



**URGENT - Medical Device Recall  
Expression Information Portal (IP5)**

**Frozen Display Numerics and Disabled Menu Keys  
*Solution Available***

Dear Customer,

Recently, you were notified of a problem with the Philips Expression Information Portal (IP5). Specifically, when the IP5 was continually powered on for more than 24 days, a graphical user interface (display screen) error occurred and this caused the numeric data on the display to freeze and disabled some menu keys. You were advised that Philips would be providing a solution to this problem. The solution is now available.

**This document 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.

Our records indicate that you have an affected product. The following page provides additional instructions and actions to be taken; refer to the "Action to Be Taken by Customer / User" section for more information.

If you need any further information or support concerning this issue, please contact your local Philips representative or the UK Philips Customer Care Service Centre on 0870 532 9741.

We apologize for any inconveniences that were caused by this problem.

Sincerely,

Rusty Kelly  
Senior Manager, Quality & Regulatory





## URGENT - Medical Device Recall Expression Information Portal (IP5)

**Frozen Display Numerics and Disabled Menu Keys  
Solution Available**

| AFFECTED PRODUCTS | Product: 865471 (Expression Information Portal IP5) / Service Number 453564251511   |
|-------------------|---|
|                   | Serial Numbers: US23200121, US23200122, US23200123, US23200124, US23200125, US23200126, US23200127, US23200128, US23200129, US23200130, US23200131, US23200132, US23200133, US23200134, US23200135, US23200136, US23200137, US23200138, US23200139, US23200140, US23200141, US23200142, US23200143, US23200144, US23200145, US23200146, US23200147, US23200148, US23200149, US23200150, US23200151, US23200152, US23200153, US23200154, US23200155, US23200156, US23200157, US23200158, US23200159, US23200160, US23200161, US23200162, US23200163, US23200164, US23200165, US23200166, US23200167, US23200168, US23200169, US23200170, US23200172, US23200173, US23200176, US23200177, US23200178, US23200179, US23200180, US23200181, US23200182, US23200183, US23200184, US23200188, US23200189, US23200190, US23200191, US23200192, US23200193, US23200194, US23200195, US23200196, US23200197, US23200198, US23200199, US23200200, US23200201, US23200202, US23200203, US23200204, US23200205, US23200206, US23200207, US23200208, US23200209, US23200210, US23200211, US23200212, US23200213, US23200214, US23200215, US23200216, US23200217, US23200218, US23200219, US23200220, US23200221, US23200222, US23200223, US23200224, US23200225, US23200226, US23200227, US23200228, US23200229, US23200230, US23200231, US23200232, US23200233, US23200234, US23200235, US23200236, US23200237, US23200238, US23200239, US23200240, US23200241, US23200242, US23200243, US23200244, US23200245, US23200246, US23200247, US23200248, US23200249, US23200250, US23200251, US23200252, US23200253, US23200254, US23200255, US23200256, US23200258, US23200259, US23200260, US23200261, US23200262, US23200263, US23200264, US23200265, US23200266, US23200267, US23200268, US23200269, US23200270, US23200271, US23200272, US23200273, US23200274, US23200275, US23200276, US23200277, US23200278, US23200279, US23200280, US23200281, US23200282, US23200283, US23200284, US23200285, US23200286, US23200287, US23200288, US23200289, US23200290, US23200291, US23200292, US23200293, US23200294, US23200295, US23200296, US23200297, US23200298, US23200299, US23200300, US23200301, US23200302, US23200303, US23200304, US23200305, US23200306, US23200307, US23200308, US23200309, US23200310, US23200311, US23200312, US23200313, US23200314, US23200315, US23200316, US23200317, US23200318, US23200319, US23200320, US23200321, US23200322, US23200323, US23200324, US23200325, US23200326, US23200327, US23200328, US23200329, US23200330, US23200331, US23200332, US23200333, US23200334, US23200335, US23200336, US23200337, US23200338, US23200339, US23200340, US23200341, US23200342, US23200343, US23200344, US23200345, US23200346, US23200347, US23200349, US23200350, US23200351, US23200352, US23200353, US23200354, US23200355, US23200357, US23200358, US23200359, US23200360, US23200361, US23200362, US23200363, US23200364, US23200365, US23200366, US23200367, US23200368, US23200369, US23200370, US23200371, US23200372, US23200373, US23200374, US23200375, US23200376, US23200377, US23200378, US23200379, US23200380, US23200381, US23200382, US23200383, US23200385, US23200386, US23200387, US23200388, US23200389, US23200390, US23200391, US23200393, US23200394, US23200395, US23200397, US23200398, US23200399, US23200400, US23200401, US23200402, US23200403, US23200405, US23200406, US23200407, US23200408, US23200410, US23200413, US23200415, US23200416, US23200419, US23200421, US23200422, US23200423, US23200424, US23200425, US23200427, US23200428, US23200429, US23200431, US23200434, US34600510, US34600511, US34600512, US34600513, US34600514, US34600515, US34600516, US34600517, US34600518, US34600519, US34600520, US34600521, US34600522, US34600523, US34600524, US34600525, US34600526, US34600528, US34600529, US34600530, US34600531, US34600532, US34600533, US34600534, US34600535, US34600536, US34600537, US34600538, US34600539, US34600540, US34600541, US34600542, US34600543, US34600544, US34600545, US34600546, US34600547, US34600548, US34600549, US34600550, US34600551, US34600552, US34600553, US34600554, US34600555, US34600556, US34600557, US34600558, US34600559, US34600560, US34600561, US34600562, US34600563, US34600564, US34600565, US34600566, US34600567, US34600568, US34600569, US34600570, US34600571, US34600572, US34600573, US34600574, US34600575, |



## URGENT - Medical Device Recall Expression Information Portal (IP5)



### Frozen Display Numerics and Disabled Menu Keys *Solution Available*

|                            |   |
|----------------------------|---|
|                            | <p>US34600576, US34600577, US34600578, US34600579, US34600580, US34600581, US34600582, US34600583, US34600584, US34600585, US34600586, US34600587, US34600588, US34600589, US34600590, US34600591, US34600592, US34600592, US34600593, US34600594, US34600595, US34600596, US34600597, US34600598, US34600599, US34600600, US34600601, US34600602, US34600603, US34600604, US34600605, US34600606, US34600607, US34600608, US34600609, US34600610, US34600611, US34600612, US34600613, US34600614, US34600615, US34600616, US34600617, US34600618, US34600619, US34600620, US34600621, US34600622, US34600623, US34600624, US34600625, US34600626, US34600627, US34600628, US34600629, US34600630, US34600631, US34600632, US34600633, US34600634, US34600635, US34600636, US34600637, US34600638, US34600639, US34600640, US34600641, US34600642, US34600643, US34600644, US34600645, US34600646, US34600647, US34600648, US34600649, US34600650, US34600651, US34600652, US34600653, US34600654, US34600655, US34600656, US34600657, US34600658, US34600659, US34600660, US34600661, US34600662, US34600663, US34600664, US34600665, US34600666, US34600667, US34600668, US34600669, US34600670, US34600671, US34600672, US34600673, US34600674, US34600675, US34600676, US34600677, US34600678, US34600679, US34600680, US34600681, US34600682, US34600683, US34600684, US34600685, US34600686, US34600687, US34600688, US34600689, US34600690, US34600691, US34600692, US34600693, US34600694, US34600695, US34600696, US34600697, US34600698, US34600699, US34600700, US34600701, US34600702, US34600703, US34600704, US34600705, US34600706, US34600707, US34600708, US34600709, US34600710, US34600711, US34600712, US34600713, US34600714, US34600715, US34600716, US34600717, US34600718, US34600719, US34600720, US34600721, US34600722, US34600723, US34600724, US34600725, US34600726, US34600727, US34600728, US34600729, US34600730, US34600731, US34600732, US34600733, US34600734, US34600735, US34600736, US34600737, US34600738, US34600739, US34600740, US34600741, US34600742, US34600743, US34600744, US34600745, US34600746, US34600747, US34600748, US34600749, US34600750, US34600751, US34600752, US34600753, US34600754, US34600755, US34600756, US34600757, US34600758, US34600759, US34600760, US34600761, US34600762, US34600763, US34600764, US34600765, US34600766, US34600767, US34600768, US34600769, US34600770, US34600771, US34600772, US34600773, US34600774, US34600775, US34600776, US34600777, US34600778, US34600779, US34600780, US34600781, US34600782, US34600783, US34600784, US34600785, US34600786, US34600787, US34600788, US34600789, US34600790, US34600791, US34600792, US34600793, US34600794, US34600795, US34600796, US34600797, US34600798, US34600799, US34600800, US34600801, US34600802, US34600803, US34600804, US34600805, US41600814, US41600815, US41600816, US41600817, US41600818, US41600819, US41600820, US41600821, US41600822, US41600823, US41600824, US41600825, US41600826, US41600827, US41600828, US41600829, US41600830, US41600831, US41600832, US41600833, US41600834, US41600835, US41600836, US41600837, US41600838, US41600839, US41600840, US41600841, US41600842, US41600843, US41600844, US41600845, US41600846, US41600847, US41600848, US41600849, US41600850, US41600851, US41600852, US41600853, US41600854, US41600855, US41600856, US41600857, US41600858, US41600859, US41600860, US41600861, US41600862, US41600863, US41600865, US41600866, US41600867, US41600868, US41600869, US41600870, US41600871</p> |
| <b>PROBLEM DESCRIPTION</b> | <p>Continuous use of the IP5 for more than 24 days, without power cycling, results in a graphical user interface (display screen) error, which causes the numeric data on the display to freeze and disables some menu keys. Waveform data displayed and audible alarms are not impacted by this problem and continue to function properly.</p> <p><i>NOTE: The IP5 is intended to be used as a secondary display control unit for the Expression MRI Patient Monitoring System and the Expression MR200 MRI Patient Monitoring System. This problem does not impact the Expression MRI Patient Monitoring System or the Expression MR200 MRI Patient Monitoring System, only the IP5.</i></p>  |



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|  |  |
|--|--|
| <b>HAZARD INVOLVED</b>                       | Delay in treatment of the patient caused by the displayed numeric value not correlating with the patient’s clinical status.  |
| <b>HOW TO IDENTIFY AFFECTED PRODUCTS</b>     |  <p>The picture to the left shows the back of the IP5. The serial number of the IP5 can be found on the service label in the area that is circled.</p>  |
| <b>ACTION TO BE TAKEN BY CUSTOMER / USER</b> | <p>Until your device is updated, ensure that the IP5 is power cycled once every day. This prevents the issue from occurring. A power cycle is performed by pressing the power switch located on the side of the IP5. The power switch is denoted by the following symbol: .</p> <p>Updated software will be installed in your device in order to address this issue. After the software update is installed, if the device is allowed to run for an extended period of time, the device will begin to notify you of the need to power cycle the device using various degrees of warning “restart required” prompts (dialog boxes). These prompts feature a “Remind me later” button that allows you to delay the action. However, after the device has been running continuously for 21 days, the dialog box will be updated and displayed every minute for 10 minutes. If the device is not power cycled when this time expires, the device will power down and sound a tone to inform you of the action.</p> <p>Please find included with this communication, excerpts from the device’s Instructions for Use (IfU) that describes how this software update functions and when to expect the “restart required” prompts. Please ensure that this updated functionality is communicated to all users and that this letter containing the IfU excerpts is retained with the IP5 Instructions for Use.</p> |
| <b>ACTIONS PLANNED BY PHILIPS</b>            | A Philips representative will contact you regarding your affected device. All affected devices will have a software update installed in order to address the problem. This corrective action will be implemented free of charge by Philips.  |
| <b>FURTHER INFORMATION AND SUPPORT</b>       | If you need any further information or support concerning this issue, please contact your local Philips representative or the UK Philips Customer Care Service Centre on 0870 532 9741.  |



## Power-Cycling Requirement during Extended Operating Periods

Software resources internal to the system require the IP5 to be periodically power-cycled.

To remind you of this important operating requirement, the IP5 will notify you with various degrees of warning “restart required” prompts to ensure that daily operations are not impacted. These prompts (dialog boxes) feature a “Remind me later” button that allows you to delay the action; however, if ignored for a long duration, a shut down will be automatically initiated as described below.

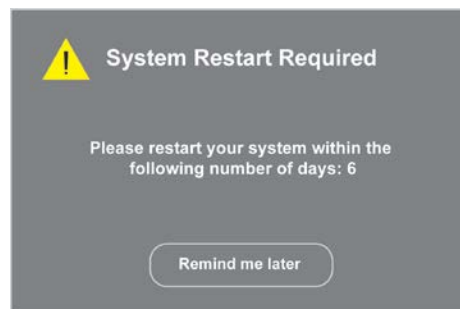
### System Restart Required within Days

If the system has been running for 16 days without power-cycling, a dialog box with the following message will be displayed:

**Please restart your system within the following number of days: X**

where:

X is the number of days before the system will be shut down (see example below). This dialog box will be updated and displayed every 8 hours thereafter until 21 days have elapsed (including those initial 16 days).



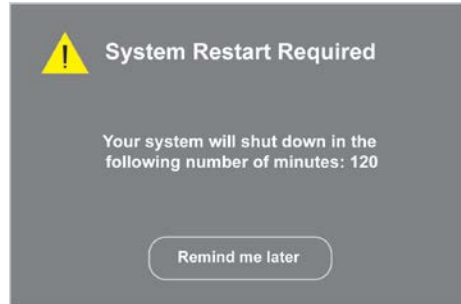
### System Restart Required within Minutes

After the system has been running continuously for 21 days, a dialog box with the following message will be displayed:

**Your system will shut down in the following number of minutes: XXX**

where:

XXX is the number of minutes before the system will be shut down (see example below). This dialog box will be updated and displayed every 15 minutes thereafter until 10 minutes before automatic shut down will occur.



## System Shut Down Imminent

After the system has been running continuously for 21 days and 10 minutes, the dialog box will be updated and displayed every minute (60 seconds) for the next 10 minutes. If the IP5 is not restarted when this time-out period is reached, the system will power down the IP5 and sound a tone to inform you of the action.

### To restart the system

Press the power switch to turn off the IP5, and then press it again to turn on the IP5.



#### WARNING

To avoid the warning prompts or automatic shut down, regularly power cycle the IP5. Failure to do so will result in an automatic shut down of the IP5.

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