



Urgent Field Safety Notice – Recall
RetCam Envision

Date: 03rd March 2021
FSN Reference: CAPA005078
FSCA Reference: V45903

Dear Valued Customer,

You are receiving this information as our records indicate you have received the RetCam Envision. This notice needs to be passed to all those who need to be aware within your organisation or to any organisation where the affected items have been transferred.

Please transfer this notice to other organisations on which this action has an impact.

Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.

Intended use of the RetCam Envision

The RetCam Envision is used for

- General ophthalmic imaging including retinal, corneal, and external imaging.
- Photodocumentation of pediatric ocular diseases including retinopathy of prematurity (ROP)
- Screening for Type 2 pre-threshold retinopathy of prematurity (ROP) (zone 1, stage 1 or 2, without plus disease, or zone 2, stage 3, without plus disease) or treatment requiring ROP, defined as Type 1 ROP (zone 1, any stage, with plus disease; zone 1, stage 3 without plus disease; or zone 2, stage 2 or 3, with plus disease) or threshold ROP (at least 5 contiguous or 8 non-contiguous clock hours of stage 3 in zone 1 or 2, with plus disease)^{1,2} in 35-37 week postmenstrual infants.

Description of the issue:

Natus has become aware of manufacturing issues relating to the epoxy adhesive fill between the contact lens and the stainless steel end cap on the model 130 Degree Lens (P/N 60-000090) lens piece which are resulting in unevenness, discontinuities, edges, and voids in the epoxy surface.

Affected Items:

The affected item is the RetCam Envision lens. Please see below table with details of legal manufacturer and affected Part Number -

Legal Manufacturer	Description	Part Number
Natus Medical Incorporated, DBA Excel-Tech Ltd. (XLTEK) 2568 Bristol Circle, Oakville, Ontario, Canada	RetCam Envision Lens	60-000090



Hazard associated with this issue:

The presence of this manufacturing defect may result in damage to the patient cornea due to either increased pressure being applied by the clinician on the cornea or corneal abrasion.

The defects in the epoxy adhesive may also impact the cleaning and disinfection processes , the result of which would be patient , user infection.

Action to be taken:

We, Natus Medical are performing a voluntary recall of the affected items.

Please return the affected items at your earliest convenience to the following address -

Natus Manufacturing Limited
IDA Business Park,
Gort,
Co. Galway,
H91 PD92
Ireland

Please complete and return the customer reply form to Natus at the following address:

Email: RetCamService@natus.com

Please be aware that your Competent (Regulatory) Authority has been informed of this communication.



CUSTOMER REPLY FORM
TO BE COMPLETED BY RECIPIENT

Customer Name: _____

Facility Name: _____

Facility Address: _____

City, State Country _____

Postal Code _____

Email address: _____

Contact Name: _____

Phone Number: _____

SR number: _____

Please complete for received items

We hereby declare that we are aware of the product recall by Natus Medical Incorporated.
Please mark as appropriate:

- ☐ We do not have any of the affected products
- ☐ We do have the affected product(s) and will return it/them

List Serial Number(s) of affected device:

Name of Person completing these actions (please print): _____

Signature: _____ **Date:** _____

Title: _____ **Phone:** _____