



**Technical Service Bulletin**

**ALL PRODUCTS**

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INFORMATION ONLY**

**Manufacturer: Welch Allyn**

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**Subject:** TSB-CRACKED PLASTICS PROCESSING STEPS

**Distribution Scope:** Welch Allyn Global Technical Support, Product, Field & Customer Service teams  
WA ASP's

**Product(s) Referenced:** Including but not limited to the following:  
SureTemp Plus Thermometer Probes  
**Vital Signs Monitors:**  
- Spot  
- Spot LXi  
- Connex Vital Signs Monitor  
- Accessory Cable Management Stand  
**Green Series Lights:**  
- Exam Light IV (focusing sleeve)  
Micropaq  
Vaginal Speculum Illuminator  
ProBP  
Li Ion Handle  
Cardio Products  
- CP50  
- CP150  
Video Colposcope

**Summary:** The use of cleaners/disinfectants which contain quaternary ammonium have demonstrated negative effects on plastics used in these products, causing them to crack.

**Issue:** Our investigation has revealed that the active ingredient of quaternary ammonium found in certain wipe products can cause the plastic to become brittle and fracture when stress is applied (see below).

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These quaternary ammonium based wipes are made by several companies; the more popular brands are PDI Sani-Cloth (Plus, Super, AF & AFIII), Metrex CaviWipes and Ecolab DisCide.

See examples below.



SPOT



CVSM



CVSM



ACM



ACM



ACM



SURETEMP PLUS PROBE

**Action:** Provide process guidelines surrounding products in the list above to make the customer experience as painless as possible. Some areas in question would be products, warranty, loaners, and any other business decisions. The guidelines listed in the Service Strategy section below applies to customers stating the plastic for one or more of the following products is cracking.

- CVSM
- SPOT and SPOT LXi
- Accessory Cord Management (ACM) stand
- SureTemp Plus Thermometer Probes;
- Exam Light IV (focusing sleeve)
- Micropaq
- Vaginal Speculum Illuminator
- ProBP
- Li Ion Handle
- CP50 and CP150
- Video Colposcope

**Reference to Standards:** • 21 CFR Part 820, ISO 13485, MPD SOP-0002

**Service Strategy:**

**Customer Care**

1. Follow the standard complaint process. Cracks are coded as DEVICE-PHYSICAL DAMAGE-MECHANICAL.
2. Try to determine if the product was cracked as a result of being dropped or hit by another object.
  - If it was cracked from being dropped or hit, record this information in the service notification long text.
  - If it was not cracked from being dropped or hit, ask which solution is used to clean the product and how frequently the product is cleaned. If possible, have them describe the cleaning policy/process. Record this information in the service notification long text. If possible, attempt to obtain pictures of the products claiming to be cracked. Include these pictures in the service notification (excluding SureTemp Plus probes).
  - If it cannot be determined if the product was cracked as a result of being dropped or hit, record this information in the service notification long text.
3. For products where cracking is determined to be due to chemical damage, provide an RMA for products being returned.
  - For ACM, Li Ion and Vaginal Speculum /Illuminator (no product will be returned), provide a replacement order and inform customer to scrap on site.
  - GS EXAM LIGHT IV (Focus Sleeve only): We replace the focusing sleeve only at no charge and refer the customer to the DFU (713315) for proper cleaning instructions.
  - For SureTemp Plus probes (from handheld or LAVS devices), check plug lot code to see if covered under 1 year warranty, if

so, replace SureTemp Plus probes immediately. If not under warranty customer will need to buy new probe via current process.

- Customer Care should email a copy of the CSB to the customer or direct them to its location on the WEB site.
- Welch Allyn will offer up to two (2) loaners, if applicable, under warranty while the customer’s products are returned for repair.

**Product Service**

1. All CVSM, SPOT, SPOT LXI, CP50, CP150, ProBP, Micropaq and/or Video Colposcope housing components exhibiting cracks should be replaced. In addition, they should be inspected, and replaced if signs of stress are present.
2. All chemically cracked housing repairs should be charged to the warranty account.
3. A copy of the CSB 80018520 should be included with the repaired product when returned to the customer. Make note that this was done in the repair order.
4. Additional repairs determined to be needed that are not associated with cracked housing should not be charged to the product’s warranty account. The standard repair process and customer notification process should be utilized for the additional repairs.

**Note:** Repairs of products returned a second time for cracking of components that have been replaced should not be charged to warranty.

**Required Materials:** 80018520 CSB-CLEANING AND DISINFECTION RECOMMENDATION

**Quality Documents:** **All service centers using SAP to record service transactions:** For each product serviced, record the service activity in SAP.  
**All other service centers and Field Service:** For each product serviced, complete and file a service report and attach to the service DHR.

**Notes:**

1. Contact Welch Allyn regarding any questions or concerns from this or other issues.
2. Drawings, illustrations, and part numbers in this document are for reference purposes only and subject to change.

**End of Bulletin**

Revision History					
Version	Description	Change #	Init	Release Date	Appr
A	Initial Release of document	D*	MEB	D*	D*
B	Updated Product(s) Referenced, Issue, Customer Care and Product Service sections	D*	MEB	D*	D*
<b>D* SEE SAP DIR FOR CHANGE NUMBER, APPROVER NAME AND DATE OF APPROVAL</b>					