610030024	610030064	610040033	610040074	610040121	610050102	610070025
	609080027	609120005	610020015	610030025	610030065	610040034	610040075	610040122	610050104	610070027
	609080028	609120006	610020016	610030026	610030066	610040035	610040077	610040123	610050108	610070029
	609080029	609120007	610020017	610030027	610030067	610040036	610040078	610040125	610050109	610070030
	609080030	609120008	610020018	610030028	610030068	610040037	610040079	610040126	610050110	610070032
	609080031	609120009	610020019	610030029	610030069	610040038	610040080	610040127	610050111	610070033
	609080032	609120010	610020020	610030030	610030070	610040039	610040081	610040135	610050112	610070034
	609080033	610010001	610020021	610030031	610030071	610040041	610040082	610050001	610050113	610070035
	609080036	610010002	610020022	610030032	610040001	610040042	610040083	610050002	610050115	610070036
	609080039	610010003	610020023	610030033	610040002	610040043	610040084	610050008	610050116	610070041
609080041	610010004	610020024	610030034	610040003	610040044	610040085	610050009	610050117	610070046	
609080043	610010005	610020025	610030035	610040004	610040045	610040086	610050013	610050118	610070047	
609080044	610010006	610020026	610030036	610040005	610040046	610040087	610050018	610050119	610070048	
609080045	610010007	610020027	610030037	610040007	610040047	610040088	610050019	610050124	610070049	
609080050	610010008	610020028	610030038	610040008	610040048	610040089	610050023	610050130	610070050	
609080053	610010009	610020029	610030039	610040009	610040049	610040090	610050027	610050132	610070051	

PRODUCT CODE	SERIAL NUMBER	SERIAL NUMBER	SERIAL NUMBER	PRODUCT CODE	SERIAL NUMBER	SERIAL NUMBER	SERIAL NUMBER	SERIAL NUMBER	SERIAL NUMBER	SERIAL NUMBER
425-10	610070052	610080061	610080100	425-30	607120066	608070021	608100007	608100050	608110032	608120041
	610070053	610080062	610080101		607120070	608070022	608100008	608100051	608110043	608120042
	610070054	610080063	610080102		607120077	608070023	608100010	608100053	608110049	608120043
	610070055	610080064	610080103		607120079	608070024	608100011	608100054	608110051	608120044
	610070056	610080065	610080104		607120084	608070025	608100013	608100055	608110065	608120047
	610070057	610080066	610080105		607120085	608070026	608100014	608100056	608110067	608120049
	610080005	610080067	610080106		607120088	608070028	608100015	608100057	608120001	608120050
	610080007	610080068	610080107		607120094	608070029	608100016	608100060	608120003	608120051
	610080009	610080069	610080108		607120097	608070030	608100017	608100063	608120004	608120052
	610080010	610080070	610080109		607120099	608070031	608100018	608100064	608120005	608120053
	610080011	610080071	610080110		607120111	608070032	608100019	608100067	608120006	608120055
	610080012	610080072	610080111		608010013	608070033	608100020	608100068	608120007	608120056
	610080013	610080073	610080112		608010023	608070034	608100021	608100070	608120008	608120060
	610080014	610080074	610080113		608010024	608070035	608100022	608100074	608120009	608120061
	610080015	610080075	610080114		608010026	608070036	608100023	608100076	608120010	608120062
	610080017	610080076	610080115		608010027	608070037	608100024	608100077	608120011	608120063
	610080018	610080077	610080116		608010029	608070038	608100025	608100078	608120013	608120064
	610080019	610080078	610080117		608010030	608070039	608100027	608100080	608120014	608120065
	610080030	610080079	610080118		608010031	608070040	608100028	608100081	608120015	608120066
	610080032	610080080	610080119		608010032	608070041	608100030	608100084	608120016	608120069
	610080041	610080081	610080120		608010034	608070045	608100031	608100088	608120017	608120070
	610080042	610080082	610080121		608010036	608070046	608100032	608100089	608120019	608120071
	610080043	610080083	610080122		608010041	608070047	608100033	608100091	608120021	608120072
	610080044	610080084	610080123		608010047	608070048	608100034	608100093	608120022	608120074
	610080045	610080085	610080124		608010049	608070049	608100035	608100094	608120023	608120075
	610080047	610080086	610080125		608010056	608070050	608100036	608100095	608120024	608120076
	610080048	610080087	610080126		608010058	608070062	608100037	608100097	608120026	608120078
	610080049	610080088	610080127		608010061	608070065	608100038	608100098	608120027	608120079
	610080050	610080089	610080128		608010062	608070068	608100039	608100099	608120028	608120080
	610080051	610080090	610080129		608010067	608070070	608100040	608100101	608120029	609010002
	610080052	610080091	610080130		608070012	608070092	608100041	608100102	608120030	609010003
	610080053	610080092	610080131		608070013	608070108	608100042	608100104	608120031	
610080054	610080093	610090003	608070014	608090009	608100043	608100106	608120034			
610080055	610080094	610090006	608070015	608090019	608100044	608100107	608120035			
610080056	610080095	610090009	608070016	608090025	608100045	608100109	608120036			
610080057	610080096	607120066	608070017	608090047	608100046	608110010	608120037			
610080058	610080097		608070018	608100001	608100047	608110011	608120038			
610080059	610080098		608070019	608100002	608100048	608110012	608120039			
610080060	610080099		608070020	608100005	608100049	608110019	608120040			

## **FIELD SAFETY CORRECTIVE ACTION - ACKNOWLEDGEMENT FORM**

**CONCHATHERM® NEPTUNE™ HEATED HUMIDIFIER FIELD ACTION BY TELEFLEX - IMMEDIATE ATTENTION REQUIRED**

**RETURN COMPLETED FORM IMMEDIATELY TO: [orders.intl@teleflex.com](mailto:orders.intl@teleflex.com) or by fax on +353 (0)1 4370773**

Please check the appropriate box and return this form to above referenced Fax/email.

- No, our inventory **does not include** products affected by this Field Action.
- Yes, Our inventory **does include** products affected by this Field Action. If Yes please carry out the Speaker Check for each unit within your possession

Speaker Check	<p>Please carry out the following check and indicate the results below:</p> <ul style="list-style-type: none"> <li>• Check for the presence of an audio alarm simply by turning the unit on</li> <li>• If the unit emits a sound during power up the speaker has passed, please mark the 'Pass' check box below</li> <li>- If the unit does not emit a sound during power-up the speaker has failed, please mark the 'Fail' check box below</li> <li>- Until the units are replaced, all units are to be checked <u>prior</u> to each use.</li> <li>- For units that are currently in use, be aware that the unit may not provide an audible alarm. Increased awareness/monitoring for observation of the visual alarm indicator is required.</li> </ul>
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PRODUCT CODE	SERIAL NUMBER	SPEAKER CHECK	PRODUCT CODE	SERIAL NUMBER	SPEAKER CHECK
		<input type="checkbox"/> Pass <input type="checkbox"/> Fail			<input type="checkbox"/> Pass <input type="checkbox"/> Fail
		<input type="checkbox"/> Pass <input type="checkbox"/> Fail			<input type="checkbox"/> Pass <input type="checkbox"/> Fail
		<input type="checkbox"/> Pass <input type="checkbox"/> Fail			<input type="checkbox"/> Pass <input type="checkbox"/> Fail
		<input type="checkbox"/> Pass <input type="checkbox"/> Fail			<input type="checkbox"/> Pass <input type="checkbox"/> Fail
		<input type="checkbox"/> Pass <input type="checkbox"/> Fail			<input type="checkbox"/> Pass <input type="checkbox"/> Fail
		<input type="checkbox"/> Pass <input type="checkbox"/> Fail			<input type="checkbox"/> Pass <input type="checkbox"/> Fail
		<input type="checkbox"/> Pass <input type="checkbox"/> Fail			<input type="checkbox"/> Pass <input type="checkbox"/> Fail
		<input type="checkbox"/> Pass <input type="checkbox"/> Fail			<input type="checkbox"/> Pass <input type="checkbox"/> Fail

**Complete this form and return to Teleflex immediately by using the fax number or e-mail referred to above**

<b>Print Name / Title</b>		<b>Date</b>	
<b>Signature:</b>		<b>Telephone #</b>	
<b>Institution Name</b>		<b>City</b>	
<b>Address</b>		<b>Address</b>	

**Customer No**