

Customer Letter
06152012



FSCA – Field Safety Corrective Action
Malfunctioning Product
superDimension® Systems

Attention: Risk Management Director/ O.R. Materials Manager

Please forward this communication to all Users of the superDimension System

Dear Customer,

superDimension, Inc., is conducting a correction of certain superDimension Systems operating Software Version 4.0 – 4.9. The affected systems are sold under the product code AAS00016-xx.

The products being corrected have been found to malfunction when connected to the superDimension Locatable Guide (LG). Specifically, the Systems using Software Version 4.0-4.9 will not recognize the Locatable Guide, and then generates the following error message: "The location processor was not detected. Please check that the Power Supply is connected and the switch is ON, check the connection to the PC and Press "Retry"." superDimension has concluded that this malfunction may lead to prolonged or canceled procedures.

Users of the superDimension Systems are instructed to discontinue use of the System if the software version is 4.0-4.9. superDimension recommends that the user place a label on the system that indicates "Do Not Use – Under Correction." superDimension will update these systems onsite at the user location.

Users of the superDimension Systems with Software Versions other than 4.0-4.9 may continue to use the System. The Software Version can be identified on the main launch screen. The Part Number and Serial Number are located on the System label.



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The Serial Numbers of affected AAS00016-xx are as follows:

S030097	S0030044	S030065	S030092	S030579	S420011	S420102
I4202008	S0030045	S030066	S030092	S030586	S420012	S420105
I4202012	S00312	S030067	S030094	S030587	S420013	S420107
S0030011	S030043	S030069	S030096	S030588	S420015	S420108
S0030013	S030046	S030070	S030098	S030604	S420019	S420109
S0030014	S030049	S030072	S030099	S030605	S420020	S420110
S0030015	S030052	S030075	S030102	S030608	S420021	S420112
S0030017	S030054	S030076	S030105	S030609	S420026	S420114
S0030021	S030056	S030077	S030449	S300049	S420036	S420125
S0030022	S030057	S030080	S030477	S300082	S420037	S830001
S0030023	S030058	S030081	S030492	S310078	S420077	
S0030024	S030059	S030083	S030541	S310100	S420079	
S0030025	S030060	S030085	S030546	S420006	S420080	
S0030026	S030061	S030087	S030547	S420008	S420092	
S0030042	S030064	S030089	S030573	S420009	S420100	

REQUIRED ACTIONS:

1. If you are a user that has a System utilizing Software Version 4.0-4.9, immediately discontinue use of the unit. superDimension recommends that the user place a label on the system that indicates "Do Not Use – Under Correction."
2. Immediately advise all users of the superDimension System at your institution of this correction.
3. A superDimension Sales Representative will contact you to schedule a System update. Should you have questions in the interim period, please contact superDimension Customer Service at 763.210.4080.
4. **All accounts are required to complete and submit the attached Product Correction Report form and return it to superDimension.** Your response is vital to our monitoring the effectiveness of this voluntary correction.
5. If you are a user that has a System with Software Versions other than 4.0-4.9 you do not need to discontinue the use of the unit.

The completed Product Correction Report can be faxed to superDimension at
763.210.4098


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This voluntary correction is limited to the serial numbers listed in the table above on superDimension System Software Version 4.0-4.9 and does **NOT** affect any other part numbers or serial numbers of superDimension Systems. This voluntary correction does not affect the use of Systems with Software Versions other than Version 4.0-4.9. superDimension has received five (5) reports which resulted in a prolonged or cancelled procedure due to this issue.

We sincerely apologize for any inconvenience this may cause and thank you for your business and continued support. This action is being taken with the full knowledge of the Food and Drug Administration. If you have any questions or concerns, please do not hesitate to contact your superDimension representative or Quality Assurance at 763.210.4057.

Sincerely,


Brent Boucher
Vice President and General Manager
superDimension, Inc.


Karyl Haskell
Vice President, Quality and Regulatory Affairs
superDimension, Inc.



SYSTEM CORRECTION REPORT

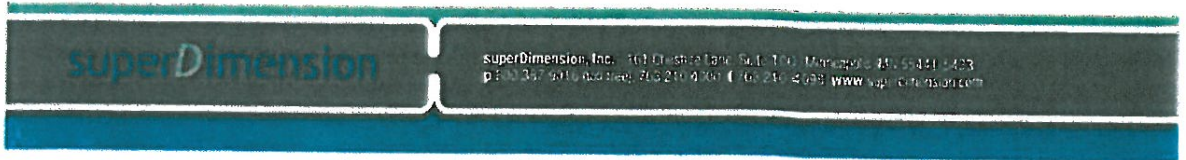
Users of the superDimension System with Software Version 4.x are instructed to discontinue use of the System immediately. superDimension recommends that the user place a label on the system that indicates "Do Not Use – Under Correction." A superDimension representative will contact you to schedule a Software Update. Users of the superDimension System with Software Versions other than 4.x may continue to use System. The software version can be found on the main launch screen of the superDimension System. The Part Number and Serial number are located on the System label.

All accounts are required to complete this form and return this form to acknowledge receipt of this Voluntary Correction Notice.

List of affected Serial Numbers

S030097	S0030044	S030065	S030092	S030579	S420011	S420102
I4202008	S0030045	S030066	S030092	S030586	S420012	S420105
I4202012	S00312	S030067	S030094	S030587	S420013	S420107
S0030011	S030043	S030069	S030096	S030588	S420015	S420108
S0030013	S030046	S030070	S030098	S030604	S420019	S420109
S0030014	S030049	S030072	S030099	S030605	S420020	S420110
S0030015	S030052	S030075	S030102	S030608	S420021	S420112
S0030017	S030054	S030076	S030105	S030609	S420026	S420114
S0030021	S030056	S030077	S030449	S300049	S420036	S420125
S0030022	S030057	S030080	S030477	S300082	S420037	S830001
S0030023	S030058	S030081	S030492	S310078	S420077	
S0030024	S030059	S030083	S030541	S310100	S420079	
S0030025	S030060	S030085	S030546	S420006	S420080	
S0030026	S030061	S030087	S030547	S420008	S420092	
S0030042	S030064	S030089	S030573	S420009	S420100	

PRODUCT CORRECTION REPORT
061512



Unit Serial Number(s): _____

Unit Serial Number is included in the list above and the account has discontinued use of the System.

Unit Serial Number is not included in the list above and the account may continue to use the System.

Name

Signature

Date

Direct Phone #

Email address

Account Address (city, state, zip code) _____

PLEASE FAX THIS COMPLETED FORM TO superDimension AT (763) 210-4098