CALCIVIS Imaging System

Image Interpretation Guidelines

T001/cisw/v1/Feb2024

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The Calcivis imaging system uses a recombinant photoprotein that reacts with free calcium ions resulting in a flash of light.

Bound calcium in the form of crystalline hydroxyapatite does not react with the photoprotein and therefore no signal is produced.

The strength of signal is related to the concentration of available free calcium ions, which are an indication of the degree of active demineralization (activity).

The degree of active demineralization ranges from no active demineralization through mild and moderate to high levels.

No active demineralization indicates a negative activity status (sound or arrested). Mild, moderate and high levels indicate a positive activity status (active lesion).

Indications for use

The Calcivis Imaging System is intended to be used by dental healthcare professionals on patients (6 years and older) with, or at risk of developing, demineralization associated with caries lesions, on accessible coronal tooth surfaces.

The Calcivis Imaging System is indicated for use to provide images of active demineralization on tooth surfaces, as an aid to the assessment, diagnosis, monitoring and treatment planning for demineralization associated with caries lesions.

Moderate and High Levels of Active demineralization (associated with pre-cavitated caries lesions)

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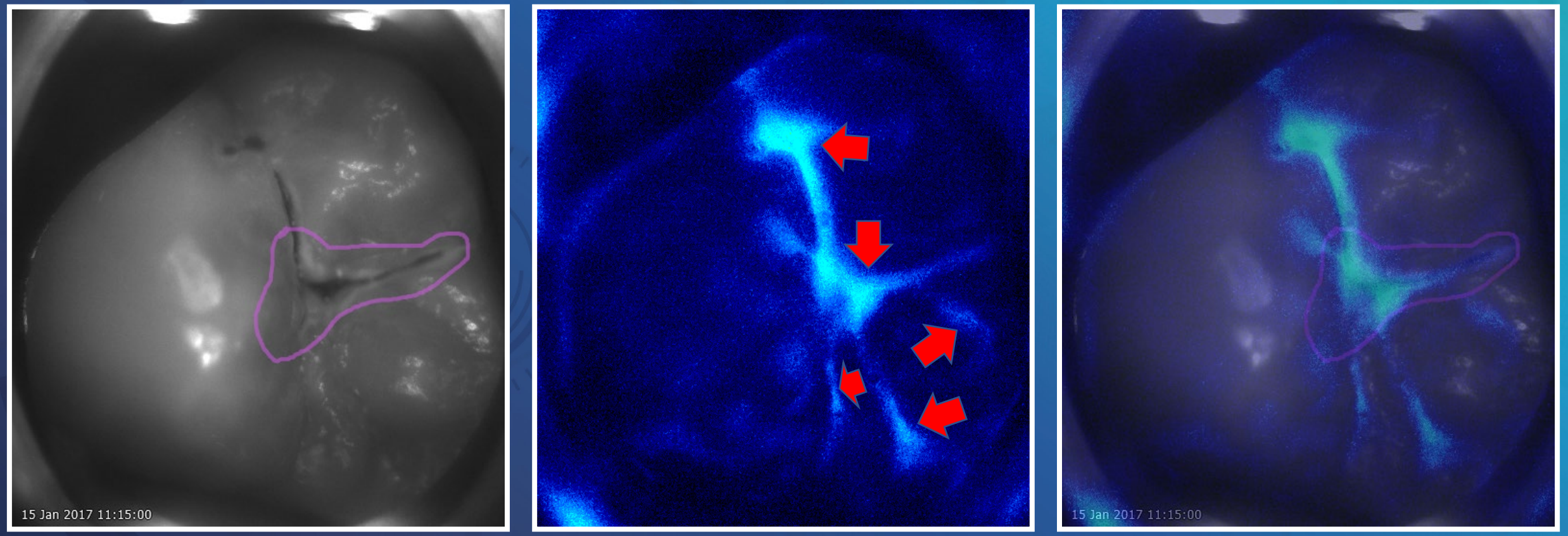
Fig. 1 – moderate active demineralization, associated with caries



Tooth 31 (LR7) Occ - moderate level of active demineralization (red arrows) in area marked by clinician before imaging, and also outside the area marked, indicating demineralization more extensive than initially thought.

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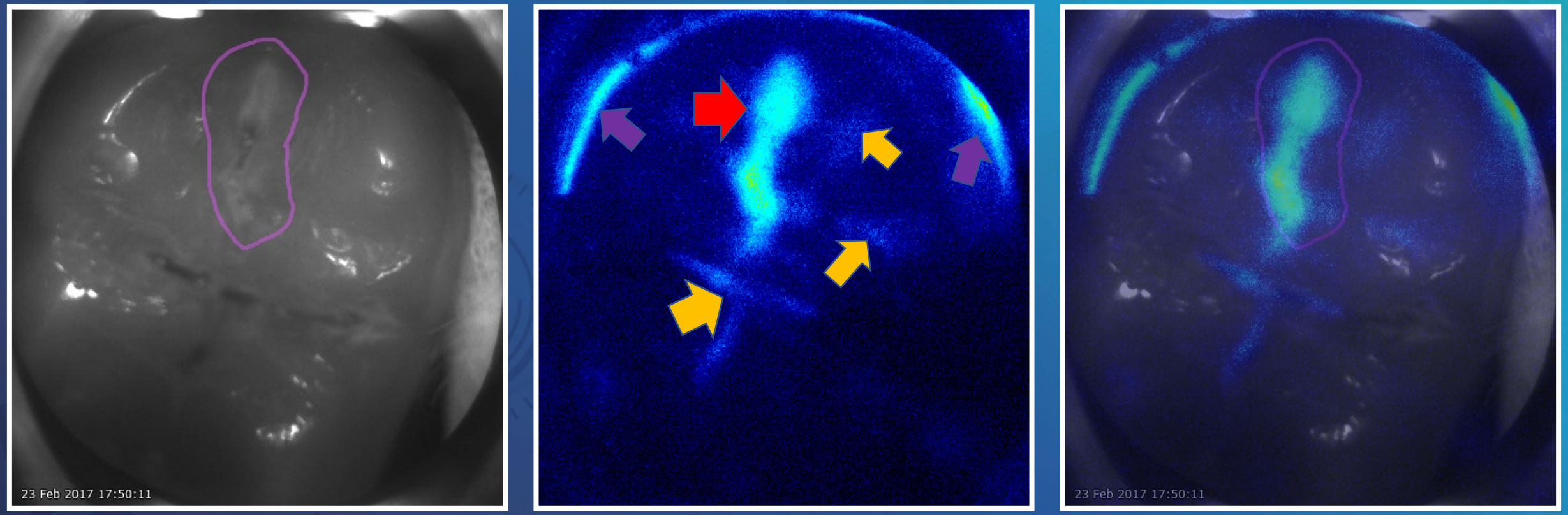
Fig. 2 – moderate and mild active demineralization, associated with caries



Tooth 31 (LR7) Occ - moderate level of active demineralization (red arrow) in area marked by clinician before imaging, and also mild levels (orange arrows) outside the area marked.
Signal around edges of tooth caused by saliva (purple arrows).

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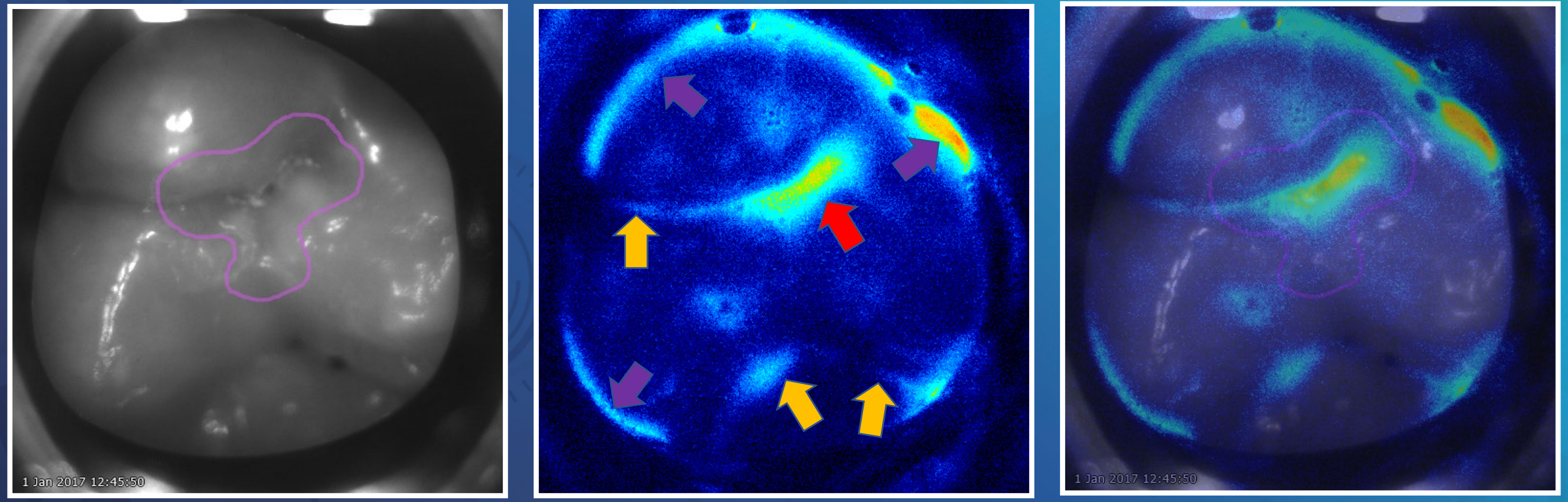
Fig. 3 – high, moderate and mild active demineralization, associated with caries



Tooth 3 (UR6) Occ - high level of active demineralization (red arrow) in area marked by clinician, and also mild and moderate activity (orange arrows) outside area marked, indicating demineralization more extensive than initially thought.
Signal around edge of tooth caused by saliva (purple arrows).

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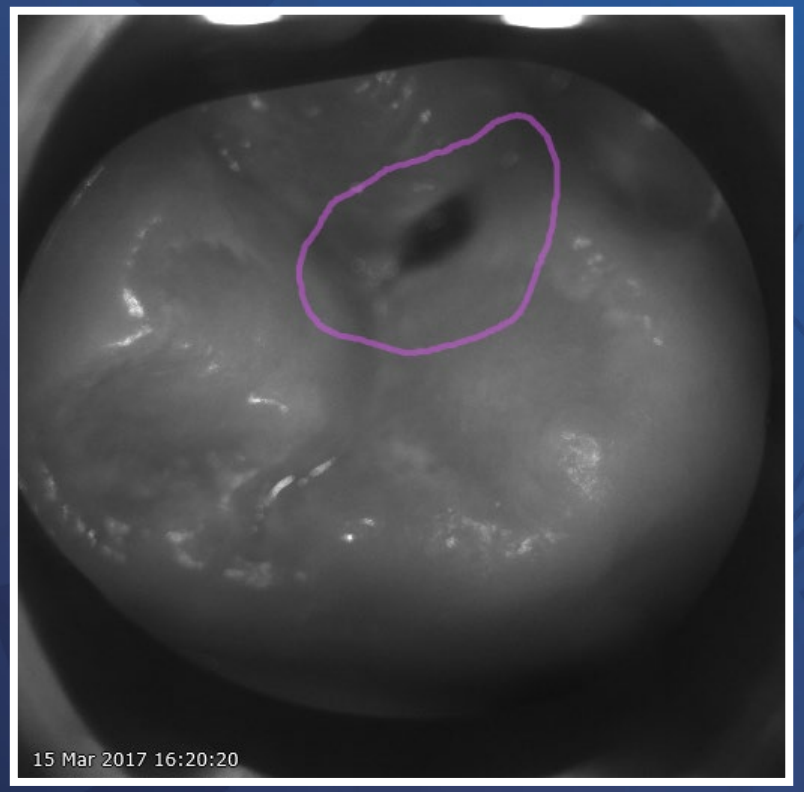
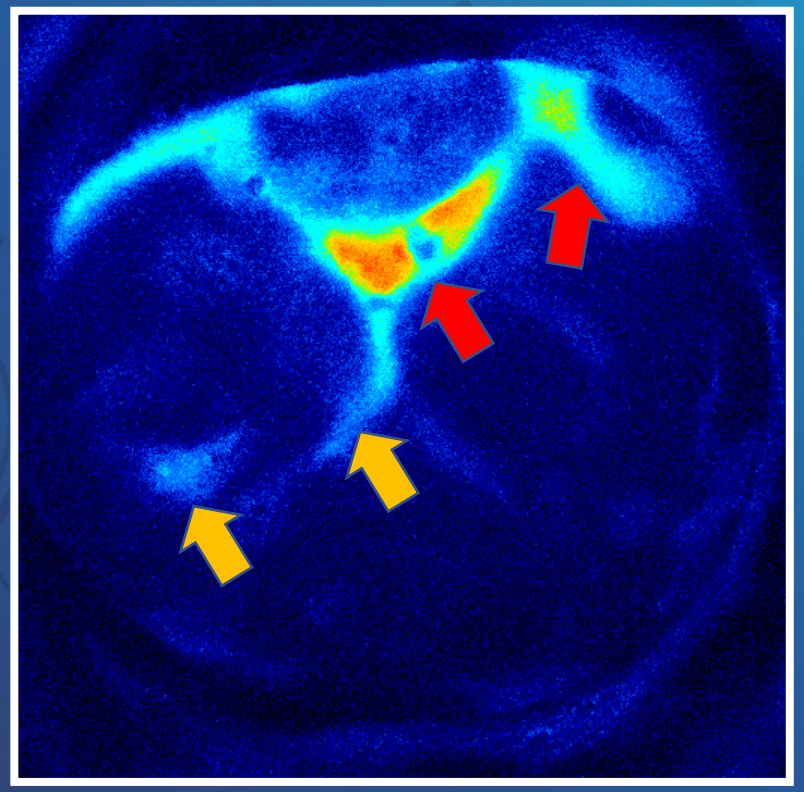
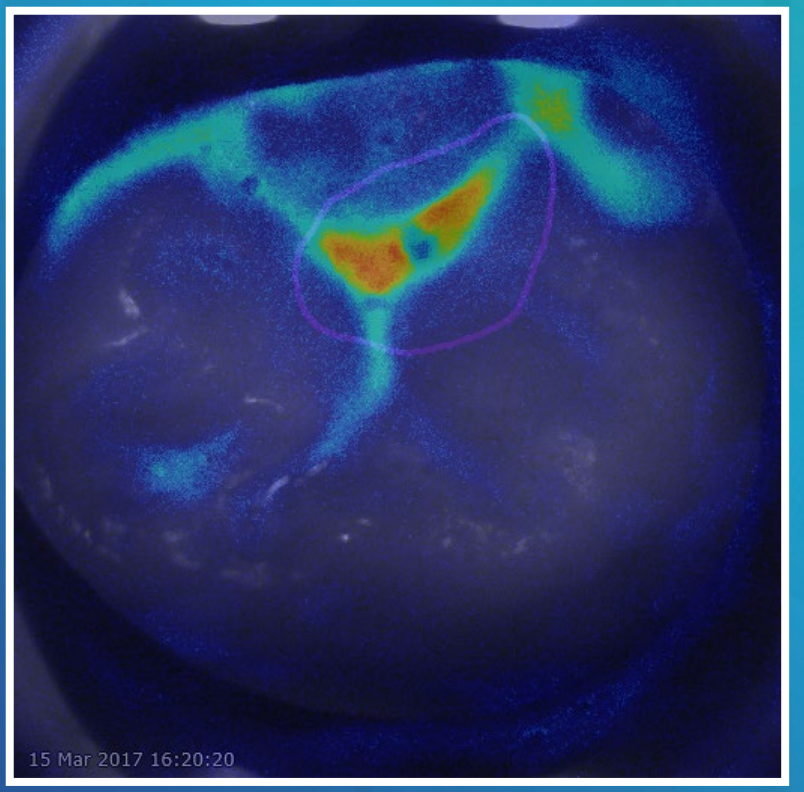
Fig. 4 – high, moderate and mild active demineralization, associated with caries







Tooth 15 (UL7) Occ - high level of active demineralization in area marked by clinician and also mild and moderate activity outside the area marked (orange arrows), indicating demineralization more extensive than initially thought.

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Mild Levels of Active demineralization

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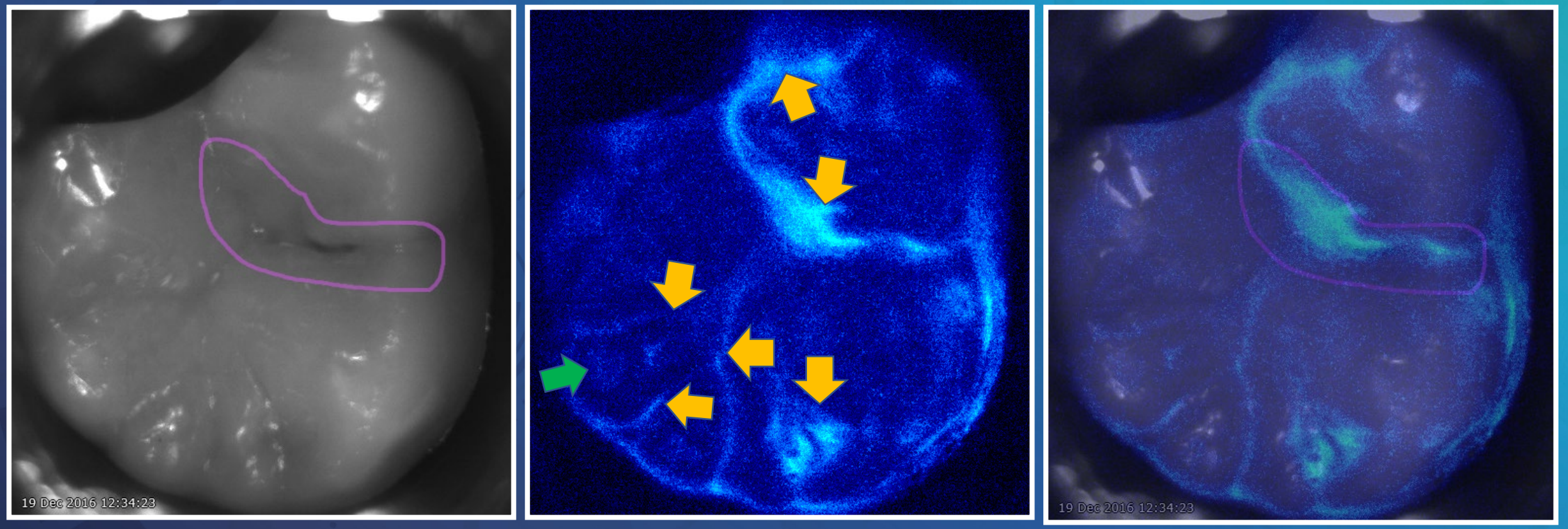
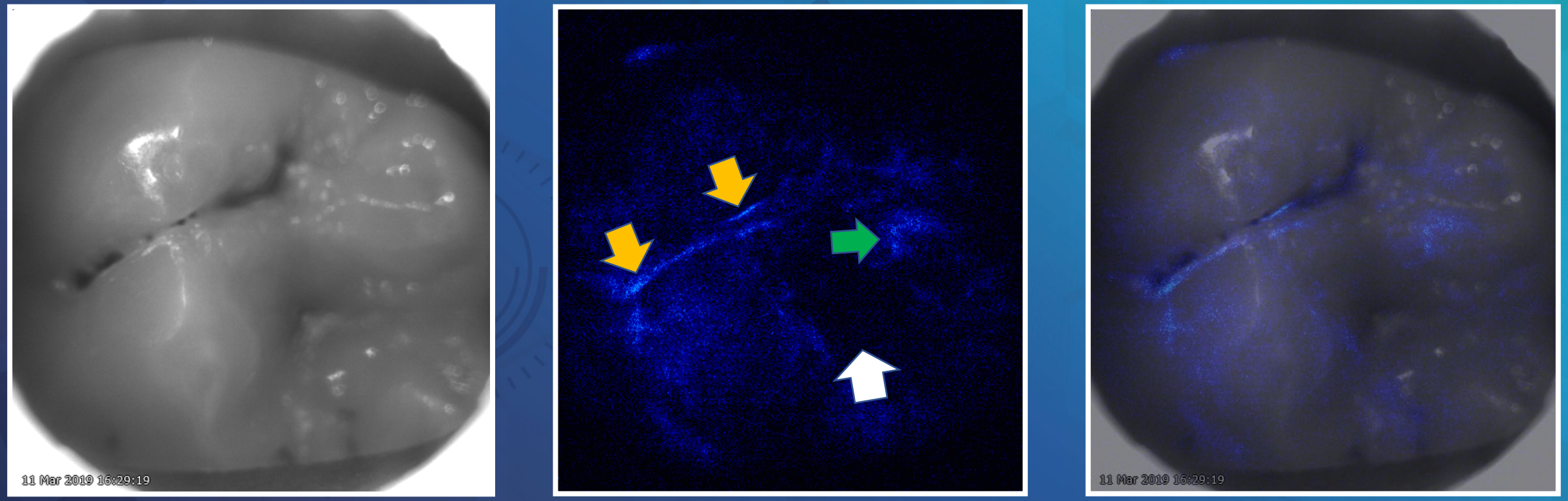
Fig. 5 – mild active demineralization, associated with caries



Tooth 3 (UR6) Occ - mild level of active demineralization (yellow arrows) in area marked by clinician and also outside area marked, indicating demineralization more extensive than initially thought.
Area of non-caries related demineralization indicated by green arrow.

Fig. 6 – mild active demineralization, associated with caries.

Arrested lesion with no activity.



Tooth 3 (UR6) Occ - mild level of active demineralization (yellow arrows) associated with fissure. White arrow indicates arrested lesion with no activity.
Areas of non-caries related demineralization indicated by green arrow.

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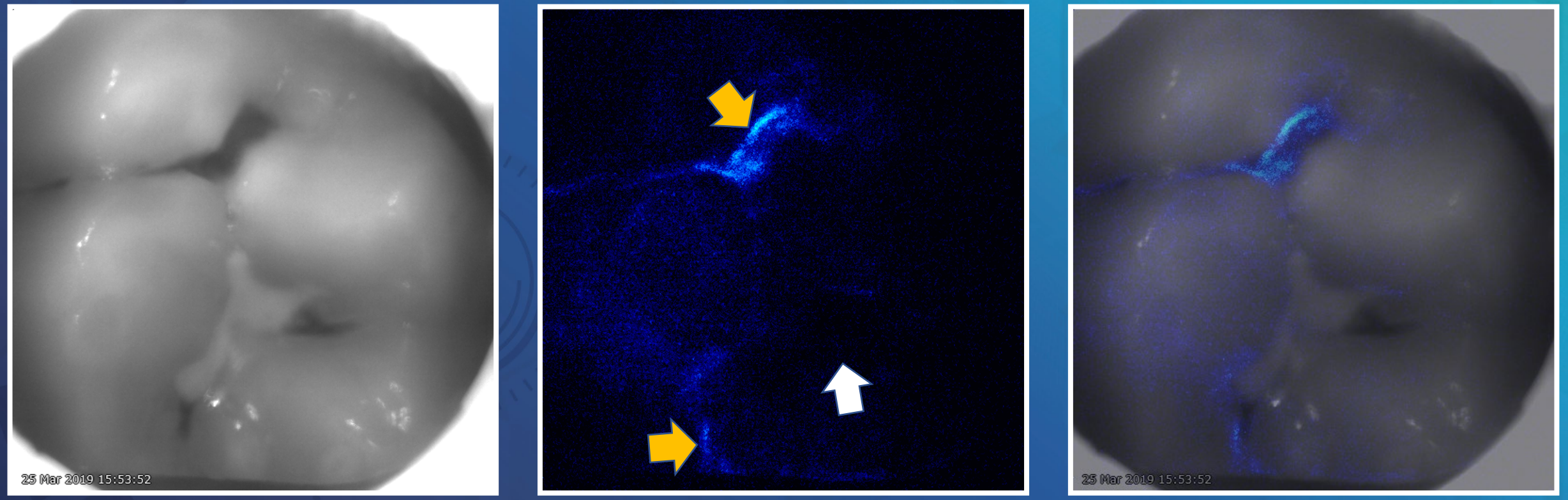
Fig. 7 - mild active demineralization associated with caries.
Arrested lesion with no activity.



Tooth 3 (UR6) Occ - mild level of active demineralization (yellow arrows) associated with deep fissure (distal) and fissure sealant (mesial).
White arrow indicates arrested lesion.

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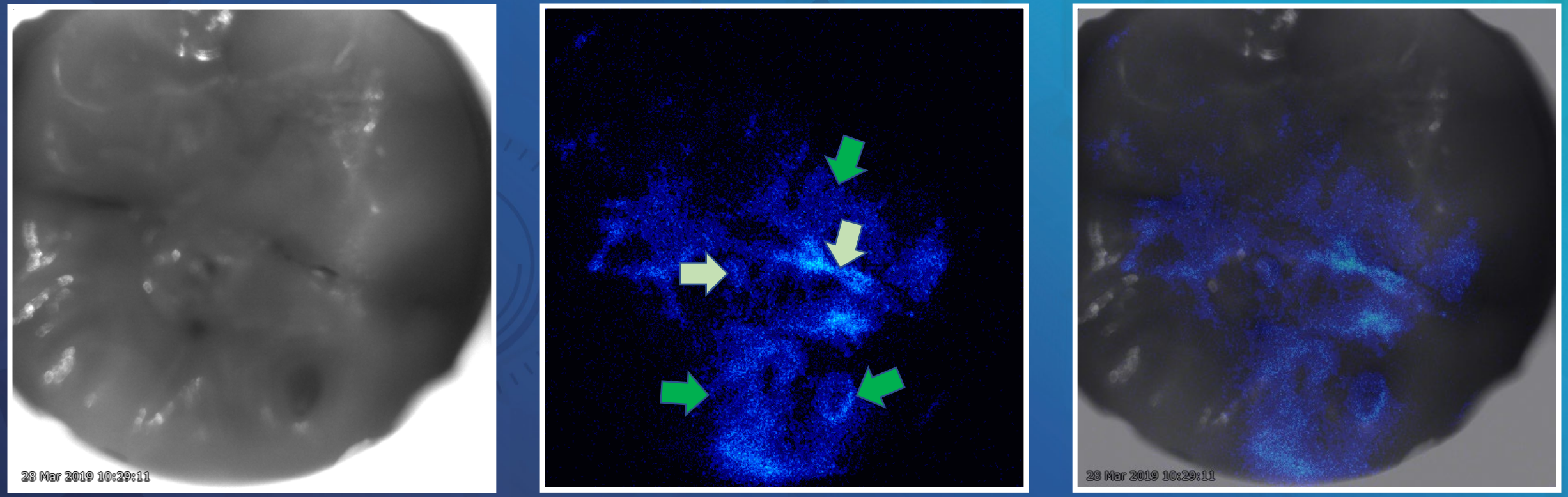
Fig. 8 – mild active demineralization, associated with caries



Tooth 19 (LL6) Occ - mild level of active demineralization across the occlusal surface. Areas of non-caries related demineralization indicated by green arrows, with areas of demineralization associated with previous caries lesion in pit and fissure indicated by light green arrows.

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Sound teeth and Inactive lesions (no active demineralization)

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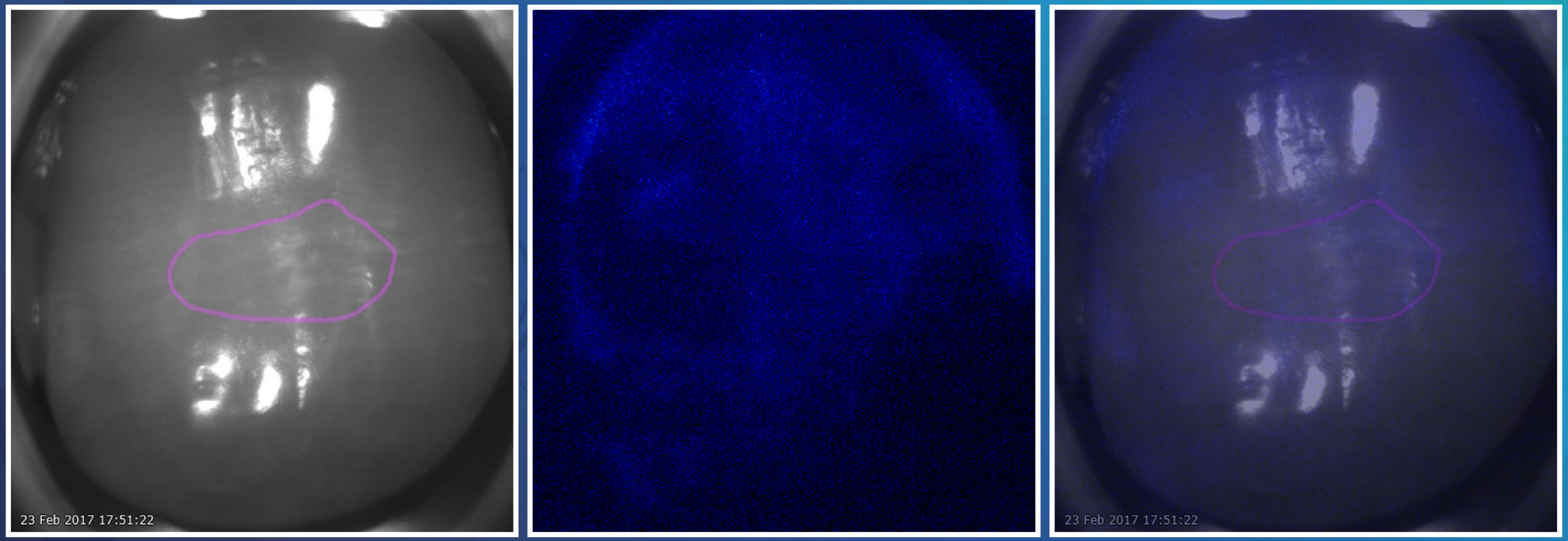
Fig. 9 – sound tooth, no active demineralization



Tooth 8 (UR1) Buc - no luminescence on buccal surface of tooth in area marked before imaging.

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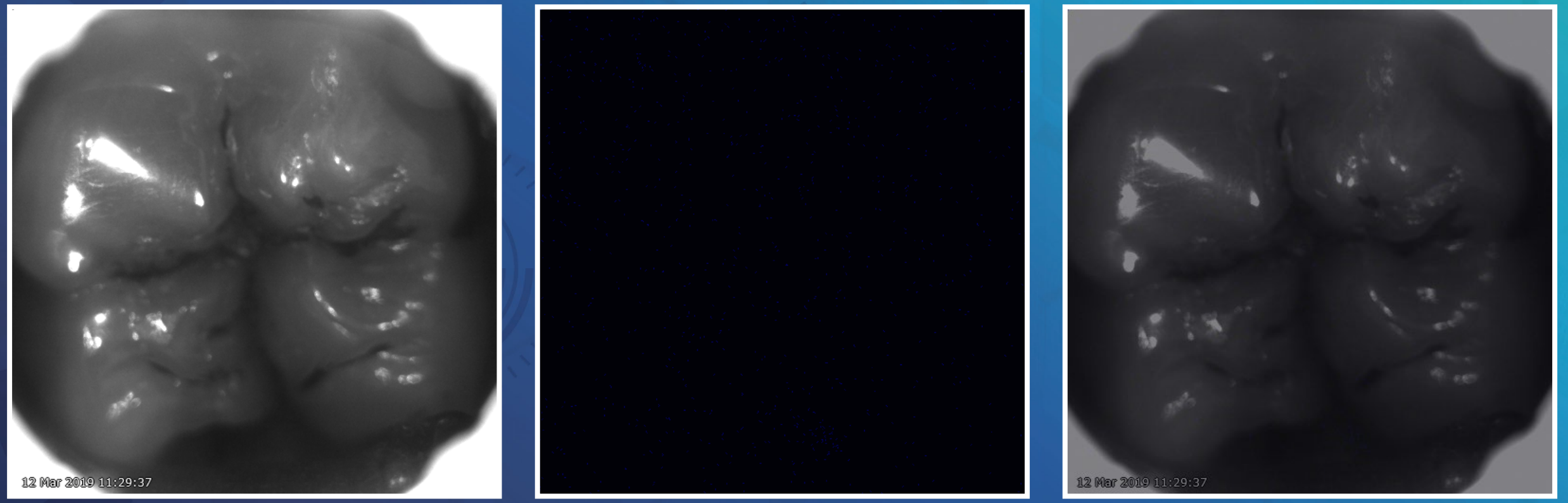
Fig. 10 – sound tooth, no active demineralization



Tooth 30 (LR6) Occ - Occlusal surface of sound tooth showing no luminescence.

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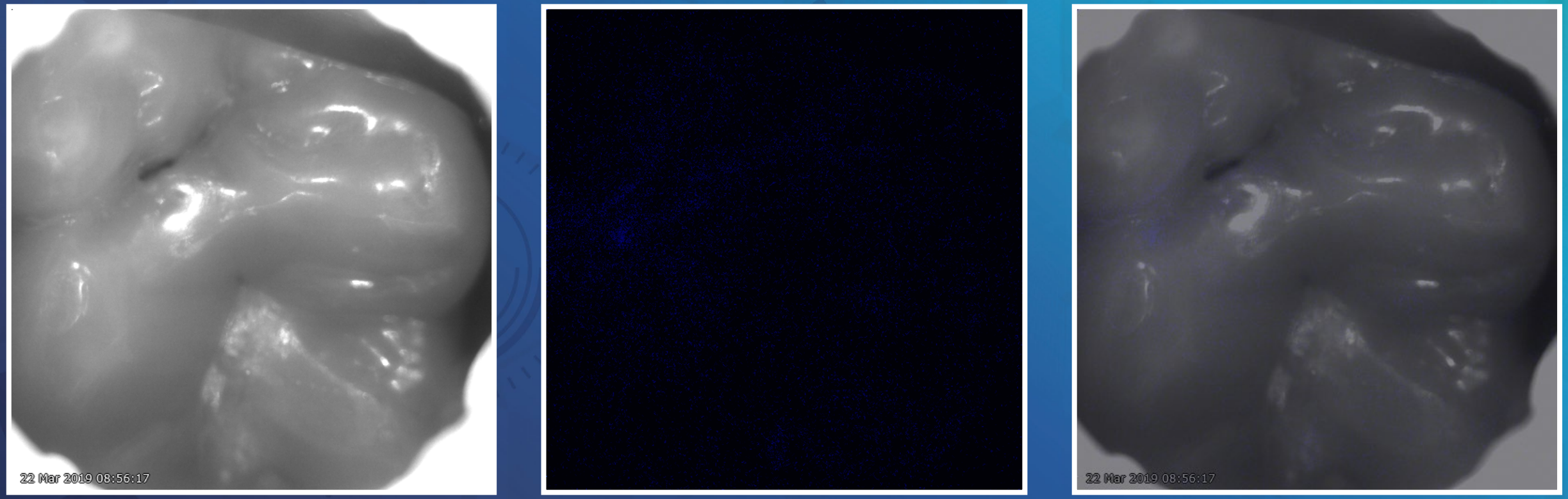
Fig. 11 – sound tooth, no active demineralization



Tooth 3 (UR6) Occ - occlusal surface of sound tooth showing no luminescence.

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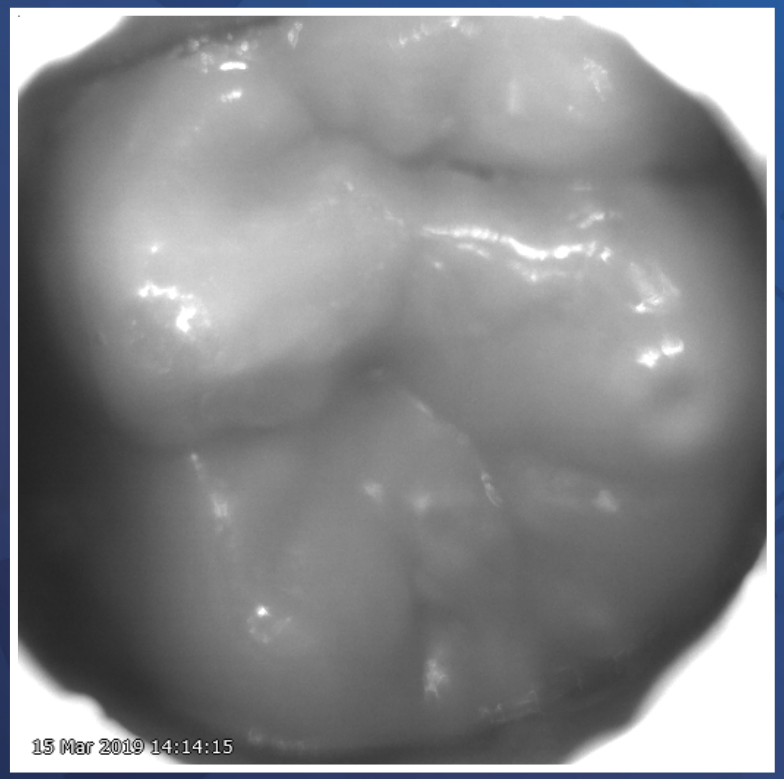
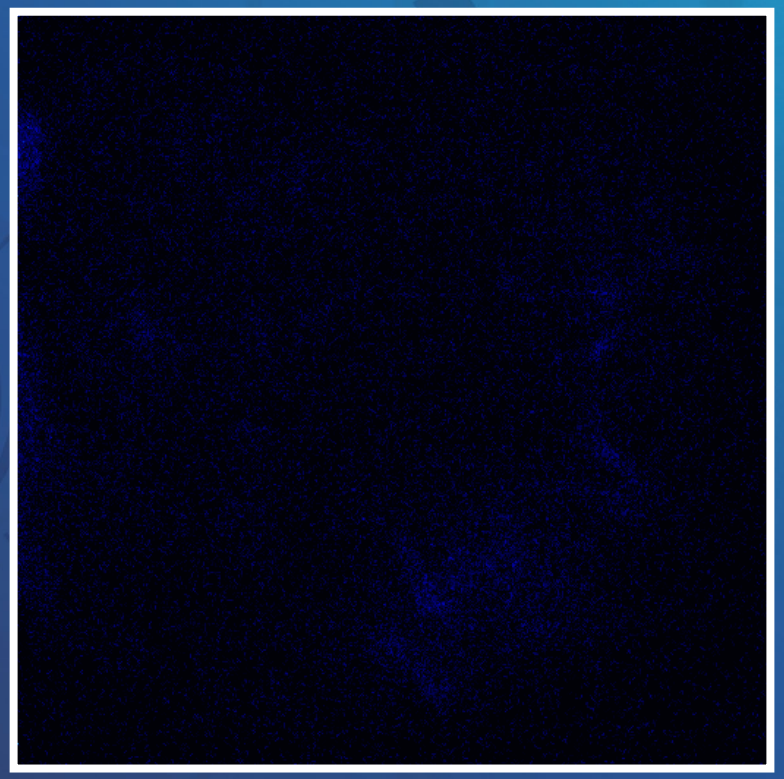
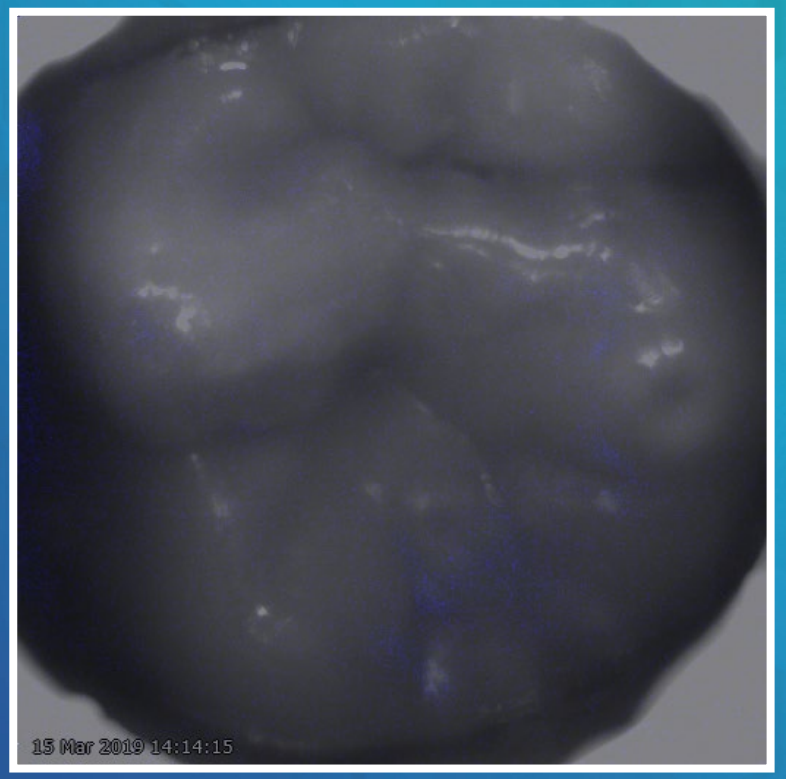
Fig. 12 – sound tooth, no active demineralization







Tooth 31 (LR7) Occ - occlusal surface of sound tooth showing no luminescence.

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Active demineralization at margins of restorations

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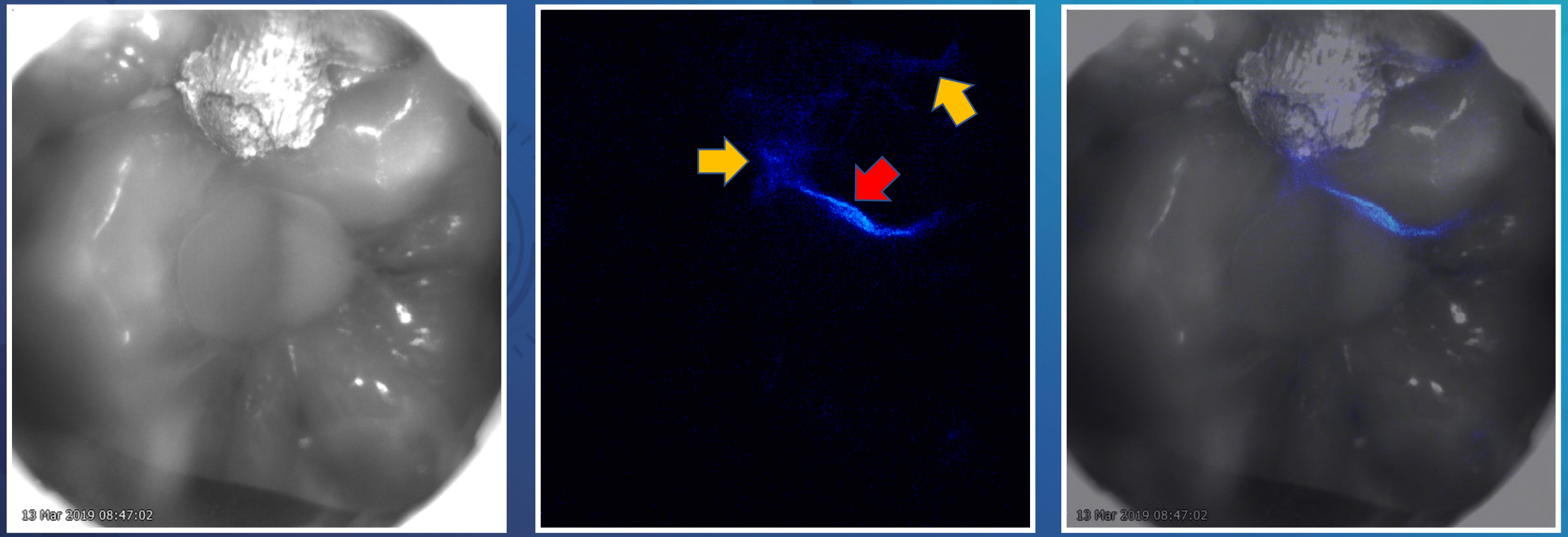
Fig. 13 – active demineralization at margins of restorations



Tooth 3 (UR6) Occ - active demineralization on margin of fissure sealant (red arrow) and possible activity on edges of amalgam (yellow arrows).

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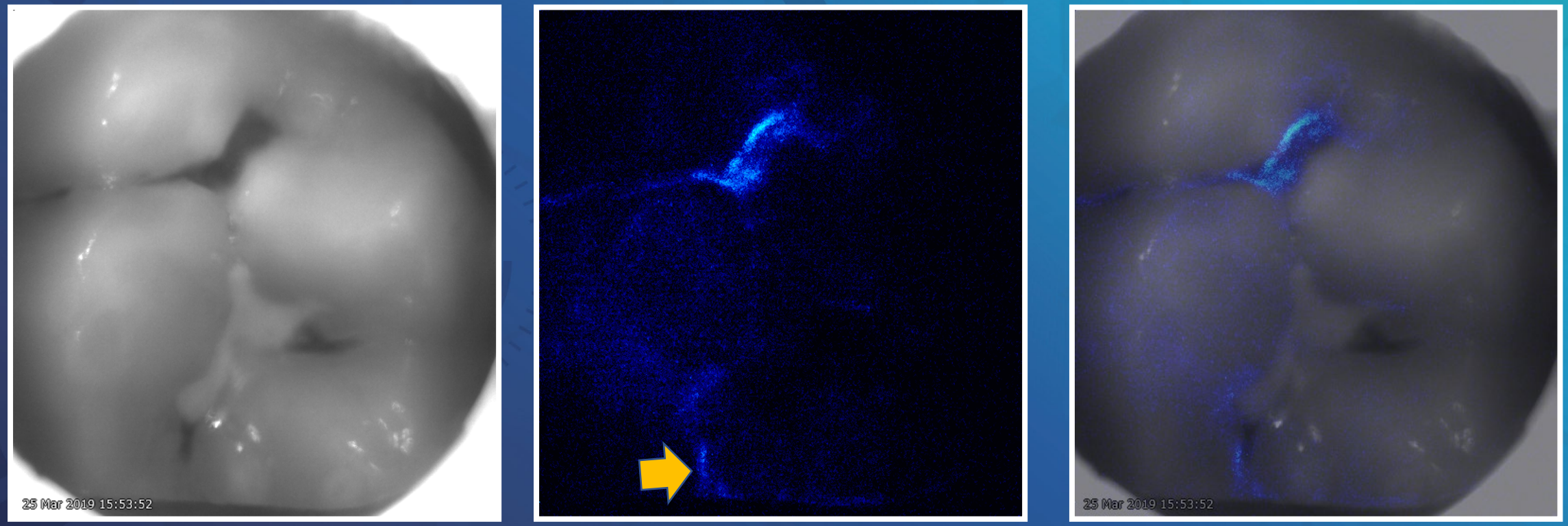
Fig. 14 – low active demineralization at margins of restorations



Tooth 3 (UR6) Occ - low level of active demineralization at lower edge of fissure sealant marked by yellow arrow.

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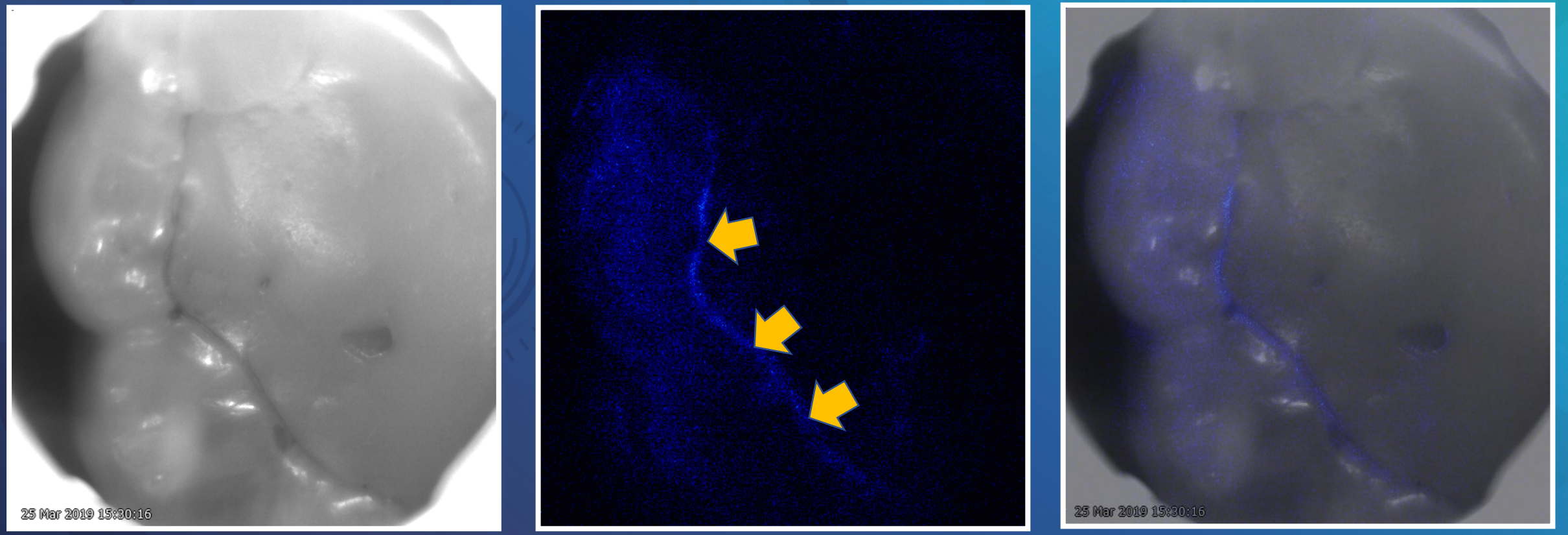
Fig. 15 – low active demineralization at margins of restorations



Tooth 3 (UR6) Occ - low level of active demineralization on edge of composite restoration marked by yellow arrows.

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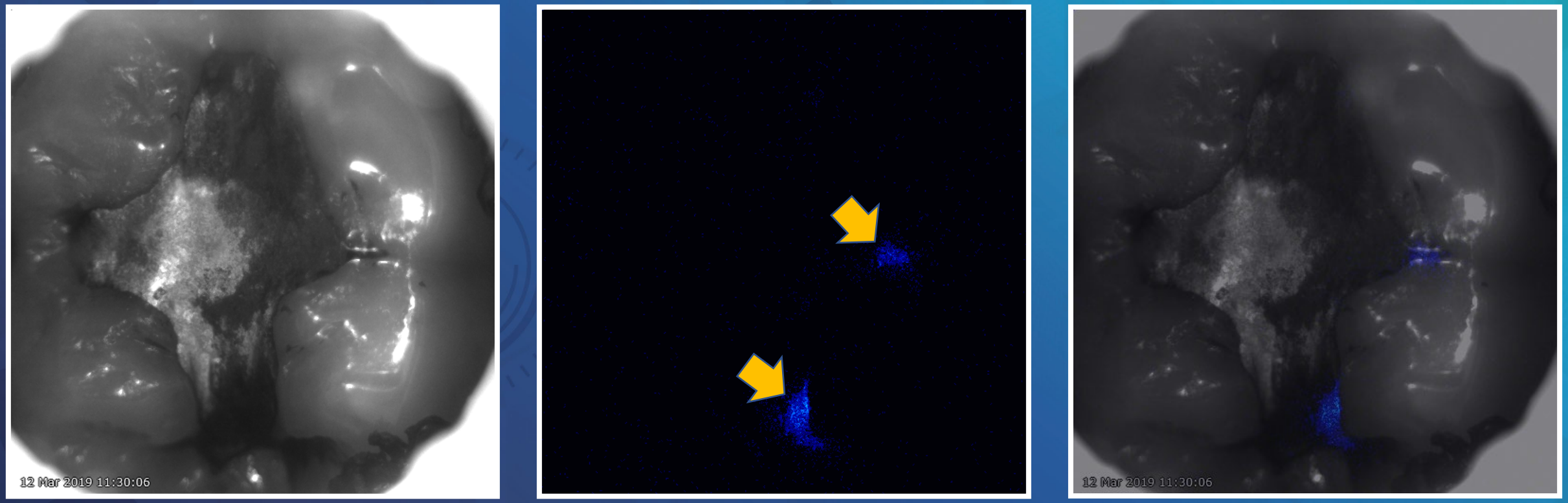
Fig. 16 – low active demineralization at margins of restorations



Tooth 19 (LL6) Occ - low level of active demineralization at outer edges of restoration marked by yellow arrows.

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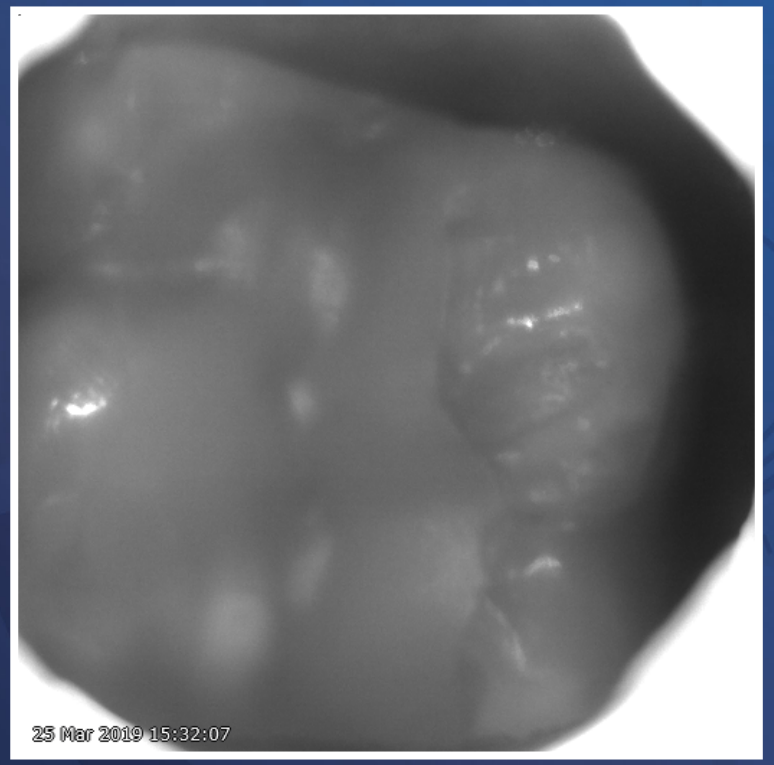
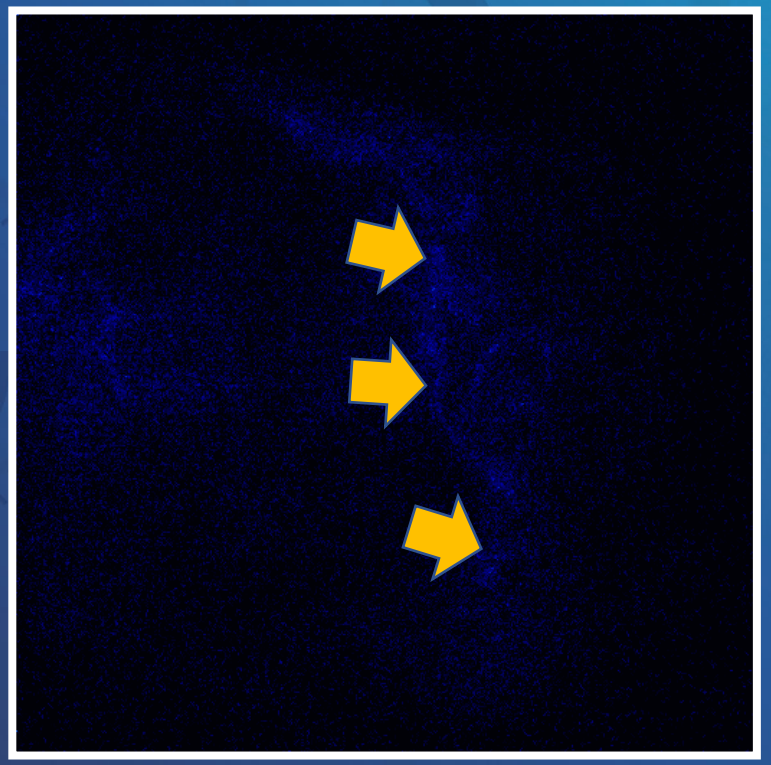
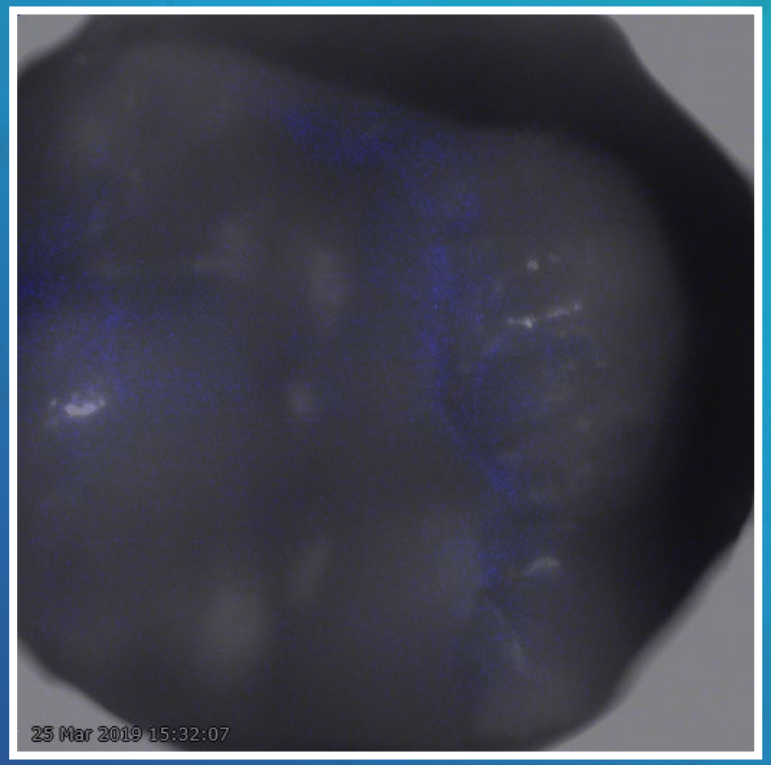
Fig. 17 – low active demineralization at margins of restorations







Tooth 3 (UR6) Occ - low level of active demineralization along edge of composite filling marked by yellow arrows.

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Non-caries related demineralization

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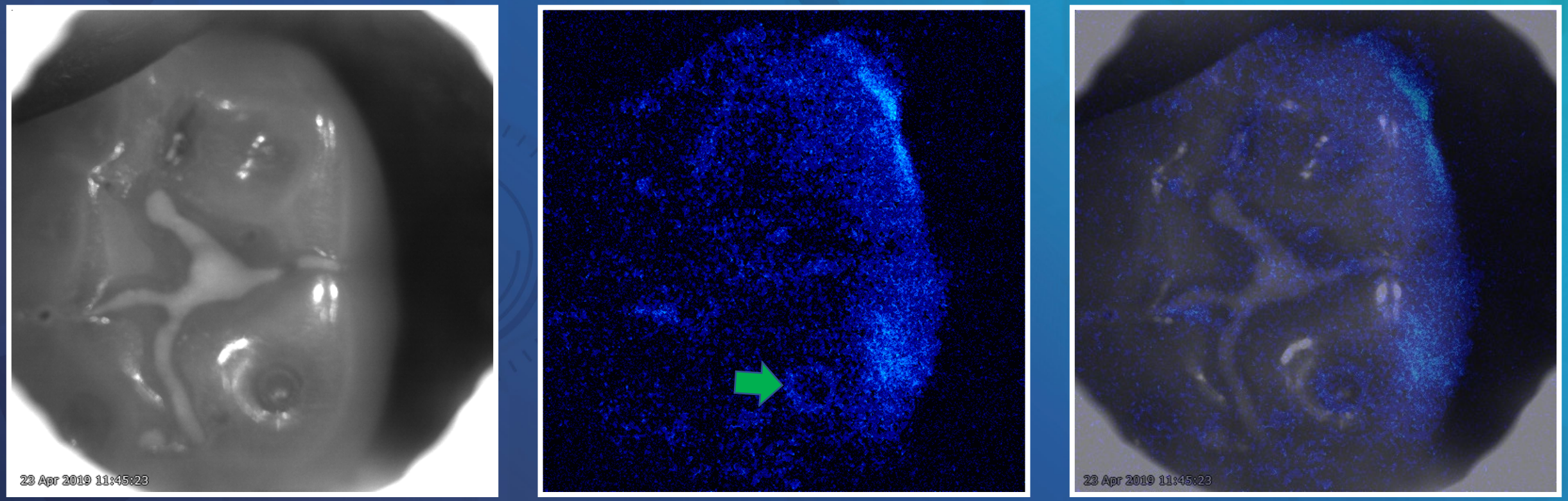
Fig. 18 - low level of non-caries associated active demineralization



Tooth 30 (LR6) Occ - Low level signal with circle of non-caries associated active demineralization on cusps (green arrow).

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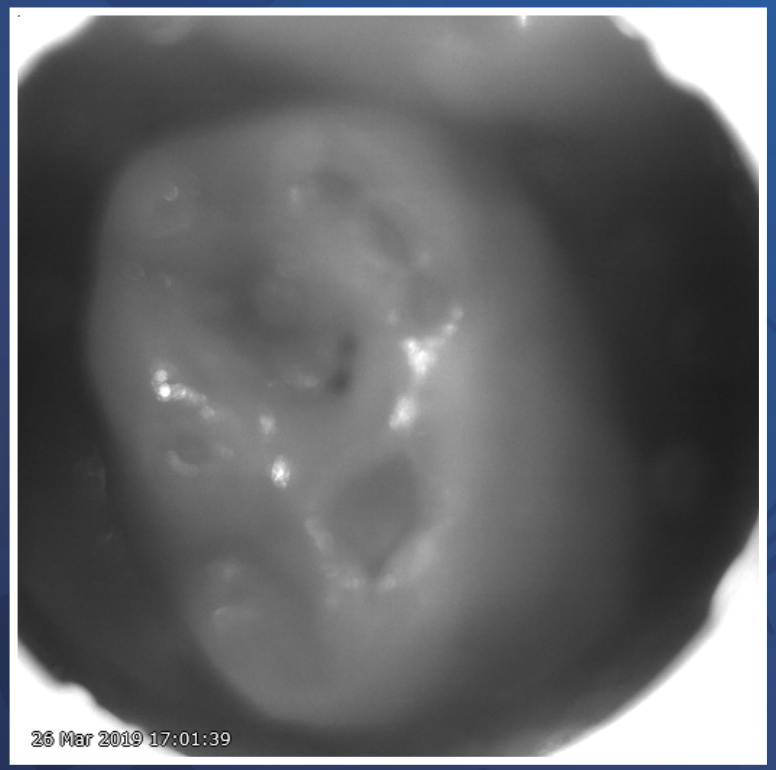
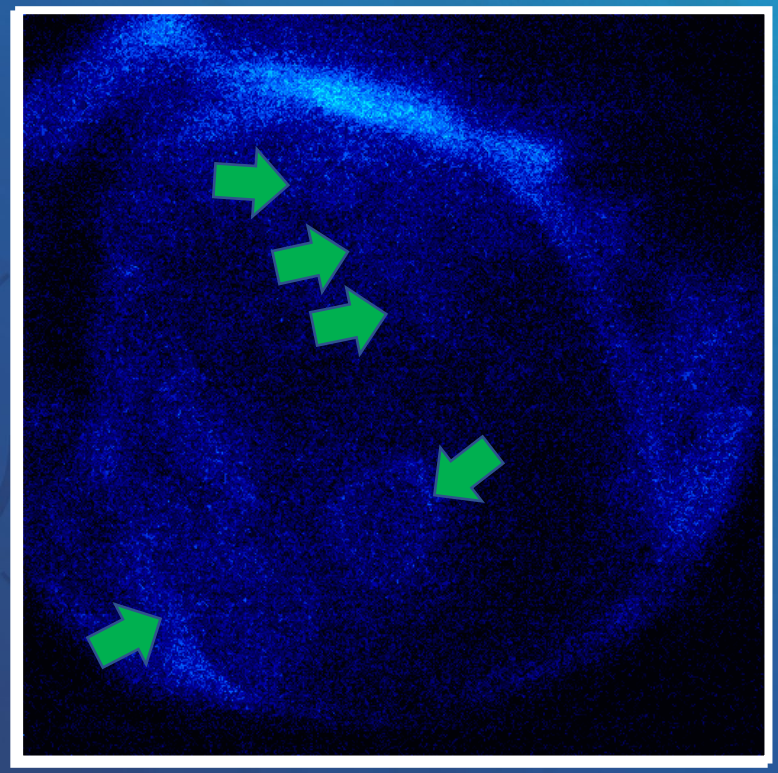
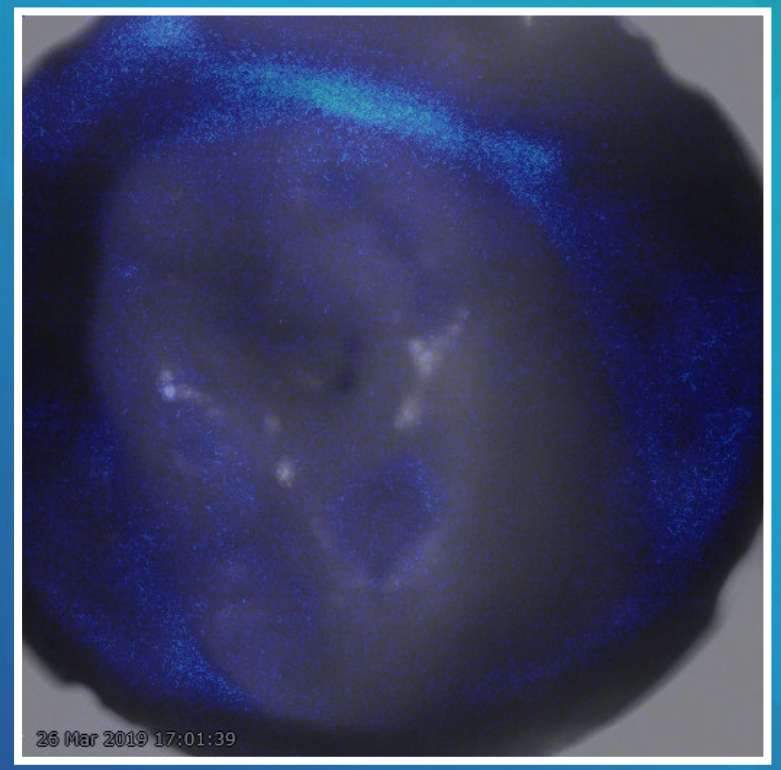
Figure 19 - low level of non-caries associated active demineralization.







Tooth 21 (LLD) Occ - low level (circle) of non-caries associated active demineralization on cusps.

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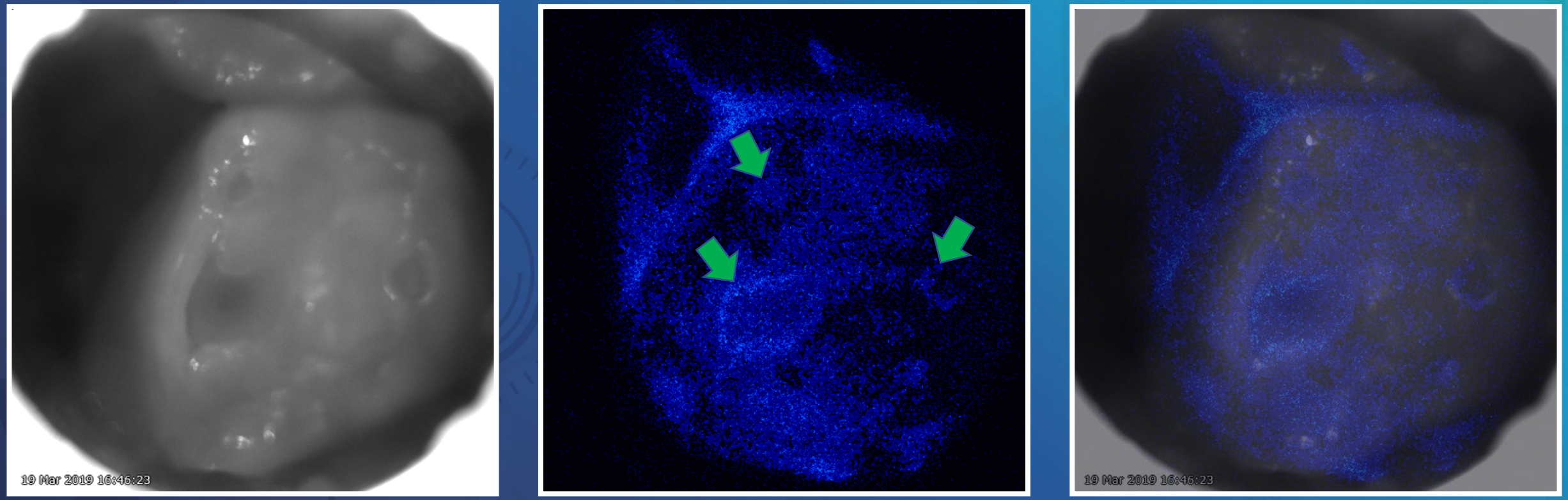
Figure 20 - low level of non-caries associated active demineralization



Tooth 12 (ULD) Occ - low level of non-caries associated active demineralization with delineated areas.

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Potential Confounding Factors

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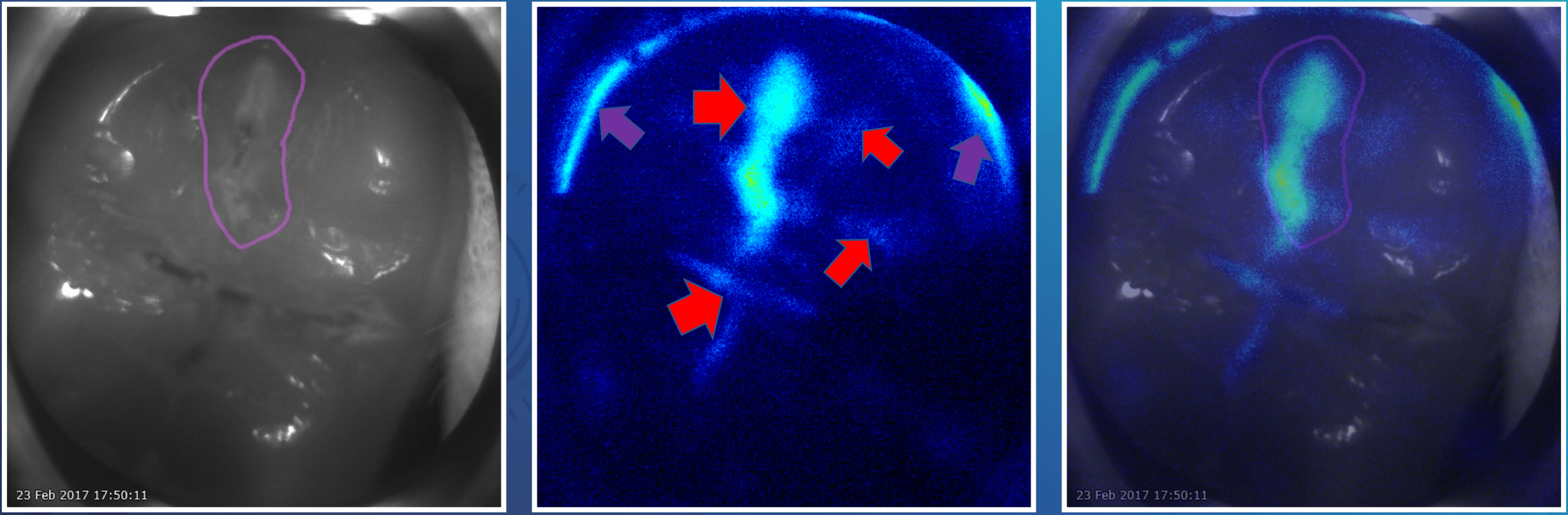
Fig. 21 – signal around edge of tooth caused by saliva



Tooth 31 (LR7) Occ - obvious moderate level of active demineralization (red arrows) in area marked by clinician before imaging, and also around the outside area marked. **Signal around edges of tooth caused by saliva (purple arrows).**

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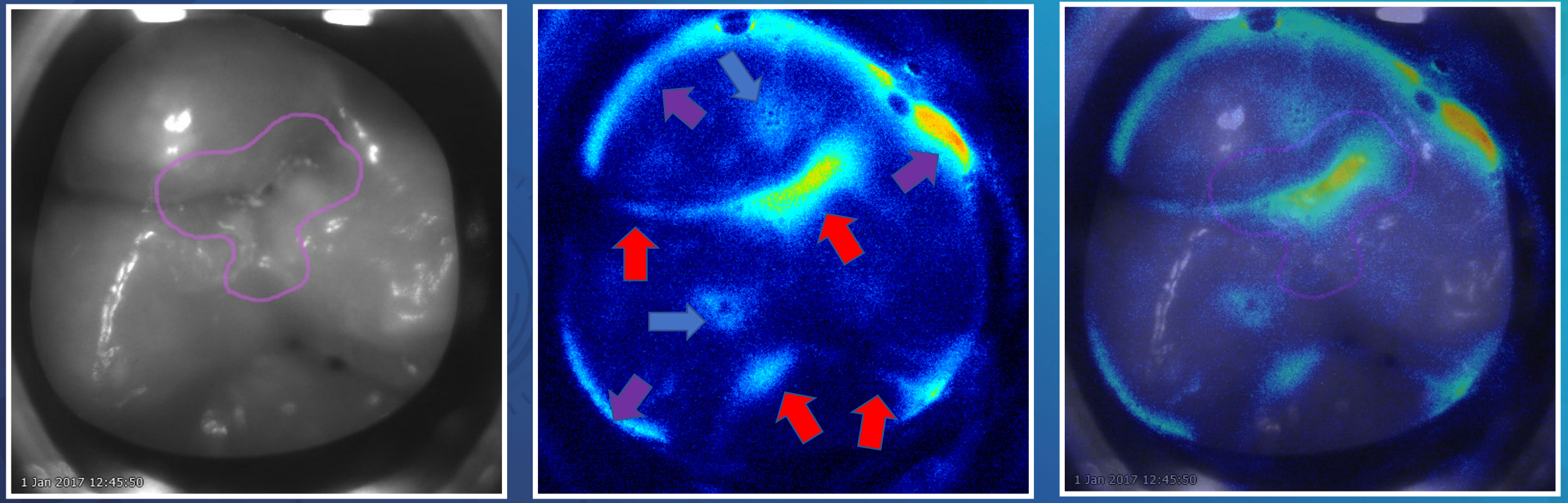
Figure 22 – signal around upper edge of tooth caused by saliva



Tooth 3 (UR6) Occ - high level of active demineralization (red arrows) in area marked by clinician, and also outside area marked, indicating demineralization more extensive than initially thought.

Areas of potential developmental hypo-mineralization are indicated by blue arrows.

Signal around edge of tooth caused by saliva (purple arrows).

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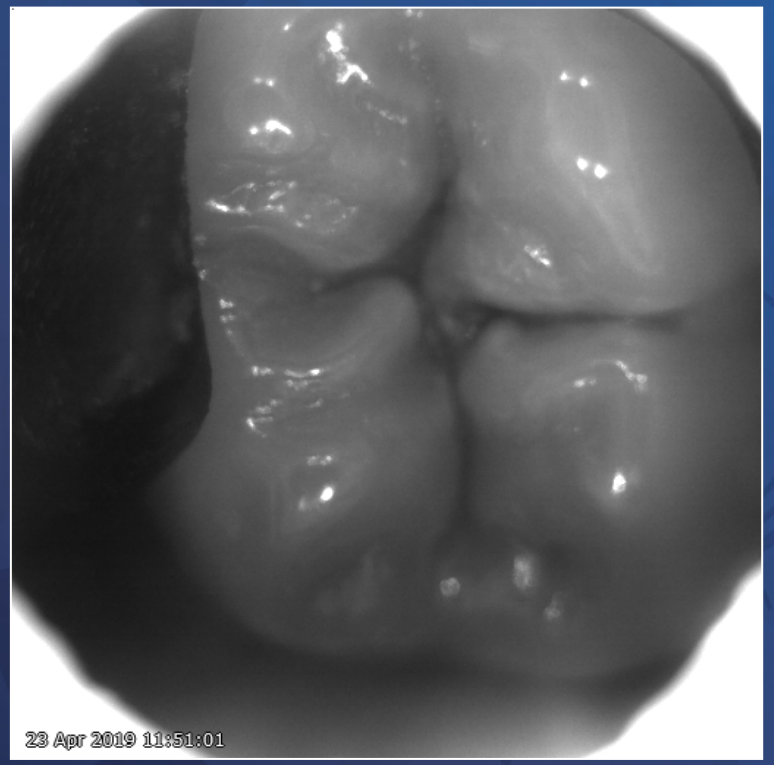
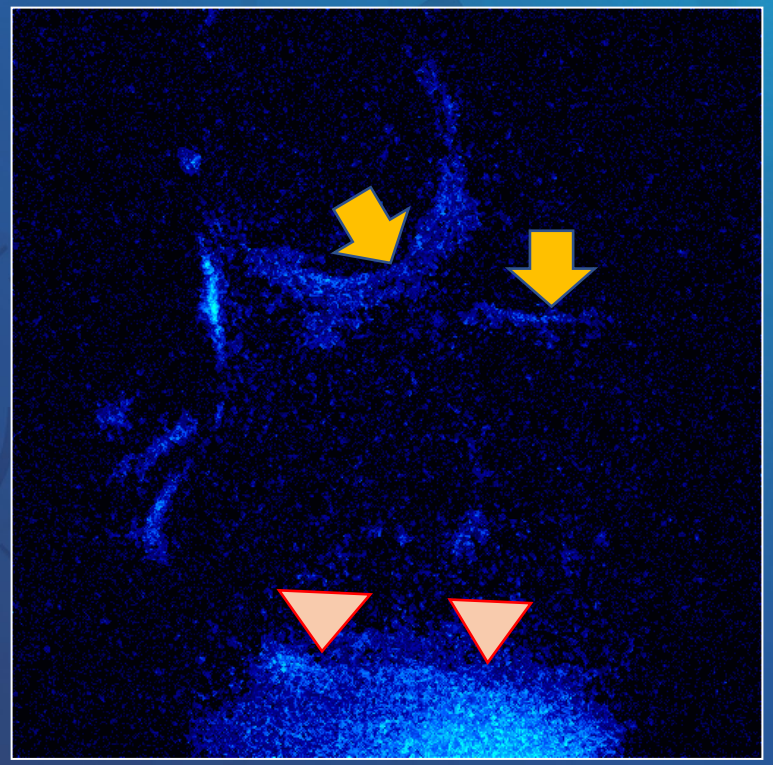
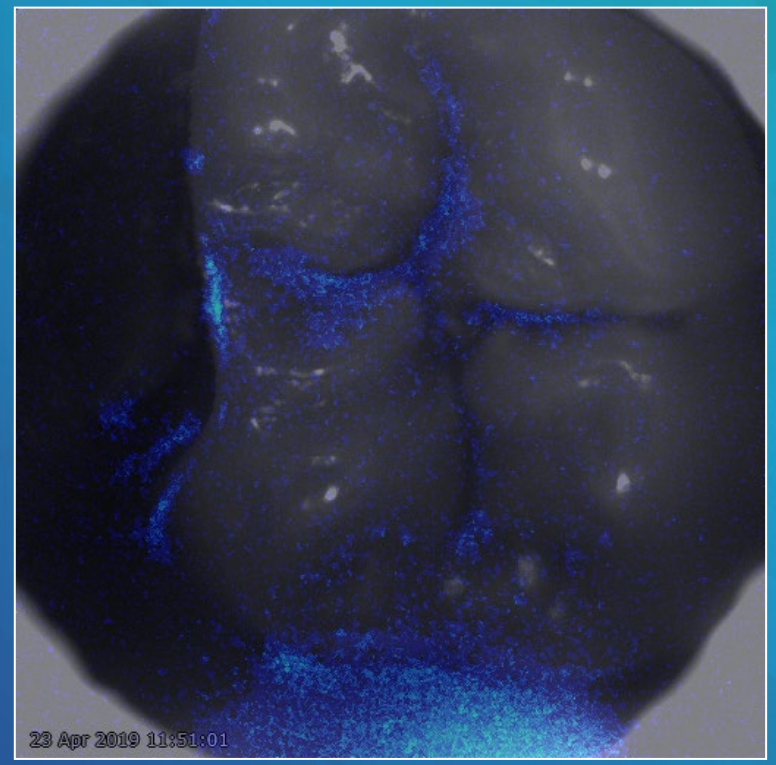
Figure 23 - signal at lower edge from light ingress







Tooth 18 (LL7) Occ - low level of active demineralization associated with fissure.
Bright area at lower edge from light ingress.

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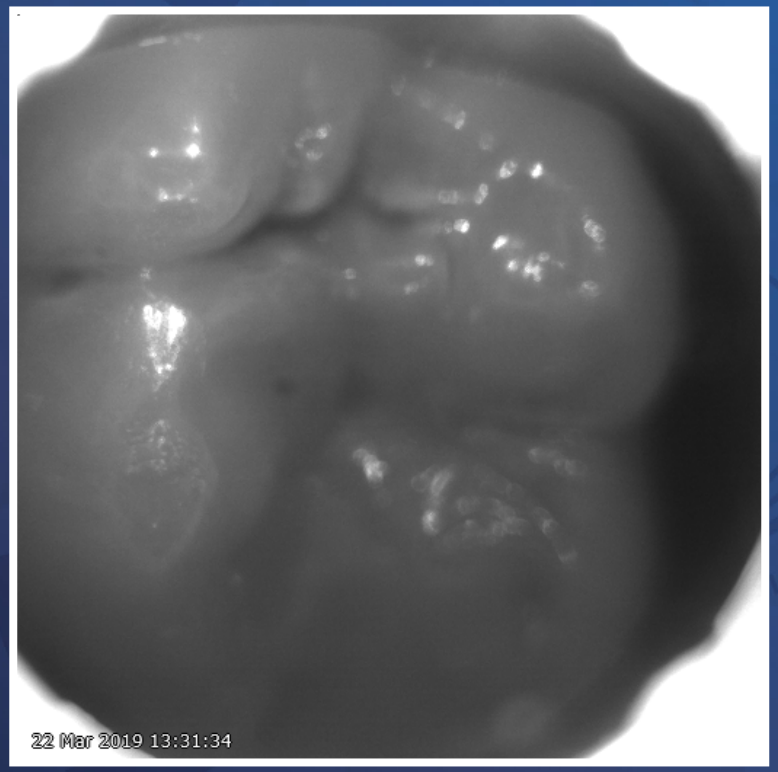
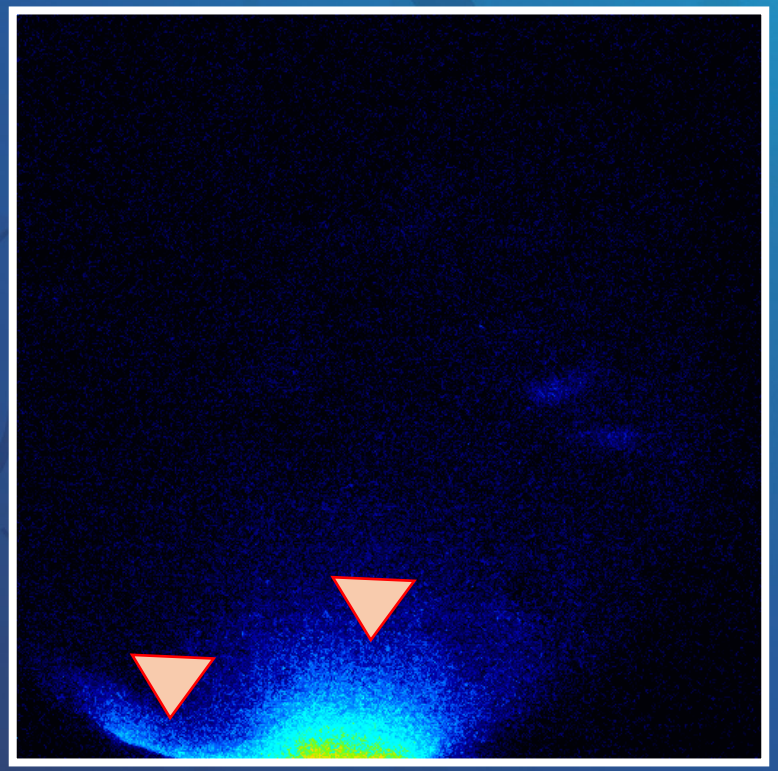
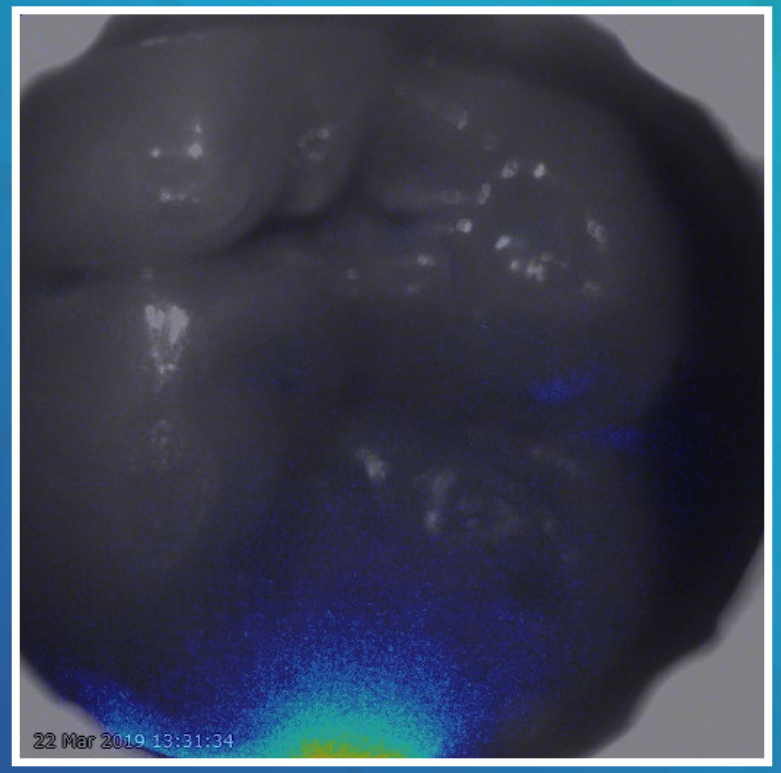
Figure 24 - signal at lower edge from light ingress







Tooth 3 (UR6) Occ - **Light ingress on lower edge**.

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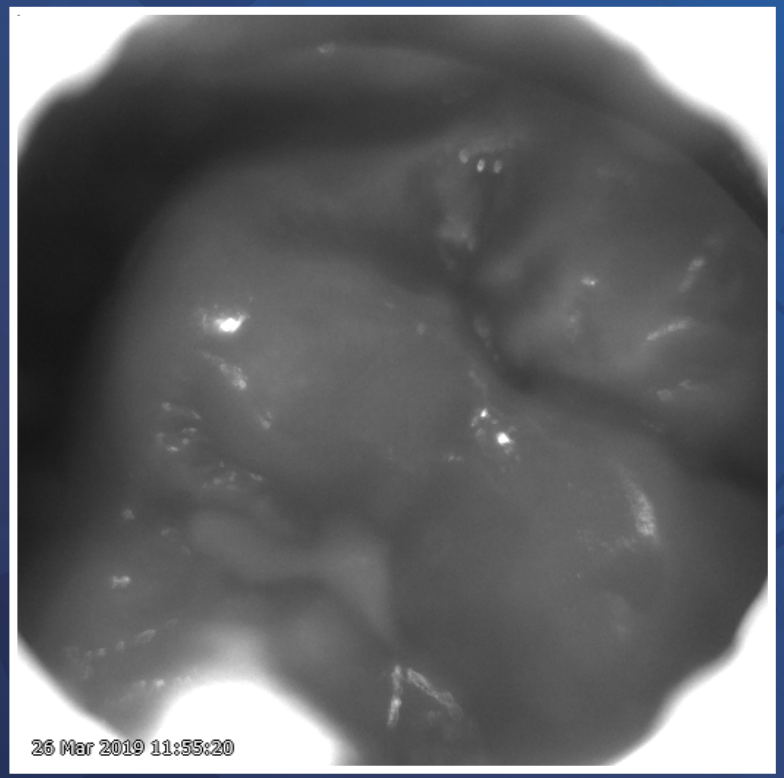
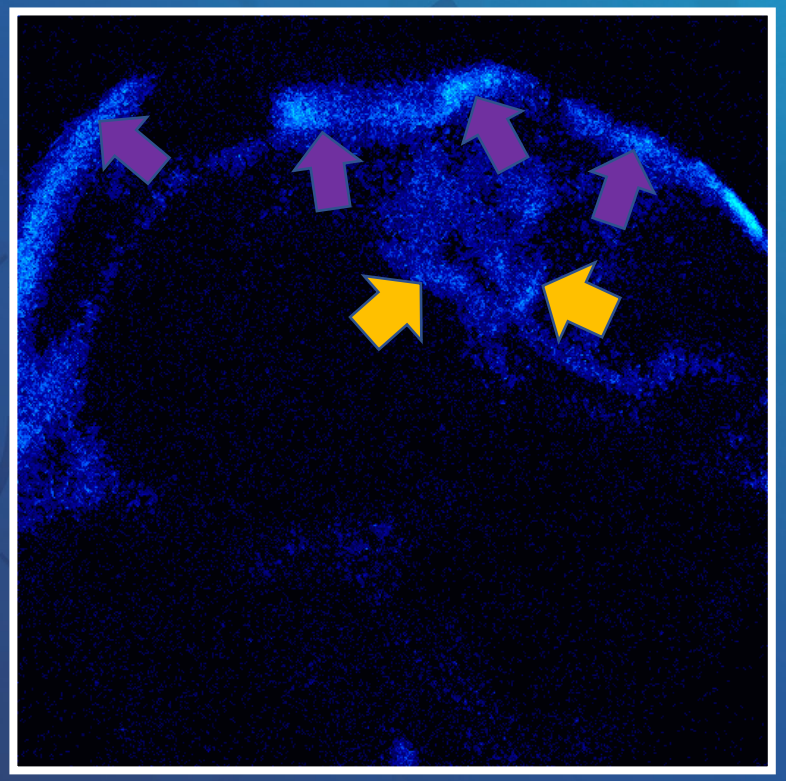
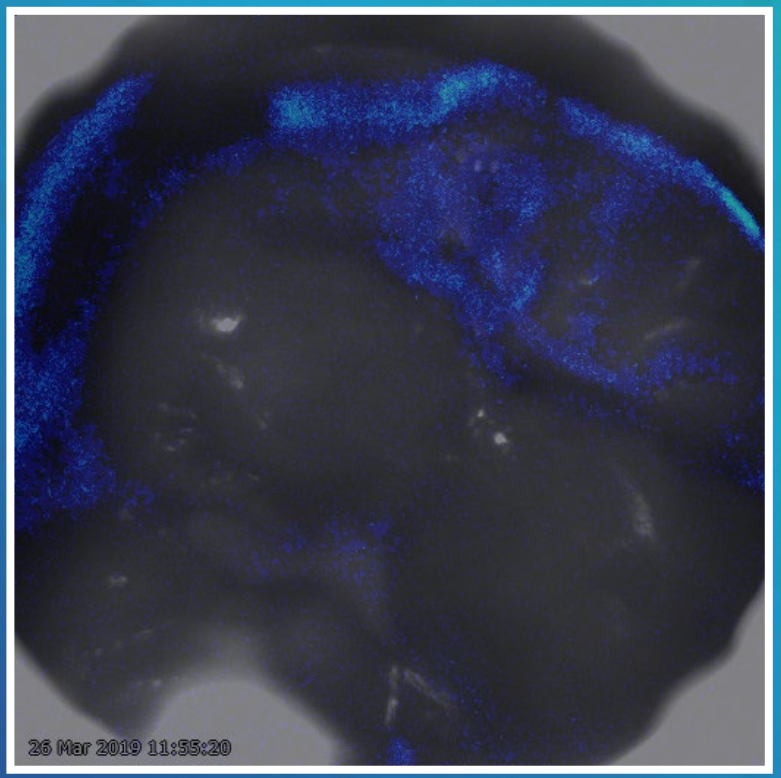
Figure 25 - signal caused by saliva from adjacent tooth







Tooth 14 (UL6) Occ - low level of active demineralization on tooth surface (yellow arrows), but area **around edge of tooth due to saliva from adjacent tooth purple arrows).**

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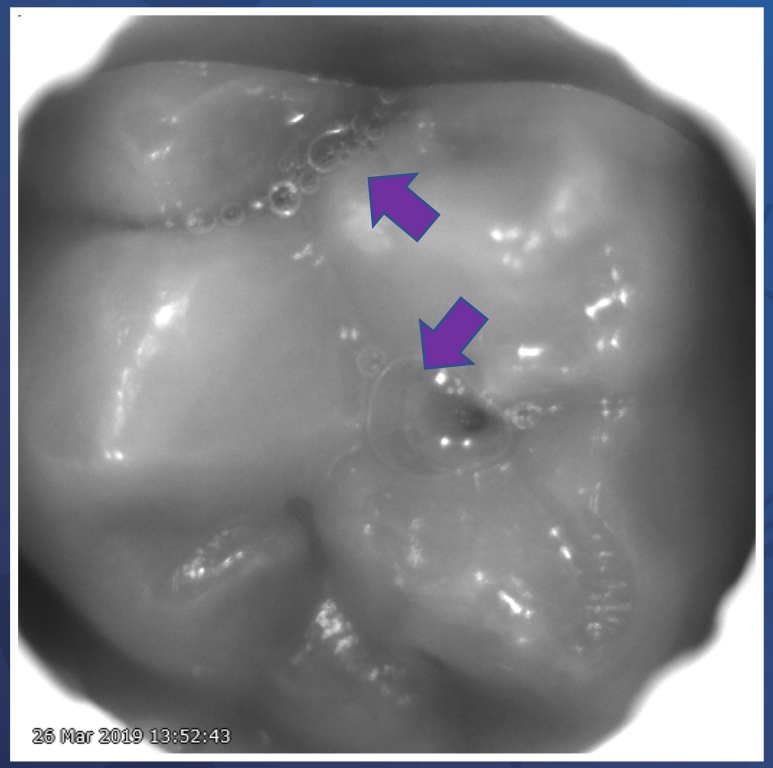
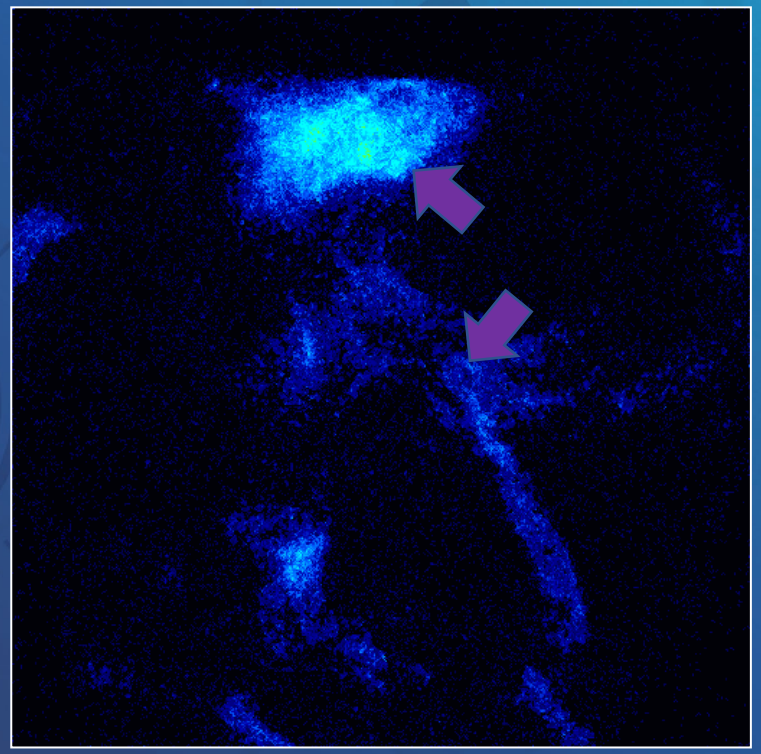
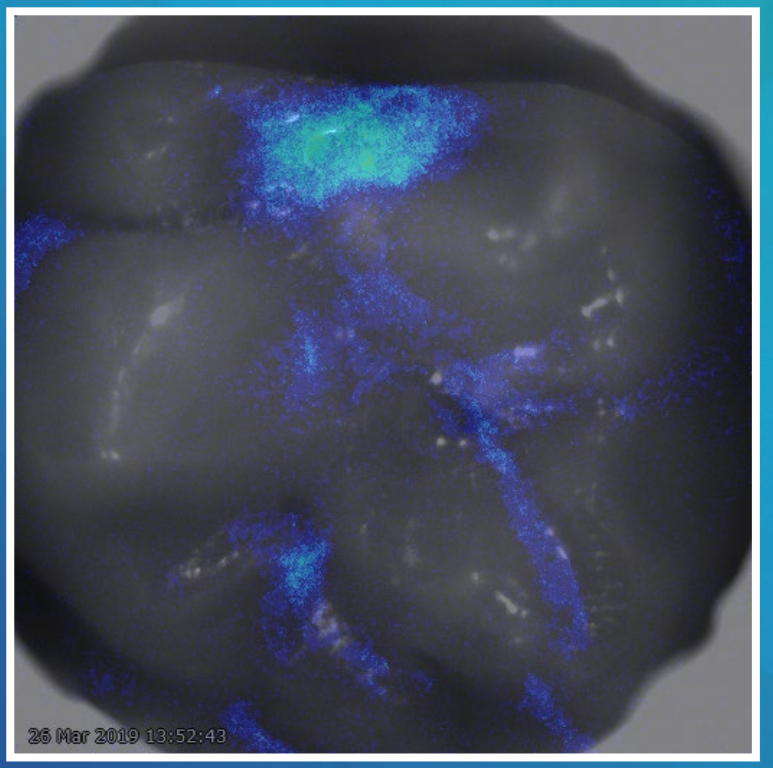
Fig. 26 – main signal due to bubbles of saliva







Tooth 3 (UR6) Occ - although some low levels of active demineralization noted, main areas of signal (purple arrows) due to **bubbles of saliva – tooth not dried sufficiently.**
Should be reimaged after rinse and dry.

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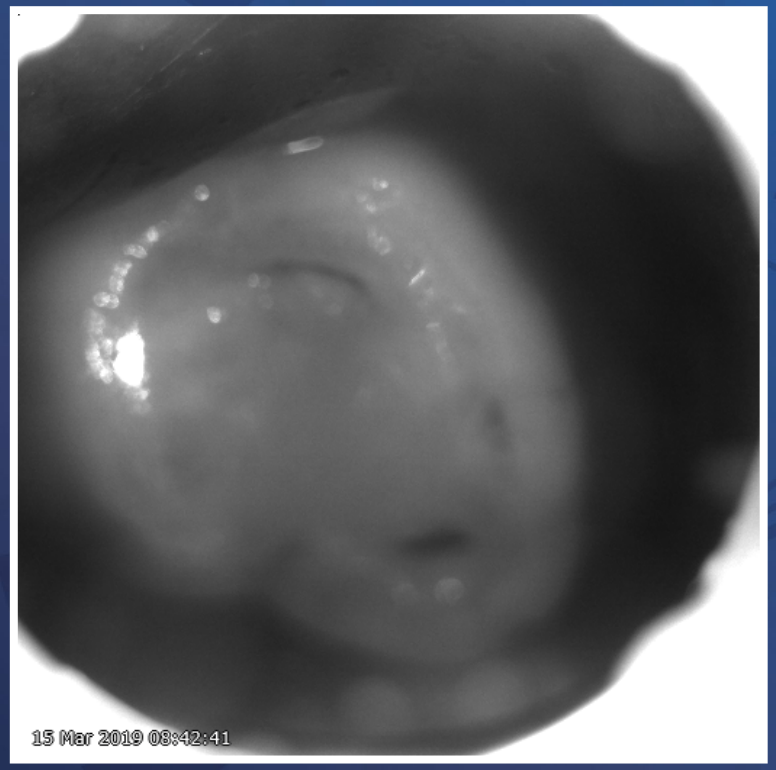
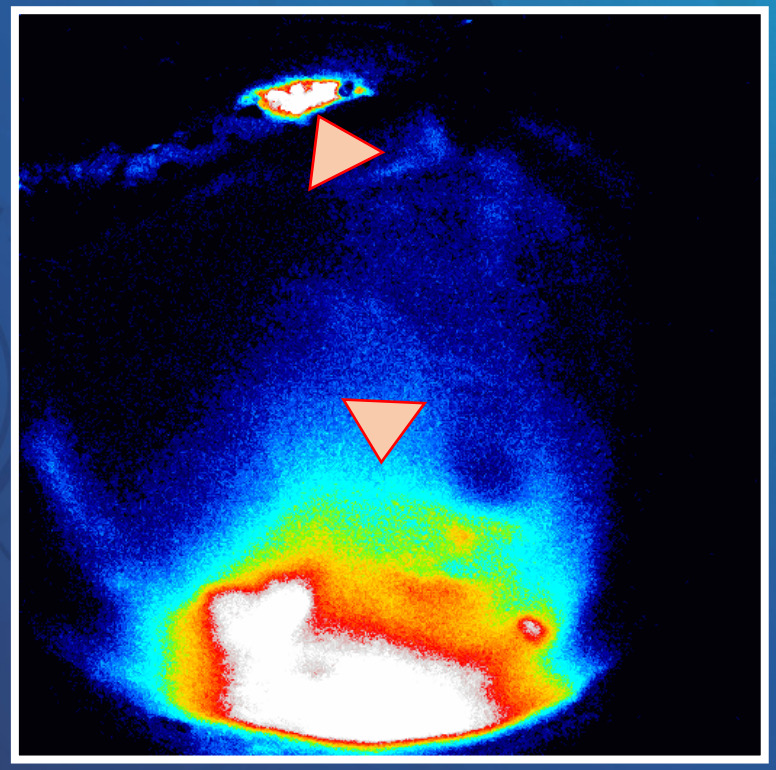
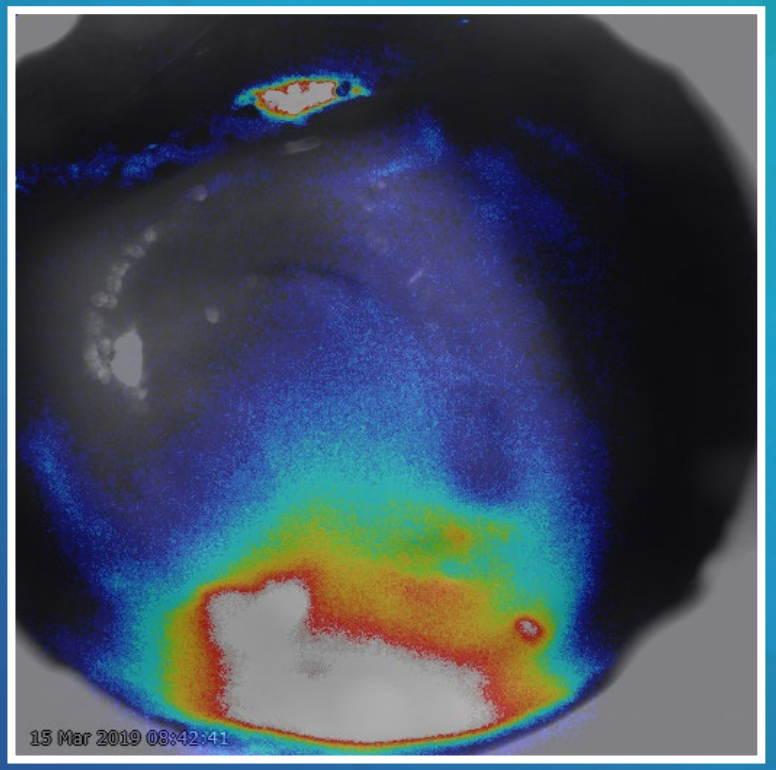
Figure 27 – image uninterpretable due to light ingress and poor focus







Tooth 5 (URD) Occ - image uninterpretable due to light ingress.
Also, the picture is out of focus as the device should be pressed firmly against the tooth surface.

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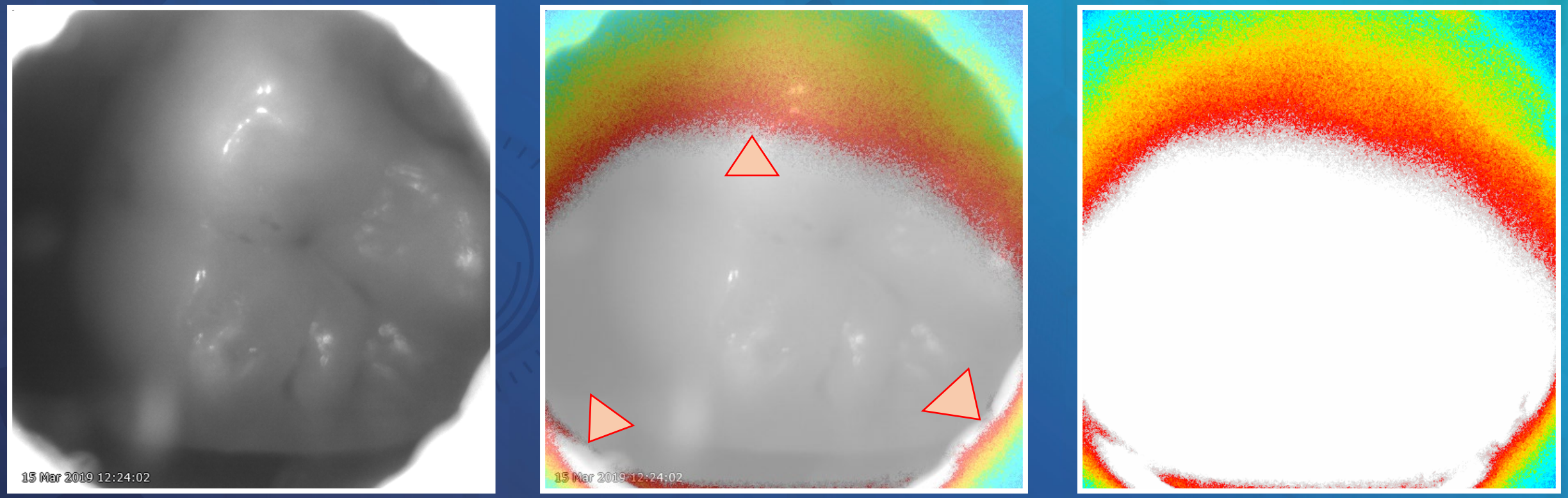
Figure 28 – overhead light left on



Tooth 14 (UL6) Occ - image uninterpretable –overhead light left on.

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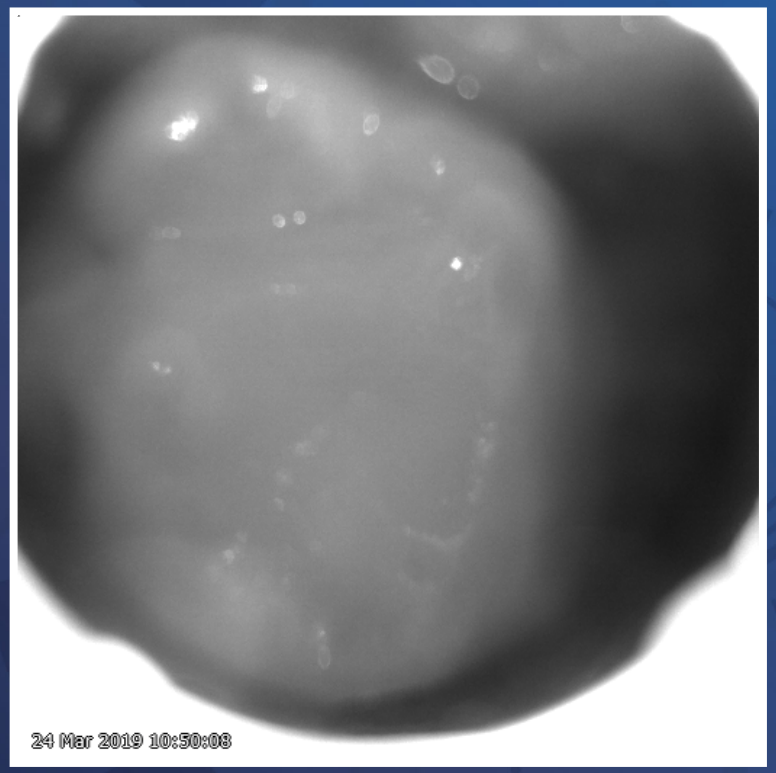
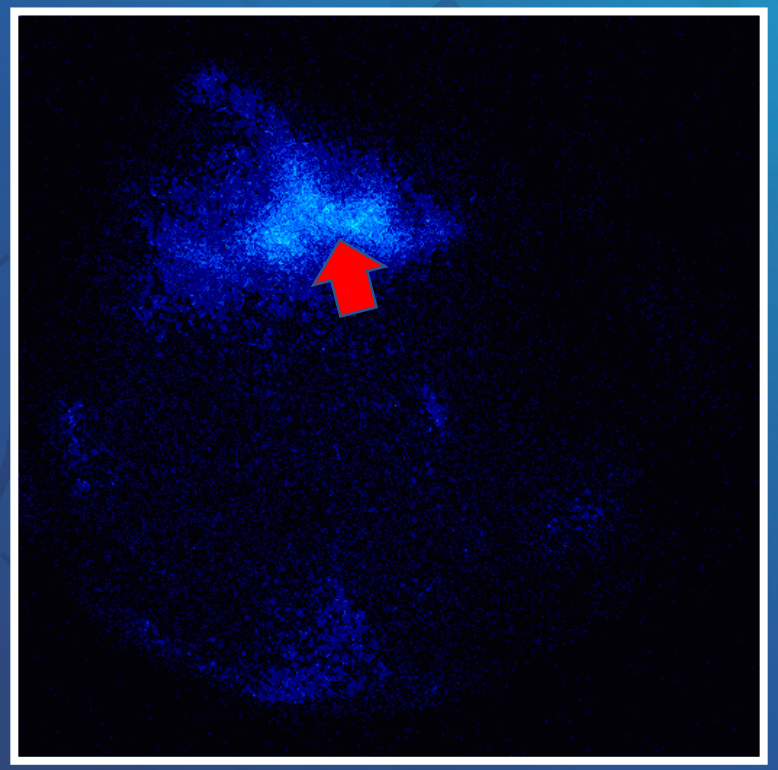
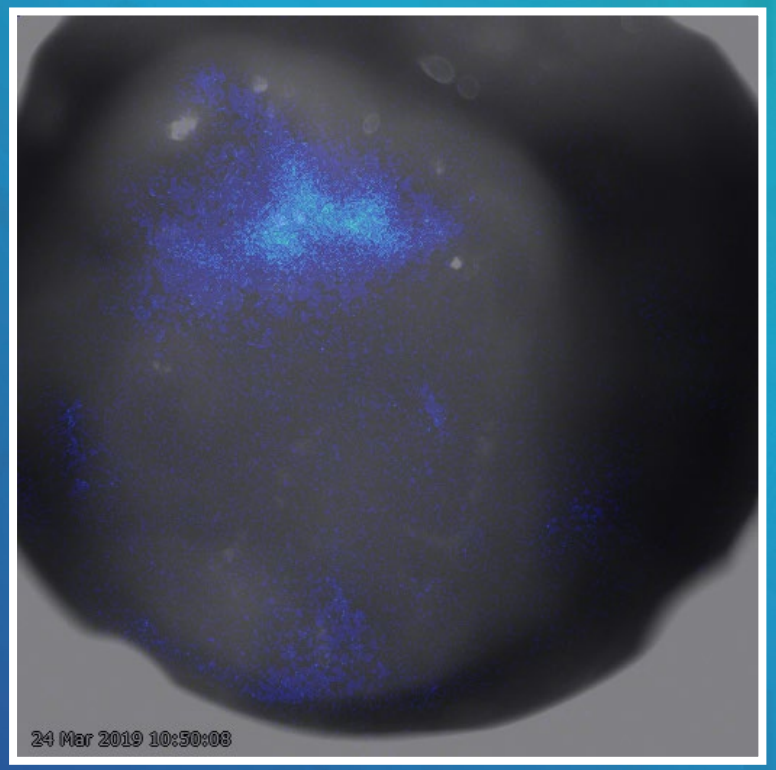
Figure 29- interpretation difficult as image out of focus







Tooth 5 (URD) Occ - active demineralization noted, but unclear if associated with caries lesion due to image being out of focus

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