

Urgent Field Action Notice for Cryostat Devices

Attention: Lab Manager, Cryostat Users

August 27, 2024

Dear Valued Customer,

Leica Biosystems is issuing this notification letter to inform you about a field action involving the cryostat devices. You are receiving this notification as our records indicate that you have received one or more of the devices concerned.

Affected Devices:

Leica CM1950: 155, 159, 168, 170, 173, 176, 178, 179, 185, 186, 190, 191, 193, 199, 203, 215, 216, 217, 218, 227, 236, 237, 238, 239, 249, 264, 268, 273, 275, 276, 277, 279, 287, 288, 291, 292, 295, 298, 305, 313, 314, 316, 318, 319, 321, 322, 324, 328, 330, 332, 335, 337, 340, 343, 351, 354, 356, 357, 358, 364, 365, 367, 369, 373, 374, 380, 382, 383, 387, 389, 391, 395, 398, 399, 407, 420, 422, 423, 426, 427, 428, 429, 432, 435, 436, 437, 438, 439, 443, 447, 449, 450, 451, 452, 453, 454, 462, 472, 476, 477, 478, 479, 481, 484, 485, 492, 495, 496, 497, 498, 502, 505, 508, 514, 522, 524, 527, 530, 535, 539, 543, 548, 552, 553, 554, 556, 557, 558, 559, 561, 566, 567, 576, 577, 579, 581, 585

Leica CM3050 S: 1512, 1531, 1567, 1577, 1579, 1607, 1608, 1622, 1631, 1647, 1731, 1768, 1808, 1864, 1870, 1925, 1943, 1993, 1994, 2005, 2048, 2057, 2093, 2119, 2121, 2235, 2240, 2259, 2269, 2282, 2283, 2334, 2335, 2384, 2392, 2402, 2416, 2418, 2421, 2425, 2431, 2446, 2456, 2461, 2463, 2465, 2469, 2471, 2474, 2490, 2492, 2503, 2506, 2520, 2522, 2524, 2525, 2529, 2533, 2546, 2553, 2558, 2560, 2564, 2571, 2573, 2574, 2580, 2583, 2588, 2592, 2593, 2597, 2605, 2609, 2624, 2627, 2632, 2633, 2636, 2638, 2676, 2691, 2700, 2706, 2707, 2712, 2722, 2724, 2736, 2737, 2742, 2749, 2755, 2774, 2777, 2781, 2791, 2797, 2804, 2805, 2813, 2814, 2840, 2853, 2856, 2857, 2864, 2874, 2885, 2886, 2890, 2891, 2893, 2908, 2909, 2918, 2931, 2932, 2934, 2935, 2936, 2943, 2944, 2964, 2969, 2975, 2978, 2979, 2995, 2996, 2997, 3002, 3004, 3009, 3012, 3018, 3026, 3030, 3037, 3044, 3048, 3052, 3078, 3093, 3097, 3098, 3103, 3116, 3129, 3130, 3136, 3137, 3139, 3141, 3151, 3157, 3162, 3163, 3165, 3168, 3170, 3174, 3187, 3198, 3199, 3201, 3207, 3208, 3210, 3213, 3217, 3218, 3219, 3227, 3229, 3230, 3238, 3240, 3249, 3252, 3257, 3257, 3259, 3260, 3274, 3277, 3285, 3295, 3296, 3303, 3304, 3307, 3317, 3319,

Leica CM3050 S: 3320, 3321, 3322, 3333, 3337, 3338, 3342, 3344, 3346, 3349, 3351, 3352, 3354, 3368, 3372, 3374, 3375, 3376, 3383, 3385, 3386, 3394, 3396, 3398, 3401, 3404, 3417, 3420, 3421, 3424, 3425, 3428, 3430, 3431, 3434, 3436, 3438, 3451, 3456, 3457, 3459, 3466, 3468, 3469, 3482, 3485, 3496, 3507, 3508, 3514, 3515, 3522, 3526, 3533, 3534, 3535, 3540, 3548, 3555, 3557, 3559, 3562, 3564, 3566, 3567, 3568, 3571, 3584, 3585, 3588, 3589, 3593, 3603, 3604, 3606, 3609, 3613, 3616, 3617, 3630, 3633, 3638, 3641, 3644, 3658, 3662, 3668, 3669, 3677, 3683, 3691, 3695, 3699, 3705, 3706, 3710, 3714, 3715, 3716, 3719, 3720, 3729, 3730, 3734, 3738, 3741, 3748, 3755, 3758, 3759, 3773, 3778, 3780, 3783, 3789, 3795, 3801, 3802, 3803, 3821, 3824, 3832, 3838, 3839, 3840, 3847, 3852, 3867, 3869, 3874, 3878, 3881, 3883, 3897, 3901, 3905, 3907, 3908, 3912, 3915, 3917, 3920, 3923, 3932, 3937, 3944, 3945, 3951, 3952, 3954, 3956, 3966, 3970, 3979, 3981, 3994, 3999, 4002, 4004, 4008, 4009, 4011, 4012, 4014, 4020, 4023, 4043, 4044, 4053, 4054, 4056, 4065, 4070, 4085, 4086, 4087, 4094, 4096, 4099, 4113, 4119, 4122, 4124, 4125, 4127, 4137, 4142, 4145, 4149, 4150, 4154, 4155, 4156, 4161, 4162, 4169, 4171, 4174, 4176, 4186, 4193, 4197, 4203, 4204, 4212, 4213, 4223, 4228, 4231, 4237, 4242, 4252, 4263, 4269, 4270, 4278, 4279, 4280, 4282, 4284, 4287, 4293, 4294, 4297, 4299, 4301, 4304, 4307, 4310, 4311, 4317, 4320, 4322, 4326, 4327, 4332, 4335, 4341, 4349, 4351, 4353, 4354, 4366, 4367, 4368, 4369, 4375, 4376, 4378, 4379, 4384, 4387, 4391, 4393, 4394, 4399, 4400, 4401, 4405, 4413, 4415, 4422, 4429, 4445, 4454, 4462, 4463, 4467, 4468, 4476, 4477, 4479, 4483, 4491, 4497, 4498, 4499, 4503, 4507, 4510, 4513, 4514, 4517, 4518, 4519, 4520, 4521, 4525, 4526, 4527, 4528, 4534, 4535, 4537, 4538, 4547, 4548, 4552, 4557, 4557, 4561, 4565, 4569, 4572, 4573, 4575, 4580, 4585, 4592, 4593, 4599, 4600, 4613, 4615, 4616, 4618, 4620, 4621, 4621, 4622, 4625, 4626, 4641, 4643, 4644, 4649, 4653, 4654, 4655, 4659, 4660, 4664, 4669, 4674, 4675, 4678, 4686, 4693, 4696, 4698, 4701, 4702, 4703, 4706, 4707, 4708, 4713, 4714, 4715, 4716, 4716, 4719, 4721, 4723, 4724, 4727, 4728, 4734, 4735, 4740, 4745, 4753, 4755, 4761, 4764, 4773, 4774, 4775, 4781, 4783, 4792, 4795, 4797, 4801, 4802, 4803, 4804, 4807, 4811, 4816, 4819, 4827, 4833, 4836, 4839, 4845, 4850, 4851, 4852, 4853, 4864, 4868, 4870, 4871, 4875, 4876, 4878, 4879, 4886, 4888, 4896, 4907, 4908, 4909, 4911, 4915, 4916, 4918, 4920, 4921, 4926, 4928, 4933, 4938, 4939, 4940, 4943, 4946, 4948, 4952, 4953, 4958, 4961, 4963, 4966, 4970, 4978, 4979, 4981, 4983, 4985, 4988, 4989, 4991, 4998, 5000, 5003, 5004, 5007, 5008, 5011, 5013, 5015, 5018, 5021, 5025, 5029, 5037, 5042, 5046, 5048, 5049, 5053, 5063, 5065, 5068, 5070, 5072, 5079, 5081, 5082, 5083, 5088, 5104, 5109, 5111, 5112, 5119, 5124, 5126, 5127, 5131, 5141, 5145, 5146, 5147, 5152, 5153, 5155, 5156, 5157, 5159, 5169, 5171, 5179, 5183, 5195, 5197, 5200, 5201, 5202, 5207, 5208, 5212, 5217, 5218, 5221, 5224, 5226, 5227, 5228, 5230, 5234, 5243, 5245, 5246, 5257, 5265

Leica CM1850 UV: 144, 148, 161, 182, 210, 211, 235, 236, 250, 251, 254, 258, 281, 297, 298, 299, 308, 320, 331, 333, 334, 372, 373, 385, 388, 396, 420, 432, 434, 436, 446, 451, 465, 483, 485, 503, 507, 530, 531, 569, 596, 603, 608, 615, 627, 630, 645, 649, 653, 659, 665, 667, 676, 697, 753, 762, 764, 769, 778, 801, 804, 817, 830, 832, 842, 845, 852, 864, 867, 873, 890, 891, 897, 899, 902, 903, 904, 913, 937, 938, 939, 940, 942, 944, 965, 1011, 1034, 1057, 1061, 1085, 1147, 1160, 1174, 1176, 1207, 1219, 1220, 1228, 1232, 1234, 1240, 1249, 1250, 1251, 1258, 1281, 1293, 1298, 1300, 1304, 1309, 1315, 1326,

Leica CM1850 UV: 1329, 1341, 1356, 1358, 1372, 1388, 1409, 1424, 1426, 1430, 1432, 1449, 1473, 1491, 1497, 1526, 1528, 1535, 1537

Leica CM1850: 154, 156, 165, 175, 189, 189, 190, 201, 210, 216, 217, 236, 237, 253, 260, 265, 267, 301, 302, 304, 329, 332, 332, 333, 345, 349, 370, 370, 376, 378, 381, 382, 400, 411, 416, 417, 429, 447, 453, 454, 454, 455, 457, 461, 469, 472, 475, 482, 494, 497, 511, 513, 514, 517, 526, 573, 576, 597, 598, 602, 608, 610, 626, 646, 655, 658, 671, 672, 684, 693, 698, 702, 702, 703, 708, 709, 711, 729, 730, 757, 765, 771, 772, 776, 777, 786, 792, 794, 798, 802, 811, 860, 868, 870, 871, 885, 894, 895, 896, 904, 915, 917, 917, 923, 949, 952, 960, 961, 970, 979, 987, 991, 997, 1005, 1016, 1017, 1031, 1037, 1044, 1045, 1047, 1055, 1059, 1063, 1067, 1076, 1076, 1095, 1110, 1121, 1128, 1137, 1149, 1153, 1154, 1157, 1164, 1186, 1187, 1196, 1200, 1208, 1255, 1259, 1272, 1278, 1280, 1307, 1310, 1312, 1313, 1315, 1317, 1320, 1321, 1325, 1336, 1340, 1344, 1345, 1347, 1367, 1387, 1389, 1403, 1407, 1439, 1448, 1452, 1453, 1454, 1457, 1474, 1476, 1488, 1492, 1494, 1524, 1527, 1542, 1545, 1561, 1613, 1622, 1630, 1636, 1663, 1678, 1684, 1716, 1727, 1728, 1729, 1742, 1753, 1776, 1784, 1827, 1843, 1850, 1856, 1858, 1874, 1878, 1884, 1885, 1887, 1890, 1922, 1950, 1957, 1963, 1981, 2018, 2020, 2028, 2032, 2033, 2040, 2068, 2089, 2090, 2097, 2115, 2136, 2139, 2144, 2145, 2160, 2172, 2200, 2215, 2227, 2237, 2243, 2260, 2284, 2286, 2310, 2335, 2347, 2363, 2390, 2396, 2402, 2413, 2425, 2461, 2485, 2486, 2503, 2506, 2509, 2524, 2538, 2540, 2567, 2586, 2591, 2599, 2617, 2628, 2632, 2651, 2655, 2675, 2699, 2707, 2717, 2728, 2735, 2736, 2750, 2757, 2780, 2782, 2788, 2794, 2798, 2805, 2812, 2815, 2851, 2861, 2866, 2870, 2873, 2884, 2890, 2903, 2906, 2909, 2911, 2925, 2935, 2936, 2939, 2955, 2968, 2978, 3008, 3017, 3024, 3025, 3030, 3045, 3057, 3063, 3068, 3069, 3080, 3096, 3107, 3134, 3152, 3156, 3168, 3170, 3186, 3187, 3193, 3197, 3199, 3202, 3207, 3211, 3216, 3217, 3222, 3239, 3241, 3242, 3251, 3252, 3255, 3260, 3261, 3269, 3276, 3281, 3296, 3303, 3306, 3316, 3318, 3321, 3322, 3333, 3346, 3354, 3357, 3363, 3367, 3400, 3407, 3408, 3415, 3416, 3421, 3425, 3427, 3435, 3441, 3445, 3471, 3478, 3488, 3493, 3496, 3498, 3499, 3501, 3502, 3508, 3517, 3524, 3527, 3534, 3540, 3558, 3589, 3598, 3600, 3603, 3606, 3611, 3631, 3640, 3642, 3647, 3679, 3680, 3682, 3688, 3689, 3713, 3714, 3728, 3744, 3760, 3786, 3797, 3807, 3817, 3819, 3820, 3824, 3845, 3869, 3874, 3876, 3892, 3897, 3927, 3946, 3948, 3960, 3976, 3980, 3988, 4014, 4040, 4049, 4079, 4113, 4114, 4118, 4129, 4137, 4159, 4160, 4164, 4167, 4171, 4174, 4175, 4180, 4200, 4202, 4211, 4228, 4231, 4234, 4252, 4264, 4267, 4276, 4289, 4334, 4341, 4355, 4358, 4385, 4411, 4414, 4416, 4428, 4439, 4443, 4444, 4444, 4465, 4466, 4471, 4478, 4492, 4502, 4527, 4548, 4551, 4588, 4589, 4593, 4595, 4608, 4619, 4639, 4660, 4670, 4715, 4720, 4721, 4722, 4723, 4728, 4733, 4743, 4774, 4790, 4791, 4797, 4809, 4810, 4816, 4818, 4825, 4827, 4828, 4831, 4833, 4849, 4859, 4861, 4866, 4869, 4870, 4898, 4913, 4925, 4938, 4945, 4947, 4954, 4955, 4960, 4976, 4989, 5001, 5030, 5032, 5036, 5052, 5064, 5081, 5082, 5090, 5095, 5104, 5108, 5158, 5159, 5163, 5185, 5187, 5267, 5280, 5294, 5307, 5315, 5335, 5355, 5361, 5371, 5393, 5396, 5425, 5446, 5461, 5465, 5466, 5469, 5489, 5491, 5495, 5507, 5508, 5517, 5530, 5531, 5534, 5542, 5543, 5564, 5579, 5607, 5620, 5631, 5656, 5659, 5660, 5668, 5674, 5676, 5681, 5716, 5727, 5734, 5740, 5742, 5747, 5755, 5781, 5786, 5787, 5805, 5813, 5814

Leica CM1510 S: 5065, 5075, 5103, 5108, 5138, 5197, 5269, 5305, 5330, 5348, 5359, 5362, 5367, 5400, 5423, 5438, 5457, 5461, 5467, 5478, 5510, 5531, 5537, 5625, 5649, 5667, 5679, 5780, 5804, 5805, 5818, 5886, 5901, 5913, 5966, 5982, 5996

Leica CM1100:	168, 251, 311, 349, 365, 372, 380, 404, 413, 485, 488, 556, 581, 634, 658, 674, 689, 711, 735, 740, 746, 766, 786, 790, 807, 849, 860, 866, 880, 904, 914, 931, 934, 946, 958, 968, 975, 976, 987, 990, 999
Leica CM1500:	1177, 1578, 2066, 2301, 2342, 2346, 2369, 2453, 2475, 2508, 2519, 2737, 2836, 2879, 2908, 2972, 2977, 2978, 2982, 2990, 3470, 3840
Leica CM1800:	0247, 1082, 2792, 2996
Leica CM1900:	101, 157, 203, 349, 379, 379, 383, 430, 439, 463, 522, 550, 557, 558, 563, 617, 629, 652, 657, 684, 703, 794, 808, 842, 845, 849, 850, 856, 870, 871, 876, 880, 881, 884, 908, 911, 916, 925, 932, 939, 941, 957, 960, 963, 974, 994, 995, 1001, 1009, 1011, 1018, 1031, 1057, 1071, 1094, 1114, 1159, 1170, 1186, 1187, 1198, 1235, 1236, 1239, 1267, 1295, 1328, 1329, 1330, 1331, 1379, 1383, 1393, 1400, 1432, 1452, 1479, 1481, 1489, 1491, 1494, 1497, 1508, 1513, 1514, 1520, 1538, 1540, 1557, 1558, 1577, 1586, 1591, 1592, 1598, 1601, 1602, 1603, 1605, 1606, 1617, 1634, 1636, 1675, 1679, 1691, 1706, 1732, 1743, 1747, 1749, 1752, 1753, 1771, 1777, 1783, 1804, 1806, 1808, 1809, 1819, 1839, 1885, 1904, 1928, 1952, 1953, 1962, 1986, 1989, 1992, 1995, 1997, 2000, 2002, 2004, 2005, 2020, 2025, 2027, 2028, 2058, 2066, 2068, 2072, 2074, 2116, 2126, 2137, 2143, 2152, 2169, 2173, 2190, 2204, 2213, 2240, 2252, 2255, 2265, 2300, 2306, 2321, 2324, 2336, 2349, 2359, 2361, 2371, 2372, 2376, 2385, 2420, 2428, 2430, 2434, 2459, 2460, 2463, 2472, 2477, 2483, 2496, 2501, 2514, 2523, 2526, 2527, 2532, 2534, 2536, 2542, 2550, 2565, 2566, 2572, 2602, 2605, 2610, 2617, 2664, 2666, 2682, 2688, 2691, 2694, 2695, 2717, 2742, 2749, 2765, 2766, 2774, 2797, 2801, 2805, 2807, 2810, 2814, 2832, 2856, 2868, 2871, 2874, 2902, 2915, 2922, 2929, 2954, 2994, 3027, 3037, 3038, 3071, 3072, 3080, 3095, 3178, 3204, 3228, 3243, 3247, 3254, 3269, 3283, 3314, 3358, 3380, 3393, 3469, 3485, 3487, 3510, 3519, 3531, 3561, 3601, 3686, 3691, 3698, 3767, 3779, 3784, 3826, 3833, 3883, 3905, 3906, 3974, 4002, 4009
Leica CM1900 UV:	584, 2023, 2433, 3105, 3113, 3125, 3128, 3129, 3130, 3132, 3193, 3213, 3240, 3241, 3248, 3261, 3279, 3294, 3324, 3326, 3330, 3346, 3349, 3362, 3372, 3377, 3402, 3408, 3409, 3412, 3413, 3415, 3434, 3443, 3450, 3476, 3492, 3493, 3511, 3527, 3528, 3529, 3550, 3552, 3553, 3555, 3557, 3559, 3560, 3571, 3596, 3610, 3615, 3648, 3657, 3658, 3661, 3668, 3670, 3675, 3687, 3702, 3704, 3708, 3709, 3720, 3722, 3733, 3763, 3765, 3816, 3848, 3856, 3869, 3932, 4006
Leica CM3000:	0932
Leica CM3050:	1545, 1652, 1672, 1676, 1715, 1715, 1734, 1893, 1901, 1902, 1910, 1935, 1960, 1964, 1966, 1993, 2009, 2026, 2039, 2060, 2074, 2132, 2137, 2146, 2153, 2161, 2172, 2173, 2198, 2214, 2220, 2225, 2251, 2257, 2260, 2261, 2270, 2289, 2307, 2318, 2413, 2445, 2569, 2865, 2930, 4027, 4164

Description of the Problem:

As part of our post market surveillance, we recognized that some customers are using flammable freezing sprays within the cryostat chamber. All flammable freezing sprays can potentially ignite and therefore can cause serious injuries. The flammability is indicated on the labelling of these sprays. The cryostat labelling, however, did not include any specific warning about usage of flammable freezing sprays prior to 2019. As part of this field action, we are providing updated labelling for the affected devices, to add a clear visual reinforcement that no flammable freezing sprays should be used within the cryostat chamber.

Advice on Immediate Actions to Be Taken:



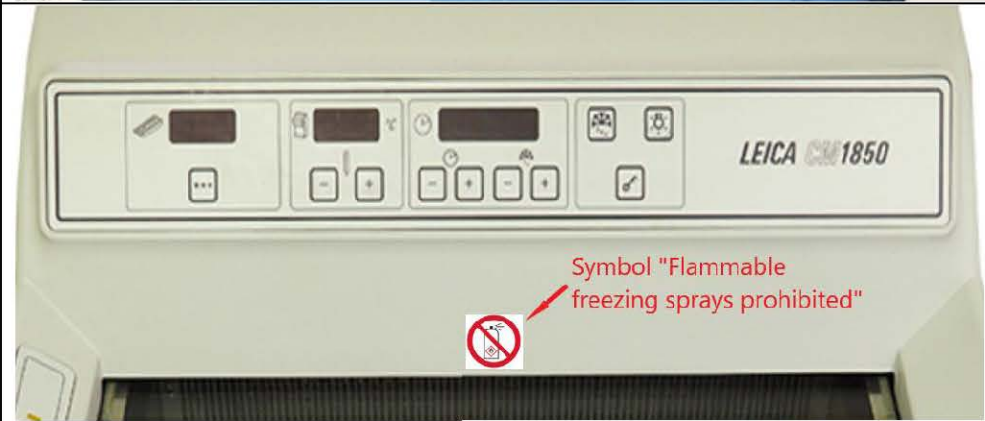

As an immediate action, we ask you to update the instrument labelling by placing the attached adhesive label as shown below on the devices, as well as adding a supplemental sheet to the current Instructions for Use (IFU).



1. Application of the Adhesive Label:

First clean the surface around the area where the adhesive label shall be placed (grease free). Then remove the provided adhesive label from the foil and place it on the surface as shown in the pictures below.

Positioning Symbol „Flammable freezing sprays prohibited“	Device
	<p>Leica CM1950</p>

 <p>LEICA CM3050 S Symbol "Flammable freezing sprays prohibited"</p>	<p>Leica CM3050 S</p>
 <p>LEICA CM1850 UV Symbol "Flammable Ag Protect freezing sprays prohibited"</p>	<p>Leica CM1850 UV</p>
 <p>LEICA CM1850 Symbol "Flammable freezing sprays prohibited"</p>	<p>Leica CM1850</p>
 <p>LEICA CM1510 S Symbol "Flammable freezing sprays prohibited"</p>	<p>Leica CM1510 S</p>

 <p>Symbol "Flammable freezing sprays prohibited"</p>	<p>Leica CM1100</p>
 <p>Symbol „Flammable freezing sprays prohibited"</p>	<p>Leica CM1500</p>
 <p>Symbol „Flammable freezing sprays prohibited"</p>	<p>Leica CM1800</p>
 <p>Symbol „Flammable freezing sprays prohibited"</p>	<p>Leica CM1900/UV</p>
 <p>Symbol „Flammable freezing sprays prohibited"</p>	<p>Leica CM3000</p>
 <p>Symbol „Flammable freezing sprays prohibited"</p>	<p>Leica CM3050</p>

2. Addition of the Safety Amendment to the Instructions for Use (IFU):

Add the safety amendment, attached to this notification, to the cryostat Instructions for Use (IFU).

Your prompt assistance to place the provided adhesive label nearby the cryostat chamber of the instrument and to add the safety amendment in the IFU is appreciated and necessary to prevent a possible serious adverse event.

Transmission of This Field Action Notice:

Kindly please pass this notification letter to users of these affected products and to all those within your organization where the affected devices have been transferred.

Please maintain awareness of this field action and resulting action to ensure effectiveness of the corrective action.

Contact Reference Person:

Should you have any questions, please contact:

Heather Jensen

Leica Biosystems

5205 US Highway 12, Richmond, IL 60071 USA

Tel.: +1-815-298-8371

heather.jensen@leicabiosystems.com

Please sign the enclosed Acknowledgement Form to confirm that you have received and understood this field action notice.

We are sincerely sorry for any inconvenience caused by this issue.

Best regards,

Signed by:



Signer Name: Heather Jensen
Signing Reason: I approve this document
Signing Time: 27-Aug-2024 | 07:15:04 PDT

Heather Jensen

A43332916CAE4983B221EB3795148427

Director, Post Market Surveillance

Leica Biosystems, Quality & Regulatory Affairs Multifunction/General - Regulatory Global

(The undersigned confirms that the field action letter is being made with the knowledge of the relevant Health Authorities)

ACKNOWLEDGEMENT FORM

Please record the serial number(s) of your device(s):

(The serial number can be found on the identification plate on the rear of the device.)

Leica CM1100 _____	Leica CM3050 _____
Leica CM1950 _____	Leica CM1850 _____
Leica CM1850UV _____	Leica CM1510 S _____
Leica CM1500 _____	Leica CM1800 _____
Leica CM1900 _____	Leica CM1900 UV _____
Leica CM3000 _____	Leica CM3050 S _____

- None of the units above are affected or still in use.

Please acknowledge by checking the boxes below.

- I have read and understood the field action notice.
- I have placed the provided adhesive label near the cryostat chamber as mentioned in the "Advice on Immediate Action to be Taken".
- I have added the provided safety amendment to the IFU as mentioned in the "Advice on Immediate Action to be Taken".

Name: _____

Title: _____

Phone: _____

Firm Name: _____

Address: _____

City/State: _____

Signature: _____

Please complete and return this **ACKNOWLEDGEMENT FORM** within 5 days after receipt to the below email address:

LBSNUS.Field-Action@leicabiosystems.com