

California Device Recall Information Sheet

Food and Drug Branch – Device Recalls

DATEX--OHMEDA, INC. GE Healthcare Giraffe Incubator Carestation CS1, Infant Incubator

Recall Date	Product Description	Recalling Firm	Recall Reason
10/31/2024	GE Healthcare Giraffe Incubator Carestation CS1, Infant Incubator. Model Numbers: 2082844-002-01040417; 2082844-002-01044956; 2082844-002-01058424; 2082844-002-01069017; 2082844-002-01089666; 2082844-002-01090474; 2082844-002-01091269; 2082844-002-01093489; 2082844-002-01113262; 2082844-002-01113711; 2082844-002-01123085; 2082844-002-01123918; 2082844-002-01128966; 2082844-002-01133042; 2082844-002-01146447; 2082844-002-100205; 2082844-002-100749; 2082844-002-100752; 2082844-002-100995; 2082844-002-101425; 2082844-002-523548; 2082844-002-529928; 2082844-002-594800; 2082844-002-643544; 2082844-002-925841; 2082844-002-965540; 2082844-002-982916;	DATEX--OHMEDA, INC.	Prior to current established manufacturing practices, higher levels of airborne formaldehyde exposure from newly manufactured incubators could be seen during clinical use that would rapidly decrease over a week. Affected customers were notified in June 2023 to run incubators for a week to potentially off gas any residual airborne formaldehyde. The general scientific consensus is that sensory irritation of the eyes is the most sensitive endpoint with respect to exposure to airborne formaldehyde and is the adverse effect clinically experienced at the lowest concentration.

	2082844-002-983420; 2082844-002-993905; 2082844-002-995018; 2082844-002-995799; 2082844-002-998943; Radiant infant warmer		
--	--	--	--

Recall Class	Product Identification	Distribution	Affected Dates
I	2082844-002-01040417, UDI: (01)00840682116855(21)TAAC7 0003(11)230106, (01)00840682116855(21)TAAC7 0004(11)230109, (01)00840682116855(21)TAAC7 0011(11)230110, (01)00840682116855(21)TAAC7 0012(11)230110, (01)00840682116855(21)TAAC7 0013(11)230111, (01)00840682116855(21)TAAC7 0015(11)230112, (01)00840682116855(21)TAAC7 0016(11)230112, (01)00840682116855(21)TAAC7 0020(11)230112, (01)00840682116855(21)TAAC7 0022(11)230112, (01)00840682116855(21)TAAC7 0024(11)230112, (01)00840682116855(21)TAAC7 0147(11)230317, (01)00840682116855(21)TAAC7 0148(11)230317, (01)00840682116855(21)TAAC7 0149(11)230317, (01)00840682116855(21)TAAC7 0150(11)230317, (01)00840682116855(21)TAAC7 0152(11)230320, (01)00840682116855(21)TAAC7 0153(11)230320, (01)00840682116855(21)TAAC7 0155(11)230322, (01)00840682116855(21)TAAC7	224 units worldwide	June 2023 and prior

	0158(11)230322, (01)00840682116855(21)TAAC7 0159(11)230323, (01)00840682116855(21)TAAC7 0160(11)230323, (01)00840682116855(21)TAAC7 0161(11)230323, (01)00840682116855(21)TAAC7 0162(11)230323, (01)00840682116855(21)TAAC7 0163(11)230324, (01)00840682116855(21)TAAC7 0164(11)230324, (01)00840682116855(21)TAAC7 0165(11)230324, (01)00840682116855(21)TAAC7 0166(11)230324, (01)00840682116855(21)TAAC7 0167(11)230327, (01)00840682116855(21)TAAC7 0169(11)230327, (01)00840682116855(21)TAAC7 0170(11)230327, (01)00840682116855(21)TAAC7 0171(11)230328, (01)00840682116855(21)TAAC7 0177(11)230330, (01)00840682116855(21)TAAC7 0178(11)230330, (01)00840682116855(21)TAAC7 0179(11)230331, (01)00840682116855(21)TAAC7 0181(11)230331, (01)00840682116855(21)TAAC7 0182(11)230331, (01)00840682116855(21)TAAC7 0184(11)230331, (01)00840682116855(21)TAAC7 0192(11)230405, (01)00840682116855(21)TAAC7 0193(11)230405, (01)00840682116855(21)TAAC7 0196(11)230405, (01)00840682116855(21)TAAC7 0197(11)230405, (01)00840682116855(21)TAAC7 0200(11)230407, (01)00840682116855(21)TAAC7		
--	--	--	--

	0201(11)230407, (01)00840682116855(21)TAAC7 0202(11)230407, (01)00840682116855(21)TAAC7 0203(11)230407, (01)00840682116855(21)TAAC7 0204(11)230407, (01)00840682116855(21)TAAC7 0205(11)230407, (01)00840682116855(21)TAAC7 0208(11)230411, (01)00840682116855(21)TAAC7 0209(11)230411, (01)00840682116855(21)TAAC7 0210(11)230411, (01)00840682116855(21)TAAC7 0211(11)230414, (01)00840682116855(21)TAAC7 0212(11)230414, (01)00840682116855(21)TAAC7 0213(11)230414, (01)00840682116855(21)TAAC7 0214(11)230414, (01)00840682116855(21)TAAC7 0215(11)230417, (01)00840682116855(21)TAAC7 0216(11)230417, (01)00840682116855(21)TAAC7 0217(11)230417, (01)00840682116855(21)TAAC7 0218(11)230417, (01)00840682116855(21)TAAC7 0223(11)230418, (01)00840682116855(21)TAAC7 0224(11)230418, (01)00840682116855(21)TAAC7 0225(11)230418, (01)00840682116855(21)TAAC7 0226(11)230418, (01)00840682116855(21)TAAC7 0227(11)230418, (01)00840682116855(21)TAAC7 0228(11)230418, (01)00840682116855(21)TAAC7 0229(11)230419, (01)00840682116855(21)TAAC7 0242(11)230421, (01)00840682116855(21)TAAC7		
--	--	--	--

	0243(11)230421, (01)00840682116855(21)TAAC7 0244(11)230421, (01)00840682116855(21)TAAC7 0245(11)230421, (01)00840682116855(21)TAAC7 0246(11)230421, (01)00840682116855(21)TAAC7 0247(11)230421 2082844-002-01044956, UDI: (01)008406821168552(21)TAA23 140007SA(11)230404, (01)008406821168552(21)TAA23 140008SA(11)230404 2082844-002-01058424, UDI: (01)00840682116855(21)TAAC7 0142(11)230213 2082844-002-01069017, UDI: (01)008406821168552(21)TAA23 110001SA(11)230316, (01)008406821168552(21)TAA23 110002SA(11)230316, (01)008406821168552(21)TAA23 110003SA(11)230316 2082844-002-01089666, UDI: (01)00840682116855(21)TAAC7 0124(11)230201 2082844-002-01090474, UDI: (01)00840682116855(21)TAAC7 0126(11)230201, (01)00840682116855(21)TAAC7 0128(11)230206, (01)00840682116862(21)TAAC7 0132(11)230206, (01)00840682116855(21)TAAC7 0133(11)230206, (01)00840682116855(21)TAAC7 0125(11)230201,		
--	--	--	--

	(01)00840682116855(21)TAAC7 0127(11)230206, (01)00840682116855(21)TAAC7 0129(11)230206, (01)00840682116855(21)TAAC7 0131(11)230206, (01)00840682116855(21)TAAC7 0136(11)230206, (01)00840682116855(21)TAAC7 0137(11)230206 2082844-002-01091269, UDI: (01)008406821168552(21)TAA23 090001SA(11)230228 228 2082844-002-01093489, UDI: (01)00840682116855(21)TAAC7 0187(11)230403, (01)00840682116855(21)TAAC7 0188(11)230403, (01)00840682116855(21)TAAC7 0189(11)230403, (01)00840682116855(21)TAAC7 0190(11)230403, (01)00840682116855(21)TAAC7 0191(11)230403 2082844-002-01113262, UDI: (01)008406821168552(21)TAA23 050010SA(11)230130, (01)008406821168552(21)TAA23 050011SA(11)230130, (01)008406821168552(21)TAA23 050012SA(11)230130, (01)008406821168552(21)TAA23 050013SA(11)230130 2082844-002-01113711, UDI: (01)008406821168552(21)TAA23 130005SA(11)230328, (01)008406821168552(21)TAA23 130007SA(11)230329, (01)008406821168552(21)TAA23 130008SA(11)230329,		
--	--	--	--

	(01)008406821168552(21)TAA23 130009SA(11)230329 2082844-002-01123085, UDI: (01)008406821168552(21)TAA23 190005SA(11)230513, (01)008406821168552(21)TAA23 190006SA(11)230513, (01)008406821168552(21)TAA23 190007SA(11)230513, (01)008406821168552(21)TAA23 190008SA(11)230513, (01)008406821168552(21)TAA23 190009SA(11)230513, (01)008406821168552(21)TAA23 190010SA(11)230513 2082844-002-01123918, UDI: (01)008406821168552(21)TAA23 130001SA(11)230328 2082844-002-01128966, UDI: (01)008406821168552(21)TAA23 040022SA(11)230127 2082844-002-01133042, UDI: (01)008406821168552(21)TAA23 130003SA(11)230328, (01)008406821168552(21)TAA23 130004SA(11)230328, (01)008406821168552(21)TAA23 130006SA(11)230329 2082844-002-01146447, UDI: (01)008406821168552(21)TAA23 100001SA(11)230307 2082844-002-100205, UDI: (01)008406821168552(21)TAA23 030030SA(11)230121 2082844-002-100749,		
--	--	--	--

	UDI: (01)00840682116855(21)TAAC7 0272(11)230426 2082844-002-100752, UDI: (01)00840682116855(21)TAAC7 0075(11)230123, (01)00840682116855(21)TAAC7 0083(11)230124, (01)00840682116855(21)TAAC7 0084(11)230124, (01)00840682116855(21)TAAC7 0086(11)230125, (01)00840682116855(21)TAAC7 0087(11)230125 2082844-002-100995, UDI: (01)008406821168552(21)TAA23 090003SA(11)230228, (01)008406821168552(21)TAA23 090004SA(11)230228, (01)008406821168552(21)TAA23 090005SA(11)230228, (01)008406821168552(21)TAA23 090006SA(11)230228, (01)008406821168552(21)TAA23 090002SA(11)230228, (01)008406821168552(21)TAA23 090007SA(11)230228 2082844-002-101425, UDI: (01)008406821168552(21)TAA23 190003SA(11)230512, (01)008406821168552(21)TAA23 160001SA(11)230419, (01)008406821168552(21)TAA23 170001SA(11)230424, (01)008406821168552(21)TAA23 130031SA(11)230331, (01)008406821168552(21)TAA23 130032SA(11)230331, (01)008406821168552(21)TAA23 130033SA(11)230331, (01)008406821168552(21)TAA23 130034SA(11)230331,		
--	---	--	--

	(01)008406821168552(21)TAA23 130035SA(11)230331, (01)008406821168552(21)TAA23 130036SA(11)230331, (01)008406821168552(21)TAA23 130021SA(11)230330, (01)00840682116855(21)TAAC7 0143(11)230224, (01)00840682116855(21)TAAC7 0144(11)230224, (01)00840682116855(21)TAAC7 0145(11)230224, (01)008406821168552(21)TAA23 130025SA(11)230331, (01)008406821168552(21)TAA23 130026SA(11)230331, (01)008406821168552(21)TAA23 130027SA(11)230331, (01)008406821168552(21)TAA23 130028SA(11)230331, (01)008406821168552(21)TAA23 130029SA(11)230331, (01)008406821168552(21)TAA23 130030SA(11)230331, (01)00840682116855(21)TAAC7 0146(11)230313, (01)008406821168552(21)TAA23 140001SA(11)230403, (01)008406821168552(21)TAA23 140002SA(11)230403, (01)008406821168552(21)TAA23 130022SA(11)230330, (01)008406821168552(21)TAA23 130023SA(11)230330, (01)008406821168552(21)TAA23 130024SA(11)230330, (01)008406821168552(21)TAA23 160002SA(11)230419 2082844-002-523548, UDI: (01)00840682116855(21)TAAW6 2043(11)170130; (01)00840682116855(21)TAAZ70 271(11)200224 2082844-002-529928, UDI:		
--	---	--	--

	(01)008406821168552(21)TAA23 130002SA(11)230328 2082844-002-594800, UDI: (01)00840682116855(21)TAAB7 0352(11)220520 2082844-002-643544, UDI: (01)008406821168552(21)TAA23 030023SA(11)230120, (01)008406821168552(21)TAA23 030024SA(11)230120, (01)008406821168552(21)TAA23 030025SA(11)230120 2082844-002-925841, UDI: (01)00840682116855(21)TAAB7 0547(11)220815 2082844-002-965540, UDI: (01)00840682116855(21)TAAB7 0617(11)220826, (01)00840682116855(21)TAAB7 0665(11)220928, (01)00840682116855(21)TAAB7 0666(11)220928, (01)00840682116855(21)TAAB7 0670(11)220929, (01)00840682116855(21)TAAB7 0671(11)220929, (01)00840682116855(21)TAAB7 0681(11)221003, (01)00840682116855(21)TAAB7 0691(11)221004, (01)00840682116855(21)TAAB7 0702(11)221005, (01)00840682116855(21)TAAB7 0703(11)221005, (01)00840682116855(21)TAAB7 0732(11)221010 082844-002-982916, UDI: (01)00840682116855(21)TAAC7		
--	--	--	--

	0033(11)230113, (01)00840682116855(21)TAAC7 0037(11)230116, (01)00840682116855(21)TAAC7 0044(11)230116, (01)00840682116855(21)TAAC7 0052(11)230119, (01)00840682116855(21)TAAC7 0058(11)230119, (01)00840682116855(21)TAAC7 0059(11)230119, (01)00840682116855(21)TAAC7 0060(11)230119, (01)00840682116855(21)TAAC7 0065(11)230120, (01)00840682116855(21)TAAC7 0067(11)230123, (01)00840682116855(21)TAAC7 0068(11)230123, (01)00840682116855(21)TAAB7 0608(11)220824; 2082844-002-983420, UDI: (01)00840682116855(21)TAAC7 0076(11)230123, (01)00840682116855(21)TAAC7 0078(11)230124, (01)00840682116855(21)TAAC7 0079(11)230124, (01)00840682116855(21)TAAC7 0082(11)230124, (01)00840682116855(21)TAAC7 0089(11)230125, (01)00840682116855(21)TAAC7 0090(11)230125, (01)00840682116855(21)TAAC7 0092(11)230126, (01)00840682116855(21)TAAC7 0093(11)230126 2082844-002-993905, UDI: (01)008406821168552(21)TAA23 040004SA(11)230123, (01)008406821168552(21)TAA23 040005SA(11)230123, (01)008406821168552(21)TAA23		
--	--	--	--

	040006SA(11)230124, (01)008406821168552(21)TAA23 050014SA(11)230130 2082844-002-995018, UDI: (01)00840682116855(21)TAAB7 0551(11)220815, (01)00840682116855(21)TAAB7 0558(11)220819 2082844-002-995799, UDI: (01)008406821168552(21)TAA23 040019SA(11)230127, (01)008406821168552(21)TAA23 040020SA(11)230127, (01)008406821168552(21)TAA23 190004SA(11)230513, (01)008406821168552(21)TAA23 160007SA(11)230420, (01)008406821168552(21)TAA23 160009SA(11)230420, (01)008406821168552(21)TAA23 130015SA(11)230329, (01)008406821168552(21)TAA23 130016SA(11)230329, (01)008406821168552(21)TAA23 130017SA(11)230329, (01)008406821168552(21)TAA23 130018SA(11)230329, (01)008406821168552(21)TAA23 130020SA(11)230329, (01)008406821168552(21)TAA23 160003SA(11)230419, (01)008406821168552(21)TAA23 160004SA(11)230419, (01)008406821168552(21)TAA23 160005SA(11)230419, (01)008406821168552(21)TAA23 160006SA(11)230419, (01)008406821168552(21)TAA23 160008SA(11)230420, (01)008406821168552(21)TAA23 160010SA(11)230420, (01)008406821168552(21)TAA23 160011SA(11)230420, (01)008406821168552(21)TAA23		
--	---	--	--

	200003SA(11)230515, (01)008406821168552(21)TAA23 200004SA(11)230515, (01)008406821168552(21)TAA23 200005SA(11)230515, (01)008406821168552(21)TAA23 200006SA(11)230515, (01)008406821168552(21)TAA23 200007SA(11)230515, (01)008406821168552(21)TAA23 200008SA(11)230515, (01)008406821168552(21)TAA23 200009SA(11)230515, (01)008406821168552(21)TAA23 200010SA(11)230515, (01)008406821168552(21)TAA23 130019SA(11)230329 2082844-002-998943, UDI: (01)00840682116855(21)TAAC7 0050(11)230119, (01)00840682116855(21)TAAC7 0053(11)230119, (01)00840682116855(21)TAAC7 0110(11)230130		
--	--	--	--

For additional information, please visit the [FDA Website](#).