

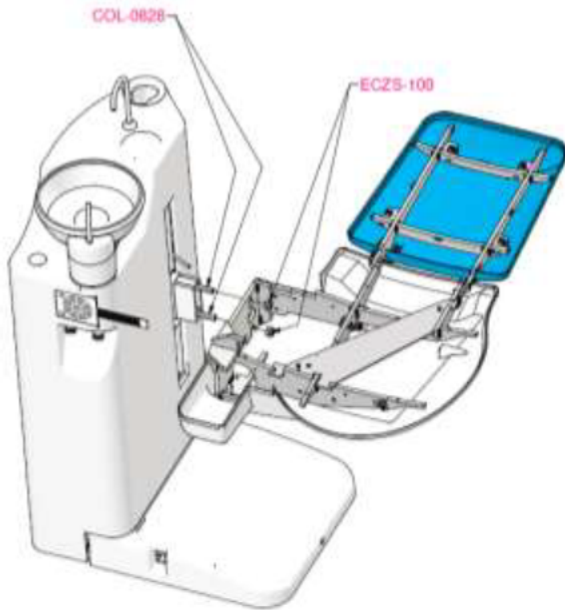
FSN ref : 24\_FSN\_001  
Date : 29/03/2024

	Destinataires <i>Recipients</i> : dealers, customers Ile-de-France, ANSM et notified body.
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Objet de l'avertissement *Notice subject* : Following a recent corrective action, the AIREL-QUETIN group wishes to inform you of a defect identified on the VZR120-060 reference screws used on all K2 units

<b>I. INFORMATIONS SUR LES EQUIPEMENTS CONCERNES</b> <i>INFORMATION ON AFFECTED DEVICES</i>			
1- Type d'appareil <i>Device type</i> : K2 dental chair.			
2- Utilisation prévue <i>Intended use</i> : the K2 chair associated with the K2 dental unit is intended to enable the detection and treatment and/or implementation of preventive dental care			
3- Détails concernant les dispositifs concernés par l'action de sécurité <i>Details of the devices affected by the safety notice</i> :			
Chair reference	Chair serial number	Unit reference	Unit serial number
1900.100	235AC112	1900.200	345AC112
1900.100	235AC109	1900.200	345AC109
1900.100	235AC110	1900.200	345AC110
1900.100	235AC113	1900.200	345AC113
1900.100	235AC103	1900.200	345AC103
1900.100	235AC104	1900.200	345AC107
1900.100	235AC108	1900.200	345AC108
1901.100	236AC101	1901.700	348AB106
1902.100	239AC103	1902.200	349AC103
1900.100	235AC114	1900.200	345AC114
1902.100	239AC102	1902.200	349AC102
1900.100	235AC106	1900.200	345AC105
1900.100	235AC107	1900.200	345AC104

<b>II. RAISON DE L'ACTION CORRECTIVE DE SECURITE SUR LE TERRAIN (FSCA)</b> <i>REASON FOR FIELD SAFETY CORRECTIVE ACTION (FSCA)</i>
1. Description du problème <i>Description of the product problem</i>
As part of the improvement of the installation ergonomics of the K2 trolley sub-assembly, part number BU-221/00, the reference screws COL-0828 have been replaced by the equivalent reference VZR120-060 the 01/02/2024. However, during assembly, a case of a screw breaking (see image below) was observed.



Analysis and investigations have shown that the breakage occurs during the tightening of the ECZS-100 nut. Although this failure is not systematic and could not be reproduced during factory testing, as a precautionary and safety precaution, the screws of the equipment affected by this safety advisory must be replaced with those used prior to this modification (COL-0828). These screws are part of the initial design of the equipment and do not affect its safety.

## 2. Risques Risks

The risk associated with this defect is a tilting of the chair seat, which can potentially lead to injury to the patient.

**To date, no incident on any installed equipment has been reported.**

## III. ACTIONS A ENTREPRENDRE ACTIONS TO BE UNDERTAKEN

### 1- Mesures prise par le fabricant Action taken by the manufacturer

Replacement of the screws with the original part number (COL-0828, see the plan below) of equipment in production serial numbers:

Chair serial number	Unit serial number
239AC107	349AC107
239AC108	349AC108
235AC116	345AC116
235AC117	345AC117
239AC105	349AC105
239AC106	349AC106
239AC104	349AC104
235AC111	345AC111
236AC104	347AC102

Sending the safety notice to all customers affected by this safety issue.

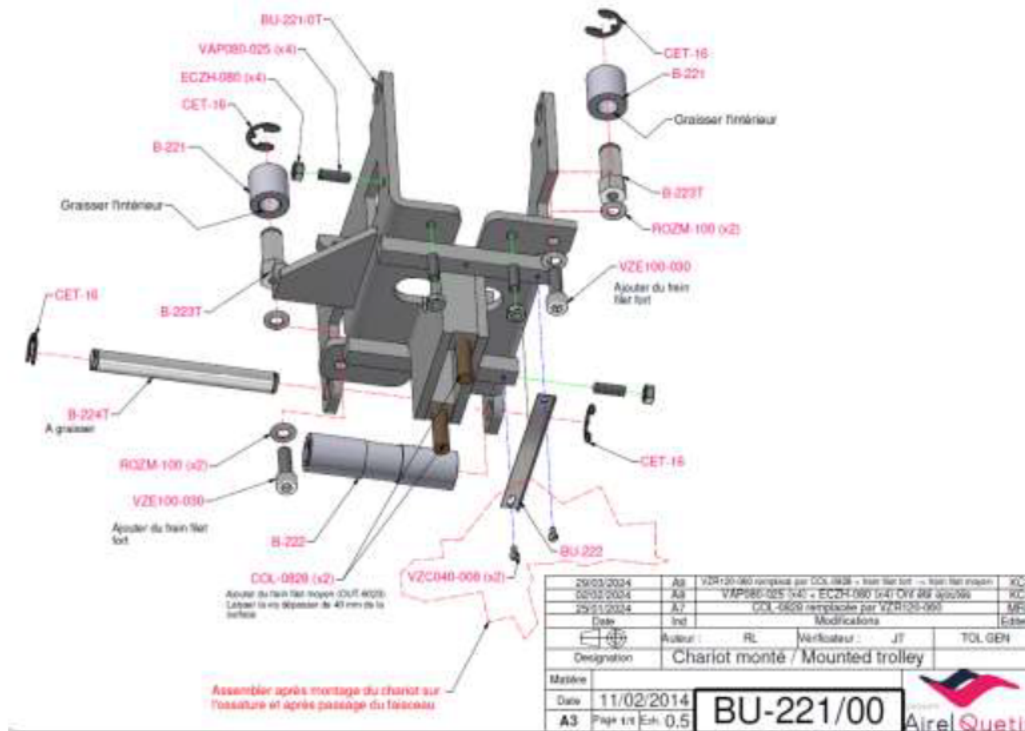
### 2- Types d'action à entreprendre par les distributeurs/techniciens Types of actions to be taken by dealers/technicians

- Identify Device   
  Quarantine Device   
  Return Device  
 Destroy Device   
  Modification device   
  Other (specify) :

### 3- Actions de correction et corrective destinées aux utilisateurs (distributeurs/clients) Immediate and corrective actions for users (dealers/customers)

**Immediate action :**

Replace the screws with the original part number (COL-0828, see the plan below) following the instruction reference IN-SAV-16: if there is any difficulty in loosening the screws, the pin must be heated to soften the threadlocker using an induction heater. If the screws break during loosening, the carriage will need to be replaced.



**Corrective action :**

Inspect the equipment in accordance with the checklist attached to the instruction to be returned to the following address: [qualite@airel.com](mailto:qualite@airel.com)

Please contact the person in charge of monitoring the action at AIREL for the planning of the intervention in conjunction with your authorized technicians.

**Contact details of the person in charge of monitoring the action:**

Mr. Olivier DROUET  
 Tel: 01.48.82.58.32  
 E-mail: [support@airel.com](mailto:support@airel.com)

4- Délai de mise en place de l'action *Delay in setting up the action*: without any delay

Attached response form must be returned to us within 15 days at the address [qualite@airel.com](mailto:qualite@airel.com)

**IMPORTANT NOTE**

This notice should be given to all persons who need to be notified within your organization or any organization where the potentially affected devices have been transferred. Please read this fact sheet and the resulting action in order to ensure the effectiveness of the actions. Please remain informed of this notice and the resulting actions for an appropriate period of time to ensure the effectiveness of the corrective actions. Please report all incidents related to the device to the manufacturer, distributor

Thanking you in advance for your cooperation,  
Regards

**FORMULAIRE A RETOURNER**  
*FORM TO RETURN*

Your feedback is request to this FSCA by e-mail to [qualite@airel.com](mailto:qualite@airel.com) within 15 calendar days after you gave received this notice.

<b>1- FSN information</b>	
Référence de la FSN <i>FSN Reference number</i>	24_FSN_001
Date de la FSN <i>FSN Date*</i>	29/03/2024
Nom du dispositif <i>Device name</i>	Unit K2
Numéro de série du dispositif concerné <i>Serial Number</i>	

<b>2- Coordonnées du client <i>Customer Details</i></b>	
Nom du distributeur <i>Dealer name</i>	
Nom du contact <i>Contact name</i>	
Titre ou fonction <i>Title or Function</i>	
Numéro de téléphone <i>Telephone number</i>	
E-mail	
Nom du client <i>Customer name</i>	
Adresse du client <i>Customer adress</i>	

<b>3- Actions entreprise <i>Action undertaken</i></b>
<input type="checkbox"/> Je confirme avoir reçu l'avis de sécurité sur le terrain et que j'ai lu et compris son contenu. <i>I confirm receipt of the Field Safety Notice and that I read and understood its content</i>
<input type="checkbox"/> Je confirme avoir communiqué l'avis de sécurité aux utilisateurs concernés <i>I confirm that I have communicated the safety notice to the affected users</i>
<input type="checkbox"/> J'ai effectué toutes les actions demandées par le FSN <i>I performed all actions requested by the FSN.</i>
<input type="checkbox"/> Les informations et les actions requises ont été portées à l'attention de tous les utilisateurs concernés et exécutées. <i>The information and required actions have been brought to the attention of all relevant users and executed.</i>

Date :  
 Nom *Name* et signature

**It's important that your organisation takes the action detailed in the FSN and confirms that you have received the FSN.  
 Your organisation(s) reply is the evidence we need to monitor the progress of the corrective**