

**URGENT – Medical Device Correction
SureSigns Patient Monitors**

Dear Customer,

A problem has been identified with Philips SureSigns VS2+ Patient Monitors that, if it were to occur, could pose a risk for patients. This Field Safety Notice is intended to inform you about:

- what the problem is and under what circumstances it can occur,
- the actions that should be taken in order to prevent risks for patients, and
- the actions planned by Philips Healthcare to correct the problem.

This Field Safety Notice contains important information for the continued safe and proper use of your equipment

Please review the following information with all members of your staff who need to be aware of the contents of this communication. It is important to understand the implications of this communication.

Please retain a copy with the equipment Instructions for Use.

Philips Healthcare has identified that it is possible for the Philips SureSigns VS2+ Patient Monitors to lock up and stop monitoring during patient use. If the VS2+ is in NBP Interval mode with a patient being continuously monitored for SpO2 and NBP and the VS2+ locks up, then NBP and SpO2 will not be measured and the device alarms will not be functional. In such cases, a delay in treatment could occur if a clinician is not aware that the VS2+ is no longer monitoring.

Philips Healthcare is conducting field action to correct these devices. Please refer to the following pages which provide instructions for actions to be taken. Follow the "ACTION TO BE TAKEN BY CUSTOMER/USER" section of the instructions.

This issue has been reported to the appropriate regulatory agencies.

I sincerely regret the inconvenience that this may cause you. Philips Healthcare has a well-earned reputation for providing products and services of the highest quality. Your satisfaction with Philips Healthcare products and with our response to this issue is very important to us. Contact your local Philips Healthcare representative if you have any questions or concerns: at [<Philips representative contact details to be completed by the KM/country>](#).

Sincerely,



David J. Lanfranchi
Director, Quality and Regulatory Affairs
Philips Healthcare

**URGENT – Medical Device Correction
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AFFECTED PRODUCTS	<p>Model: VS2+</p> <p>Product: 863278, 863279</p> <p>Serial Numbers:</p> <p>CN14800428, CN14800429, CN14800430, CN14800431, CN14800432, CN14800433, CN14800434, CN14800435, CN14800436, CN14800437, CN14800438, CN14800439, CN14800440, CN14800756, CN14800763, CN14800764, CN14800765, CN14800772, CN14800773, CN14800822, CN14800823, CN14800824, CN14800979, CN14801332, CN21201423, CN21201625, CN21202029, CN21202030, CN21202031, CN21202032, CN21202033, CN21202034, CN21202234, CN21202239, CN21202240, CN21202241, CN21202242, CN21202243, CN21202317, CN21202320, CN21202347, CN21202348, CN21202349, CN21202350, CN21202351, CN21202376, CN21202435, CN21202606, CN21202607, CN21202862, CN21202863, CN21202883, CN21203006, CN21203007, CN21203008, CN21203009, CN21203010, CN21203073, CN21203180, CN21203304, CN21203307, CN21203308, CN21203309, CN21203310, CN21203311, CN21203312, CN21203707, CN21203781, CN21203794, CN21203795, CN21203796, CN21203797, CN21203949, CN21203950, CN21203951, CN21203952, CN21203953, CN21204204, CN21204205, CN21204206, CN21204207, CN21204208, CN21204209, CN21204210, CN21204211, CN21203057, CN14800484, CN14800744, CN14800745, CN14800746, CN21203044, CN21203045, CN21203068, CN21203069, CN21203070, CN21203071, CN14800485, CN14800486, CN14800749, CN14800750, CN14800751, CN14800752, CN14800770, CN14800771, CN14800893, CN21201756, CN21201757, CN21201758, CN21201759, CN21201760, CN21202164, CN21202165, CN21202166, CN21202167, CN21202168, CN21202169, CN21202170, CN21202171, CN21202172, CN21202173, CN21202174, CN21202175, CN21202176, CN21202177, CN21202178, CN21202202, CN21202610, CN21202864, CN21203209, CN21203210, CN21203639, CN14801200, CN14801201, CN14801202, CN14801203, CN14801204, CN14801205, CN14801206, CN14801207, CN14801208, CN14801209, CN14801210, CN14801212, CN14801213, CN14801217, CN14801278, CN14801279, CN14801280, CN14801281, CN21201576, CN21201613, CN21202313, CN21202367, CN21202368, CN21202371, CN21202657, CN21203072, CN21203416, CN21203887, CN21203961, CN21203970, CN21204148, CN21204318, CN21202393, CN21202394, CN21203746, CN21203747, CN21203748, CN21203749, CN21201924, CN21201925, CN21201926, CN21201927, CN21201928, CN21201929, CN21201930, CN21201931, CN21201932, CN21201942, CN21202263, CN21202264, CN21202669, CN21202727, CN21202728, CN21202729, CN21202730, CN21202819, CN21202842, CN21202843, CN21202844, CN21202845, CN21202846, CN21202847, CN21202848, CN21202849, CN21202850, CN21202851, CN21202852, CN21202853, CN21202854, CN21202855, CN21202856, CN21202926, CN21202927, CN21202928, CN21202929, CN21202930, CN21202931, CN21202932, CN21202933, CN21202934, CN21202935, CN21202936, CN21202937, CN21202938, CN21202939, CN21202940, CN21202941, CN21202942, CN21202943, CN21202944, CN21202945, CN21202946, CN21202947, CN21202948, CN21202949, CN21202950, CN21202951, CN21202952, CN21202953, CN21202954, CN21202955, CN21202956, CN21202957, CN21202958, CN21202959, CN21202960, CN21202961, CN21202962, CN21202963, CN21202964, CN21202965, CN21202966, CN21202967, CN21202968, CN21202969, CN21202970, CN21202971, CN21202972, CN21202973, CN21202974, CN21202975, CN21202976, CN21202977, CN21202978, CN21202979, CN21202980, CN21202981, CN21202982, CN21202983, CN21202984, CN21202985, CN21202986, CN21202987, CN21202988, CN21202989, CN21202990, CN21202991, CN21203197, CN21203198, CN21203199, CN21203200, CN21203201, CN21203202, CN21203203, CN21203204, CN21203205, CN21203206, CN21203340, CN21203341, CN21203342, CN21203343, CN21203344, CN21203345, CN21203346, CN21203347, CN21203348, CN21203349, CN21203350, CN21203351, CN21203352, CN21203353, CN21203354, CN21203355, CN21203356, CN21203357, CN21203358, CN21203359, CN21203360, CN21203725, CN21203726, CN21203727, CN21203728, CN21203729, CN21203730, CN21203731, CN21203740, CN21204314, CN21202373, CN14800478, CN14800481, CN14800637, CN14800699, CN14800700, CN14800891, CN14800892, CN14800968, CN14800969,</p>
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URGENT – Medical Device Correction
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SureSigns Patient Monitors**

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URGENT – Medical Device Correction
SureSigns Patient Monitors

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URGENT – Medical Device Correction
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SureSigns Patient Monitors

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**URGENT – Medical Device Correction
SureSigns Patient Monitors**

	<p>CN21202508, CN21202509, CN21202510, CN21202511, CN21202512, CN21202513, CN21202514, CN21202670, CN21202671, CN21202672, CN21202673, CN21202674, CN21202675, CN21202681, CN21202682, CN21202684, CN21202685, CN21202686, CN21202687, CN21202841, CN21203031, CN21203046, CN21203047, CN21203048, CN21203049, CN21203050, CN21203051, CN21203052, CN21203053, CN21203074, CN21203075, CN21203076, CN21203077, CN21203078, CN21203079, CN21203080, CN21203081, CN21203082, CN21203083, CN21203084, CN21203085, CN21203086, CN21203087, CN21203088, CN21203089, CN21203090, CN21203091, CN21203092, CN21203093, CN21203094, CN21203095, CN21203154, CN21203155, CN21203156, CN21203157, CN21203189, CN21203190, CN21203191, CN21203192, CN21203193, CN21203194, CN21203214, CN21203215, CN21203216, CN21203217, CN21203218, CN21203219, CN21203220, CN21203221, CN21203232, CN21203233, CN21203234, CN21203235, CN21203236, CN21203237, CN21203238, CN21203239, CN21203240, CN21203241, CN21203242, CN21203243, CN21203244, CN21203245, CN21203246, CN21203247, CN21203248, CN21203249, CN21203250, CN21203251, CN21203252, CN21203290, CN21203291, CN21203292, CN21203293, CN21203294, CN21203295, CN21203296, CN21203297, CN21203323, CN21203324, CN21203337, CN21203338, CN21203339, CN21203363, CN21203383, CN21203384, CN21203385, CN21203386, CN21203387, CN21203393, CN21203394, CN21203395, CN21203396, CN21203397, CN21203404, CN21203405, CN21203406, CN21203407, CN21203408, CN21203409, CN21203410, CN21203411, CN21203412, CN21203413, CN21203414, CN21203417, CN21203462, CN21203463, CN21203464, CN21203465, CN21203466, CN21203467, CN21203636, CN21203709, CN21203710, CN21203711, CN21203712, CN21203741, CN21203750, CN21203751, CN21203752, CN21203753, CN21203829, CN21203830, CN21203831, CN21203832, CN21203833, CN21203834, CN21203835, CN21203836, CN21203837, CN21203838, CN21203871, CN21203872, CN21203873, CN21203874, CN21203875, CN21203876, CN21203877, CN21203878, CN21203879, CN21203880, CN21203881, CN21203882, CN21203883, CN21203884, CN21203885, CN21203900, CN21203901, CN21203902, CN21203903, CN21203904, CN21203905, CN21203906, CN21203907, CN21203908, CN21203909, CN21203910, CN21203911, CN21203912, CN21203913, CN21203914, CN21203915, CN21203916, CN21203917, CN21203918, CN21203919, CN21203920, CN21203921, CN21203922, CN21203923, CN21203954, CN21203955, CN21203956, CN21203957, CN21203958, CN21203962, CN21203963, CN21203964, CN21203971, CN21203972, CN21203973, CN21203974, CN21203975, CN21203976, CN21203977, CN21203978, CN21203979, CN21203980, CN21203981, CN21203982, CN21203983, CN21203984, CN21203995, CN21203996, CN21203997, CN21203998, CN21204006, CN21204012, CN21204014, CN21204015, CN21204123, CN21204124, CN21204212, CN21204213, CN21204216, CN21204217, CN21204275, CN21204276, CN21204277, CN21204278, CN21204279, CN21204280, CN21204281, CN21204282, CN21204316, CN21204326, CN21204327, CN21204328, CN21204373, CN21204374, USPP3NCK10</p>
<p>PROBLEM DESCRIPTION</p>	<p>Philips Healthcare has identified that it is possible for the SureSigns VS2+ Patient Monitor to lock up and stop monitoring during patient use.</p> <p>This has been identified by 5 customers and a total of 10 devices (0.3% of shipped devices).</p>
<p>HAZARD INVOLVED</p>	<p>If the device is in NBP Interval mode with a patient being continuously monitored for SpO2 and NBP and the device locks up, then NBP and SpO2 will not be measured and the device alarms will not be functional. In such cases, a delay in treatment could occur if a clinician is not aware that the device is no longer monitoring.</p>

URGENT – Medical Device Correction SureSigns Patient Monitors

<p>HOW TO IDENTIFY AFFECTED PRODUCTS</p>	<p>The AFFECTED PRODUCTS section of this notice lists the models, part numbers and serial numbers affected by this correction. The part number (REF) and serial number are located on the identification label on the rear of the device.</p>
<p>ACTION TO BE TAKEN BY CUSTOMER / USER</p>	<p>Affected products may continue to be used while waiting for the correction from Philips if the unit is not used in NBP Interval mode.</p> <p>To determine that the device is not in NBP Interval mode, place the device in Vital Signs Display Mode or Display Waveform Mode. Ensure that the word “Off” appears next to the NBP Interval icon on the screen. This is shown below:</p> <div style="text-align: center;"> <p style="text-align: center;">Vital Signs Display Mode</p> </div> <div style="text-align: center; margin-top: 20px;"> <p style="text-align: center;">Display Waveform Mode</p> </div>

URGENT – Medical Device Correction SureSigns Patient Monitors

	<p>If the device is in NBP Interval mode, use the Clear Program option to delete the NBP Interval program. When you select the Clear Program button, all settings are cleared and the program returns to its default values.</p> <p>To clear the NBP Interval program</p> <ol style="list-style-type: none"> 1. Rotate the wheel to highlight the NBP numeric pane. 2. Press the wheel. The Blood Pressure Menu appears. Current settings are displayed. 3. Rotate the wheel to highlight the NBP Interval button. Press the wheel. 4. The NBP Interval Menu appears. 5. Rotate the wheel to highlight the Clear Program button, and then press the wheel. A confirmation window appears. 6. Select Yes to confirm that you want to clear the NBP program. <p>If the device is still in NBP Interval mode remove the device from service and contact Philips.</p>
NOTE	If the VS2+ locks up: disconnect power, remove battery. Reconnect battery and power up after 60 seconds.
ACTIONS PLANNED BY PHILIPS HEALTHCARE	<p>Philips Healthcare is completing the design to correct this issue, which is expected to be available within 7 weeks. Philip will correct the issue free of charge.</p> <p>A Philips Healthcare representative will contact you to arrange for the correction of all affected devices.</p>
FURTHER INFORMATION AND SUPPORT	If you need any further information or support concerning this issue, please contact <Philips representative contact details to be completed by the KM / country> .