

FSCA Ref 3006510

ABAXIS Europe GmbH • Bunsenstr. 9-11 • 64347 Griesheim • Germany

## Urgent Field Safety Notice

### Re: Repaired Piccolo Xpress clinical chemistry device

Dear Customer,

Zoetis/Abaxis is issuing a Field Safety Corrective Action for the Piccolo Xpress Chemistry Analyzer. According to our distribution records, your organization may have received an impacted product.

Product/Commercial Name: Piccolo Xpress Chemistry Analyzer

Device Model REF: 1100-1001

Serial Number: P29799

Intended Purpose: The Piccolo Xpress chemistry analyzer provides quantitative in-vitro determinations of clinical chemistry analytes in lithium-heparinized whole blood, heparinized plasma, or serum.

**Description of the problem:** A recent review identified that a low number of Zoetis/Abaxis customers may have received an incorrect power supply with a higher Voltage (SKU 45025696, 19V 120W) accompanied to their returned serviced Piccolo Xpress analyzer. The use of the higher voltage power supply may make the device prone to short circuit and/or cause overheating of internal components.

**Risk:** Overheating of internal components may lead to a device short circuit, burning or hot odor, device shut down, and/or operational disruption, i.e., delayed test. Based on the product design and low voltage, a safety hazard for the operator is not expected but cannot be excluded. Please disconnect device in case of a short circuit and ensure air ventilation.

#### **Required Action:**

1. Immediately disconnect your analyzer from the current power supply
2. Review the brand of the power supply that you have received with Service RMA

#### **If you have received a power supply branded as: *FranMar* (Output: 19V, 130W)**

Please do not reconnect your analyzer. Await the arrival of your replacement power supply before resuming use.

#### **If your power supply is labeled “VOLGEN ASSY” or “CUI INC”:**

You have received the correct power supply. You may continue to use your Piccolo Xpress analyzer as normal and retain the received power supply as a spare.

Table 1. Power Supply Comparison

Correct Power Supply	Incorrect Power Supply
<div data-bbox="210 273 667 600"> </div> <p data-bbox="199 631 638 705">Volgen: EMI11011H, Output 16 V, 7.5 A <b>45021641</b> POWER SUPPLY VOLGEN ASSY (Output: 16 V, 120 W Max)</p> <p data-bbox="199 728 582 801">CUI: SDI120-16-U, Output 16 V, 7.5 A <b>45021643</b> POWER SUPPLY CUI ASSY (Output: 16 V, 120 W Max)</p>	<div data-bbox="869 280 1053 616"> </div> <p data-bbox="869 631 1340 705">FranMar: FDM-180-S24B-4, Output: 19 V, 6.84 A <b>45025696</b> AC ADAPT ANALYSER 130 W (Output 19V, 130W Max)</p>

**Corrective Action:** As a preventive measure we are proactively sending the correct replacement power supply to all effected customers.

We sincerely apologize for any inconvenience this may have caused.

Please send back the information of power supply model you have received to:

[int.piccolosupport@zoetis.com](mailto:int.piccolosupport@zoetis.com)

RMA Number: 300141380 \_\_\_\_\_

Power Supply Model: \_\_\_\_\_

Date and Signature: \_\_\_\_\_

The health authority has been advised of the Field Safety Corrective Action.

UK Representative:  
MDSS-UK RP Ltd.  
Parkway House, Palatine Rd, Northenden, Wythenshawe,  
Manchester M22 4DB  
United Kingdom  
+44 (0)7898 375115  
info@mdss-ukrp.com