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SIRIO H3: virtual navigation system to support radiological procedures with percutaneous access

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Methods

Agenas is a public body. Its mission is to promote innovation and development within the Italian national healthcare service and provide an Early Awareness and Alert (EAA) service by Horizon Scanning (HS) activities in the field of new and emerging health technologies. A full description of the methods used for the production of the present HS report can be found at www.agenas.it

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Limitations

This report is based on information available when the research was done and does not contain data on subsequent developments or improvements of the evaluated technology. The observations made on effectiveness, safety or cost-effectiveness of the technology evaluated in the report are to be considered current, but may change as more evidence becomes available if an update of the document is commissioned.

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Declaration of Conflict of Interest

The authors declare that they will not receive either benefits or harm from the publication of this report. None of the authors have or have held shares, consultancies or personal relationships with any of the producers of the devices assessed in this document.

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Name of the technology/procedure:

SIRIO H3: virtual navigation system to support radiological procedures with percutaneous access

Target population

Patient candidates to tissue biopsy or drug/ablation therapy in a specific pathologic area are the population that could benefit from the SIRIO H3.

Description of the procedure and technology

X-ray, ultrasound, Computed Tomography (CT), Magnetic Resonance Imaging (MRI) scanning are often used as a guide for mini invasive procedures through the percutaneous insertion of a biopsy needle [ACR, 2018]. Biopsy is a medical procedure consisting of taking a small sample of tissue or cells for further microscopic evaluation. Transthoracic needle biopsy (TNB) is a minimally invasive procedure useful when imaging tests cannot exclude the malignancy of a nodule lung and/or it is difficult to reach the lesion by bronchoscopy or other methods [ACR, 2018]. Needle biopsy is less invasive than surgical ones and may not require general anesthesia.

The standard technique is the introduction of a needle for CT-guided biopsy during CT scan to allow the exact location of the lesion. However, this technique has some limitations with regards to high adsorbed doses, execution time and the inability to visualize in real time needle progression in reaching the lesion [Iannelli, 2018]. Virtual navigation systems are emerging tools in percutaneous imaging-guided procedures using electro-magnetic, optical or hybrid tracking during operations [Faiella, 2018]. Virtual CT-guided navigation system for biopsy provides a 3D reconstruction from a data set of acquired CT images through automatic procedures.

In comparison with traditional techniques, the use of CT-guided navigation system technologies allows faster operations, with greater efficacy and also with a reduction in radiation dose for both to patient and medical staff.

SIRIO H3 is a CT-guided navigation system designed to support radiological interventional procedures. Moreover, it is an aid for percutaneous interventions such as biopsies and/or thermal ablations in different anatomical areas, such as the lungs, bones and kidneys.

Clinical importance and burden of disease

Biopsies are performed to diagnose or to confirm infections, inflammations and tumors affecting various internal organs, as well as to evaluate the course of pathologies and to establish the possible therapies to be administered. It is commonly used to diagnose liver diseases, acute or chronic kidney diseases, pathologies affecting the lungs and the pleura, the prostate etc. Biopsies are mostly performed for insight into possible cancerous conditions.

It was estimated that around 371,000 new cancer diagnoses (excluding skin cancer) occurred in Italy in 2019 (53% among men and 47% among women). Breast cancer, lung carcinomas in women and, in both genders, pancreas, thyroid and melanomas (especially in southern Italy) are growing.

In the entire population, with the exception of skin carcinomas, the five most frequent tumor sites involve breast (14%), colorectal (13%), lung (11%), prostate (10%) and bladder (8%) [AIRTUM, 2019]. In 2017, deaths due to tumors were 179,502 (100,003 among men and 79,499 among women) Cancer conditions with the highest number of deaths were lung cancer (33,759), followed by colorectal cancer (19,355), breast (12,942), pancreas (12,347) and liver (9,214 9214) [ISTAT, 2017].

In the period 2005-2009, compared to previous one (2000-2004), the proportion or survivors increased for both men (54% vs 51%) and women (63% vs 60%) since initial cancer diagnosis. In 2019, lung cancer was the second most frequent condition in men (15%) and the third most frequent in women (12%). Estimates of new lung cancer diagnosis is around to 42,500 cases (29,500 in men and 13,000 in women). Lung cancer is the leading cause of death (12%) of all malignancies in the whole Italian population and the 5-year survival rate of lung cancer patients is equal to 16%. [AIRTUM, 2019].

Early diagnosis of a suspected lesion allows treatment to be started previously and can improve the prognosis in terms of survival and quality of life.

Products, manufacturers, distributors and approval

SIRIO H3 by Masmec SpA received the CE mark in 2013 and the FDA 510(k) clearance in November 2017. In Italy, according to the *Classificazione Nazionale dei Dispositivi Medici (CND)* SIRIO H3 is classified under the class "*CND: Z12011401 – SURGICAL NAVIGATION SYSTEM*" and registered with the number 358838 within the Italian National medical device database (BD/RDM). SIRIO H3 is classified in I risk class.

SIRIO H3 is a medical device supporting minimally invasive interventional radiology procedures (under CT guidance) performed on the thoracic district and that involves the insertion of a probe needle (SIRIO H3 IFU). In particular, the system acts as an aid for biopsy samplings and thermoablation procedures of pulmonary nodules. SIRIO H3 is indicated in those cases defined by medical staff in which clinical conditions require an interventional radiology procedure in the thoracic district through the insertion of a probe needle (SIRIO H3 IFU).

According to the manufacturer, SIRIO H3 is based on 3D reconstructed CT images, and allows navigation of the anatomical district of interest, to identify the needle trajectory and to track it until the neoformation/lesion is reached, even for small lesions (less than 1cm).

SIRIO system is composed of an instrumented column, an intervention kit, an infrared optical sensor, a disposable sterile kit, a posture tracking system, breathing sensors and a needle support [Caparelli, 2015]. The instrumented column is equipped with a visualization and image processing unit, where the reconstructed 3D model of the anatomical district of interest (virtual space) is visualized and on which the procedure is performed, and an infrared camera allowing to follow the intervention needle and the patient in the navigable virtual space using a tracking technology. The infrared camera receives the emitted radiation by the reflective elements placed on the intervention kit and calculates their position in space. Starting from tomographic scan DICOM images, the system reconstructs the three-dimensional model of the anatomical district of interest. The infrared system detects the relative position of the needle and the advancement inside the patient's chest through a real-time tracking system [Caparelli, 2015]. The virtual model helps the interventional radiologist to assess the area and the initial insertion trajectory with better approximation, as well as any corrections.

The tracking posture procedure monitors the correspondence between reality and three-dimensional reconstruction using single-use passive markers placed in appropriate areas of the patient. The accuracy of path in that system is <2 mm [Caparelli, 2015]. The virtual navigation is intended to drastically reduce, time procedure, number of CT scans and consequently adsorbed radiation dose by patient and healthcare personnel.

Product name [Manufacturer]	Distributor	CE Mark	BD/RDM	FDA
SIRIO H3 [Masmec SpA]	Masmec SpA	☑	☑	☑

Roll out in Italy

SIRIO's first version was launched in Italy in 2010 and a newer version in 2013. According to the manufacturer, in Italy SIRIO H3 is used in Piemonte, Lombardia, Toscana, Emilia-Romagna, Abruzzo, Lazio, Campania, Puglia e Basilicata, mainly in public hospitals. Only two healthcare Centres are private.

☐ Pre-marketing	☐ On the market for 1-6 months	☐ On the market for 7-12 months
☑ On the market for more than 12 months	☐ Not identified	

Setting

SIRIO H3 is used in a CT interventional radiology room.

☐ Home	☑ Hospital	☐ Outpatient
☐ Accident and Emergency	☐ Other:	

Comparators

The standard of care is represented by procedure using only CT as aid for minimally invasive surgery.

Effectiveness and safety

We searched the major databases including MEDLINE (search date 29/04/2020), Clinicaltrials.gov and Cochrane Library looking for studies on humans, published from 2010 to 2020, in Italian or English, reporting on effectiveness and safety of SIRIO H3 MASMEC for all those who have to undergo a biopsy or need drug/ablation therapy in a defined area. Search results (n=59: 43 Pubmed, 13 Cochrane, 3 Other sources, 1 citation duplication) were screened by reading title and abstract. Twelve articles were considered eligible for full-text analysis. No clinical trials or systematic reviews were identified. Six studies were pertinent to SIRIO. The list of studies read in full text, included and excluded (with reasons for exclusion) is in Appendix 1.

Comparative studies

The article of Grasso et al [Grasso, 2012] reports a prospective study in performing percutaneous lung biopsy (PLB) with the enrollment of 180 consecutive subjects, over a period of 14 months. Patients, not randomized, were equally divided into a control group (group C) and a study group (group S). Parameters were measured in both groups of patients as follows: a) time of execution of the procedure; b) total number of CT scans performed and x-ray dose; c) diameter of the lesion biopsied; d) technical success (achievement of the target lesion) and diagnostic success (final pathological diagnosis); e) procedural complications. The time of execution the procedure has shown to be substantially shorter than that of procedures performed with the traditional technique (mean execution time 14 minutes vs 24 minutes), with a statistically significant difference ($P<0.001$). The number of CT scans performed ($z = 5.64$) and, consequently, the mean x-ray dose (CTDIvol) administered to patients ($P<0.001$) were significantly lower with augmented reality navigation system. As far as the diameter of the lesion biopsied, a pathological diagnosis was reached in 96%

of cases in group S and 90% of cases in group C. Complete technical success was obtained in all patients enrolled. Although the diagnostic performance was slightly higher for group S (96%) than group C (90%), the difference was not statistically significant, probably because PLB is a highly effective diagnostic procedure that leaves not much room for additional improvement. Finally, the rate of procedural complications did not show statistically significant differences between subjects who underwent biopsy assisted by the navigation system with augmented reality (14%) and those who underwent CT-guided biopsy with the traditional technique (17%). In terms of patients' safety, 40 patients (not included in the sample referred to in the present study) underwent a procedure in which radiologists reached the target with traditional CT guidance but worked under constant monitoring of the navigation system with augmented reality. All needle movements and the trajectory followed by the operator for each individual patient were recorded and compared with the trajectory that the same operator would have adopted at the beginning of the procedure, following the instructions provided by the navigation system with augmented reality. In all these cases, and in subsequent patients included in group S, there were no rough system errors that put patients' safety at risk or exposed patients to further complications.

Grasso and colleagues [Grasso, 2013 (J Int CARS)] performed SIRIO-guided PLB in 197 patients (121 male, 76 female, mean age 66.8±12 years). Results obtained from this group were compared with those obtained from a cohort of 72 patients (48 males, 24 females, 69.1±10 years), who received standard CT-guided PLBs during a 6-month period ahead of SIRIO availability. Differences in number of CT scans, patient radiation exposure and procedural time in both groups of patients (SIRIO vs standard CT-guided PLBs) were evaluated by mean and standard deviation. In particular, number of CT scans was significantly lower in SIRIO group and the 95th percentile was reached between 8 and 10 scans with SIRIO and between 16 and 18 with the conventional CT approach. Also, radiation dose was lower in SIRIO group (the 95th percentile was reached between 7.5 and 10mSv with SIRIO; with the standard CT-guided PLBs, the 95th was reached between 20 and 22.5mSv) as well as procedural time. SIRIO-guided PLBs showed a sensitivity of 89.1%, a specificity of 96.9% and an accuracy of 95.4%. When procedures are stratified in terms of lesion size (≤20mm and >20mm), the accuracy is similar in both groups for lesions >20mm (93.7 %in the SIRIO-guided PLBs group vs. 92.3% in the standard CT-guided PLBs group); on the contrary, SIRIO showed a marked accuracy improvement for lesions ≤20mm (96.8 vs. 91.4%). The overall pneumothorax rate was significantly lower with SIRIO than in the group undergoing standard CT-guided PLBs (9.1 vs. 16.7%, $p<0.01$).

Iannelli et al [Iannelli, 2018] studied 200 prospective patients from January 2014 to December 2015 to evaluate the effectiveness of SIRIO in performing lung biopsies, with particular attention to lesions smaller than 1 cm, compared to traditional procedure. Results have been divided according to lesion dimensions. The authors found a statistically significant decrease in the execution of biopsies with lesions ≤10mm with greater efficacy in terms of reduction of the absorbed dose (mean 43.4 vs 131.5, SD 0.9 vs 5.1), procedural time (mean 28.9 vs 39.5, SD 0.8 vs 4.6) and of the CT scanner tube (mean 17.5 vs 35.4, SD 1.0 vs 4.2), compared to the standard procedures. Regarding safety issues, using SIRIO safest and shorter path can be there followed, with the option of avoiding adjacent anatomical structures. This has sharply reduced peri-procedural complications compared to standard practice (9 vs 5).

The article of Grasso et al [Grasso, 2013 (Eur Radiol)] studied 52 consecutive patients. In a previous experience [Grasso, 2013 (J Int CARS)], authors validated an optical CT based navigation system while performing percutaneous lung biopsies (PLBs). The aim of the present study was to evaluate the optical navigation system while performing PLBs with a low-dose (LD) CT protocol in terms of the technical feasibility, patients' radiation exposure, imaging quality and complication rate. Patients were enrolled according to the intention-to-treat principle and randomized into two different groups: group 1 (15 male, 10 female) underwent PLBs under guidance of the optical CT-based navigation system; group 2 (16 male, 11 female) underwent PLBs under guidance of the optical CT-based navigation system with an LD CT protocol. A two-sample t-test was performed to compare the patients' demographics (age), lesion size (similar in both groups), chest radiation dose (significantly lower in group 2), needle path length (similar in both groups), needle repositioning and procedural time (similar in both groups); P<0.05 was considered significant. Descriptive statistics were used for technical success (100% in both groups), lesion location, diagnosis, complication rate (similar in both groups) and group 2 CT image quality (in group 2 was always rated as adequate and as excellent in 15 cases (56.0 %)). The radiation dose to the patients' chest was significantly lower in group 2. The needle path was similar in both groups as well as needle and procedural time. Complication rates were similar in both groups.

Non comparative studies

Faiella et al [Faiella, 2018] enrolled a total of 496 patients (mean age 69.4 ± 9.6; 307 male, 189 female) from July 2012 to March 2016 in order to investigate and validate the CT navigation system and to evaluate PLB accuracy based on dimension and location of suspected lesions. Evaluation of maximum lesion diameter (LD), lesion localization, procedural time (PT), histological sample validity, minimum lesion distance from pleural surface (DPS), needle distance travelled during the procedure (DTP) and recovery requirement for major complications were recorded for each patient. The radiation dose to the patient's chest was estimated by means of the total dose-length product (TDLP) and then the effective dose was obtained by a specific formula. All patients underwent PLB. In all cases a CT image demonstrating the needle tip within the target lesion was obtained. In each patient, the procedure was successfully completed, with a definitive histopathological diagnosis in 96.2% of cases. Complications were recorded in 156 patients (31.4%): in 133 patients, were minor (26.8%), in only 23 patients (4.6%) were recorded major complications. The use of the navigation system allowed a good success in terms of diagnostic value, even in small lesions and in case of wide DTP. About procedural complications, this study demonstrated that in patients with major complications (31.4%) there was a higher value of DTP compared to patients with minor complications. Procedural time (mean 29.5 min) decreased compared to previous published studies adopting standard CT-guidance (up to 60 min). It has been assessed the difference between a CT-guided lung biopsy performed with or without the interposition of a bone structure, which can be avoided using the navigation system: the difference between DPS and DTP was statistically significant (p < 0.01) both in patients presenting an interposed structure and in the whole population. These properties proved to be more useful in difficult cases, particularly when the pulmonary lesion was small (< 15 mm) or located at a greater distance from the pleural margin (> 45 mm) or close to critical structures.

In their article, Caparelli et al [Caparelli, 2015] retrieved evidence in terms of effectiveness from other comparative studies [Grasso, 2012; Grasso, 2013 (J Int CARS); Grasso, 2013 (Eur Radiol)], already cited. As far as safety issues, the first phase of technical evaluation consisted in analyzing device features that could affect patients' safety. SIRIO H3 did not show any important risks: it has been designed as aid for minimally invasive surgery, all used materials in the patient area are sterile, disposable and non-toxic, also not placed in contact with the damaged skin. Following the path shown on the screen, the operator can insert the needle into the chest and advance it to the target lesion with a maximum error of 1,5% for the ideal needle trajectory. Dangers associated with the use of SIRIO are few, due to the fact that is Class I medical device. On the whole, authors evaluate the risks associated to possible hazard situations as acceptable.

Potential benefits to patients

One of the most interesting aspects of the image-based navigation systems is the use of "augmented reality", a technique that allows to augment the real visual field of the physician, using information from a 3-dimensional virtual volume generated with the help of images previously acquired from the same patient. In this way, radiologists can choose the point of cutaneous insertion more easily and can rapidly identify the best trajectory to reach the lesion for biopsy, improving also patients' physical comfort during the procedure [Caparelli, 2015; Grasso, 2012]. The system automatically identifies the target and graphically traces the trajectory, extending the line on which the needle is localized in the virtual volume. [Grasso, 2012].This means the increase of both accuracy (especially for small lesions) [Hwang, 2018; Grasso 2012; Han, 2018; Faiella, 2018] and safety, as well as the reduction of absorbed ionizing radiation doses [Caparelli, 2015; Grasso, 2012]. This guiding system has the technical strength of providing real-time virtual navigation of biopsy needles based on volume CT data, allowing a flexible selection of the needle route under convenient operating conditions. This implies a significant protective factor for pneumothorax because it reduces unnecessary redirections [Fior, 2019]. Some highlighted also a reduction in complications rates [Faiella, 2018; Iannelli 2018] and a promising procedure in increasing the number of patients and nodules to be treated [Caparelli, 2015].

☐ Mortality reduction or increased survival	☑ Reduction of the morbidity	☐ Improved quality of life (patient/users)
☐ Improved patient monitoring	☐ Other: Reduction of the toxicity	☐ Not identified

Cost of the technology/procedure

Manufacturers have been contacted through an 'ad hoc' questionnaire sent by e-mail (March 2019). As already mentioned, the technology is used on patients who need to undergo a percutaneous CT guided procedure, for the diagnosis of a suspected lesion or the therapy of a tumor (ablation type), that is neoplastic patients who need to characterize the lesion and/or to treat it. The device is intended as assisted technology for biopsy procedures, particularly for pulmonary biopsies. As stated by the manufacturer, device cost (VAT excluded) is €139,000. According to manufactures, procedures carried out with SIRIO H3 are not reimbursed at national level and services are reimbursed according to non-specific DRG, chosen autonomously by each Region (for example, the remuneration for percutaneous lung biopsy procedure for each region can range from €250,00 to €775,00).
Electronic searches to find economic evaluations and cost analysis on SIRIO H3 were performed on bibliographic databases (PubMed, and Cochrane Library) in the period April-May 2020. As far as the economic aspects, totally the search yielded one paper, that is a preliminary HTA study on guidance system for interventional radiology [Caparelli, 2015]. Interventional radiologists using SIRIO H3 into clinical practice have been subjected to a questionnaire regarding the use of this technology, connected to the patient and also considering their workload. Authors concluded that the costs of the technology should be necessarily compared to the provided benefits if the device was covered by a public reimbursement policy [Caparelli, 2015]. However, it is worth pointing out that as literature is scarce in terms of economic evaluation studies, this lack of evidence is a relevant issue that cannot be neglected.

☑ Increased costs compared to alternative treatments	☐ Increased costs due to increased demand	☐ Increased costs due to the required investments
☐ New costs	☐Other: Reduction of costs linked to the reduction of re-intervention rate	☐ Not identified

Potential structural and organisational impact

Structural impact

No structural impact is needed for SIRIO H3.

☐ Increase in requirement of instruments	☐ Always be used	☐ Can be used only under specific circumstances
☐ Decrease in requirement of instruments	☑ Other: no structural impact	☐ Not identified

Organisational impact

Currently, SIRIO H3 is used by an interventional radiologist performing the procedure, a nurse handling sterile devices and a radiology technician performing patient CT scan according to a pre-set protocol. The manufacturer declared there are no studies investigating learning curve, anyway they registered directly from users a considerably reduction of operating times.

☐ Increase in the number of procedures	☐ Re-organisation required	☑ Training required for users
☐ Reduction in the number of procedures	☐ Other:	☐ Not identified

Conclusions

SIRIO H3 is meant for use for all those who have to undergo a biopsy or need drug/ablation therapy in a defined area. As reported by the authors, in the retrieved literature, the device appears to be a promising alternative to current practice. The available evidence (four comparative studies and two non-comparative studies) shows the increase of both accuracy (especially for small lesions) and safety, as well as the reduction of absorbed ionizing radiation doses, number of complications and procedural time. However, given that no randomized controlled trial is available at present and current evidence base is restricted to a few studies, further research is needed to assess the clinical properties of the device.

Future prospects

We are not aware of any further potential developments of SIRIO H3 technology. A similar system available on market is the CAS-ONE IR (CAScination AG). C-arm cone-beam computed tomography (CBCT) systems such as the AXIOM Artis dTA/VB30 (Siemens) and Allura Xper FD20 (Philips Healthcare) equipped with virtual guidance (iGuide, Siemens Medical Solutions; XperGuide, Philips Healthcare) are possible alternative solutions for percutaneous pulmonary biopsy [Kim, 2015].

Evidence searches

Searches of databases including (PubMed, Cochrane Library and ClinicalTrial.gov) in the period April-May 2020 using the following keywords:

PubMed

Search		Query	Items found
#6		Search ((((((((((((tomography OR x-ray OR spiral))) AND (computed))) OR ((CT OR (CT-guided) OR (computer assisted tomography) OR (Interventional radiology)))))) AND (((((((((percutaneous OR mininvasiv*))) OR (minimally invasive))) AND ((procedure OR access OR surgery)))) AND needle))))) AND (((Virtual OR (augmented reality))))) Filters: published in the last 10 years; Humans	43
#5	#3 AND #4	Search ((((((((((((tomography OR x-ray OR spiral))) AND (computed))) OR ((CT OR (CT-guided) OR (computer assisted tomography) OR (Interventional radiology)))))) AND (((((((((percutaneous OR mininvasiv*))) OR (minimally invasive))) AND ((procedure OR access OR surgery)))) AND needle))))) AND (((Virtual OR (augmented reality)))))	66
#4		Search ((Virtual OR (augmented reality)))	63874
#3	#2 AND #1	Search (((((((((tomography OR x-ray OR spiral))) AND (computed))) OR ((CT OR (CT-guided) OR (computer assisted tomography) OR (Interventional radiology)))))) AND (((((((((percutaneous OR mininvasiv*))) OR (minimally invasive))) AND ((procedure OR access OR surgery)))) AND needle)))	3633
#2		Search ((((((tomography OR x-ray OR spiral))) AND (computed))) OR ((CT OR (CT-guided) OR (computer assisted tomography) OR (Interventional radiology))))	839209
#1		Search ((((((((percutaneous OR mininvasiv*))) OR (minimally invasive))) AND ((procedure OR access OR surgery)))) AND needle)	12199

ClinicalTrials.gov.

No Studies found for: "SIRIO H3" OR "Masmec"

Cochrane Library

"virtual navigation system" or "augmented reality" in All Text AND needle in All Text - with Cochrane Library publication date Between Jan 2010 and Mar 2020 (Word variations have been searched)

Items found:
0 Cochrane Reviews matching
0 Cochrane Protocols matching
13 Trials matching
0 Editorials matching
0 Special collections matching
0 Clinical Answers matching

Appendix 1

List of included / excluded studies

Pubmed, Cochrane, Clinical trials	
Fior D, Vacirca F, Leni D, Pagni F, Ippolito D, Riva L, Sironi S, Corso R. Virtual Guidance of Percutaneous Transthoracic Needle Biopsy with C-Arm Cone-Beam CT: Diagnostic Accuracy, Risk Factors and Effective Radiation Dose. Cardiovasc Intervent Radiol. 2019 May;42(5):712-719. doi: 10.1007/s00270-019-02163-3. Epub 2019 Jan 16	Excluded: intervention does not include SIRIO H3
Iannelli G, Caivano R, Villonio A, Semeraro V, Lucarelli NM, Ganimede MP, Gisone V, Dinardo G, Bruno S, Macarini L, Guglielmi G, Cammarota A. Percutaneous Computed Tomography-Guided Lung Biopsies using a Virtual Navigation Guidance: Our Experience. Cancer Invest. 2018;36(6):349-355. doi: 10.1080/07357907.2018.1498877. Epub 2018 Aug 10.	Included
Hwang EJ, Kim H, Park CM, Yoon SH, Lim HJ, Goo JM. Cone beam computed tomography virtual navigation-guided transthoracic biopsy of small (≤ 1 cm) pulmonary nodules: impact of nodule visibility during real-time fluoroscopy. Br J Radiol. 2018 Jul;91(1087):20170805. doi: 10.1259/bjr.20170805. Epub 2018 Apr 10	Excluded: intervention does not include SIRIO H3
Han Y, Kim HJ, Kong KA, Kim SJ, Lee SH, Ryu YJ, Lee JH, Kim Y, Shim SS, Chang JH. Diagnosis of small pulmonary lesions by transbronchial lung biopsy with radial endobronchial ultrasound and virtual bronchoscopic navigation versus CT-guided transthoracic needle biopsy: A systematic review and meta-analysis. PLoS One. 2018 Jan 22;13(1):e0191590. doi: 10.1371/journal.pone.0191590. eCollection 2018	Excluded: intervention is not virtual navigation
Faiella E, Frauenfelder G, Santucci D, Luppi G, Schena E, Beomonte Zobel B, Grasso RF. Percutaneous low-dose CT-guided lung biopsy with an augmented reality navigation system: validation of the technique on 496 suspected lesions. Clin Imaging. 2018 May - Jun; 49:101-105. doi: 10.1016/j.clinimag.2017.11.013. Epub 2017 Dec 5.	Included
Kim H, Park CM, Lee SM, Goo JM. C-Arm Cone-Beam CT Virtual Navigation-Guided Percutaneous Mediastinal Mass Biopsy: Diagnostic Accuracy and Complications. Eur Radiol. 2015 Dec;25(12):3508-17. doi: 10.1007/s00330-015-3762-8. Epub 2015 Apr 28.	Excluded: intervention does not include SIRIO H3
Mastmeyer A, Hecht T, Fortmeier D, Handels H. Ray-casting based evaluation framework for haptic force feedback during percutaneous transhepatic catheter drainage punctures. Int J Comput Assist Radiol Surg. 2014 May; 9:421-31. doi: 10.1007/s11548-013-0959-7. Epub 2013 Nov 27.	Excluded: not pertinent
Grasso RF, Luppi G, Cazzato RL, Faiella E, D'Agostino F, Beomonte Zobel D, De Lena M. Percutaneous computed tomography-guided lung biopsies: preliminary results using	Included

an augmented reality navigation system. Tumori. 2012 Nov;98:775-82. doi: 10.1700/1217.13503.	
Choo JY, Park CM, Lee NK, Lee SM, Lee HJ, Goo JM. Percutaneous transthoracic needle biopsy of small (≤ 1 cm) lung nodules under C-arm cone-beam CT virtual navigation guidance. . Eur Radiol. 2013 Mar;23:712-9. doi: 10.1007/s00330-012-2644-6. Epub 2012 Sep 14.	Excluded: intervention does not include SIRIO H3
Other sources	
Caparelli C, Carpino G, Brunetti G, Larizza P, Guglielmelli E. A preliminary health technology assessment of a guidance system for interventional radiology. Conf Proc IEEE Eng Med Biol Soc. 2015;2015:450-453. doi:10.1109/EMBC.2015.7318396	Included
Grasso R F, Faiella E, Luppi G, Schena E, Giurazza F, Del Vecchio R, D'Agostino F, Cazzato RL, Zobel BB, "Percutaneous lung biopsy: comparison between an augmented reality CT navigation system and standard CT-guided technique", International Journal of Computer Assisted Radiology and Surgery, 2013, 1-12	Included
Grasso RF, Cazzato RL, Luppi G, et al. Percutaneous lung biopsies: performance of an optical CT-based navigation system with a low-dose protocol. Eur Radiol. 2013;23(11):3071-3076. doi:10.1007/s00330-013-2932-9	Included

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Agenas, Manuale delle procedure HTA, http://www.agenas.it/images/agenas/hta/Manuale_delle_procedure_HTA_def_20.9.2018_full.pdf , last access 24/06/2019

Agenas, Piano triennale per la prevenzione della corruzione e la trasparenza, http://www.agenas.it/images/agenas/trasparenza/piano_corruzione_trasparenza/PTPCT_2019-2021_def.pdf, last access 24/06/2019

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Glossary

BD/RDM: Italian Medical device database (http://www.salute.gov.it/dispositivi/paginainternasf.jsp?id=499&menu=repertorio).

CND: Italian medical devices classification (Classificazione Nazionale dei Dispositivi Medici)

CT: Computed Tomography

FDA: Food and Drug Administration

MRI: Magnetic Resonance Imaging