



23 October 2013

Urgent Field Safety Notice GemStar™ Desk Top Power Supply, 3V_{DC}

Product name:	GemStar™ Desk Top Power Supply, 3V _{DC}
List Number:	13072-92-05
EMEA FA ID:	Q.FA.EMEA.2013.030
Date:	23 rd October 2013

Dear Healthcare Professional and Hospira Customer,

Hospira Inc. (Hospira) has identified a potential risk with the Desk Top GemStar Power Supply.

Issue: Through trended customer reports, Hospira has become aware that the GemStar infusion pump does not receive direct current (DC) power from the desk top power supply in some situations. One report has been received whereby the user observed smoke and found that the GemStar infusion pump was operating on battery power while connected to the 3VDC desk top power supply. No reports of injury to patients or staff have been received to date.

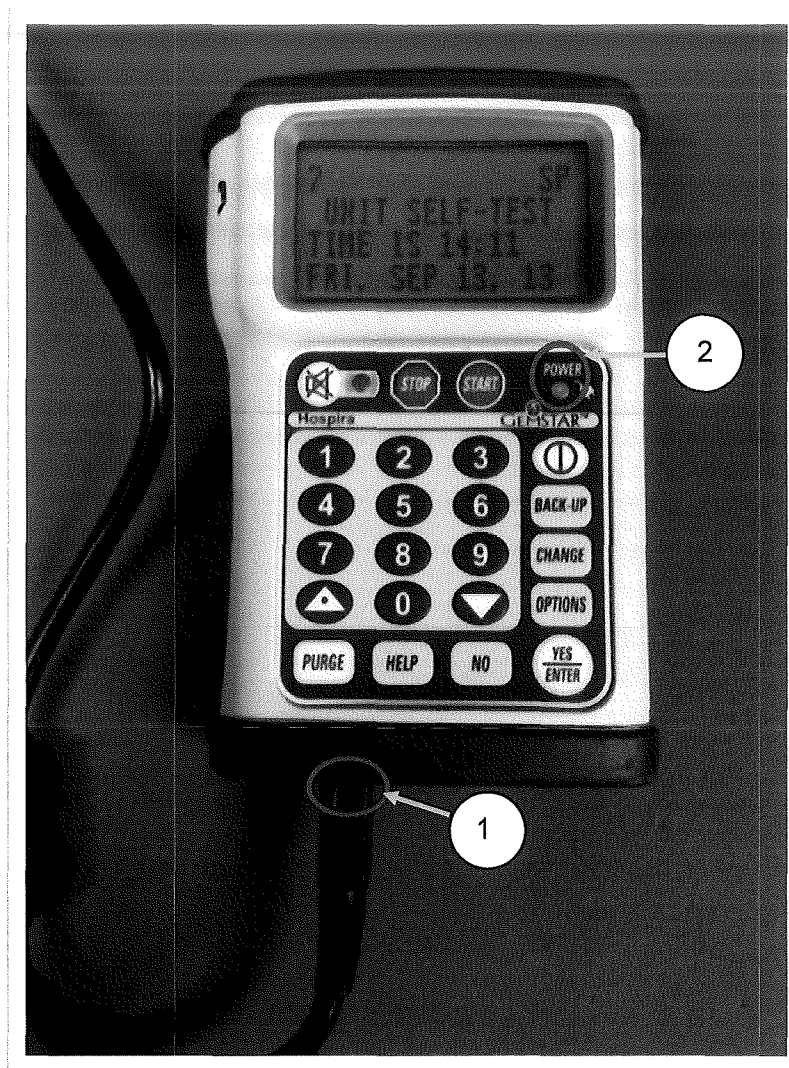
Risk to Health: If the GemStar desk top power supply fails, a planned infusion therapy may be delayed while provisions are made for an alternate method of administration. A prolonged delay of a critical parenteral therapy could potentially result in serious injury or death.

Affected Product Details: The product impacted by this issue is identified in the table below:

GemStar Power Supply	List Number
Desk Top Power Supply	13072-92-05

Actions to be taken: Hospira recommends that users take the following precautions and actions:

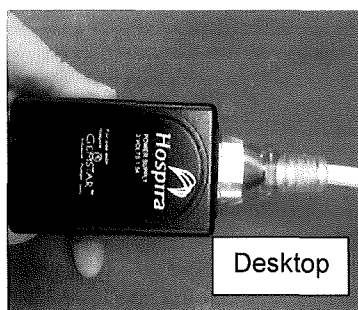
1. Avoid dropping the desk top power supply on hard surfaces, such as concrete floors, as this may result in internal damage that renders the power supply non-functional.
2. Ensure that the female end of the desk top power supply cord is securely fastened to the male end of the desk top power supply inlet to avoid arcing. Avoid wiggling the cord when inserting and removing the desk top power supply cord from the desk top power supply inlet.
3. After plugging the desk top power cord into the GemStar infusion pump power inlet connector (1), verify that the power source green light is lit (2). If the desk top power supply is connected to the GemStar infusion pump and the power source green light is not lit or the GemStar infusion pump displays the message "Using Batteries" upon power up of the device, the desk top power supply should be replaced.



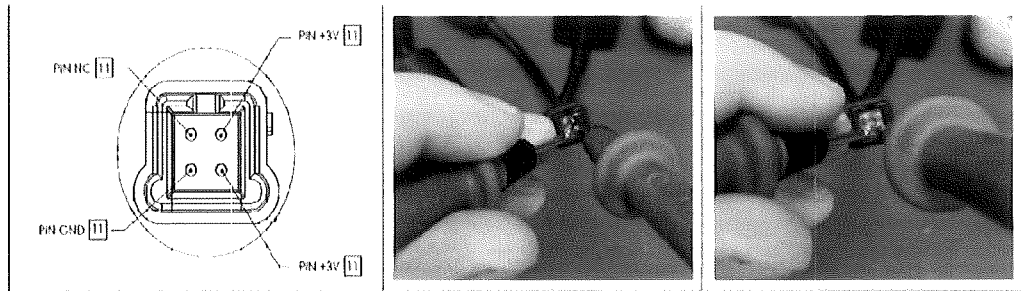
4. Ensure two fresh, disposable AA batteries are installed in the GemStar infusion pump for backup power when using other external power sources (e.g., AC mains adaptor, docking station or battery pack) as instructed in the System Operating Manual.
5. Check the power supply V_{DC} output on a quarterly basis according to the procedure described below. The output should be $3.00 V_{DC} \pm 0.20 V_{DC}$. If not, the desk top power supply should be replaced.

Procedure for measuring the DC output voltage:

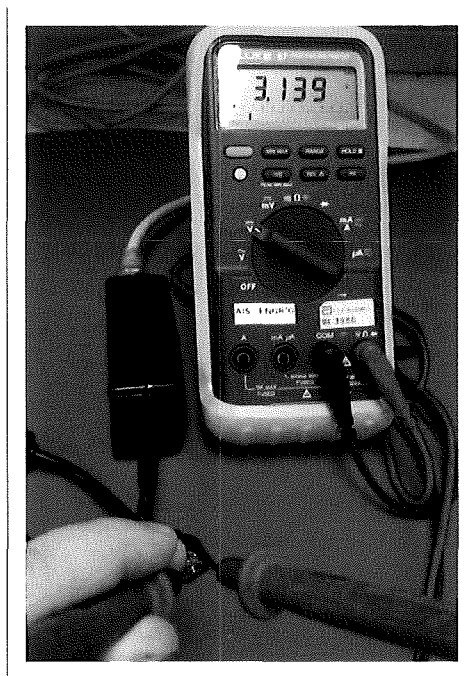
1. Connect the desk top power supply in to an AC power outlet



- Using a calibrated Voltmeter, measure DC voltage output voltage between the pins +3V and GND as indicated below:



- Voltage reading should be 3.00+/- 0.20 V_{DC}.



Product Correction: There is no need to return your GemStar desk top power supply. Hospira has implemented improvements in the manufacturing process to improve the robustness of the GemStar desk top power supply. No further action is necessary.



Please forward this Urgent Field Safety Notice to all colleagues within your organization who need to be aware of it or to any organization or persons where the potentially affected devices have been transferred. Please maintain awareness of this notice.

Hospira is committed to providing you with the highest level of service, product quality and reliability. We appreciate your understanding and we regret any inconvenience this notice may cause you.


Please complete the attached Reply Form indicating the number of impacted devices at your facility and return it to the fax number or e-mail address on the form, even if you do not have the affected product.

Should you have any further questions please do not hesitate to contact your local Hospira office:

Hospira contact	Contact details	Areas of support
Hospira EMEA Product Safety	T: +44 1926 834 400 Email to: devicecomplaintsemea@hospira.com	To report adverse events or product complaints
Hospira EMEA Quality	T: +31 36 5274 720 F: +31 36 5274 701 Email to: devicesfieldactions@hospira.com	Additional information and technical assistance
Local Contacts		

The Competent Authorities in all countries affected by this action have been informed of this Urgent Field Safety Notice

Yours sincerely,



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Section A

Hospital / Facility Details

Please fill out the information below and fax the completed form to Hospira at [local fax number].

Name of Hospital / Facility:	
Hospital / Facility Address:	
Telephone Number:	
Name:	
Signature:	
Date:	

Section B

I have read and understood the contents of this Urgent Field Safety Notice, and circulated it to all staff/departments that use this product.