



CALIFORNIA DEVICE RECALL INFORMATION SHEET

HeartSine Technologies Ltd PAD-PAKs for Inoperable Battery and Electrode Cartridge

Recall Date	Product Description	Recalling Firm	Recall Reason
7/19/2023	PAD-PAK HeartSine, REF: PAD-PAK-01, PAD-PAK-03 AND PAD-PAK-03j, CE0123 sold separately and with the HeartSine Samaritan Public Access Defibrillator models: 350P/360P/450P/500P	HeartSine Technologies Ltd Belfast, United Kingdom	Single use battery and electrode cartridge may be rendered inoperable due to depleted battery cells which could prevent the defibrillator from analyzing patient condition or delivering therapy correctly.

Recall Class	Product Identification	Distribution	Affected Dates
II	PAD-PAK Model #/UDI-DI #: 360-BAS-UK-10/05060167122606, 350-BAS-UK-10/05060167121418, 350-BAS-AS-10/05060167121371, 350-BAS-CF-10/05060167124747, 350-BAS-CN-10/05060167121593, 350-BAS-JA-08/05060167124525, 350-BAS-KO-10/05060167121517, 350-BAS-MS-10/05060167120800, 350-BAS-USROW-10/05060167121630, 360-BAS-AS-10/05060167122514, 360-BAS-CN-10/05060167125751, 360-BAS-KO-10/05060167122712, 360-BAS-SJ-10/05060167128028, 450-BAS-JA-08/05060167127663, 500-BAS-AS-	37 Units in California	April 2023 and Prior

10/05060167125812, 500-BAS-CF-10/05060167125836, 500-BAS-CN-10/05060167125843, 500-BAS-KO-10/05060167126444, 500-BAS-TH-10/05060167125997, 500-BAS-UK-10/05060167122453, PAD-PAK-01/05060167120466, PAD-PAK-03/05060167121234, PAD-PAK-03j/05060167124754
Models/Lot # 360-BAS-UK-10/ A3659, A3655, A3664, A3654, A3803, A3829, A3840, A3842, A3848, A3840, A3843, A3842, A3844, A3842, J0754, J0754, J0755, J0752, J0798; 350-BAS-UK-10/ A3664, A3799, A3803, A3829, A3840, A3846, J0753, J0753, J0754, J0756; 350-BAS-AS-10/ A3656; 350-BAS-CF-10/ A3635, A3805, J0801; 350-BAS-CN-10/ A3633, A3636, A3805, A3833, J0801; 350-BAS-JA-08/ A3779 A3783, A3780, A3783, J0758, J0758; 350-BAS-KO-10/ J0753; 350-BAS-MS-10/ J0753; 350-BAS-USROW-10/ A3644; 360-BAS-AS-10/ A3656; 360-BAS-CN-10/ A3635; 360-BAS-KO-10/ A3660 A3646, A3665, J0753, J0754; 360-BAS-SJ-10/ A3660; 450-BAS-JA-08/ A3779, A3783, A3788, A3821; 500-BAS-AS-10/ A3656; 500-BAS-CF-10/ A3635; 500-BAS-CN-10/ A3632, A3635, A3634, A3681; 500-BAS-KO-10/ A3660; 500-BAS-TH-10/ J0754, J0755, J0754; 500-BAS-UK-10/ A3654, A3654, A3664, A3664, A3765, A3787, A3801, A3840, J0753, J0755, J0754, J0756, J0748, J0798; PAD-PAK-01/ A3632 A3633 A3634 A3635 A3636 A3637 A3642 A3656 A3657 A3657 A3657 A3662 A3669 A3681 A3678 A3682 A3766, A3777 A3778 A3781 A3782 A3805 A3807 A3833 A3833 A3834 A3834 A3832 A3840 J0759 J0761 J0760; PAD-PAK-03/ A3638 A3639 A3640

	<p>A3658 A3644 A3644 A3655 A3666 A3653 A3652 A3641 A3643 A3660 A3664 A3665 A3672 A3663 A3668 A3667 A3661 A3659 A3764 A3765 A3770 A3772 A3773 A3774 A3775 A3776 A3779 A3784 A3785 A3786 A3787 A3787 A3785 A3799 A3799 A3800 A3801 A3802 A3802 A3803 A3804 A3829 A3829 A3840 A3845 A3846 A3847 A3849 A3849 A3845 J0749 J0749 J0748 J0750 J0751 J0752 J0753 J0753 J0754 J0756 J0786 J0786 J0790 J0791 J0787 J0788 J0788 J0789 J0792 J0792 J0795 J0794 J0793 J0792 J0796 J0797 J0798 J0799; PAD-PAK-03j/ A3788 and A3821</p>		
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