

**MRI fusion biopsy in people with suspected prostate cancer  
(DAP 64)**

**Erratum to the EAG Diagnostic Assessment Report**

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**Completed on** 23/11/2022

In response to the DAR consultation responses collated by NICE and sent to the EAG on 22/11/2022, the EAG provide the following erratum to the report. These amendments do not change the overall conclusions of the report.

1. **Section 2.3.6:** In response to comment #3, the EAG added information on micro-ultrasound page 40 from:

“The ExactVu device includes a FusionVu feature that enables software fusion biopsy.”

*To:*

“The ExactVu device includes a micro-ultrasound (high-resolution ultrasound at >20MHz) and a FusionVu feature that enables software fusion biopsy.”

The updated page 40 is reproduced below.

through a magnetic tracker, which is attached to the probe during freehand biopsies. The system can automatically adjust for patient movement, or the user can manually adjust the contours when a patient moves.

The BiopSee records all positions of the needle and shows the coverage of the prostate. Image measurements such as prostate and lesion volumes are also possible. The data is stored locally and can be connected to a PACS for import and export of images.

### **1.1.1 bkFusion (BK Medical UK Ltd and MIM Software Inc)**

BK Medical UK Ltd offers three versions of bkFusion software: one for transrectal, one for freehand transperineal and one for stabilised transperineal biopsies. The software can be integrated into either the bk3000 or bk5000 ultrasounds. The bkFusion system uses rigid estimation to account for prostate deformation. Predictive Fusion software re-orientates the MRI image before the biopsy. The transrectal and freehand transperineal fusion systems comprises a magnetic field generator and sensor to track the probe position.

Image measurements such as prostate volume are possible. A detailed report of the biopsy can be saved locally, or transferred to a PACS.

### **1.1.2 Fusion Bx 2.0 (Focal Healthcare)**

The Fusion Bx 2.0 is a biopsy device that includes a counter-balanced, semi-robotic arm that is mounted to a mobile cart. The Fusion Bx 2.0 comprises Fusion MR software which is compatible with third party ultrasounds. The system uses both elastic and rigid estimation to account for prostate deformation, and supports both transrectal and transperineal biopsies. Patient movements are tracked with sensors inside the semi-robotic arm.

The software allows image measurements such as prostate volume and distances can be calculated. Data on the biopsied samples and the regions of interest are recorded on a 3D image of the prostate. The system can connect to PACS using a wired Ethernet or Wi-Fi connection.

### **1.1.3 FusionVu (ExactImaging)**

The ExactVu device includes a micro-ultrasound (high-resolution ultrasound at >20MHz) and a FusionVu feature that enables software fusion biopsy. A stabiliser arm or stepper is available for stabilised biopsies, and freehand biopsies are also possible. The system uses rigid estimation followed by real-time visualisation of the lesions using micro-ultrasound, and supports both transperineal and transrectal biopsies. The system tracks and adjusts for patient movement using data from a movement sensor together with the live ultrasound images.

2. **Appendix 11:** In response to comment #6, the EAG added information on the number of uses (“24”) and the source (“Exact Imaging response to EAG RFI”) for the FusionVu guide to Table 100 (page 348).

The updated page 348 is reproduced below.

|               |   |   |                            |
|---------------|---|---|----------------------------|
| BiopSee       | Urologists/radiologists                 | Not described                           | 3 hours                    |
|               | Nurses                                  |   | 1 hour                     |
| Fusion Bx 2.0 | Urologists, nurses and/ or sonographers | Video training                          | 1 hour                     |
|               |   | Hands-on training with phantom prostate | 0.5-0.75 hours             |
|               |   | Support to clinical cases               | 10-20 casers over 2-3 days |

CNS, clinical nurse specialist; IT, Information Technology; ODP, Operating Department Practitioner; OPD, Outpatient department.

**Table 1 Additional time of software fusion vs. cognitive fusion biopsy according to the companies**

| Fusion system  | MRI contouring | Connect fusion system to ultrasound | Contouring ultrasound |
|----------------|----------------|-------------------------------------|-----------------------|
| bkFusion       | 3 – 5 minutes  | NR                                  | -*                    |
| FusionVu       | 1 minutes      | NR                                  | 10 seconds            |
| KOELIS Trinity | 5 minutes      | NR                                  | 5 minutes             |
| BiopSee        | 1-2 minutes    | NR                                  | <1 minute             |
| Fusion Bx 2.0  | 8 -10 minutes  | 30 seconds                          | 5 – 10 minutes        |

\*Company states that bkFusion does not require ultrasound contouring; NR, not reported

**Table 2 Summary of information on the costs of transperineal needle positioning freehand devices in a previous DAR and from the companies' responses to RFIs**

| Device         | Manufacturer  | Compatible with                        | Cost of device | Number of uses | Reprocessing | Co-axial needle | Source   |
|----------------|---------------|--|----------------|----------------|--------------|-----------------|--|
| PrecisionPoint | BXTAccelyon   | KOELIS Trinity, BiopSee, Fusion Bx 2.0 | £206.16        | 1              | -            | -               | Southampton DAR <sup>126</sup> ; Inflated to 2020/2021 price year <sup>163</sup> |
|                |               |  | £250.00        | NR             | NR           | NR              | KOELIS and Kebomed response to NICE and/or EAG RFI                               |
|                |               |  | £350.00        | NR             | NR           | NR              | Focal Healthcare response to NICE and/or EAG RFI                                 |
|                |               |  | £150-£250      | NR             | NR           | NR              | Medcom response to NICE and/or EAG RFI   |
| FusionVu guide | Exact Imaging | FusionVu                               | £1,333         | 24             | -            | -               | Exact Imaging response to EAG RFI  |
| EZU-PA3        | Hitachi       | ?                                      | £1971.66**     | 100***         | £5.15        | £22.06          | Southampton DAR <sup>126</sup> ; Inflated to 2020/2021 price year <sup>163</sup> |