



**CALIFORNIA DEVICE RECALL INFORMATION SHEET**

**Datascope/Getinge/Maquet Recalls Cardiosave Hybrid/Rescue Intra-Aortic Balloon Pump Battery Packs Due to Risk of Battery Failure**

Recall Date	Product Description	Recalling Firm	Recall Reason
10/20/2021	<p><b>Cardiosave Li-Ion Battery Pack, Component of the Cardiosave Hybrid Intra-Aortic Balloon Pump (IABP)</b></p> <p>Part No. 0146-00-0097.</p>	<p><b>Getinge,</b> Wayne, New Jersey</p>	<p>Risk of the battery failing and having a shortened run-time due to substandard batteries not meeting performance specifications, which may cause the device to stop working when operated by battery only. If a patient requires life-supporting therapy with an IABP and the device does not work or if therapy is stopped during use due to battery failure, the patient will be at risk of serious injury, including death.</p>

Recall Class	Product Identification	Distribution	Affected Dates
I	<p>Serial Numbers 192224349IP 191908720IP 202369811IP 202791944IP 191848115IP 192099841IP 192103741IP 192104141IP 171218521PE 181642339PE 202321308IP 191912520IP 191874716IP 191922620IP 181642639PE 192185446IP 171277935PE 192190247IP 202400219IP 202323808IP 191910720IP 181661142PE 192245250IP 202599332IP 181645841PE 181526530PE 202403719IP 181705244PE 192104541IP 191787312IP 181646041PE 191955422IP 202389919IP 191822513IP 191853415IP 192004724IP 192196447IP 192155645IP 202330609IP 171325749PE 192018828IP</p>	<p>13 units in California</p>	<p>September 2017 to August, 2021</p>

<p> 191778911IP 192187947IP 192196247IP  181609237PE 192098341IP 191972823IP  191860615IP 202719740IP 202334109IP  202651035IP 191852615IP 192173146IP  202386519IP 202398619IP 202416720IP  202599432IP 191956322IP 192205847IP  192220349IP 192081138IP 202617233IP  181659242PE 202266705IP 171255732PE  192179046IP 192179246IP 202280605IP  181673143PE 192083838IP 192106442IP  192216649IP 191956122IP 181721730IP  191943120IP 191971023IP 181405120PE  181474326PE 181440222PE 192225649IP  191969623IP 192220749IP 181706344PE  181694644PE 191968223IP 202593632IP  191863015IP 171264133PE 191872616IP  181487828PE 171337749PE 181477426PE  181748032IP 191790412IP 191902319IP  192195547IP 192200947IP 191968723IP  202552831IP 191806513IP 202401419IP  191904319IP 181492328PE 202388319IP  202482724IP 192241550IP 171339849PE  191831214IP 192084038IP 181694244PE  192210249IP 202725540IP 171345550PE  171348550PE 191915920IP 202371511IP  202723440IP 202367411IP 202279305IP  181513630PE 181703744PE 202389819IP  192175646IP 192107842IP 202394719IP  202401619IP 192204947IP 202654636IP  192196647IP 192200647IP 202782744IP </p>		
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