Basic diagnostic requirements for the results of AI service operation

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Content

Stages of introduction of Experiment directions in 2023: COMPUTED TOMOGRAPHY

№	Modality	Field of study	Service type	Target pathology	Quarter of the introduction of directions 2023
-	CT	Chest	Comprehensive	7+ pathologies (obligatory)	1
-		Chest	Comprehensive	9+ pathologies (7 obligatory + 2 optional)	4
1		Chest (obligatory)	Non-comprehensive	Impairment of lung airness	3
			Non-comprehensive	Covid-19	only in 1-2 quarters
2			Non-comprehensive	Lung cancer	1
3			Non-comprehensive	Osteoporosis	1
4			Non-comprehensive	Hydrothorax	1
5			Non-comprehensive	Coronary calcium	1
6			Non-comprehensive	Thoracic aorta diameter	1
7			Non-comprehensive	Pulmonary trunk diameter	1
8		Chest (optional)	Non-comprehensive	Lymph nodes	1
9			Non-comprehensive	Pulmonary emphysema	1
10			Non-comprehensive	Tuberculosis	1
11			Non-comprehensive	Sarcoidosis	1
12			Non-comprehensive	Bronchiectatic disease	1
13			Non-comprehensive	Paracardial fat	1
14			Non-comprehensive	Rib/s fracture	1
15			Non-comprehensive	Focal changes in the structure of chest bones	1
16			Non-comprehensive	Adrenal gland lesions	1

Stages of introduction of Experiment directions in 2023: COMPUTED TOMOGRAPHY

№	Modality	Field of study	Service type	Target pathology	Quarter of the introduction of directions 2023
-	CT	Brain	Comprehensive	Strokes (Intracranial hemorrhage +Ischemic stroke)	4
17			Non-comprehensive	Intracranial hemorrhage	1
			Non-comprehensive	Ischemic stroke	1
18			Non-comprehensive	Automated routine measurement of brain structures	3
-		Abdomen	Comprehensive	6+ pathologies (obligatory)	3
19		Abdomen (obligatory)	Non-comprehensive	Urolithiasis	1
20			Non-comprehensive	Adrenal gland lesions	1
21			Non-comprehensive	Liver lesions	1
22			Non-comprehensive	Renal lesions	1
23			Non-comprehensive	Osteoporosis	1
24			Non-comprehensive	Abdominal aortic aneurysm	1
25		Abdomen (optional)	Non-comprehensive	Focal changes in the structure of abdominal and pelvic bones	3
26			Non-comprehensive	Automated routine kidney measurement	3
27			Non-comprehensive	Automated routine liver measurement	3
28			Non-comprehensive	Automated routine measurement of pancreas and spleen	3
29			Non-comprehensive	Gallstone disease	3

Stages of introduction of Experiment directions in 2023: X-RAY / FLUOROGRAPHY

№	Modality	Field of study	Service type	Target pathology	Quarter of the introduction of directions 2023
30	Fluorography	Chest	Comprehensive (BDR as for mono-service)	pleural effusion, pneumothorax, focal pulmonary opacity, infiltration/consolidation, dissemination, cavity, atelectasis, calcification/calcified pulmonary shadow, mediastinal widening, cardiomegaly, cortical bone fracture, consolidated fracture	1
31	X-ray	Chest	Comprehensive (BDR as for mono-service)	pleural effusion, pneumothorax, focal pulmonary opacity, infiltration/consolidation, dissemination, cavity, atelectasis, calcification/calcified lung shadow, mediastinal widening, cardiomegaly, cortical bone fracture, consolidated fracture	1*

*only in the first and second quarters

Stages of introduction of Experiment directions in 2023: X-RAY / FLUOROGRAPHY

№	Modality	Field of study	Service type	Target pathology	Quarter of the introduction of directions 2023
-	X-ray	Chest	Comprehensive	pulmonary tuberculosis, pneumonia, purulent-necrotic diseases, lung masses, pleural effusion, pneumothorax, atelectasis, mediastinal pathology, cardiomegaly, rib/s fracture.	3

Stages of introduction of Experiment directions in 2023: X-RAY

№	Modality	Field of study	Service type	Target pathology	Quarter of the introduction of directions 2023
32	X-ray	Wrist joint	Non-comprehensive	Fracture	1
33		Shoulder joint	Non-comprehensive	Fracture	1
34		Hip joint	Non-comprehensive	Arthrosis	1
35				Fracture	1
36		Knee joint	Non-comprehensive	Arthrosis	1
37		Ankle joint	Non-comprehensive	Fracture	1
38		Foot	Non-comprehensive	Transverse flat feet	2
39			Non-comprehensive	Longitudinal flat feet	1
-			Comprehensive	Longitudinal and transverse flat feet	3
40		Head	Non-comprehensive	Sinusitis	1
41		Spine	Non-comprehensive	Vertebral fractures	1
42			Non-comprehensive	Osteochondrosis	1
43			Non-comprehensive	Scoliosis	1
44			Non-comprehensive	Spondylolisthesis	1

Stages of introduction of Experiment directions in 2023: MAMMOGRAPHY, MAGNETIC RESONANCE IMAGING

№	Modality	Field of study	Service type	Target pathology	Quarter of the introduction of directions 2023
45	MMG	Breast	Non-comprehensive	Breast cancer	1
46	MRI	Brain	Non-comprehensive	Multiple sclerosis	1
47			Non-comprehensive	Intracranial neoplasms	1
48			Non-comprehensive	Automated routine measurement of brain structures	4
49	MRI	Cervical spine	Non-comprehensive	Focal changes in the bone structure of the vertebrae	4
50			Non-comprehensive	Protrusions and hernias of the intervertebral discs, spinal canal stenosis	4
51		Thoracic spine	Non-comprehensive	Focal changes in the bone structure of the vertebrae	4
52			Non-comprehensive	Protrusions and hernias of the intervertebral discs, spinal canal stenosis	4
53		Lumbosacral spine	Non-comprehensive	Focal changes in the bone structure of the vertebrae	4
54			Non-comprehensive	Protrusions and hernias of the intervertebral discs, spinal canal stenosis	1
55		Pelvic organs	Non-comprehensive	Rectal cancer	4
56			Non-comprehensive	Automated routine measurement of the uterus	4
57			Non-comprehensive	Automated routine measurement of the prostate gland	4
58		Knee joint	Non-comprehensive	Articular cartilage damage (chondromalacia)	4

Baseline diagnostic requirements for AI service results to identify lung lesions consistent with COVID-19 on CT scan

Diagnostic study	Clinical task being performed by AI service	Preliminary phase (retrospective study) – signs of studies of the calibration dataset	Main phase (prospective study) – signs for which positive and negative results of the AI service are expected	Content of the AI service response	AI service response format	A form of the AI-service response provision
Chest computed tomography	Detection of computed tomography signs consistent with coronavirus infection (COVID-19)	**Signs of pathology are present:** A*. 1. Bilateral ground glass opacities of pulmonary parenchyma, mainly peripheral distribution with or without consolidation and the air bronchogram sign. 2. Bilateral pulmonary infiltration of “crazy paving” type (ground-glass opacities with superimposed interlobular septal thickening), mainly peripheral distribution, with or without consolidation and the air bronchogram sign. B. (for the preliminary phase only) 1. Positive results of RT-PCR test for COVID-19. 2. Established diagnosis of U07.1 (Coronavirus infection (COVID-19), virus identified). One sign suffices to classify a study as a pathology. * On native images		**Obligatory** – probability of COVID-19 lung involvement (signs from the A-list)	Number	Apache Kafka Message
				Obligatory – grading the severity of lung involvement according to the CT 0-4 classification including a probability of falling into each category	Number CT-0 – probability CT-1 – probability CT-2 – probability CT-3 – probability CT-4 – probability	Apache Kafka Message + DICOM SR
				Obligatory – parenchymal damage (%) for each lung separately	Number	Apache Kafka Message + DICOM SR
		Signs of pathology are absent: none of the radiologic signs from the A-list		**Obligatory** – localization of detected pathological findings	Contour/ mask	DICOM

SOURCES:
1. Radiological diagnosis of the coronavirus infection (COVID-19): organization, methodology, results' interpretation - guidelines S.P. Morozov, N. Protsenko, S.Smetanina [et al.] //Series "Best practices of radiology and instrumental diagnostics" – Issue 65. – M. : Center for Diagnostics and Telemedicine of the Moscow Healthcare Department, 2020. – 80 p. – URL: https://tele-med.ai/documents/500/19_ЛУЧЕВАЯ__ДИАГНОСТИКА__КОРОНАВИРУСНОЙ__БОЛЕЗНИ.pdf (дата обращения : 24.05.2021).
2. The Ministry of Health of the Russian Federation. Interim guidelines. Prevention, diagnostics and treatment of the new coronavirus infection (COVID-19). Version 15 (22.02.2022)

Baseline diagnostic requirements for AI service results to identify pulmonary emphysema on CT scan

Diagnostic study	Clinical task being performed by AI service	Preliminary phase (retrospective study) – signs of studies of the calibration dataset	Main phase (prospective study) – signs for which positive and negative results of the AI service are expected	Content of the AI service response	AI service response format	A form of the AI-service response provision
Chest computed tomography	Detection of emphysematous lung changes	**Signs of pathology are present:** presence of ≥ 6 % (in both lungs) of voxels* with CT density ≤-950 HU (emphysematous changes) on native images.		**Obligatory** – probability of emphysema	Number	Apache Kafka Message
				Obligatory – emphysematous lesions (%) in both lungs	Number	Apache Kafka Message + DICOM/DICOM SR
				Obligatory – emphysematous lesions (%) separately for each lung	Number	Apache Kafka Message + DICOM/DICOM SR
		Signs of pathology are absent: less than 6% of emphysematous changes (in both lungs) on native images.		**Obligatory** – localization of detected signs	Contour/ mask	DICOM

* Without including bronchial lumen voxels

SOURCES:

1. Lynch, D.A., Austin, J.H., Hogg, J.C., Grenier, P.A., Kauczor, H.U., Bankier, A.A., Barr, R.G., Colby, T.V., Galvin, J.R., Gevenois, P.A. and Coxson, H.O., 2015. CT-definable subtypes of chronic obstructive pulmonary disease: a statement of the Fleischner Society. Radiology, 277(1), p.192
2. Hersh, C.P., Washko, G.R., Estépar, R.S.J., Lutz, S., Friedman, P.J., Han, M.K., Hokanson, J.E., Judy, P.F., Lynch, D.A., Make, B.J. and Marchetti, N., 2013. Paired inspiratory-expiratory chest CT scans to assess for small airways disease in COPD. Respiratory research, 14(1), pp.1-11

Baseline diagnostic requirements for AI service results to identify signs of malignant lung neoplasms on CT scan

Diagnostic study	Clinical task being performed by AI service	Preliminary phase (retrospective study) – signs of studies of the calibration dataset	Main phase (prospective study) – signs for which positive and negative results of the AI service are expected	Content of the AI service response	AI service response format	A form of the AI-service response provision
Chest computed tomography	Detection of CT signs consistent with malignant lung neoplasm	**Signs of pathology are present:** A. 1. At least one solid or subsolid nodule (only a solid component is measured) whose average size* ≥ 6 mm (volume ≥ 100 mm^3) in native images. B. (for the preliminary phase only) 1. Results of pathomorphological examination – a malignant neoplasm. One sign suffices to classify a study as a pathology.		**Obligatory** – probability of the signs of a malignant neoplasm in the entire study	Number	Apache Kafka Message
				Obligatory – mean size (mm) of each** pulmonary nodule	Text	Apache Kafka Message + DICOM SR
				Obligatory – volume (mm^3) of each** pulmonary nodule	Text	Apache Kafka Message + DICOM SR
		Signs of pathology are absent: not a single nodule meets the requirements.		**Obligatory** – localization of detected nodules	Contour/ mask	DICOM

* The average size is the arithmetic mean of the measurements taken along long- and perpendicular short-axis, rounded to the nearest integer number

** If there are up to and including 4 nodules in the study, whose average size is ≥ 6 mm, each of them should be measured; if there are 5 or more nodules with the average size ≥ 6 mm, only the largest should be measured

SOURCES:

1. Guidelines for lung cancer screening/ V. Gombolevsky, I. Blokhin, A. Laipan [et al.] //Series “Best practices of radiology and instrumental diagnostics” –1 . Issue 56. M. Center for Diagnostics and Telemedicine of the Moscow Healthcare Department, 2020. – 60 p. – URL: https://tele-med.ai/biblioteka-dokumentov/metodicheskie-rekomendacii-po-skriningu-raka-legkogo (24.05.2021).
2. MacMahon H., Naidich D.P., Goo J.M. et al. Guidelines for Management of Incidental Pulmonary Nodules Detected on CT Images: From the Fleischner Society 2017 // Radiology. – 2017. – Jul. – Vol. 284, №1. – P. 228–243. – DOI: 10.1148/radiol.2017161659.
3. Clinical recommendations of the Ministry of Health of the Russian Federation "Malignant neoplasm of the bronchi and lung". – M., 2021. ID 30. – URL: https://cr.minzdrav.gov.ru/recomend/30 (accessed on : 15.06.2021).
4. R. Peters , M. Heuvelmans , S. Brinkhof , P.V. Ooijen , M. Oudkerk , P. de Jong , R. Vliegenthart , et al. , Prevalence of pulmonary multi-nodularity in CT lung cancer screening, European Congress of Radiology, 2015

Baseline diagnostic requirements for AI service results to identify signs of malignant lung neoplasms on LDCT scan

Diagnostic study	Clinical task being performed by AI service	Preliminary phase (retrospective study) – signs of studies of the calibration dataset	Main phase (prospective study) – signs for which positive and negative results of the AI service are expected	Content of the AI service response	AI service response format	A form of the AI-service response provision
Chest low-dose computed tomography	Detection of CT signs consistent with malignant lung neoplasm	**Signs of pathology are present:** 1. At least one solid or subsolid nodule (only a solid component is measured) whose average size* ≥ 6 mm (volume ≥ 100 mm^3) in native images. 2. At least one nodule of ground glass opacity of the average size* ≥ 30 mm (volume ≥ 14,137 mm^3) in native images. 3. Results of pathomorphological examination – a malignant neoplasm. One sign suffices to classify a study as a pathology.		**Obligatory** – probability of the signs of a malignant neoplasm in the entire study	Number	Apache Kafka Message
				Obligatory – localization of detected nodules	Contour/ mask	DICOM
				Obligatory – volume of each** pulmonary nodule (mm^3)	Text	Apache Kafka Message + DICOM SR
				Obligatory – mean size (mm) of each** pulmonary nodule	Text	Apache Kafka Message + DICOM SR
		Signs of pathology are absent: not a single nodule meets the requirements.		**Obligatory** – classification of lung nodules according to the Lung-RADS system (v.1.1)	Text Lung RADS 0 - probability (number) Lung RADS 1 - probability (number) Lung RADS 2 - probability (number) Lung RADS 3 - probability (number) Lung RADS 4A - probability (number) Lung RADS 4B - probability (number)	Apache Kafka Message + DICOM SR

NOTE:

* The average size is the arithmetic mean of the measurements taken along long- and perpendicular short-axis, rounded to one value after the decimal point

** If there are up to and including 4 nodules in the study, whose average size is ≥ 6 mm, each of them should be measured; if there are 5 or more nodules with the average size ≥ 6 mm, only the largest one should be measured

SOURCES: 1. Application of the Lung-RADS system in lung cancer screening (an adapted version of the classification system of the American Radiological Society for the description, processing, and standardization of data on the chest low-dose computed tomography): methodological recommendations / comp. A. E. Nikolaev, A. P. Gonchar, A. N. Shapiev [et al.] // https://tele-med.ai/biblioteka-dokumentov/primenenie-sistemy-lung-rads-v-skrininge-raka-legkogo-adaptirovannaya-versiya-klassifikacionnoj-sistemy-amerikanskogo-radiologicheskogo-obshestva-dlya-opisaniya-obrabotki-i-standartizacii-dannyh-pri-nizkodoznoj-kompyuternoj-tomografii-organov-grudnoj-klet

2. R. Peters , M. Heuvelmans , S. Brinkhof , P.V. Ooijen , M. Oudkerk , P. de Jong , R. Vliegenthart , et al. , Prevalence of pulmonary multi-nodularity in CT lung cancer screening, European Congress of Radiology, 2015 https://epos.myesr.org/poster/esr/ecr2015/C-0573

Baseline diagnostic requirements for AI service results to identify free fluid (effusion) in the pleural cavity on CT scan

Diagnostic study	Clinical task being performed by AI service	Preliminary phase (retrospective study) – signs of studies of the calibration dataset	Main phase (prospective study) – signs for which positive and negative results of the AI service are expected	Content of the AI service response	AI service response format	A form of the AI-service response provision
Chest computed tomography	Detection of hydrothorax (pleural effusion) in the pleural cavities	**Signs of target pathology are present:** A. 1. There is a crescent-shaped accumulation of fluid (effusion) with a density of 0–30 HU in the pleural cavity in the gravity-dependent parts of the chest on native images B. (for the preliminary phase only) 1. Diagnosis verification with a pleural puncture 2. Assigned ICD code - J90. One sign suffices to classify a study as a pathology.		**Obligatory** – probability of pleural effusion	Number	Apache Kafka Message
				Obligatory – volume of the pleural effusion (ml) for each lung	Number	Apache Kafka Message + DICOM/DICOM SR
		Signs of pathology are absent: none of the radiologic signs from the A-list.		**Obligatory** – mean pleural effusion density (HU) for each lung	Number	Apache Kafka Message + DICOM/DICOM SR
				Obligatory – localization of detected pathological findings	Contour/ mask	DICOM

SOURCES :

1. Muller's Imaging of the Chest E-Book: Expert Radiology Series, authors: Christopher Walker, Jonathan Hero Chung, p. 964
2. Pleural effusion Lung lesions: MSD manual. Version for professionals. – URL: : msdmanuals.com.
3. Pleural effusion: Radiology Reference Article. – URL: Radiopaedia.org
4. Liu, F., Huang, Y.C., Ng, Y.B. and Liang, J.H., 2016. Differentiate pleural effusion from hemothorax after blunt chest trauma; comparison of computed tomography attenuation values. Journal of Acute Medicine, 6(1), pp.1-6.

Baseline diagnostic requirements for AI service results to identify thoracic lymph nodes on CT scan

Diagnostic study	Clinical task being performed by AI service	Preliminary phase (retrospective study) – signs of studies of the calibration dataset	Main phase (prospective study) – signs for which positive and negative results of the AI service are expected	Content of the AI service response	AI service response format	A form of the AI-service response provision
Chest computed tomography	Detection of enlarged lymph nodes (lymphadenopathy)	**Signs of target pathology are present:** presence of thoracic lymph nodes including conglomerates measuring ≥ 10 mm along the short axis on native images.		**Obligatory –** probability of enlarged lymph nodes	Number	Apache Kafka Message
				Obligatory – size of the largest lymph node (mm)	Number	Apache Kafka Message + DICOM SR
				Obligatory – localization of detected lymph nodes	Contour/ mask	DICOM
		Signs of pathology are absent: absence of thoracic lymph nodes measuring ≥ 10 mm along the short axis in native images.		**Optional** – presence of calcified thoracic lymph nodes	Text (present/ absent)	Apache Kafka Message + DICOM SR
				Optional – classification of lymph nodes as per IASLC	Text	Apache Kafka Message + DICOM SR

SOURCES:
1. . Classification of regional mediastinal lymph nodes according to the International Association for the Study of Lung Cancer (IASLC): reference guidelines. M. Suchilova, A. Nikolayev, M. Suleimanova [et al.] //Series "Best practices of radiology and instrumental diagnostics" – Issue 64. – M.: Center for Diagnostics and Telemedicine of the Moscow Healthcare Department, 2020. – 30 p.
2. Mediastinal lymph node enlargement. – URL: https://radiopaedia.org/articles/mediastinal-lymph-node-enlargement?lang=us

Baseline diagnostic requirements for AI service results to identify pulmonary tuberculosis on CT scan

Diagnostic study	Clinical task being performed by AI service	Preliminary phase (retrospective study) – signs of studies of the calibration dataset	Main phase (prospective study) – signs for which positive and negative results of the AI service are expected	Content of the AI service response	AI service response format	A form of the AI-service response provision
Chest computed tomography	Detection of CT signs consistent with pulmonary tuberculosis	**Signs of target pathology are present:** A. 1. Focal lesions (groups of foci localized in one or both lungs limited by 1-2 segments; dissemination – lesions affected four or more segments in both lungs, mainly symmetrical). 2. Infiltration of the lung parenchyma is commonly localized in the peripheral parts of lungs and subpleural regions (acinar, lobular and lobar). 3. Air cavity (dilated bronchial lumen, destruction, cavern – can be either single or multiple). 4. A rounded formation, more often located in the cortical parts of the upper lung lobes, larger than 10 mm, mainly perifocal, containing calcifications, isolated foci and local fibrosis. 5. Volume reduction of a segment or lobe due to pronounced fibrosis or pulmonary cirrhosis in combination with connivent lumens of deformed segmental and subsegmental bronchi. 6. Mainly unilateral enlargement of the intrathoracic lymph nodes (commonly affected tracheobronchial and bronchopulmonary lymph nodes with possible merge in the conglomerates). 7. Pleural effusion, possibly in combination with air in the pleural cavity (mostly in young age). 8. Calcifications in the intrapulmonary lymph nodes, commonly in combination with calcifications in the lung tissue. B. (for the preliminary phase only) 1. Positive laboratory test for mycobacterium tuberculosis in the sputum (AFB+, MBT+) 2. Positive T-SPOT, Diaskintest or Mantoux test. 3. Established diagnosis (A-15, A-19, B-20, B-90). Possibly, a combination of several signs in the study		**Obligatory** – probability of tuberculosis	Number	Apache Kafka Message
				Obligatory – localization of detected pathological findings	Contour	DICOM
		Signs of pathology are absent: none of the signs from the A-list				

SOURCES :

1. Guide to diagnostic radiology of the chest organs/ G. Trufanova, G. Mitusova, A. Grishchenkova
2. "Phthisiology" National guideline /Edited by Acad. of RAMS M. Perelman
3. Spiral and multilayer computed tomography, Volume II /Mathias Prokop, Michael Galanski

Baseline diagnostic requirements for AI service results to identify sarcoidosis on CT scan

Diagnostic study	Clinical task being performed by AI service	Preliminary phase (retrospective study) – signs of studies of the calibration dataset	Main phase (prospective study) – signs for which positive and negative results of the AI service are expected	Content of the AI service response	AI service response format	A form of the AI-service response provision
Chest computed tomography	Detection of CT signs consistent with sarcoidosis	**Signs of target pathology are present:** A. Presence on native images: 1. Focal lesion (symmetric lymphatic dissemination invading four or more segments in both lungs, mainly the perihilar and middle areas), usually larger than 1-6 mm. 2. Interstitial changes – thickening of the central interstitium, often with peribronchovascular "muffs", and peripheral interstitium (interlobular and intralobular). 3. Symmetrical enlargement of the intrathoracic lymph nodes, more often in the right tracheobronchial and bronchopulmonary groups, rarely merging into the conglomerates. 4. Calcified chest lymph nodes Calcification of VGLU in the form of "shells" and "clumps". 5. Predominantly peribronchovascular lung fibrosis (sometimes developing sarcoids – thick fibrous changes in the perihilar areas), rarely accompanied with "honeycomb lung". B. (for the preliminary phase only) Histological verification		**Obligatory** – probability of sarcoidosis	Number	Apache Kafka Message
				Obligatory – localization of detected pathological findings	Contour/ mask	DICOM
		Signs of pathology are absent: none of the signs from A-list		**Obligatory** – classification of the found pathological changes according to the disease stages (I, II, III and IV)	Text	Apache Kafka Message + DICOM/DICOM SR

SOURCES :

1. Guide to diagnostic radiology of the chest organs/ G. Trufanova, G. Mitusova, A. Grishchenkova – СПб.: Медкнига «ЭЛБИ-СПб», 2013. – 400 с.
2. Spiral and multilayer computed tomography, Volume II /Mathias Prokop, Michael Galanski, Vol. II. M., 2011. – 712 p.
3. V. Amosov, A. Speranskaya. Radiation diagnosis of interstitial lung diseases. St.P: Medkniga "ELBI-SPB", 2015. – 176 p
4. I. Sokolina. Computed tomography in the diagnosis of pulmonary sarcoidosis: dissertation abstract for PhD, M., 2005
5. Sarcoidosis. CT diagnosis and differential diagnosis of sarcoidosis. – URL: https://radiomed.ru/impress/sarkoidoz-kt-diagnostika-i-differencialnaya-diagnostika-sarkoidoza-pr

Baseline diagnostic requirements for AI service results to identify bronchiectasis on CT scan (up to 4Q2023)

Diagnostic study	Clinical task being performed by AI service	Preliminary phase (retrospective study) – signs of studies of the calibration dataset	Main phase (prospective study) – signs for which positive and negative results of the AI service are expected	Content of the AI service response	AI service response format	A form of the AI-service response provision
Chest computed tomography	Detection of bronchiectasis	**Signs of target pathology are present:** A. 1. Presence of a bronchus dilatation in native images B. (for the preliminary phase only) 1. Diagnosis verification with bronchoscopy. 2. Established ICD-10 diagnosis of J47. One sign suffices to classify a study as a pathology		**Obligatory –** probability of bronchiectasis	Number	Apache Kafka Message
				Optional – bronchoarterial ratio	Number	Apache Kafka Message + DICOM SR
		Signs of target pathology are absent: none of the signs from the A-list.		**Obligatory –** localization of bronchiectasis	Contour/ mask	DICOM

SOURCES:

1. Bronchiectasis. Lung lesions: MSD manual. Version for professionals. – URL: msdmanuals.com.
2. Bronchiectasis. Radiology Reference Article. – URL: Radiopaedia.org.

Baseline diagnostic requirements for AI service results to identify bronchiectasis on CT scan (starting 4Q2023)

Diagnostic study	Clinical task being performed by AI service	Preliminary phase (retrospective study) – signs of studies of the calibration dataset	Main phase (prospective study) – signs for which positive and negative results of the AI service are expected	Content of the AI service response	AI service response format	A form of the AI-service response provision
Chest computed tomography	Detection of bronchiectasis	**Signs of target pathology are present:** A. 1. Presence of a bronchus dilatation, whose diameter ≥1.5 times exceeds the diameter of the nearby artery (bronchiectasis) in native images. 2. Presence of a bronchus dilatation while the nearby artery is undetectable in native images. B. (for the preliminary phase only) 1. Diagnosis verification with bronchoscopy. 2. Established ICD-10 diagnosis of J47. One sign suffices to classify a study as a pathology		**Obligatory –** probability of bronchiectasis	Number	Apache Kafka Message
				Obligatory – bronchoarterial ratio for item 1 of the A-list	Number	Apache Kafka Message + DICOM SR
				Optional – bronchoarterial ratio for item 2 of the A-list		
		Signs of target pathology are absent: none of the signs from the A-list.		**Obligatory** – localization of bronchiectasis	Contour/ mask	DICOM

SOURCES:

1. Bronchiectasis. Lung lesions: MSD manual. Version for professionals. – URL: msdmanuals.com.
2. Bronchiectasis. Radiology Reference Article. – URL: Radiopaedia.org.

Baseline diagnostic requirements for AI service results to identify compression vertebral fractures on CT scan

Diagnostic study	Clinical task being performed by AI service	Preliminary phase (retrospective study) – signs of studies of the calibration dataset	Main phase (prospective study) – signs for which positive and negative results of the AI service are expected	Content of the AI service response	AI service response format	A form of the AI-service response provision
Chest computed tomography	Detection and localization of compression vertebral fractures with compression degree more than 25% according to the Genant semi-quantitative grading (grades 2-3)	**Signs of target pathology are present:** 1. A presence of vertebrae with compressive deformation of the bodies ≥ 25% in native images, according to the Genant semi-quantitative classification grade 2–3. A deformity degree is calculated using the following formula: *Deformity degree = (maximal vertebra size – minimal vertebra size)/maximal vertebra size*100 % (equation 1).* 2. Reduction in bone mineral density in Th11–L3 vertebral bodies (ideally L1–L2) in native images according to ACR 2018, ISCD 2019 criteria.		**Obligatory** – probability of at least one vertebra with a deformity degree ≥ 25 %	Number	Apache Kafka Message
				Obligatory – labelling (numbering) all vertebrae with a height loss of ≥ 25%	Text	DICOM
				Obligatory – graphical display of the vertebrae height in the anterior, middle or posterior parts (contour) for all analysed vertebrae	Contour	DICOM
				Obligatory – numerical value of the deformity degree in % (for all vertebrae with height loss of ≥ 25%), indicating the Genant score		
		Signs of target pathology are absent: 1. The vertebra bodies in native images in the presented study have a deformity degree less than 25% according to the equation (1). 2. Bone mineral density in the vertebral bodies in native images is within the normal range.		**Optional** – measurement of the mineral density (or HU) of the cancellous bone of Th12–L3 vertebral bodies indicating a number of the vertebra. Mineral bone density (or HU) is not measured for vertebrae with compression degree more than 25%. Indicate when osteoporosis is suspected, according to ACR 2018, ISCD 2019 criteria	Text	Apache Kafka Message +DICOM + DICOM SR
					Text	DICOM + DICOM SR

SOURCES: 1. Federal clinical recommendations on diagnosis, treatment and prevention of osteoporosis / G. Melnichenko, Zh. Belaya, L. Rozhinskaya [et al.] // Problems of Endocrinology. – 2017. – Vol. 63, №6. P. 392–426. – URL: https://www.probl-endojournals.ru/jour/article/view/8757 (accessed on: 24.05.2021). 2. ISCD [electronic resource] : Official Positions. 2019. – URL: https://iscd.org/learn/official-positions/ (accessed on: 24.05.2021). 3. ACR [electronic resource] : ACR–SPR–SSR Practice Parameter for the Performance of Musculoskeletal Quantitative Computed Tomography (QCT), 2018. – URL: https://www.acr.org/-/media/ACR/Files/Practice-Parameters/QCT.pdf?la=en (accessed on : 24.05.2021). 4. Genant H. K., Jergas M. Assessment of prevalent and incident vertebral fractures in osteoporosis research // Osteoporosis Int. – 2003. – Vol. 14, №3. – P. 43–55. – URL: https://doi.org/10.1007/S00198-002-1348-1. 5. Clinical guidelines of the Ministry of Health of the Russian Federation "Pathological fractures complicating osteoporosis". – M., 2018. ID 614. – URL: https://cr.minzdrav.gov.ru/schema/614_1 (accessed on : 15.06.2021).

Baseline diagnostic requirements for AI service results to identify signs of coronary artery disease (coronary calcium score) on CT and LDCT scans

Diagnostic study	Clinical task being performed by AI service	Preliminary phase (retrospective study) – signs of studies of the calibration dataset	Main phase (prospective study) – signs for which positive and negative results of the AI service are expected	Content of the AI service response	AI service response format	A form of the AI-service response provision
Chest computed tomography	Detection of coronary calcium	**Signs of target pathology are present:** Calcium score/Agatston score (a sum of the areas in the projection of the coronary arteries, multiplied by the individual density factors*) ≥ 1 in native images, or CAC-DRS A1 – A3 category *Factor 1: 130-199 HU, factor 2: 200-299 HU, factor 3: 300-399 HU, factor 4: ≥400 HU		**Obligatory** – probability of the coronary calcium presence	Number	Apache Kafka Message
				Obligatory – Agatstone score	Number	Apache Kafka Message + DICOM SR
				Obligatory – CAC-DRS category depending on the intensity of coronary calcium indicating the probability (%) of falling into each category	Text CAC-DRS A0 – probability (number) CAC-DRS A1 – probability (number) CAC-DRS A2 – probability (number) CAC-DRS A3 – probability (number)	Apache Kafka Message + DICOM SR
		Signs of target pathology are absent: absence of calcifications in the projection of coronary arteries in native images (total Agatston score = 0 or CAC-DRS A0 CAC-DRS A1 – A3 category)		**Obligatory** – localization of detected signs	Contour/mask	DICOM
				Optional – localization of findings with indication of the amount of coronary calcium in the walls of the main arteries.	Text, number	Apache Kafka Message + DICOM SR

SOURCES :

1. Agatston A. S., Janowitz W. R., Hildner F. J. et al. Quantification of coronary artery calcium using ultrafast computed tomography // J Am Coll Cardiol. –1990. – Mar 15. – Vol. 15, №4. – P. 827–832. – DOI: 10.1016/0735-1097(90)90282-t. PMID: 2407762.
2. K. Zhuravlev CT coronary angiography //Series "Best practices of radiology and instrumental diagnostics" – Issue 45. – M.: Center for Diagnostics and Telemedicine of the Moscow Healthcare Department, 2020. – 36 c. – URL: https://tele-med.ai/documents/274/1_kt-koronarografiya.pdf ((accessed on : 24.05.2021).
3. Clinical guidelines of the Ministry of Health of the Russian Federation "Stable coronary heart disease". – M., 2020. – ID 155. – URL: https://cr.minzdrav.gov.ru/recomend/155 (accessed on: 15.06.2021).
4. Hecht, H.S., Blaha, M.J., Kazerooni, E.A., Cury, R.C., Budoff, M., Leipsic, J. and Shaw, L., 2018. CAC-DRS: coronary artery calcium data and reporting system. An expert consensus document of the society of cardiovascular computed tomography (SCCT). Journal of cardiovascular computed tomography, 12(3), pp.185-191.
5. https://doi.org/10.1016/j.jcct.2016.11.003

Baseline diagnostic requirements for AI service results to identify signs of coronary artery disease (paracardial fat volume) on CT scan

Diagnostic study	Clinical task being performed by AI service	Preliminary phase (retrospective study) – signs of studies of the calibration dataset	Main phase (prospective study) – signs for which positive and negative results of the AI service are expected	Content of the AI service response	AI service response format	A form of the AI-service response provision
Chest computed tomography	Detection of a paracardial fat volume	**Signs of target pathology are present:** presence of paracardial* fat volume ≥ 200 ml in native images		**Obligatory** – probability of the presence of pericardial fat ≥ 125 ml	Number	Apache Kafka Message
				Obligatory – pericardial fat volume (ml)	Number	Apache Kafka Message + DICOM SR
				Obligatory – localization of detected signs	Contour/mask	DICOM
		Signs of target pathology are absent: paracardial fat volume is < 200 ml in the provided study.		**Obligatory** – mean pericardial fat density (HU)	Number	Apache Kafka Message + DICOM SR

*A volume of paracardial adipose tissue is summed from (a) a volume of epicardial adipose tissue located inside the pericardial sac in the atrioventricular and interventricular sulci, on the free wall and apex of the left ventricle, and around the main branches of the coronary arteries and (b) pericardial adipose tissue located outside the pericardium and adjacent to it. CT density is from -190 HU to -30 HU inclusive.

SOURCES:

1. Spearman J. V., Renker M., Schoepf U. J., Krazinski A.W. et al. Prognostic value of epicardial fat volume measurements by computed tomography: a systematic review of the literature // Eur Radiol. – 2015. – Vol. 25, №11. – P. 3372–3381. – DOI: 10.1007/s00330-015-3765-5.
2. Milanese, G., Silva, M., Bruno, L., Goldoni, M., Benedetti, G., Rossi, E., Ferrari, C., Grutta, L., Maffei, E., Toia, P., Forte, E., Bonadonna, R. C., Sverzellati, N., & Cademartiri, F. (2019). Quantification of epicardial fat with cardiac CT angiography and association with cardiovascular risk factors in symptomatic patients: from the ALTER-BIO (Alternative Cardiovascular Bio-Imaging markers) registry. *Diagnostic and interventional radiology (Ankara, Turkey)*, *25*(1), 35–41. https://doi.org/10.5152/dir.2018.18037

Baseline diagnostic requirements for AI service results to identify dilation of ascending and descending thoracic aorta on CT and LDCT scans

Diagnostic study	Clinical task being performed by AI service	Preliminary phase (retrospective study) – signs of studies of the calibration dataset	Main phase (prospective study) – signs for which positive and negative results of the AI service are expected	Content of the AI service response	AI service response format	A form of the AI-service response provision
Chest computed tomography	Detection of dilated ascending and descending thoracic aorta	**Signs of target pathology are present:** 1. The largest diameter of ascending aorta between 40 and 49 mm in the axial plane in native images is considered dilatation. 2. A diameter of ascending aorta measuring ≥ 50 mm in the axial plane in native images is considered aneurysm. 3. A diameter of descending aorta measuring ≥ 40 mm in the axial plane in native images is considered an aneurysm. One sign suffices to classify a study as a pathology.		**Obligatory** – probability of aortic dilation according to one of the pathological signs	Number	Apache Kafka Message
				Obligatory – diameter of ascending aorta on each slice (mm)	Number	DICOM
				Obligatory – diameter of descending aorta on each slice (mm)	Number	DICOM
				Obligatory – the largest diameter of ascending aorta (mm)	Number	Apache Kafka Message + DICOM SR
				Obligatory – the largest diameter of descending aorta (mm)	Number	Apache Kafka Message + DICOM SR
				Obligatory – localization of detected pathological signs	Contour/mask	DICOM
		Signs of target pathology are absent: 1. The largest diameter of the ascending aorta is < 40 mm in native images. 2. Native images of descending aorta contain no sign of pathology.		**Optional** – calcifications on the aorta walls	Text (presence/absence)	Apache Kafka Message + DICOM SR
				Optional – curvilinear reconstruction of aorta	Image series	DICOM

SOURCES: 1. Erbel R., Aboyans V., Boileau C. et al. ESC Committee for Practice Guidelines. 2014 ESC Guidelines on the diagnosis and treatment of aortic diseases: Document covering acute and chronic aortic diseases of the thoracic and abdominal aorta of the adult. The Task Force for the Diagnosis and Treatment of Aortic Diseases of the European Society of Cardiology (ESC) // Eur Heart J. – 2014. – Nov 1. – Vol. 35, №41. – P. 2873–2926. – DOI: 10.1093/eurheartj/ehu281.
2. Translation: European Society of Cardiology (ESC) Guidelines for the Diagnosis and Treatment of Aortic Diseases – URL: https://scardio.ru/content/Guidelines/Recom%20po%20aorte%207_rkj_15.pdf (accessed on : 24.05.2021).
3. V. Chernina, I. Blokhin, A. Nikolayev. [et al.] Management of incidentalomas. Section 3. Thyroid gland, pituitary gland, vessels and mediastinum / Series “Best practices of radiology and instrumental diagnostics”. – Issue 37. – M., 2019.
4. Managing Incidental Findings on Thoracic CT: Mediastinal and Cardiovascular Findings. A White Paper of the ACR Incidental Findings Committee, https://www.sciencedirect.com/science/article/pii/S154614401830530

Baseline diagnostic requirements for AI service results to identify a pulmonary trunk dilation on CT and LDCT scans

Diagnostic study	Clinical task being performed by AI service	Preliminary phase (retrospective study) – signs of studies of the calibration dataset	Main phase (prospective study) – signs for which positive and negative results of the AI service are expected	Content of the AI service response	AI service response format	A form of the AI-service response provision
Chest computed tomography	Detection of dilated pulmonary trunk. Quantification of the pulmonary trunk diameter .	**Signs of target pathology are present:** a pulmonary trunk diameter in native images is ≥ 29 mm.		**Obligatory** – probability of pulmonary trunk dilation	Number	Apache Kafka Message
				Obligatory – the largest diameter of pulmonary trunk (mm)	Number	Apache Kafka Message + DICOM SR
		Signs of target pathology are absent: the largest pulmonary trunk diameter in native images is < 29 mm.		**Obligatory** – localization of detected pathological signs	Contour/ mask	DICOM
				Optional – the largest diameter of pulmonary trunk on each slice (mm)	Number	DICOM

SOURCES :

1. Galiè N., Humbert M., Vachiery J.L. et al. ESC Scientific Document Group. 2015 ESC/ERS Guidelines for the diagnosis and treatment of pulmonary hypertension: The Joint Task Force for the Diagnosis and Treatment of Pulmonary Hypertension of the European Society of Cardiology (ESC) and the European Respiratory Society (ERS). Endorsed by: Association for European Paediatric and Congenital Cardiology (AEPC), International Society for Heart and Lung Transplantation (ISHLT) // Eur Heart J. – 2016. – Jan 1. – Vol. 37, №1. – P. 67–119. – DOI: 10.1093/eurheartj/ehv317.
2. Translation: ESC/ESC recommendations for the diagnosis and treatment of pulmonary hypertension 2015. – URL: https://scardio.ru/content/Guidelines/ESC%20_L_hypert_2015.pdf (дата обращения : 24.05.2021).

Baseline diagnostic requirements for AI service results to identify the impairment of lung airness on CT scan

Diagnostic study	Clinical task being performed by AI service	Preliminary phase (retrospective study) – signs of studies of the calibration dataset	Main phase (prospective study) – signs for which positive and negative results of the AI service are expected	Content of the AI service response	AI service response format	A form of the AI-service response provision
Chest computed tomography	Detection of CT signs consistent with impairment of lung airness	**Signs of pathology are present:** A. 1. A presence of areas of visually increased lung density on the background of normal (unchanged) lung parenchyma; 1.1. a presence of increased lung density areas as in item 1, except features correlating with a malignant neoplasm (see slide 11). B. (for the preliminary phase only) Increased lung density confirmed by 2 experts by consensus		**Obligatory** – probability of the impairment of lung airness	Number	Apache Kafka Message
		Signs of target pathology are absent: The absence of increased lung density areas correlating with the impairment of lung airness on the background of normal (unchanged) lung parenchyma.		**Obligatory** – localization of the zone identifying a side (left, right) and a lung lobe	Text, Contour/ mask	DICOM, Apache Kafka Message + DICOM SR

SOURCES :

M. Prokop, M. Galanski, “Spiral and multilayer computed tomography”, Vol. II. Study guide

Baseline diagnostic requirements for AI service results to identify adrenal gland lesions on CT scan

Diagnostic study	Clinical task being performed by AI service	Preliminary phase (retrospective study) – signs of studies of the calibration dataset	Main phase (prospective study) – signs for which positive and negative results of the AI service are expected	Content of the AI service response	AI service response format	A form of the AI-service response provision
Chest computed tomography	Detection of the adrenal gland lesions	**Signs of target pathology are present:** A lesion of the body or limbs of the adrenal gland measuring ≥ 10 mm along the short axis in native images.		**Obligatory** – probability of the adrenal gland lesion	Number	Apache Kafka Message
				Obligatory – axial dimension of the largest lesion of the adrenal glands along the short axis (if any), mm	Number	Apache Kafka Message + DICOM SR
		Signs of target pathology are absent: A dimension along the short axis of the body or limbs of the adrenal gland < 10 mm in native images.		**Obligatory** – localization of the adrenal gland lesion	Contour/mask	DICOM
				Optional – thickness of the body and limbs of the adrenal glands, mm	Number	Apache Kafka Message + DICOM SR

SOURCES:

1. Möller T.B., Moeller T. B., Reif E. Normal Findings in CT and MRI. Thieme, 2000. ISBN 9780865778641
2. Mayo-Smith W. W. et al. Management of incidental adrenal masses: a white paper of the ACR Incidental Findings Committee //Journal of the American College of Radiology. – 2017. – Т. 14. – №. 8. – С. 1038-1044

Baseline diagnostic requirements for AI service results to identify focal changes in the structure of chest bones on CT scan

Diagnostic study	Clinical task being performed by AI service	Preliminary phase (retrospective study) – signs of studies of the calibration dataset	Main phase (prospective study) – signs for which positive and negative results of the AI service are expected	Content of the AI service response	AI service response format	A form of the AI-service response provision
Chest computed tomography	Detection of CT signs consistent with the focal changes in the structure of chest bones	**Signs of target pathology are present:** A focus of bone tissue differing in density from the surrounding tissue.		**Obligatory** – probability of signs of the bone lesion	Number	Apache Kafka Message
				Obligatory – lesion localization with the indication of the bone name	Text, mask	DICOM, Apache Kafka Message + DICOM SR
		Signs of target pathology are absent: Absence of changes in the structure of chest bones.		**Obligatory** – the average lesion density	Number	DICOM, Apache Kafka Message + DICOM SR
				Obligatory – linear dimensions of the lesion (long and perpendicular to it), mm	Number	DICOM, Apache Kafka Message + DICOM SR
				Optional – vertical size of lesions > 10 mm (in mm)	Number	DICOM, Apache Kafka Message + DICOM SR

SOURCES:

1. M. Prokop, M. Galanski, “Spiral and multilayer computed tomography”, Vol. II. Study guide
2. Casey Ryan, Kelsey C. Stoltzfus, Samantha Horn, Hanbo Chen, Alexander V. Louie, Eric J. Lehrer, Daniel M. Trifiletti, Edward J. Fox, John A. Abraham, Nicholas G. Zaorsky, Epidemiology of bone metastases, Bone, Volume 158, 2022

Baseline diagnostic requirements for AI service results to identify rib/ribs fractures on CT scan (up to 4Q2023)

Diagnostic study	Clinical task being performed by AI service	Preliminary phase (retrospective study) – signs of studies of the calibration dataset	Main phase (prospective study) – signs for which positive and negative results of the AI service are expected	Content of the AI service response	AI service response format	A form of the AI-service response provision
Chest computed tomography	Identification of CT signs consistent with rib fracture	**Signs of pathology are present:** 1. Local bone contour line (cortical) interruption 2. Presence of diastasis of bone fragments		**Obligatory** – probability of signs of the rib fracture	Number	Apache Kafka Message
				Obligatory – localization of the fracture (rib number, a side – left/right, a third – anterior/lateral/posterior)	Text, mask	DICOM , DICOM SR
		Signs of target pathology are absent: Absence of changes in the structure of chest bones		**Optional** – maximum diastasis width in curvilinear reconstruction or axial plane	Number	DICOM, Apache Kafka Message + DICOM SR
				Obligatory – detailed curvilinear reconstruction of all ribs and spine on one slice	Image	DICOM SC

SOURCES:

1. M. Prokop, M. Galanski, “Spiral and multilayer computed tomography”, Vol. II. Study guide
2. Diagnostic radiology of the bones and joints diseases: National guidelines/Series "National guidelines for diagnostic radiology and therapy"/Ch. ed. of series S. Ternova; Editor-in-chief A. Morozov. – M.: GEOTAR-Media, 2016. – 832 p.

Baseline diagnostic requirements for AI service results to identify rib/ribs fractures on CT scan (starting 4Q2023)

Diagnostic study	Clinical task being performed by AI service	Preliminary phase (retrospective study) – signs of studies of the calibration dataset	Main phase (prospective study) – signs for which positive and negative results of the AI service are expected	Content of the AI service response	AI service response format	A form of the AI-service response provision
Chest computed tomography	Identification of CT signs consistent with rib fracture	**Signs of pathology are present:** 1. Local bone contour line (cortical) interruption 2. Presence of diastasis of bone fragments		**Obligatory** – probability of signs of the rib fracture	Number	Apache Kafka Message
				Obligatory – localization of the fracture (rib number, a side – left/right, a third – anterior/lateral/posterior)	Text, mask	DICOM , DICOM SR
		Signs of target pathology are absent: Absence of changes in the structure of chest bones		**Obligatory** – detailed curvilinear reconstruction of all ribs and spine on one slice	Image	DICOM SC
				Obligatory – maximum diastasis width in curvilinear reconstruction or axial plane	Number	DICOM, Apache Kafka Message + DICOM SR

SOURCES:

1. M. Prokop, M. Galanski, “Spiral and multilayer computed tomography”, Vol. II. Study guide
2. Diagnostic radiology of the bones and joints diseases: National guidelines/Series "National guidelines for diagnostic radiology and therapy"/Ch. ed. of series S. Ternova; Editor-in-chief A. Morozov. – M.: GEOTAR-Media, 2016. – 832 p.

Baseline diagnostic requirements for AI service results to identify signs of urolithiasis nephrolithiasis on CT scan

Diagnostic study	Clinical task being performed by AI service	Preliminary phase (retrospective study) – signs of studies of the calibration dataset	Main phase (prospective study) – signs for which positive and negative results of the AI service are expected	Content of the AI service response	AI service response format	A form of the AI-service response provision
Abdominal computed tomography/ Abdominal and pelvic computed tomography	Identification of urolithiasis signs	**Signs of pathology are present:** A. 1. A presence of X-ray-positive stones in the urinary system of the density more than 100 HU in native images. B. (for the preliminary phase only) 1. Assigned ICD code N20-N23		**Obligatory** – probability of X-ray-positive renal stones	Number	Apache Kafka Message
				Obligatory – localization of detected signs	Contour	DICOM
				Obligatory – dimensions of the renal stone/the largest stone on the axial slice for each organ of the urinary system (maximum and perpendicular to it), mm	Number	Apache Kafka Message + DICOM SR
				Obligatory – a mean density of the renal stone/the largest stone on the axial slice for each organ of the urinary system, HU	Number	Apache Kafka Message + DICOM SR
		Signs of pathology are absent: Absence of X-ray-positive renal stones in native images.		**Optional** - vertical dimension of the renal stone on the sagittal or coronal slice	Number	Apache Kafka Message + DICOM SR

SOURCES :

1. Karul M., Heuer R., Regier M. Multidetektor-Computertomografie der Urolithiasis: Technik und Ergebnisse // Rofo. – 2013. – Vol. 185, №2. – P. 121–127. – DOI: 10.1055/s-0032-1325458.
2. Dale J.,Gupta R. T., Marin D. et al. Prem IngerImaging Advances in Urolithiasis // J Endourol. – 2017. – Jul. – Vol. 31, №7. – P. 623–629. – DOI: 10.1089/end.2016.0695; Epub. – 2017. – Jun 20. – DOI: 10.1089/end.2016.0695.
3. URL: https://radiopaedia.org/articles/urolithiasis?lang=us.
4. Clinical guidelines of the Ministry of Health of the Russian Federation “Nephrolithiasis”. – 2020. – ID 7. – URL:https://cr.minzdrav.gov.ru/recomend/374_2
5. Webb R. W., Brant W. E., Major N.M. Fundamentals of Body CT. – 4th edition. – 2015.

Baseline diagnostic requirements for AI service results to identify signs of liver lesions on CT scan

Diagnostic study	Clinical task being performed by AI service	Preliminary phase (retrospective study) – signs of studies of the calibration dataset	Main phase (prospective study) – signs for which positive and negative results of the AI service are expected	Content of the AI service response	AI service response format	A form of the AI-service response provision
Abdominal computed tomography	Detection of computed tomography signs consistent with liver lesions	**Signs of pathology are present:** A presence of the signs of focal liver lesion, which differs in density from the surrounding liver parenchyma in native images.		**Obligatory** – probability of a liver lesion	Number	Apache Kafka Message
				Obligatory – localization of detected lesions	Contour/ mask	DICOM
				Obligatory – localization of the lever lesion by lobes (right or left)	Text	Apache Kafka Message + DICOM SR
				Obligatory – lesion density in HU (for lesions of ≥ 5 mm in size): minimum, maximum	Text	Apache Kafka Message + DICOM SR
				Obligatory – diameter of the lesions ranging from 5 mm to 10 mm; linear dimensions (long and perpendicular to it) of the lesions > 10 mm	Text	Apache Kafka Message + DICOM SR
		Signs of pathology are absent: there are no signs of a focal liver lesion, which differs in density from the surrounding liver parenchyma in native images.		**Obligatory** – a mean liver density (HU)	Number	Apache Kafka Message + DICOM SR
				Optional – a vertical linear dimension of the lesion (mm)	Text	Apache Kafka Message + DICOM SR

SOURCES: 1. Horton K. M., Bluemke D.A. , Hruban Ralph H. et al. CT and MR Imaging of Benign Hepatic and Biliary Tumors // RadioGraphics. – 1999. – Vol. 19, № 2. – URL: https://doi.org/10.1148/radiographics.19.2.g99mr04431
2. Liver lesions. – 2020. – 18 Feb. – URL: https://radiopaedia.org/articles/liver-lesions.
3. Chernina V.Yu., Blokhin I.A., Nikolaev A.E. [et al.]. Tactics of incidentaloma management. Part 1. Liver, gallbladder and bile ducts, spleen and lymph nodes // The series "Best practices of radiation and instrumental diagnostics". – Issue 35. – M., 2019. – 48 p.
4. Gore R. M. et al. Management of incidental liver lesions on CT: a white paper of the ACR Incidental Findings Committee //Journal of the American College of Radiology. – 2017. – T. 14. – №. 11. – C. 1429-1437.

Baseline diagnostic requirements for AI service results to identify signs of renal lesions on CT scan

Diagnostic study	Clinical task being performed by AI service	Preliminary phase (retrospective study) – signs of studies of the calibration dataset калибровочного набора данных	Main phase (prospective study) – signs for which positive and negative results of the AI service are expected	Content of the AI service response	AI service response format	A form of the AI-service response provision
Abdominal computed tomography	Detection of CT signs consistent with renal lesions	**Signs of pathology are present:** Signs of focal lesions in the right or left kidney, which differs in density from the surrounding parenchyma in native images.		**Obligatory** – probability of kidney lesions in native images	Number	Apache Kafka Message
				Obligatory – localization of detected lesions	Contour/ mask	DICOM
				Obligatory – lesion localization by organ (right or left kidney)	Text	Apache Kafka Message + DICOM SR
				Obligatory – lesion density in HU (for lesions ≥ 5 mm in size): minimum, maximum	Text	Apache Kafka Message + DICOM SR
		Signs of pathology are absent: no signs of a focal lesion in the right or left kidney, which differs in density from the surrounding parenchyma in native images.		**Obligatory** – diameter of the lesions ranging from 5 mm to 10 mm; linear dimensions (long and perpendicular to it) of the lesions > 10 mm	Text	Apache Kafka Message + DICOM SR
				Optional – a vertical linear dimension of the lesion (mm)	Text	Apache Kafka Message + DICOM SR

SOURCES :

1. Clinical guidelines of the Ministry of Health of the Russian Federation "Malignant neoplasms of the kidneys, renal pelvis, ureter, other and unspecified urinary organs.". – 2020. – ID 67. – URL: https://cr.minzdrav.gov.ru/recomend/67_1.
2. Radiology Assistant: Educational site of the Radiological Society of the Netherlands. [Электронный ресурс]. – URL: https://radiologyassistant.nl/abdomen/kidney/solid-masses.
3. Dyer R., Di Santis D. J., McClennan B. L. Simplified Imaging Approach for Evaluation of the Solid Renal Mass in Adults // Radiology. – 2008. – Vol. 247, № 2. – URL: https://doi.org/10.1148/radiol.2472061846.

Baseline diagnostic requirements for AI service results to identify adrenal gland lesions on CT scan

Diagnostic study	Clinical task being performed by AI service	Preliminary phase (retrospective study) – signs of studies of the calibration dataset	Main phase (prospective study) – signs for which positive and negative results of the AI service are expected	Content of the AI service response	AI service response format	A form of the AI-service response provision
Abdominal computed tomography	Detection of the adrenal gland lesions	**Signs of pathology are present:** a lesion of the body or limbs of the adrenal gland measuring ≥ 10 mm along a short axis in native images		**Obligatory** – probability of the adrenal gland lesion	Number	Apache Kafka Message
				Obligatory – axial dimension of the largest lesion of the adrenal glands along the short axis (if any), mm	Number	Apache Kafka Message + DICOM SR
				Obligatory – localization of the adrenal gland lesions	Contour/ mask	DICOM
		Signs of pathology are absent: A dimension of the body or limbs of adrenal gland along the short axis < 10 mm in native images		**Optional** – thickness of the body and limbs of the adrenal glands, mm	Number	Apache Kafka Message + DICOM SR

SOURCES:

1. Möller T.B., Moeller T. B., Reif E. Normal Findings in CT and MRI. Thieme, 2000. ISBN 9780865778641
2. Mayo-Smith W. W. et al. Management of incidental adrenal masses: a white paper of the ACR Incidental Findings Committee //Journal of the American College of Radiology. – 2017. – Т. 14. – №. 8. – С. 1038-1044

Baseline diagnostic requirements for AI service results to identify compression vertebral fractures on CT scan

Diagnostic study	Clinical task being performed by AI service	Preliminary phase (retrospective study) – signs of studies of the calibration dataset	Main phase (prospective study) – signs for which positive and negative results of the AI service are expected	Content of the AI service response	AI service response format	A form of the AI-service response provision
Abdominal computed tomography	Detection and localization of compression vertebral fractures with compression degree more than 25% according to the Genant semi-quantitative grading (grades 2-3)	**Signs of pathology are present:** 1. A presence of vertebrae with compressive deformation of the bodies ≥ 25% in native images, according to the Genant semi-quantitative classification grade 2–3. A deformity degree is calculated by the following formula: *Deformity* degree *= (maximal vertebra size – minimal vertebra size)/maximal vertebra size*100 % (equation 1).* 2. Reduction in bone mineral density in Th11–L3 vertebral bodies (ideally L1–L2) in native images according to ACR 2018, ISCD 2019 criteria.		**Obligatory** – probability of at least one vertebra with a deformity degree ≥ 25 %	Number	Apache Kafka Message
				Obligatory – labelling (numbering) all vertebrae with the deformity degree ≥ 25%	Text	DICOM
				Obligatory – graphical display of the vertebra height in the anterior, middle or posterior parts (contour) of all analysed vertebrae	Contour	DICOM
				Obligatory – numerical value of the vertebral deformity degree in % (for all vertebrae with height loss of ≥ 25%), indicating the Genant score		
		Signs of pathology are absent: 1. Vertebra bodies in native images of the presented study have a deformity degree less than 25% according to the equation (1). 2. Bone mineral density in the vertebral bodies in native images is within the normal range.		**Optional** – measurement of the mineral density (or HU) of the cancellous bone of Th12–L3 vertebral bodies indicating a number of the vertebra. Mineral bone density (or HU) is not measured for vertebrae with compression degree more than 25%. Indicate when osteoporosis is suspected, according to ACR 2018, ISCD 2019 criteria.	Text	Apache Kafka Message +DICOM + DICOM SR
					Text	Apache Kafka Message +DICOM + DICOM SR

SOURCES: 1. Federal clinical recommendations on diagnosis, treatment and prevention of osteoporosis / G. Melnichenko, Zh. Belaya, L. Rozhinskaya [et al.] // Problems of Endocrinology. – 2017. – Vol. 63, №6. P. 392–426. – URL: https://www.probl-endojournals.ru/jour/article/view/8757 (accessed on: 24.05.2021). 2. ISCD [electronic resource] : Official Positions. 2019. – URL: https://iscd.org/learn/official-positions/ (accessed on: 24.05.2021). 3. ACR [electronic resource] : ACR–SPR–SSR Practice Parameter for the Performance of Musculoskeletal Quantitative Computed Tomography (QCT), 2018. – URL: https://www.acr.org/-/media/ACR/Files/Practice-Parameters/QCT.pdf?la=en (accessed on : 24.05.2021). 4. Genant H. K., Jergas M. Assessment of prevalent and incident vertebral fractures in osteoporosis research // Osteoporosis Int. – 2003. – Vol. 14, №3. – P. 43–55. – URL: https://doi.org/10.1007/S00198-002-1348-1. 5. Clinical guidelines of the Ministry of Health of the Russian Federation “Pathological fractures complicating osteoporosis”. – M., 2018. ID 614. – URL: https://cr.minzdrav.gov.ru/schema/614_1 (accessed on : 15.06.2021).

Baseline diagnostic requirements for AI service results to identify abdominal aorta dilation on CT scan

Diagnostic study	Clinical task being performed by AI service	Preliminary phase (retrospective study) – signs of studies of the calibration dataset	Main phase (prospective study) – signs for which positive and negative results of the AI service are expected	Content of the AI service response	AI service response format	A form of the AI-service response provision
Abdominal computed tomography	Detection of dilated abdominal aorta	**Signs of pathology are present:** - The largest diameter of abdominal aorta in native images ranges from 25 to 29 mm (aortic dilatation). - The largest diameter of abdominal aorta in native images is ≥ 30 mm (aortic aneurysm). One sign suffices to classify a study as a pathology.		**Obligatory** – probability of abdominal aorta dilatation	Number	Apache Kafka Message
				Obligatory – diameter of abdominal aorta in axial plane on each slice, mm	Number	DICOM
				Obligatory – the largest diameter of abdominal aorta, mm	Number	Apache Kafka Message + DICOM SR
				Obligatory – localization of detected signs	Contour/ mask	DICOM
		Signs of pathology are absent: The largest diameter of the abdominal aorta in native images is < 25 mm.		**Optional** – calcifications on the aorta walls	Text (presence/ absence)	Apache Kafka Message + DICOM SR

SOURCES:
1. Wanhainen, A., Verzini, F., Van Herzeele, I., et al. ESVS Guidelines Committee, de Borst, G. J., Chakfe, N., … Verhagen, H. (2019). Editor's Choice – European Society for Vascular Surgery (ESVS) 2019 Clinical Practice Guidelines on the Management of Abdominal Aorto-iliac Artery Aneurysms. *European Journal of Vascular and Endovascular Surgery*, *57*(1), 8–93. https://doi.org/10.1016/j.ejvs.2018.09.020
2. Jurgens, Paul T., et al. 'Association of Abdominal Aorta Calcium and Coronary Artery Calcium with Incident Cardiovascular and Coronary Heart Disease Events in Black and White Middle-Aged People: The Coronary Artery Risk Development in Young Adults Study'. Journal of the American Heart Association, vol. 10, no. 24, Dec. 2021, p. e023037. DOI.org (Crossref), https://doi.org/10.1161/JAHA.121.023037.

Baseline diagnostic requirements for AI service results to identify gallbladder stones on CT scan

Diagnostic study	Clinical task being performed by AI service	Preliminary phase (retrospective study) – signs of studies of the calibration dataset	Main phase (prospective study) – signs for which positive and negative results of the AI service are expected	Content of the AI service response	AI service response format	A form of the AI-service response provision
Abdominal computed tomography	Detection of signs consistent with gallbladder stones	**Signs of pathology are present:** 1. There is a formation in the gallbladder cavity which is not associated with the bladder walls, with a density of more than -70 HU and up to 1500 HU, or inhomogeneous X-ray density.		**Obligatory** – probability of stones in the gallbladder cavity	Number	Apache Kafka Message
				Obligatory – the largest diameter of the stone, mm	Number	DICOM, Apache Kafka Message + DICOM SR
		Signs of pathology are absent: the absence of signs of formation in the gallbladder cavity		**Obligatory** – a number of stones	Number	DICOM, Apache Kafka Message + DICOM SR

SOURCES:

1. Shaffer EA. Epidemiology and risk factors for gallstone disease: has the paradigm changed in the 21st century? Curr Gastroenterol Rep. 2005 May;7(2):132–40. doi: 10.1007/s11894–005–0051–8. PMID: 15802102.
2. Kim MH, Lee SK, Min YI, Cho KS, Auh YH, Lee SG. Computed tomographic analysis of gallbladder stones: correlation with chemical composition and in vitro shock–wave lithotripsy. Korean J Intern Med. 1991 Jan;6(1):1–7. doi: 10.3904/kjim.1991.6.1.1. PMID: 1742250; PMCID: PMC4535016.

Baseline diagnostic requirements for AI service results to automate routine liver measurements based on CT data

Diagnostic study	Clinical task being performed by AI service	Preliminary phase (retrospective study) – signs of studies of the calibration dataset	Main phase (prospective study) – signs for which positive and negative results of the AI service are expected	Content of the AI service response	AI service response format	A form of the AI-service response provision
Abdominal computed tomography	Automation of routine measurements (dimensions, liver density, choledochus diameter, portal vein diameter)	**Measured indicators:** 1. Maximum vertical dimension 2. Maximum anteroposterior dimension 3. Maximum transverse dimension at the level of the upper pole of the right kidney 4. Mean density of the liver parenchyma (excluding vessels and ligaments) 5. Maximum diameter of the common bile duct 6. Maximum portal vein diameter		**Obligatory** – vertical, anteroposterior, transverse dimensions of the liver right lobe	Number	Apache Kafka Message + DICOM SR
				Obligatory – a mean density of the liver parenchyma	Number	DICOM, Apache Kafka Message + DICOM SR
				Obligatory – a maximum diameter of the common bile duct	Number	DICOM, Apache Kafka Message + DICOM SR
				Obligatory – a portal vein diameter	Number	DICOM, Apache Kafka Message + DICOM SR

SOURCES:

1. Muggli D, Müller M, Karlo C, Fornaro J, Marincek B, Frauenfelder T. A Simple Method to Approximate Liver Size on Cross–Sectional Images Using Living Liver Models. Clin Radiol. 2009;64(7):682–9. doi:10.1016/j.crad.2009.02.013 – Pubmed.

Baseline diagnostic requirements for AI service results to automate routine kidney measurements based on CT data

Diagnostic study	Clinical task being performed by AI service	Preliminary phase (retrospective study) – signs of studies of the calibration dataset	Main phase (prospective study) – signs for which positive and negative results of the AI service are expected	Content of the AI service response	AI service response format	A form of the AI-service response provision
Abdominal computed tomography	Automation of routine kidney measurements (kidney size, pelvicalyceal system size)	**Measured indicators:** 1. A position of the upper edge of each kidney in relation to the vertebral body 2. Length – a distance between the upper and lower edges 3. Width – a distance between the inner and outer edges 4. Thickness – a distance between the front and back edges 5. Renal pelvis size – the largest distance between the inner and outer, upper and lower edges of the pelvis		**Obligatory** – a vertebra name corresponding to the upper edge of each kidney	Number	DICOM , Apache Kafka Message + DICOM SR
				Obligatory – length, width, thickness of each kidney in mm	Number	DICOM, Apache Kafka Message + DICOM SR
				Obligatory – the largest dimensions of each renal pelvis in the axial plane in mm.*	Number	DICOM, Apache Kafka Message + DICOM SR
				Obligatory – the smallest thickness of kidney parenchyma	Number	DICOM, Apache Kafka Message + DICOM SR

*NOTE: the longest perpendicular to the long axis of the ureteropelvic junction. In the presence of parapelvic cysts, this measurement is not performed. A Service response in this case is the following: “A parapelvic cyst has been identified. Measuring the renal pelvis on native images is impossible”.

SOURCES:
1. M. R. Sapin. Anatomy textbook in 2 volumes. Vol 2
2. M. Prokop, M. Galanski, “Spiral and multilayer computed tomography”, Vol. II. Study guide

Baseline diagnostic requirements for AI service results to automate routine measurements of spleen and pancreas during CT

Diagnostic study	Clinical task being performed by AI service	Preliminary phase (retrospective study) – signs of studies of the calibration dataset	Main phase (prospective study) – signs for which positive and negative results of the AI service are expected	Content of the AI service response	AI service response format	A form of the AI-service response provision
Abdominal computed tomography	Automation of routine measurements of spleen and pancreas (size, density of the spleen and pancreas)	**Measured indicators:** 1. Spleen length – the maximum distance between the anterior and posterior edges 2. Spleen width – the largest perpendicular to the length on the same slice as the length 3. Craniocaudal size of the spleen – the largest distance between the upper and lower edges 4. Head of the pancreas – a maximum diameter to the axis 5. Body of the pancreas – a maximum diameter to the axis 6. Tail of the pancreas – a maximum diameter to the axis		**Obligatory** – length, width, height of the spleen	Number	DICOM, Apache Kafka Message + DICOM SR
				Obligatory – a diameter of the head, body, tail of the pancreas	Number	DICOM, Apache Kafka Message + DICOM SR

SOURCES:
1. M. Prokop, M. Galanski, “Spiral and multilayer computed tomography”, Vol. II. Study guide
2. Morozov S.V, Izranov V.A, Kazantseva N.V. "Diagnostic criteria of splenomegaly (review)" Bulletin of the I. Kant Baltic Federal University. Series: Natural and Medical Sciences, No. 2, 2020, pp. 89-100.

Baseline diagnostic requirements for AI service results to identify focal changes in the structure of abdominal and pelvic bones on CT scan

Diagnostic study	Clinical task being performed by AI service	Preliminary phase (retrospective study) – signs of studies of the calibration dataset	Main phase (prospective study) – signs for which positive and negative results of the AI service are expected	Content of the AI service response	AI service response format	A form of the AI-service response provision
Abdominal computed tomography	Detection of CT signs consistent with the focal changes in the structure of abdominal and pelvic bones	**Signs of pathology are present:** A presence of the focus of bone tissue differing in density from the surrounding tissue.		**Obligatory** – probability of signs of the bone lesion	Number	Apache Kafka Message
				Obligatory – localization of the lesion identifying a bone name	Text, mask	DICOM, Apache Kafka Message + DICOM SR
		Signs of pathology are absent: Absence of changes in the structure of abdominal and pelvic bones.		**Obligatory** – a mean lesion density	Number	DICOM, Apache Kafka Message + DICOM SR
				Obligatory – linear dimensions of lesions > 10 mm (long and perpendicular to it) in mm	Number	DICOM, Apache Kafka Message + DICOM SR
				Optional – a vertical dimension of the lesion in mm for lesions > 10 mm	Number	DICOM, Apache Kafka Message + DICOM SR

SOURCES:

1. M. Prokop, M. Galanski, “Spiral and multilayer computed tomography”, Vol. II. Study guide
2. Casey Ryan, Kelsey C. Stoltzfus, Samantha Horn, Hanbo Chen, Alexander V. Louie, Eric J. Lehrer, Daniel M. Trifiletti, Edward J. Fox, John A. Abraham, Nicholas G. Zaorsky, Epidemiology of bone metastases, Bone, Volume 158, 2022

Baseline diagnostic requirements for AI service results to identify acute ischemic stroke on CT scan

Diagnostic study	Clinical task being performed by AI service	Preliminary phase (retrospective study) – signs of studies of the calibration dataset	Main phase (prospective study) – signs for which positive and negative results of the AI service are expected	Content of the AI service response	AI service response format	A form of the AI-service response provision
Computed tomography of the brain	Detection of acute ischemic stroke and its ASPECTS score	**Signs of pathology are present:** A. 1. Radiological signs of the acute ischemic stroke in native images* 2. Assessment of these areas according to ASPECTS**, if the middle cerebral artery (MCA) is affected, score 0–10 B. (for preliminary phase only) Conclusion verification in dynamics (repeated brain CT)		**Obligatory** – probability of the presence of acute ischemic stroke areas	Number	Apache Kafka Message
				Obligatory – highlighting areas of acute ischemic stroke	Contour/mask/etc.	DICOM
				Obligatory – indicating areas of acute ischemic stroke (ACA, MCA, PCA, VBB).	Text	Apache Kafka Message + DICOM SR
				Obligatory – assessment of ischemic stroke areas according to ASPECTS (0-10) if the middle cerebral artery (MCA) is affected	ASPECTS 0-10, integer number, or ASPECTS not applicable	Apache Kafka Message + DICOM SR
		Signs of pathology are absent: absence of acute ischemic stroke areas in the brain in native images		**Optional** – identifying areas of post-stroke changes	Text Contour/mask	DICOM SR + DICOM

NOTE: *Early or late CT signs: URL: https://radiographia.info/article/ishemicheskiy-insult-golovnogo-mozga, https://radiopaedia.org/articles/ischaemic-stroke.
**ASPECTS (Alberta Stroke Program Early CT score): URL: https://radiographia.info/article/aspects-shkala, http://www.aspectsinstroke.com.

SOURCES: 1. Pexman J.H., Barber P.A., Hill M.D. et al. Use of the Alberta Stroke Program Early CT Score (ASPECTS) for assessing CT scans in patients with acute stroke // AJNR Am J Neuroradiol. – 2001. –Vol. 22, №8. – P. 1534–1542. 2. Aviv R. I., Mandelcorn J., Chakraborty S. et al. Alberta Stroke Program Early CT Scoring of CT perfusion in early stroke visualization and assessment // AJNR Am J Neuroradiol. –2007. – Vol. 28, №10. – P. 1975–1980. 3. Nael K., Sakai Y., Khatri P. et al. Imaging-based Selection for Endovascular Treatment in Stroke (2019) // Radiographics : a review publication of the Radiological Society of North America. – Inc. 39 (6). – P. 1696–1713. 4. A. Osborn, K. Zaltsman, M. Zavery. Radiation diagnostics. Brain. / translation from English, 3rd edition M.: Panfilov publishing, 2018. – 1216 p.

Baseline diagnostic requirements for AI service results to identify intracranial hemorrhage on CT scans

Diagnostic study	Clinical task being performed by AI service	Preliminary phase (retrospective study) – signs of studies of the calibration dataset	Main phase (prospective study) – signs for which positive and negative results of the AI service are expected иса	Content of the AI service response	AI service response format	A form of the AI-service response provision
Computed tomography of the brain	Identification of hemorrhage and automatic calculation of its volume in ml or cm^3	**Signs of pathology are present:** A. Radiological signs* consistent with hemorrhages of the following types: epidural (EDH), subdural (SDH), subarachnoid (SAH), or intracerebral** B. (for preliminary phase only) Expert verification		**Obligatory** – probability of hemorrhage	Number	Apache Kafka Message
				Obligatory – identification of the hemorrhage localization	Contour/mask	DICOM
				Obligatory – identification of the hemorrhage type	Select from the list: epidural, subdural, subarachnoid or intracerebral	Apache Kafka Message + DICOM
		Signs of pathology are absent: absence of hemorrhage areas in the brain in native images		**Obligatory** – volume calculation in ml or cm^3	Number	DICOM SR
				Optional – detection of skull fractures	Contour/mask	DICOM

NOTE: * Radiological signs: hyperdense zones (50–80 HU) in the brain tissue or in the subarachnoid, subdural or epidural spaces.
**Extended classification: URL: https://radiopaedia.org/articles/intracranial-haemorrhage.

SOURCES: 1. Sacco R. L., Kasner S. E., Broderick J. P. et al. An updated definition of stroke for the 21st century: a statement for healthcare professionals from the American Heart Association / American Stroke Association // Stroke. – 2013. – Vol. 44, №7. – P. 2064–2089.
2. Brust J.C. Current diagnosis and treatment in neurology / ed. McGraw-Hill. – 2006. –750 p.
3. A. Osborn, K. Zaltsman, M. Zavery. Radiation diagnostics. Головной мозг /пер. с англ. 3-е изд. M.: Panfilov publishing, 2018. – 1216 p.

Baseline diagnostic requirements for AI service results to automate routine measurements in CT scan of the brain

Diagnostic study	Clinical task being performed by AI service	Preliminary phase (retrospective study) – signs of studies of the calibration dataset	Main phase (prospective study) – signs for which positive and negative results of the AI service are expected	Content of the AI service response	AI service response format	A form of the AI-service response provision
Computed tomography of the brain	Automation of routine measurements (ventriculometry, displacement of median structures, measurement of the craniovertebral junction)	**Measured indicators: ventriculo-cranial ratio (VCR)** 1. VCR1 is a ratio of the distance between the most lateral portions of the anterior horns of the lateral ventricles to the distance between the inner laminas of the bones of the cranial vault at the same level. 2. VCR2 is a ratio of the distance between the heads of the caudate nuclei at the level of the bodies of the anterior horns to the distance between the convexity surfaces of the frontal lobes at the same level. 3. VCR3 is a ratio of the maximum width of the III ventricle to the greatest distance between the inner laminas of the bones of the cranial vault at the same level. 4. Width of the 3rd ventricle 5. Transverse dislocation of median brain structures >3 mm (if present) 6. A position of the cerebellar tonsils relative to the foramen magnum. Degrees of descent of the cerebellar tonsils: 0 – at the level of the upper edge of the foramen magnum, 1 – up to 3 mm below McRae/Chamberlain line, 2 – from 3 to 5 mm below McRae/Chamberlain line, 3 – more than 5 mm below McRae/Chamberlain line.		**Obligatory** – a value of the transverse dislocation, if present (mm)	Number	Apache Kafka Message + DICOM + DICOM SR
				Obligatory – values of VCR 1, VCR 2, VCR 3, width of the 3rd ventricle (mm).	Number	DICOM, Apache Kafka Message + DICOM SR
				Obligatory – displacement value of cerebellar tonsils below the edges of foramen magnum (mm)	Number	DICOM, Apache Kafka Message + DICOM SR
				Obligatory – a degree of descent of cerebellar tonsils	Number (0-3)	DICOM SR

SOURCES :

1. Hosten N., Liebig T.; translation from German; edited by Sh.Sh. Shotemora Computed tomography of the head and spine. - M.: MEDpress-inform, 2011.
2. Danchenko O.A., Rabinovich S.S., Dergilev A.P., Parlyuk O.V. "Ventriculo-cranial relationships in assessing dislocation in patients with intracranial meningeal hematomas" Polytrauma, №. 2, 2012, pp.53-58.
3. Novikov A. E., Koshelev M. Yu., Borisov P. E., and Bugrova S. G. "A meaning of ventriculometry in the diagnosis of dyscirculatory encephalopathy in computed tomography". Bulletin of the Ivanovo Medical Academy, vol. 13, No.3-4, 2008, pp. 35-38.

Baseline diagnostic requirements for AI service results to identify sinusitis on X-ray

Diagnostic study	Clinical task being performed by AI service	Preliminary phase (retrospective study) – signs of studies of the calibration dataset	Main phase (prospective study) – signs for which positive and negative results of the AI service are expected	Content of the AI service response	AI service response format	A form of the AI-service response provision
X-ray of the paranasal sinuses	Identification of decreased pneumatization/ opacification of the paranasal sinuses	**Signs of target pathology are present:** A. 1. Decreased pneumatization* of the paranasal sinuses. 2. Horizontal air-fluid level in the sinus. 3. Absence of pneumatization of the paranasal sinuses. B. (for preliminary phase only) Assigned ICD-10 code J01, J32. To classify the study as pathology, one of the signs from the A and B lists suffice.		**Obligatory** – probability of pathology in the study	Number	Apache Kafka Message
				Obligatory – localization of pathological findings	Contour	DICOM
				Obligatory – localization of pathological findings in the paranasal sinuses (left maxillary, right maxillary, left frontal and right frontal)	Text (e.g. right maxillary, frontal, etc.)	Apache Kafka Message + DICOM/DICOM SR
				Obligatory – probability of the horizontal air-fluid level or total absent pneumatization of the paranasal sinuses	Number	Apache Kafka Message + DICOM/DICOM SR
		Signs of target pathology are absent: none of the sign from the A-list.		**Obligatory** – a presence of sinus defects	Heat map/ Contour, etc.	DICOM

*Decrease of pneumatization – radiological signs of mucosal edema, or a presence of fluid/ contents in the sinus

SOURCES:

1. Acute sinusitis // Radiopaedia. – 2021. – 19 Nov. – URL: https://radiopaedia.org/articles/acute-sinusitis.
2. Fayzullin M.H. Differential X-ray diagnostics of lesions of the paranasal sinuses, tumors of the skull and brain, cranial injuries, intra– and extracranial foreign bodies (recommendations for practitioners), 2012. – 57 p.

Baseline diagnostic requirements for AI service results to identify various lung conditions on X-ray (up to Q2 2023)

Diagnostic study	Clinical task being performed by AI service	Preliminary phase (retrospective study) – signs of studies of the calibration dataset	Main phase (prospective study) – signs for which positive and negative results of the AI service are expected	Content of the AI service response	AI service response format	A form of the AI-service response provision
Chest X-ray and fluorography	Detection and localization of radiological signs (**at least 7**), consistent with the condition of interest (see a list below): 1. Tuberculosis (A15 – A16, A19) 2. Pneumonia, purulent suppurative and necrotic conditions (J10 – J18, J80 – J86) 3. Hydrothorax (J94, R09.1) 4. Pneumothorax (S27.0) 5. Atelectasis (J98.1) 6. Neoplasms (D38.1– D38.4, C34–C39) 7. Fracture of the rib(s), sternum and thoracic spine (S22) 8. Cardiomegaly (I51.7) 9. Mediastinal pathology (D15.2, D38.3, I71)	**Signs of pathology are present:** A. A presence of at least one radiological sign from the list below: 1. Pleural effusion* 2. Pneumothorax* 3. Focal pulmonary opacity* 4. Infiltration/Consolidation* 5. Dissemination* 6.Cavity* 7. Atelectasis 8. Calcification/calcified pulmonary shadow 9. Mediastinum widening 10. Cardiomegaly 11. Cortical bone fracture 12. Consolidated fracture B. (for the preliminary phase only) Positive verification of at least one of the priority nosologies.		**Obligatory** – probability of a pathology from the A-list in the entire study	Number	Apache Kafka Message
				Obligatory – probability of each radiological sign from the A-list in the entire study	Integer	Apache Kafka Message + DICOM SR
		Signs of pathology are absent: none of the radiological sign from the A-list		**Obligatory** – localization and definitive digital identification of detected signs (reported in DICOM SR)	Contour	DICOM

NOTE: *Signs that require an urgent medical decision

SOURCES: 1. Diagnostic radiology of the chest organs: national guidelines/Series "National guidelines for diagnostic radiology and therapy" / Ch. ed. series S. Ternova; Editor-in-chief of the volume V.N. Troyan, A. Shekhter. – M. : GEOTAR-Media, 2014. – 584 p.
2. Hansell D. M., Bankier A. A., MacMahon H. et al. Fleischner Society: glossary of terms for thoracic imaging // Radiology. – 2008. – Mar. – Vol. 246, №3. – Vol. 697–722. – DOI: 10.1148/radiol.2462070712.

Baseline diagnostic requirements for AI service results to identify various lung diseases on X-ray (up to Q2 2023)

Radiological finding	Features
1. Pleural effusion	Homogeneous opacity in the lower areas of lungs with the almost horizontal edge, the anatomical structure of lateral-basal areas of lungs – costodiaphragmatic sinus – are not visible.
2. Pneumothorax	Homogeneous lucency in the peripheral regions of upper lung lobes corresponding to the air distribution in the enclosed space; lung pattern in the zone of interest is not visualized (shifted).
3. Focal pulmonary opacity	A focal pulmonary opacity with impaired differentiation of the lung pattern not corresponding to the anatomical peribronchial distribution; a significant variation in localization/size/contours/shape is possible
4. Infiltration/consolidation	A focal pulmonary opacity with complete/incomplete impaired differentiation of the lung pattern, corresponding to the anatomical peribronchial/segmental/lobar distribution
5. Dissemination	Multiple same type subcentimeter focal pulmonary opacities, corresponding to the anatomical peribronchial distribution
6. Cavity	A gas-filled space displayed as a local lucency on the X-ray*
7. Atelectasis	Pulmonary volume loss due to the collapse. Subsegmental, segmental, lobar, total. Homogeneous opacity of the lung structural unit with shifting of the anatomical structures towards the collapse on top of the volume loss.
8. Calcification/calcified pulmonary shadow	A focal homogeneous high-intensity (high-density) shadow with clear contours
9. Mediastinum widening	Widening of the mediastinal shadow in both directions, local expansion of the mediastinal shadow on one side, increased transparency of the mediastinal shadow, darkening on top of the mediastinal shadow, shifting the mediastinal shadow
10. Cardiomegaly	Increase in the cardiothoracic index (the ratio of the transverse size of the heart, excluding a fat pad on the heart apex, to the internal size of the chest) more than 0.5
11. Cortical bone fracture	Local interruption of the line of the outer contour of bone, possibly with displacement/diastasis of the bone fragments
12. Consolidated fracture	Deformation of contours of the bone structures, bone callus

Baseline diagnostic requirements for AI service results to identify a complex of lung pathologies on X-ray (from Q3 2023)

Diagnostic study	Clinical task being performed by AI service	Preliminary phase (retrospective study) – signs of studies of the calibration dataset	Main phase (prospective study) – signs for which positive and negative results of the AI service are expected	Content of the AI service response	AI service response format	A form of the AI-service response provision
Chest X-ray	Detection of the presence and localization of radiological signs consistent with: • lung tuberculosis • pneumonia, purulent and necrotic conditions • hydrothorax • pneumothorax • lung atelectasis • lung tumors • rib(s) fracture • cardiomegaly • mediastinum pathology	**Signs of pathology are present:** A presence of at least one radiological sign from the list for each of the pathologies (**slides 47-55**): • pleural effusion • pneumothorax • focal opacity (including focus/tumor) • infiltration/consolidation • dissemination • cavity • atelectasis • calcification/calcified pulmonary shadow • mediastinal widening (including pulmonary hilar enlargement) • cardiomegaly • cortical bone fracture		**Obligatory** – probability of a pathology in the entire study	Number	Apache Kafka Message
				Obligatory – probability of each radiological sign in the entire study	Integer	Apache Kafka Message
				Obligatory – localization and definitive digital identification of findings (reported in DICOM SR)	Contour	DICOM, DICOM SR
				Obligatory – a text description of features from the A-list if detected. If a pathology is absent, a text description of the "norm"	Text	DICOM
		Signs of pathology are absent: none of the radiological sign from the A-list		**Obligatory** – a text description of pleural sinuses	Text	DICOM SR
				Optional – a text description of the pulmonary pattern	Text	DICOM SR
				Optional – a text description of aorta	Text	DICOM SR
				Optional – a text description of diaphragm	Text	DICOM SR

Baseline diagnostic requirements for AI service results to identify lung tuberculosis on chest X-ray

Diagnostic study	Clinical task being performed by AI service	Preliminary phase (retrospective study) – signs of studies of the calibration dataset	Main phase (prospective study) – signs for which positive and negative results of the AI service are expected	Content of the AI service response	AI service response format	A form of the AI-service response provision
Chest X-ray	Detection of the presence and localization of radiological signs consistent with lung tuberculosis	Signs of pathology are present: A. A presence of at least one radiological sign from the list below : 1. **Focus** – a focal dense lesion in lung tissue up to 1 cm (10 mm) in size within 1 or 2 segments 2. **Calcified focus** within the lung fields 3. **Dissemination** – a presence of multiple lesions localized in more than two segments in one or both lungs 4. **Miliary foci** – numerous discrete small foci up to 2 mm in size 5. **Rounded formation** – an altered area of lung tissue of varying intensity that differs from the surrounding anatomical lung structures, chest wall or mediastinum, measuring more than 1 cm in diameter 6. **Lung cavity** – a focal lucency; it may have a wall of different thickness; it may have a horizontal liquid level 7. **Shading with focal changes** – a decrease in the transparency of pulmonary fields with an indistinct contour, in combination with a focal lesion/dissemination/rounded formation 8. **Focus** with a "track" of high-density lung tissue from the focus to the lung root B. (for the preliminary phase only) 1. Positive verification by another study method 2. Established diagnosis of lung tuberculosis (A15, A16, A19)		**Obligatory** – probability of features from the A-list	Number	Apache Kafka Message
				Obligatory – localization of pathological findings, digital identification, quantity (single, multiple)	Contour	DICOM
		Signs of pathology are absent: none of the radiological sign from the A-list		**Obligatory** – text description of the detected pathology	Text	DICOM SR

SOURCES: 1. Diagnostic radiology of the chest organs: national guidelines/Series "National guidelines for diagnostic radiology and therapy" / Ch. ed. series S. Ternova; Editor-in-chief of the volume V.N. Troyan, A. Shekhter. – M. : GEOTAR-Media, 2014. – 584 p.
2. Hansell D. M., Bankier A. A., MacMahon H. et al. Fleischner Society: glossary of terms for thoracic imaging // Radiology. – 2008. – Mar. – Vol. 246, №3. – Vol. 697–722. – DOI: 10.1148/radiol.2462070712 With comments of the Expert Group of Russian Society of Radiologists and Radiation Therapists (RSRR)
3. Yablonsky P.K., Phthisiology. National Clinical Guidelines// M.: GEOTAR-Media, 2015. -240 p.

Baseline diagnostic requirements for AI service results to identify pneumonia, purulent and necrotic conditions on chest X-ray

Diagnostic study	Clinical task being performed by AI service	Preliminary phase (retrospective study) – signs of studies of the calibration dataset	Main phase (prospective study) – signs for which positive and negative results of the AI service are expected	Content of the AI service response	AI service response format	A form of the AI-service response provision
Chest X-ray	Detection of the presence and localization of radiological signs consistent with pneumonia, purulent and necrotic conditions	**Signs of pathology are present:** A. A presence of at least one radiological sign from the list below : 1. **Infiltration** – a focal lung tissue compaction without clear contours, often of irregular shape 2. **Consolidation** – a local opacity or compaction of the lung tissue, in which air lumens of bronchi are sometimes visible. A shadow intensity of the consolidation area is determined by its volume and shape. 3. **Lung cavity** – a focal lucency; it may have a wall of different thickness; it may have a horizontal liquid level B. (for the preliminary phase only) 1. Positive verification by another study method 2. Established diagnosis of pneumonia, purulent and necrotic conditions (J10–J18, J80–J86)		**Obligatory** – probability of features from the A-list	Number	Apache Kafka Message
				Obligatory – localization of pathological findings	Contour	DICOM
		Signs of pathology are absent: none of the radiological sign from the A-list		**Obligatory –** text description of the detected pathology	Text	DICOM SR

SOURCES: 1. Diagnostic radiology of the chest organs: national guidelines/Series "National guidelines for diagnostic radiology and therapy" / Ch. ed. series S. Ternova; Editor-in-chief of the volume V.N. Troyan, A. Shekhter. – M. : GEOTAR-Media, 2014. – 584 p.
2. Hansell D. M., Bankier A. A., MacMahon H. et al. Fleischner Society: glossary of terms for thoracic imaging // Radiology. – 2008. – Mar. – Vol. 246, №3. – Vol. 697–722. – DOI: 10.1148/radiol.2462070712
With comments of the Expert Group of Russian Society of Radiologists and Radiation Therapists (RSRR)

Baseline diagnostic requirements for AI service results to identify hydrothorax on chest X-ray

Diagnostic study	Clinical task being performed by AI service	Preliminary phase (retrospective study) – signs of studies of the calibration dataset	Main phase (prospective study) – signs for which positive and negative results of the AI service are expected	Content of the AI service response	AI service response format	A form of the AI-service response provision
Chest X-ray	Detection of the presence and localization of radiological signs consistent with hydrothorax	**Signs of pathology are present:** A. A presence of at least one radiological sign from the list below : 1. **Pleural effusion** – homogeneous opacity in the lower areas of the lung with the almost horizontal or Damuazo curve contour; at the same time, a costodiaphragmatic sinus is not visible **2. Subtotal/total/diffuse shading** – homogeneous decrease in the transparency of the lung fields of the almost entire lung/entire lung/both lungs, respectively B. (for the preliminary phase only) 1. Positive verification by another study method 2. Established diagnosis of hydrothorax (J94, R09.1)		**Obligatory** – probability of features from the A-list	Number	Apache Kafka Message
				Obligatory – localization of pathological findings	Contour	DICOM
		Signs of pathology are absent: none of the radiological sign from the A-list		**Obligatory –** text description of the detected pathology	Text	DICOM SR

SOURCES: 1. Diagnostic radiology of the chest organs: national guidelines/Series "National guidelines for diagnostic radiology and therapy" / Ch. ed. series S. Ternova; Editor-in-chief of the volume V.N. Troyan, A. Shekhter. – M. : GEOTAR-Media, 2014. – 584 p.
2. Hansell D. M., Bankier A. A., MacMahon H. et al. Fleischner Society: glossary of terms for thoracic imaging // Radiology. – 2008. – Mar. – Vol. 246, №3. – Vol. 697–722. – DOI: 10.1148/radiol.2462070712
With comments of the Expert Group of Russian Society of Radiologists and Radiation Therapists (RSRR)

Baseline diagnostic requirements for AI service results to identify pneumothorax on chest X-ray

Diagnostic study	Clinical task being performed by AI service	Preliminary phase (retrospective study) – signs of studies of the calibration dataset	Main phase (prospective study) – signs for which positive and negative results of the AI service are expected	Content of the AI service response	AI service response format	A form of the AI-service response provision
Chest X-ray	Detection of the presence and localization of radiological signs consistent with pneumothorax	**Signs of pathology are present:** A. A presence of at least one radiological sign from the list below: 1. **Pneumothorax** – a homogeneous increase in the transparency of the lung fields, mainly in the upper regions, in which: - a line of the visceral pleura is indicated - lung pattern is not visualized - mediastinum may shift to the healthy side and diaphragm flatten B. (for the preliminary phase only) 1. Positive verification by another study method 2. Established diagnosis of pneumothorax (S27.0)		**Obligatory** – probability of features from the A-list	Number	Apache Kafka Message
				Obligatory – localization of pathological findings	Contour	DICOM, Apache Kafka Message + DICOM SR
		Signs of pathology are absent: none of the radiological sign from the A-list		**Obligatory –** text description of the detected pathology	Text	DICOM SR

SOURCES: 1. Diagnostic radiology of the chest organs: national guidelines/Series "National guidelines for diagnostic radiology and therapy" / Ch. ed. series S. Ternova; Editor-in-chief of the volume V.N. Troyan, A. Shekhter. – M. : GEOTAR-Media, 2014. – 584 p.
2. Hansell D. M., Bankier A. A., MacMahon H. et al. Fleischner Society: glossary of terms for thoracic imaging // Radiology. – 2008. – Mar. – Vol. 246, №3. – Vol. 697–722. – DOI: 10.1148/radiol.2462070712
With comments of the Expert Group of Russian Society of Radiologists and Radiation Therapists (RSRR)

Baseline diagnostic requirements for AI service results to identify lung atelectasis on chest X-ray

Diagnostic study	Clinical task being performed by AI service	Preliminary phase (retrospective study) – signs of studies of the calibration dataset	Main phase (prospective study) – signs for which positive and negative results of the AI service are expected	Content of the AI service response	AI service response format	A form of the AI-service response provision
Chest X-ray	Detection of the presence and localization of radiological signs consistent with lung atelectasis	**Signs of pathology are present:** A. A presence of at least one radiological sign from the list below: 1. **Atelectasis** – volume reduction and compaction of the anatomical structure of lungs – a segment/lobe, while one of the compaction edge is formed by the interlobar fissure and has a clear concave contour. A volume of the collapsed part of the lung is reduced. B. (for the preliminary phase only) 1. Positive verification by another study method 2. Established diagnosis of atelectasis (J98.1)		**Obligatory** – probability of features from the A-list	Number	Apache Kafka Message
				Obligatory – localization of pathological findings	Contour	DICOM
		Signs of pathology are absent: none of the radiological sign from the A-list		**Obligatory –** text description of the detected pathology	Text	DICOM SR

SOURCES: 1. Diagnostic radiology of the chest organs: national guidelines/Series "National guidelines for diagnostic radiology and therapy" / Ch. ed. series S. Ternova; Editor-in-chief of the volume V.N. Troyan, A. Shekhter. – M. : GEOTAR-Media, 2014. – 584 p.
2. Hansell D. M., Bankier A. A., MacMahon H. et al. Fleischner Society: glossary of terms for thoracic imaging // Radiology. – 2008. – Mar. – Vol. 246, №3. – Vol. 697–722. – DOI: 10.1148/radiol.2462070712
With comments of the Expert Group of Russian Society of Radiologists and Radiation Therapists (RSRR)

Baseline diagnostic requirements for AI service results to identify lung neoplasms on chest X-ray

Diagnostic study	Clinical task being performed by AI service	Preliminary phase (retrospective study) – signs of studies of the calibration dataset	Main phase (prospective study) – signs for which positive and negative results of the AI service are expected	Content of the AI service response	AI service response format	A form of the AI-service response provision
Chest X-ray	Detection of the presence and localization of radiological signs consistent with lung neoplasm	**Signs of pathology are present:** A. A presence of at least one radiological sign from the list below: **1. Focus** – a focal dense lesion in lung tissue up to 1 cm (10 mm) in size within 1 or 2 segments 2. **Rounded formation /Nodule** – focal compaction of the lung tissue of various shapes and contours, more than 1 cm in size 3. **Dissemination** – a presence of multiple lesions localized in more than two segments in one or both lungs 4. **Enlargement/deformation** of the lung root 5. **Enlargement of mediastinal lymph nodes (mediastinal widening)** – significantly enlarged, calcified, more than 2 cm in size 6. **Atelectasis** – volume reduction and compaction of the anatomical structure of the lung – a segment/lobe, while one of the compaction edge is formed by an interlobar fissure and has a clear concave contour. A volume of the collapsed part of the lung is reduced. B. (for the preliminary phase only) 1. Positive verification by another study method 2. Established diagnosis of lung neoplasm (D38.1– D38.4, C34–C39)		**Obligatory** – probability of features from the A-list	Number	Apache Kafka Message
				Obligatory – localization of pathological findings	Contour	DICOM
		Signs of pathology are absent: none of the radiological sign from the A-list		**Obligatory –** text description of the detected pathology	Text	DICOM SR

SOURCES: 1. Diagnostic radiology of the chest organs: national guidelines/Series "National guidelines for diagnostic radiology and therapy" / Ch. ed. series S. Ternova; Editor-in-chief of the volume V.N. Troyan, A. Shekhter. – M. : GEOTAR-Media, 2014. – 584 p.
2. Hansell D. M., Bankier A. A., MacMahon H. et al. Fleischner Society: glossary of terms for thoracic imaging // Radiology. – 2008. – Mar. – Vol. 246, №3. – Vol. 697–722. – DOI: 10.1148/radiol.2462070712 With comments of the Expert Group of Russian Society of Radiologists and Radiation Therapists (RSRR)

Baseline diagnostic requirements for AI service results to identify cardiomegaly on chest X-ray

Diagnostic study	Clinical task being performed by AI service	Preliminary phase (retrospective study) – signs of studies of the calibration dataset	Main phase (prospective study) – signs for which positive and negative results of the AI service are expected	Content of the AI service response	AI service response format	A form of the AI-service response provision
Chest X-ray	Detection of the presence and localization of radiological signs consistent with cardiomegaly	**Signs of pathology are present:** A. A presence of at least one radiological sign from the list below: 1. **Enlargement of the heart shadow** – increase in the ratio of the transverse size of the heart to the largest internal size of the thorax which is more than 0.5 (cardiothoracic index) B. (for the preliminary phase only) 1. Positive verification by another study method 2. Established diagnosis of cardiomegaly (I51.7)		**Obligatory** – probability of features from the A-list	Number	Apache Kafka Message
				Obligatory – a value of the cardiothoracic ratio value	Number	Apache Kafka Message + DICOM
				Obligatory – localization of pathological findings	Contour	DICOM
		Signs of pathology are absent: none of the radiological sign from the A-list		**Obligatory –** text description of the detected pathology	Text	DICOM SR

SOURCES: 1. Diagnostic radiology of the chest organs: national guidelines/Series "National guidelines for diagnostic radiology and therapy" / Ch. ed. series S. Ternova; Editor-in-chief of the volume V.N. Troyan, A. Shekhter. – M. : GEOTAR-Media, 2014. – 584 p.
2. Hansell D. M., Bankier A. A., MacMahon H. et al. Fleischner Society: glossary of terms for thoracic imaging // Radiology. – 2008. – Mar. – Vol. 246, №3. – Vol. 697–722. – DOI: 10.1148/radiol.2462070712
With comments of the Expert Group of Russian Society of Radiologists and Radiation Therapists (RSRR)

Baseline diagnostic requirements for AI service results to identify mediastinum pathology on chest X-ray

Diagnostic study	Clinical task being performed by AI service	Preliminary phase (retrospective study) – signs of studies of the calibration dataset	Main phase (prospective study) – signs for which positive and negative results of the AI service are expected	Content of the AI service response	AI service response format	A form of the AI-service response provision
Chest X-ray	Detection of the presence and localization of radiological signs consistent with mediastinum pathology	**Signs of pathology are present:** A. A presence of at least one radiological sign from the list below: 1. **Mediastinal widening** – enlargement of the mediastinal shadow on one or both sides, partial or total, including by pneumomediastinum – vertical strips of enlightenment in the mediastinal space along the vessels and the main bronchi. B. (for the preliminary phase only) 1. Positive verification by another study method 2. Established diagnosis of mediastinum pathology (D15.2, D38.3, I71)		**Obligatory** – probability of features from the A-list	Number	Apache Kafka Message
				Obligatory – localization of pathological findings	Contour	DICOM
		Signs of pathology are absent: none of the radiological sign from the A-list		**Obligatory –** text description of the detected pathology	Text	DICOM SR

SOURCES: 1. Diagnostic radiology of the chest organs: national guidelines/Series "National guidelines for diagnostic radiology and therapy" / Ch. ed. series S. Ternova; Editor-in-chief of the volume V.N. Troyan, A. Shekhter. – M. : GEOTAR-Media, 2014. – 584 p.
2. Hansell D. M., Bankier A. A., MacMahon H. et al. Fleischner Society: glossary of terms for thoracic imaging // Radiology. – 2008. – Mar. – Vol. 246, №3. – Vol. 697–722. – DOI: 10.1148/radiol.2462070712
With comments of the Expert Group of Russian Society of Radiologists and Radiation Therapists (RSRR)

Baseline diagnostic requirements for AI service results to identify rib(s) fracture on chest X-ray

Diagnostic study	Clinical task being performed by AI service	Preliminary phase (retrospective study) – signs of studies of the calibration dataset	Main phase (prospective study) – signs for which positive and negative results of the AI service are expected	Content of the AI service response	AI service response format	A form of the AI-service response provision
Chest X-ray	Detection of the presence and localization of radiological signs consistent with rib(s) fracture	**Signs of pathology are present:** A. A presence of at least one radiological sign from the list below: 1. **Fracture** line – violation of the integrity of the rib(s) cortical bone; local interruption of the outer contour of bone, possibly with displacement/diastasis of bone fragments B. (for the preliminary phase only) 1. Positive verification by another study method 2. Established diagnosis of rib(s) fracture (S22)		**Obligatory** – probability of features from the A-list	Number	Apache Kafka Message
				Obligatory – localization of pathological findings	Contour	DICOM
		Signs of pathology are absent: none of the radiological sign from the A-list		**Obligatory –** text description of the detected pathology	Text	DICOM SR

SOURCES: 1. Diagnostic radiology of the chest organs: national guidelines/Series "National guidelines for diagnostic radiology and therapy" / Ch. ed. series S. Ternova; Editor-in-chief of the volume V.N. Troyan, A. Shekhter. – M. : GEOTAR-Media, 2014. – 584 p.
2. Hansell D. M., Bankier A. A., MacMahon H. et al. Fleischner Society: glossary of terms for thoracic imaging // Radiology. – 2008. – Mar. – Vol. 246, №3. – Vol. 697–722. – DOI: 10.1148/radiol.2462070712
With comments of the Expert Group of Russian Society of Radiologists and Radiation Therapists (RSRR)

Baseline diagnostic requirements for AI service results to identify vertebral fractures on X-ray

Diagnostic study	Clinical task being performed by AI service	Preliminary phase (retrospective study) – signs of studies of the calibration dataset	Main phase (prospective study) – signs for which positive and negative results of the AI service are expected	Content of the AI service response	AI service response format	A form of the AI-service response provision
Lateral spine X-ray (cervical, thoracic, and lumbar regions)	Detection and localization of compression vertebral fractures with loss of height over 25%	**Signs of pathology are present:** Presence of vertebrae with over 25% loss of height in the analyzed study. A deformity degree is calculated using the following formula: *Deformity* degree = *(maximal vertebra size – minimal vertebra size)/maximal vertebra size*100 %*		**Obligatory** – probability of the presence of at least one vertebra with > 25% height loss	Number	Apache Kafka Message
				Obligatory – listing the localizations of all vertebrae with > 25% height loss	Text	Apache Kafka Message + DICOM SR
				Optional – degree of compression	Text	Apache Kafka Message + DICOM SR
		Signs of pathology are absent: the bodies of all vertebrae in the analyzed study do not have height loss of 25% or more		**Optional** – localization of detected signs in X-ray images	Contour/mask	DICOM

SOURCES:

1. Kondo K.L. Osteoporotic vertebral compression fractures and vertebral augmentation // Semin Intervent Radiol. – 2008. – Vol. 25, № 4. – P. 413–424. – DOI: 10.1055/s-0028-1103000.
2. Lenchik L., Rogers L.F., Delmas P.D. et al. Diagnosis of osteoporotic vertebral fractures: importance of recognition and description by radiologists // AJR Am J Roentgenol. – 2004. – Vol. 183, №4. P. 949–958.

Baseline diagnostic requirements for AI service results to identify signs of osteochondrosis on X-ray

Diagnostic study	Clinical task being performed by AI service	Preliminary phase (retrospective study) – signs of studies of the calibration dataset	Main phase (prospective study) – signs for which positive and negative results of the AI service are expected	Content of the AI service response	AI service response format	A form of the AI-service response provision
Spine X-ray in frontal and lateral view (cervical, thoracic, and lumbar regions)	Detection of radiological signs consistent with osteochondrosis in the frontal and/or sagittal planes	**Signs of pathology are present**: A. 1.Decrease in the lumbar disc height (compared to those located above). 2. Spondylolisthesis. 3. Marginal bone growths extending endplates of vertebral bodies. 4. Subchondral osteosclerosis.		**Obligatory** – probability of signs from the A-list in the study	Number	Apache Kafka Message
		B. (for preliminary phase only) Signs of spine osteochondrosis, confirmed by two experts by consensus.		**Obligatory** – localization of findings	Contour	DICOM
		Signs of pathology are absent: absence of the indicated radiological signs.		**Obligatory** – a list of detected pathological findings	No detected signs of osteochondrosis – probability. Detected signs of osteochondrosis – probability.	DICOM SR

SOURCES: 1. Decree of the Government of the Russian Federation No. 565 dated 04.07.2013 (edited on 01.06.2020, as amended on 27.09.2021) "On approval of the Regulation on military medical expertise" 2. P. Zharkov. Osteochondrosis and other degenerative changes of the spine in adults and children. – M.: Medicine, 2014.

Baseline diagnostic requirements for AI service results to identify signs of scoliosis on X-ray

Diagnostic study	Clinical task being performed by AI service	Preliminary phase (retrospective study) – signs of studies of the calibration dataset	Main phase (prospective study) – signs for which positive and negative results of the AI service are expected	Content of the AI service response	AI service response format	A form of the AI-service response provision
Spine X-ray in frontal and lateral view (thoracic and lumbar regions)	Detection of radiological signs consistent with scoliosis in the direct projection	**Signs of pathology are present:** A. A presence of the sideways curvature of the spine (Grade I – 1-10 degree curve, grade II – 11-25 degree curve, grade III – 26-50 degree curve, grade IV – above 50 degree curve)		**Obligatory** – probability of the radiological sign A in the study	Number	Apache Kafka Message
		B. (for preliminary phase only) A sideways curvature of the spine confirmed by two experts by consensus.		**Obligatory** – localization of findings	Contour	DICOM
		Signs of pathology are absent: absence of the indicated radiological signs.		**Obligatory** – availability of information on the quantitative assessment of the angles of spine deformity in the presented study (absolute values and/or the degree of scoliosis). Direction of the scoliosis curve. In case of two opposite directed C-scoliosis, a conclusion should contain the diagnosis of "S-scoliosis" and measurement of angular deformity to the right and to the left.	Right-/left-sided C-scoliosis of the 1st grade – probability – angle; S-scoliosis of the 1-4 degree – probability – to the right 35˚, to the left 52˚.	Apache Kafka Message + DICOM SR

SOURCES:
1. Decree of the Government of the Russian Federation No. 565 dated 04.07.2013 (edited on 01.06.2020, as amended on 27.09.2021) "On approval of the Regulation on military medical expertise"
2. V. Chaklin. Scoliosis and kyphoses. – M.: Medicine, 1973.

Baseline diagnostic requirements for AI service results to identify signs of spondylolisthesis on X-ray

Diagnostic study	Clinical task being performed by AI service	Preliminary phase (retrospective study) – signs of studies of the calibration dataset	Main phase (prospective study) – signs for which positive and negative results of the AI service are expected	Content of the AI service response	AI service response format	A form of the AI-service response provision
Lateral spine X-ray (thoracic and lumbar regions)	Detection of radiological signs consistent with spondylolisthesis in the sagittal projection	**Signs of pathology are present:** A. Grade I-IV slip displacement of the overlying vertebra anteriorly or posteriorly to the underlying vertebra, as per the guidelines*		**Obligatory** – probability of the radiological sign A in the study	Number	Apache Kafka Message
		B. (for preliminary phase only) A vertebral displacement confirmed by two experts by consensus.		**Obligatory** – localization of findings	Contour/mask	DICOM
		Signs of pathology are absent: absence of the indicated radiological signs.		**Obligatory** – availability of information on the quantitative assessment of the grade of vertebra displacement in the presented study (absolute values and/or the degree of displacement). Direction of listhesis.	Grade I displacement – probability. … Grade IV displacement – probability.	Apache Kafka Message + DICOM SR

SOURCES:

1. Decree of the Government of the Russian Federation No. 565 dated 04.07.2013 (edited on 01.06.2020, as amended on 27.09.2021) "On approval of the Regulation on military medical expertise".
2. Spondylolisthesis // Radiopaedia. – 2021.– 11 Oct. – URL: https://radiopaedia.org/articles/spondylolisthesis-1.
3. Martin C.R. et al. The surgical management of degenerative lumbar spondylolisthesis: a systematic review // Spine (Phila Pa 1976). – 2007. – Vol. 32, №16. – P. 1791–1798.

Baseline diagnostic requirements for AI service results to identify signs of bone fractures on X-ray

Diagnostic study	Clinical task being performed by AI service	Preliminary phase (retrospective study) – signs of studies of the calibration dataset	Main phase (prospective study) – signs for which positive and negative results of the AI service are expected	Content of the AI service response	AI service response format	A form of the AI-service response provision
X-ray of the wrist, shoulder, hip, ankle joint	Detection of radiological signs (at least one) consistent with a bone fracture	**Signs of pathology are present:** A. 1. Presence of a fracture line in the study. 2. A zone of violation of the integrity of the cortical bone. 3. Presence of a diastasis of bone fragments at the fracture in the presented study.		**Obligatory** – probability of signs of the target pathology in the presented study	Number	Apache Kafka Message
		B. (for preliminary phase only) A bone fracture on the X-ray confirmed by two experts by consensus.		**Obligatory** – localization of findings	Contour/mask	DICOM
		Signs of pathology are absent: absence of the indicated radiological signs.		**Obligatory** – availability of the quantitative assessment of the degree of diastasis of bone fragments in the presented X-ray study	Number	DICOM SR

SOURCES: Diagnostic radiology of the bones and joints diseases: National guidelines/Series "National guidelines for diagnostic radiology and therapy"/Ch. ed. of series S. Ternova; Editor-in-chief A. Morozov. – M.: GEOTAR-Медиа, 2016.– 832 p.

Baseline diagnostic requirements for AI service results to identify signs of deforming arthrosis on X-ray

Diagnostic study	Clinical task being performed by AI service	Preliminary phase (retrospective study) – signs of studies of the calibration dataset	Main phase (prospective study) – signs for which positive and negative results of the AI service are expected	Content of the AI service response	AI service response format	A form of the AI-service response provision
Knee X-ray	Detection of radiological signs (at least one) consistent with deforming arthrosis	**Signs of pathology are present:** 1. Decrease in the height of the intra-articular gap on presented X-ray images (stage I)*. 2. Presence of marginal bone growths (osteophytes) of ≥ 2mm along the articular surfaces on the presented X-ray images (stage II). 3. Pronounced narrowing of the intra-articular gap by more than 2 times compared with the normal value + subchondral osteosclerosis (stage II). 4. Pronounced narrowing of the intra-articular gap < 1 mm, up to a complete absence (stage III)		**Obligatory** – probability of indicated radiological signs (at least one) in the entire study.	Number	Apache Kafka Message
				Obligatory – localization of the identified sign (at least one) in the entire study.	Contour/mask	DICOM
		Signs of pathology are absent: absence of the indicated radiological signs.		**Obligatory** – determination of the severity degree of identified signs –arthrosis stages 1-3.	Arthrosis stage 1 – probability. Arthrosis stage 2 – probability. Arthrosis stage 3 – probability.	Apache Kafka Message + DICOM SR

NOTE: * Arthrosis staging according to the classification of N. S. Kosinskaya (1961): Degenerative-dystrophic diseases of the osteoarticular apparatus / N. Kosinskaya. – L., 1961.

SOURCES: 1. Kellgren J. H., Lawrence J. S. Radiological assessment of osteo-arthrosis // Ann Rheum Dis. – 1957. – Dec. – Vol. 16, №4. – P. 494–502. – DOI: 10.1136/ard.16.4.494.
2. Braun H. J., Gold G. E. Diagnosis of osteoarthritis: imaging // Bone. – 2012. – Aug. – Vol. 51, №2. – P. 278–288. – DOI: 10.1016/j.bone.2011.11.019.
3. N. Kosinskaya. Degenerative-dystrophic diseases of the osteoarticular apparatus. – M.:"Kniga Po Trebovaniyu" publishing, 2013. – 245 p.
4. Clinical guidelines for the diagnosis and treatment of osteoarthritis of the All-Russian public organization "Association of rheumatologists of Russia".– 2013.

Baseline diagnostic requirements for AI service results to identify signs of deforming arthrosis on X-ray

Diagnostic study	Clinical task being performed by AI service	Preliminary phase (retrospective study) – signs of studies of the calibration dataset	Main phase (prospective study) – signs for which positive and negative results of the AI service are expected	Content of the AI service response	AI service response format	A form of the AI-service response provision
Hip X-ray	Detection of radiological signs (at least one) consistent with deforming arthrosis	**Signs of pathology are present:** A. 1. Decrease in the height of the intra-articular gap on presented X-ray images (stage 1). 2. Presence of marginal bone growths (osteophytes) along the articular surfaces on the presented X-ray images (stage 2). 3. Pronounced narrowing of the intra-articular gap up to a complete absence (stage 3)		**Obligatory** – probability of signs of the target pathology	Number	Apache Kafka Message
				Obligatory – a value of the joint space on X-ray	Number	DICOM, DICOM SR , Apache Kafka Message
				Obligatory – probability of osteophytes	Contour/mask	DICOM
		B. (for preliminary phase only) Arthrosis of the hip joint on X-ray, confirmed by two experts by consensus.		**Obligatory** – determination of the severity degree of identified signs according to the classification (arthrosis stages 1-3)	Text	DICOM SR , Apache Kafka Message
		Signs of pathology are absent: absence of the indicated radiological signs.		**Obligatory** — probability of aseptic necrosis	Number	DICOM SR , Apache Kafka Message

ИСТОЧНИКИ:

1. Kellgren J. H., Lawrence J. S. Radiological assessment of osteo-arthrosis // Ann Rheum Dis. – 1957. – Dec. – Vol. 16, №4. – P. 494–502. – DOI: 10.1136/ard.16.4.494.
2. N. Kosinskaya. Degenerative-dystrophic diseases of the osteoarticular apparatus. – M.:”Kniga Po Trebovaniyu” publishing, 2013. – 245 p.
3. Clinical guidelines for the diagnosis and treatment of osteoarthritis of the All-Russian public organization "Association of rheumatologists of Russia".– 2013.

Baseline diagnostic requirements for AI service results to identify signs of longitudinal flat feet on X-ray

Diagnostic study	Clinical task being performed by AI service	Preliminary phase (retrospective study) – signs of studies of the calibration dataset	Main phase (prospective study) – signs for which positive and negative results of the AI service are expected	Content of the AI service response	AI service response format	A form of the AI-service response provision
Foot X-ray	Detection of radiological signs (at least one) consistent with flat feet on lateral X-ray	**Signs of pathology are present:** A. A value of the angle of the foot arch of grades I – III according to the classification* B. A value of the foot arch height of grades I – III according to the classification*		**Obligatory** – probability of the A and/or B radiological signs in the study.	Number	Apache Kafka Message
		Presence of A and/or B signs, confirmed by two experts by consensus.				
		Signs of pathology are absent: Values of the angle and height of the foot arch are within the normal range* (see the classification)		**Obligatory** – graphical representation of the assessment of angle and height of the foot arch.	Contour/Labeling/ Text	DICOM /DICOM SR
				Obligatory – availability of information on the quantitative assessment of the angle and height of the foot arch with identification of the degree of changes	Flat feet grade 1 – probability. Flat feet grade 3 – probability.	Apache Kafka Message + DICOM DICOM SR

NOTE: *X-ray examination of flat feet : https://zhuravlev.info/a_14_-Рен-генологи-еска—кспер-иза-плоскос-опи

SOURCES: 1. Diagnostic radiology of the bones and joints diseases: National guidelines/Series "National guidelines for diagnostic radiology and therapy"/Ch. ed. of series S. Ternova; Editor-in-chief A. Morozov. – M.: GEOTAR-Медиа, 2016.– 832 p

2. Decree of the Government of the Russian Federation No. 565 dated 04.07.2013 (edited on 01.06.2020, as amended on 27.09.2021) "On approval of the Regulation on military medical expertise".

Baseline diagnostic requirements for AI service results to identify signs of transverse flat feet on X-ray

Diagnostic study	Clinical task being performed by AI service	Preliminary phase (retrospective study) – signs of studies of the calibration dataset	Main phase (prospective study) – signs for which positive and negative results of the AI service are expected	Content of the AI service response	AI service response format	A form of the AI-service response provision
Foot X-ray	Detection of radiological signs (at least one) consistent with transverse flat feet	**Signs of pathology are present:** A. A value of the 1st-2nd intermetatarsal angle of the foot is 10° or more. (Grade I – 10°–12°, grade II – 13°–15°, grade III – 16°–20°, grade IV – more than 20°).		**Obligatory** – probability of transverse flat feet signs in the study.	Number	Apache Kafka Message
		B. (for preliminary phase only) Transverse flat feet on X-ray, confirmed by two experts by consensus.		**Obligatory** – graphical representation of the 1st-2nd intermetatarsal angle and the angle of deviation of the big toe	Contour/mask	DICOM
		Signs of pathology are absent: absence of the indicated radiological signs.		**Obligatory** – presence of H.Valgus signs with indication of the grade: grade I – 15°–20°, grade II – 21°–30°, grade III – 31°–40°, grade IV – >40°.	Number, text	DICOM SR, Apache Kafka Message
				Obligatory – availability of information on the quantitative assessment of the 1st-2nd intermetatarsal angle and the angle of deviation of the big toe with identification of the grade of transverse flat feet.	Flat feet grade 1 – probability. Flat feet grade 4 – probability.	DICOM SR, Apache Kafka Message

SOURCES :

1. Diagnostic radiology of the bones and joints diseases: National guidelines/Series "National guidelines for diagnostic radiology and therapy"/Ch. ed. of series S. Ternova; Editor-in-chief A. Morozov. – M.: GEOTAR-Медиа, 2016.– 832 p
2. Decree of the Government of the Russian Federation No. 565 dated 04.07.2013 (edited on 01.06.2020, as amended on 27.09.2021) "On approval of the Regulation on military medical expertise".
3. Serova N.S., Belyaev A.S., Bobrov D.S., and Ternovoy K.S. "Modern radiological diagnostics of acquired flat feet in adults" Bulletin of Radiology and Radiation Therapy, vol. 98, no. 5, 2017, pp. 275-280

Baseline diagnostic requirements for AI service results to identify signs of breast cancer based on screening mammography

Diagnostic study	Clinical task being performed by AI service	Preliminary phase (retrospective study) – signs of studies of the calibration dataset	Main phase (prospective study) – signs for which positive and negative results of the AI service are expected	Content of the AI service response	AI service response format	A form of the AI-service response provision
Screening mammography	Detection and localization of findings consistent with breast cancer	**Signs of pathology are present:** A. BI-RADS 3–5 B. (for preliminary phase only) Results of pathomorphological examination – malignant neoplasm.		**Obligatory** – probability of breast cancer signs in the entire study (C50) – see A-list.	Fractional or integer number	Apache Kafka Message
				Obligatory – X-ray density of the structure according to ACR (for each breast).	Text	DICOM SR
				Obligatory – presence of calcifications.		
				Obligatory – a type of calcifications (benign/suspicious).		
				Obligatory – distribution of calcifications.		
				Optional – localization of calcifications.		
				Obligatory – presence of breast formations.	Contour, text	DICOM, DICOM SR
				Obligatory – localization of breast formations (quadrant).	Text	DICOM SR
				Obligatory – detection of disruption of the tissue architectonics.		
				Obligatory – localization of the disrupted tissue architectonics (quadrant).		
		Signs of pathology are absent: BI-RADS 1–2		**Obligatory** – detection of altered axillary lymph nodes.		
				Obligatory – BI-RADS classification report for each breast.		

SOURCES: 1. Organization of a population-based breast cancer screening program for women: guidelines/ S.P. Morozov, N. N. Vetsheva, V. Didenko [et al.] //Series "Best practices of radiology and instrumental diagnostics" – Issue 55. – M. : Center for Diagnostics and Telemedicine of the Moscow Healthcare Department, 2020. – 44 c. – URL: https://tele-med.ai/biblioteka-dokumentov/organizaciya-programmy-populyacionnogo-skrininga-zlokachestvennyh-novoobrazovanij-molochnoj-zhelezy-sredi-zhenskogo-naseleniya (accessed on : 15.06.2021).
2. Clinical guidelines of the Ministry of Health of the Russian Federation "Benign mammary dysplasia". – 2020. – ID 598. – URL: https://cr.minzdrav.gov.ru/recomend/598 (15.06.2021).

Baseline diagnostic requirements for AI service results to identify multiple sclerosis on brain MRI

Diagnostic study	Clinical task being performed by AI service	Preliminary phase (retrospective study) – signs of studies of the calibration dataset	Main phase (prospective study) – signs for which positive and negative results of the AI service are expected	Content of the AI service response	AI service response format	A form of the AI-service response provision
Magnetic resonance imaging of the brain	Detection of multiple sclerosis and its differential diagnosis from other pathologies	**Signs of pathology are present:** A. 1. MRI without contrast enhancement: presence of hyperintensive demyelinating lesions ≥1 no less than 3 mm in size along the long axis on T2- and/or FLAIR in two or more locations: juxtacortical or subcortical, periventricular, infratentorial (McDonald criteria*) – pathognomonic. 2. MRI with contrast enhancement: presence of lesions ≥1 accumulated a contrast agent on post-contrast T1-images – pathognomonic. B. (for preliminary phase only) Expert verification		**Obligatory** – probability of multiple sclerosis	Number	Apache Kafka Message
				Obligatory – contouring of demyelinating lesions with colour differentiation by localization: juxtacortical and subcortical – pink, periventricular – yellow, infratentorial – blue.	Contour	DICOM
				Obligatory – a total number of demyelinating lesions on non-contrast series; a total number of lesions accumulating the contrast agent.	Integer number	DICOM SR+Apache Kafka Message
				Obligatory – highlighting the lesions accumulating the contrast agent.	Contour	DICOM
		Signs of pathology are absent: absence of the above pathological signs.		**Optional** – calculation of the total volume of demyelinating lesions.	Table, text	DICOM SR
				Optional – calculation of the volume of demyelinating lesions in each of the localizations (juxtacortical and subcortical, periventricular, infratentorial).	Table, text	DICOM SR

SOURCES: 1. Thompson A. J., Banwell B. L,. Barkhof F. et al. Diagnosis of multiple sclerosis: 2017 revisions of the McDonald criteria // Lancet Neurol. – 2018 . – Feb. – Vol. 17, №2. – P. 162–173. – DOI: 10.1016/S1474-4422(17)30470-2.
2. Application of the MAGNIMS criteria for the diagnosis and management of multiple sclerosis / V. Gombolevsky, A. Laipan, A. Shapiev [et al.] //Series "Best practices of radiology and instrumental diagnostics" – Issue 11. – M., 2018. – 12 c. – URL: https://tele-med.ai/biblioteka-dokumentov/metodicheskie-rekomendacii-po-primeneniyu-kriteriev-diagnostiki-i-kontrolya-rasseyannogo-skleroza-po-magnims (дата обращения : 15.06.2021).

Baseline diagnostic requirements for AI service results to identify intracranial neoplasms on MRI

Diagnostic study	Clinical task being performed by AI service	Preliminary phase (retrospective study) – signs of studies of the calibration dataset	Main phase (prospective study) – signs for which positive and negative results of the AI service are expected	Content of the AI service response	AI service response format	A form of the AI-service response provision
Magnetic resonance imaging of the brain	Detection and localization of intracranial neoplasms (extracerebral, intracranial)	**Signs of pathology are present:** A. 1. Non-contrast MRI: MRI signs of 1 and more hyper-, isointense or mixed intracranial neoplasms surrounded or not surrounded by a hypertense edema (extracerebral or intracranial localization) on T2 FLAIR in axial/sagittal/coronal planes. 2. Contrast-enhanced MRI: homogeneous or non-homogeneous accumulation of contrast agent at the neoplasm site observed on post-contrast T1 (subject to comparison with the contrast-free T2). B. (for preliminary phase only) Expert verification by using clinical and laboratory data (histological examination).		**Obligatory** – probability of the indicated MRI signs in the entire study	Text, fractional or integer number	Apache Kafka message
				Obligatory – contouring all intracranial neoplasms on non-contrast series with colour differentiation by localization: extracerebral – red, intracranial – green.	Contour, mask	DICOM
				Obligatory (if post-contrast T1 series is available) – contouring of the intracranial neoplasms that accumulate the contrast agent (if the accumulation is homogeneous) or all areas in the intracranial neoplasms accumulating CA (if the accumulation is heterogeneous), comparison with T2 FLAIR series in the same plane.		
				Obligatory – quantification of the intracranial neoplasms on T2 FLAIR and post-contrast T1 series (for each series separately).	Text, fractional or integer number	DICOM SR + Apache Kafka message
				Obligatory – volume of each neoplasm, two dimensions of each neoplasm on T2 FLAIR and post-contrast T1 series.	Text, fractional or integer number	DICOM SR + DICOM + Apache Kafka message
				Optional – segmentation of the edema area on post-contrast T1 series.	Contour, mask	DICOM
		Signs of pathology are absent: absence of the indicated MRI signs.		**Optional** – comparison of the neoplasm size in dynamics when compared with the previous MRI (if available) on T2 FLAIR and post-contrast T1 series.	Text, fractional or integer number	DICOM SR

SOURCES: 1. Smithuis R., Montanera W. Neuroradiology: Brain Tumor Index. The Radiology Assistant. Brain Tumor. – URL: http://radiologyassistant.nl/neuroradiology/brain-tumor (дата обращения : 10.04.2021). 2. Louis D. N., Perry A., Reifenberger G. et al. The 2016 World Health Organization Classification of Tumors of the Central Nervous System: a summary // Acta Neuropathol. – 2016. – Jun. – Vol. 131, №6. – P. 803–820. – DOI: 10.1007/s00401-016-1545-1. 3. Price E. B. , Moss H. E. Osborn's Brain: Imaging, Pathology, and Anatomy // Neuro-Ophthalmology. – 2014. – Vol. 2, №38. – P. 96–97. – DOI: 10.3109/01658107.2013.874459. 4. Chukwueke U. N., Wen P. Y. Use of the Response Assessment in Neuro-Oncology (RANO) criteria in clinical trials and clinical practice // CNS Oncol. – 2019. – Mar 1. – Vol. 8, №1. – CNS28. – DOI: 10.2217/cns-2018-0007. 5. Eisele S. C, Wen P.Y., Lee E. Q. Assessment of Brain Tumor Response: RANO and Its Offspring // Curr Treat Options Oncol. – 2016. – Jul. – Vol. 17, №7. – P. 35. – DOI: 10.1007/s11864-016-0413-5. 6. Clinical guidelines of the Ministry of Health of the Russian Federation "Primary tumors of the central nervous system". – 2020. – ID 578. – URL: https://cr.minzdrav.gov.ru/recomend/578 (15.06.2021).

Basic diagnostic requirements for the results of AI service for automating routine measurements of the brain during MRI 1/2

Diagnostic study	Clinical task being performed by AI service	Preliminary phase (retrospective study) – signs of studies of the calibration dataset	Main phase (prospective study) – signs for which positive and negative results of the AI service are expected	Content of the AI service response	AI service response format	A form of the AI-service response provision
Magnetic resonance imaging of the brain	Automation of routine measurements (ventriculometry, midline shift in brain, measurement of the craniovertebral junction, severity of white matter changes, intracranial volumes)	**Measurable indicators:** 1. VCR1 is a ratio of the distance between the most lateral parts of the anterior horns of lateral ventricles to the distance between the inner plates of the bones of the cranial vault at the same level. 2. VCR2 is a ratio of the distance between the heads of the caudate nucleus at the level of the bodies of anterior horns to the distance between the convexital surfaces of the frontal lobes at the same level. 3. VCR3 is defined as a ratio of the maximum width of the third ventricle to the greatest distance between the inner plates of the bones of the cranial vault at the same level. 4. Width of the third ventricle 5. Transverse shift of the midline brain structures >3 mm (if any) 6. A position of the cerebellar tonsils relative to the foramen magnum. Degrees of the cerebellar tonsillar descent: 0 – at the level of the upper edge of the foramen magnum, 1 – up to 3 mm below the McRae/Chamberlain line, 2 – from 3 to 5 mm below the McRae/Chamberlain line, 3 – more than 5 mm below the McRae/Chamberlain line.		**Obligatory** – displacement value of the cerebellar tonsils in relation to the edges of the foramen magnum (in mm)	Number	DICOM SR, Apache Kafka Message, DICOM
				Obligatory – a degree of the cerebellar tonsillar descent	Number (0-3)	DICOM SR
				Obligatory – values of VCR 1, VCR 2, VCR 3, width of the third ventricle (in mm)	Number	DICOM, DICOM SR, Apache Kafka Message
				Obligatory – a value of the transverse shift, if any (in mm)	Number	Apache Kafka Message + DICOM + DICOM SR

SOURCES:

1. Kornienko VN, Pronin IN. Diagnostic Neuroradiology. Springer Verlag 2008
2. Chiapparini L, Saletti V, Solero CL et-al. Neuroradiological diagnosis of Chiari malformations. Neurol Sci 2011; 32: 283-6.

Basic diagnostic requirements for the results of AI services for automating routine measurements of the brain during MRI 2/2

Diagnostic study	Clinical task being performed by AI service	Preliminary phase (retrospective study) – signs of studies of the calibration dataset	Main phase (prospective study) – signs for which positive and negative results of the AI service are expected	Content of the AI service response	AI service response format	A form of the AI-service response provision
Magnetic resonance imaging of the brain	Automation of routine measurements (ventriculometry, midline shift in brain, measurement of the craniovertebral junction, severity of white matter changes, intracranial volumes)	**Measurable indicators:** 7. Assessment of the severity of white matter hyperintensity (WMH)*. Hyperintense foci in T2-FLAIR mode, grades: 0 – none; 1 – individual foci; 2 – multiple foci; partially merging with each other; 3 – consolidated zones of WMH. 8. Intracranial volume, total brain volume, volume of intracranial cerebrospinal fluid on T1.		**Obligatory** – severity of signs of WMH, grade	Number Mask	DICOM SR, DICOM, Apache Kafka Message
				Obligatory – a volume of WMH foci (total)	Number	DICOM SR, Apache Kafka Message
				Obligatory – intracranial volume, total brain volume, volume of intracranial cerebrospinal fluid on T1	Number	DICOM SR, Apache Kafka Message
				Optional – segmentation of white and gray matter, their volumes	Number	DICOM SR, Apache Kafka Message

NOTE:
*for vascular pathology corresponds to the Fazekas scale: https://radiopaedia.org/articles/fazekas-scale-for-white-matter-lesions?lang=us

SOURCES:
1. Kim KW, MacFall JR, Payne ME. Classification of white matter lesions on magnetic resonance imaging in elderly persons. Biol. Psychiatry. 2008;64 (4)
2. Structural MRI: Morphometry. (2019) Digestive diseases and sciences. 63 (12): 399.

Baseline diagnostic requirements for AI service results to identify protrusions, herniated discs and spinal stenosis on MRI

Diagnostic study	Clinical task being performed by AI service	Preliminary phase (retrospective study) – signs of studies of the calibration dataset	Main phase (prospective study) – signs for which positive and negative results of the AI service are expected	Content of the AI service response	AI service response format	A form of the AI-service response provision
Magnetic resonance imaging of the lumbosacral spine	Detection and localization of MRI signs (at least one) consistent with degenerative-dystrophic changes in intervertebral discs of the lumbosacral spine on T2WI in sagittal and axial planes	**Signs of pathology are present:** A. On native images the following is being detected: dorsal protrusions of the intervertebral discs beyond the disc space (endplate edges of the adjacent vertebrae) in the area of interest spreading into the lumen of the spinal canal, in accordance with the Lumbar disc nomenclature, version 2.0. In the presence of a sign, a dural sac is measured at the level of all intervertebral discs: a) anteroposterior size of the dural sac in axial planes; b) frontal size of the dural sac in axial planes; c) anteroposterior size of the dural sac in sagittal planes; d) area of the dural sac lumen at the discs' level in axial planes. B. (for preliminary phase only) Presence of protruding discs, confirmed by 2 experts by consensus		**Obligatory** – probability of the indicated MRI sign in the entire study.	Number	Apache Kafka, message
				Obligatory – visualization of the finding on the image.	Contour/mask	DICOM
				Obligatory – measurement of the anteroposterior size of the protruded discs in sagittal planes (mm).	Number	Apache Kafka message + DICOM,
				Obligatory – measurement of the dural sac sizes in accordance with the A-list.	Number	DICOM, DICOM SR, Apache Kafka message
		Signs of pathology are absent: absence of the indicated MRI signs		**Optional** – numbering of vertebrae	Text+number	DICOM, DICOM SR

SOURCES: Williams A. L., Murtagh F. R., Rothman S. L., Sze G. K. Lumbar disc nomenclature: version 2.0 // AJNR Am J Neuroradiol. – 2014. – Nov–Dec. – Vol. 35, №11. – P. 2029. – DOI: 10.3174/ajnr.A4108.

Baseline diagnostic requirements for AI service results to identify protrusions, herniated discs and spinal stenosis on MRI

Diagnostic study	Clinical task being performed by AI service	Preliminary phase (retrospective study) – signs of studies of the calibration dataset	Main phase (prospective study) – signs for which positive and negative results of the AI service are expected	Content of the AI service response	AI service response format	Форма A form of the AI-service response provision
Magnetic resonance imaging of the cervical spine	Detection and localization of MRI signs (at least one) consistent with degenerative-dystrophic changes in intervertebral lumbosacral discs of the cervical spine on T2WI in sagittal and axial planes	**Signs of pathology are present:** A. On native images the following is being detected: dorsal protrusions of the intervertebral discs beyond the disc space (endplate edges of the adjacent vertebrae) in the area of interest spreading into the lumen of the spinal canal, in accordance with the Lumbar disc nomenclature, version 2.0 In the presence of a sign, a dural sac is measured at the level of all intervertebral discs: a) anteroposterior size of the dural sac in axial planes; b) frontal size of the dural sac in axial planes; c) anteroposterior size of the dural sac in sagittal planes; d) the area of the dural sac lumen at the discs' level in axial planes. B. (for preliminary phase only) Presence of protruding discs, confirmed by 2 experts by consensus		**Obligatory** – probability of the indicated MRI sign in the entire study	Number	Apache Kafka, message
				Obligatory – visualization of the finding on the image	Contour/mask	DICOM
				Obligatory – measurement of the anteroposterior size of the protruded discs in sagittal planes (mm)	Number	Apache Kafka message + DICOM,
				Obligatory – measurement of the dural sac sizes in accordance with the A-list	Fractional or integer number	DICOM, DICOM SR, Apache Kafka message
		Signs of pathology are absent: absence of the indicated MRI signs		**Optional** – numbering of vertebrae	Text + number	DICOM, DICOM SR

SOURCES: Williams A. L., Murtagh F. R., Rothman S. L., Sze G. K. Lumbar disc nomenclature: version 2.0 // AJNR Am J Neuroradiol. – 2014. – Nov–Dec. – Vol. 35, №11. – P. 2029. – DOI: 10.3174/ajnr.A4108.

Baseline diagnostic requirements for AI service results to identify protrusions, herniated discs and spinal stenosis on MRI

Diagnostic study	Clinical task being performed by AI service	Preliminary phase (retrospective study) – signs of studies of the calibration dataset	Main phase (prospective study) – signs for which positive and negative results of the AI service are expected	Content of the AI service response	AI service response format	A form of the AI-service response provision
Magnetic resonance imaging of the thoracic spine	Detection and localization of MRI signs (at least one) consistent with degenerative-dystrophic changes in intervertebral lumbosacral discs of the thoracic spine on T2WI in sagittal and axial planes	**Signs of pathology are present:** A. On native images the following is being detected: dorsal protrusions of the intervertebral discs beyond the disc space (endplate edges of the adjacent vertebrae) in the area of interest spreading into the lumen of the spinal canal, in accordance with the Lumbar disc nomenclature, version 2.0 In the presence of a sign, a dural sac is measured at the level of all intervertebral discs: a) anteroposterior size of the dural sac in axial planes; b) frontal size of the dural sac in axial planes; c) anteroposterior size of the dural sac in sagittal planes; d) the area of the dural sac lumen at the discs' level in axial planes. B. (for preliminary phase only) Presence of protruding discs, confirmed by 2 experts by consensus		**Obligatory** – probability of the indicated MRI sign in the entire study	Number	Apache Kafka, message
				Obligatory – visualization of the finding on an image	Contour/mask	DICOM
				Obligatory – measurement of the anteroposterior size of the protruded discs in sagittal planes (mm)	Number	Apache Kafka message + DICOM,
				Obligatory – measurement of the dural sac sizes in accordance with the A-list	Fractional or integer number	DICOM, DICOM SR, Apache Kafka message
		Signs of pathology are absent: absence of the indicated MRI signs		**Optional** – numbering of vertebrae	Text+number	DICOM, DICOM SR

SOURCES: Williams A. L., Murtagh F. R., Rothman S. L., Sze G. K. Lumbar disc nomenclature: version 2.0 // AJNR Am J Neuroradiol. – 2014. – Nov–Dec. – Vol. 35, №11. – P. 2029. – DOI: 10.3174/ajnr.A4108.

Baseline diagnostic requirements for AI service results to identify focal changes in the bone structure of the spine on MRI

Diagnostic study	Clinical task being performed by AI service	Preliminary phase (retrospective study) – signs of studies of the calibration dataset	Main phase (prospective study) – signs for which positive and negative results of the AI service are expected	Content of the AI service response	AI service response format	A form of the AI-service response provision
Magnetic resonance imaging of the cervical spine	Detection of MRI signs consistent with focal changes in the bone structure of the cervical spine	**Signs of pathology are present:** A. 1. Periosteal reaction 2. A focus of the altered MR signal in the structure of vertebrae B. (for preliminary phase only) A presence of focal changes in the bone structure of the spine, confirmed by 2 experts by consensus.		**Obligatory** – probability of signs of the foci of altered MR signal of the vertebrae' bone structure	Number	Apache Kafka, message
				Obligatory – localization of identified foci with indication of the vertebra name	Contour/mask	DICOM
					Text	Apache Kafka, message, DICOM SR
				Obligatory – measurement of anterior-posterior, transverse and vertical size of the foci of the vertebrae' bone structure (in mm)	Number	DICOM SR
		Signs of pathology are absent: absence of the indicated MRI signs.		**Obligatory** – a presence or absence of contrast if post-contrast series is available	Text	Apache Kafka message + DICOM,

SOURCES:

V.N. Kornienko, Diagnostic neuroradiology/V.N. Kornienko, I.N. Pronin. - M., Publishing house Andreeva T.M., 2007. - 1327 p

Baseline diagnostic requirements for AI service results to identify focal changes in the bone structure of the spine on MRI

Diagnostic study	Clinical task being performed by AI service	Preliminary phase (retrospective study) – signs of studies of the calibration dataset	Main phase (prospective study) – signs for which positive and negative results of the AI service are expected	Content of the AI service response	AI service response format	A form of the AI-service response provision
Magnetic resonance imaging of the thoracic spine	Detection of MRI signs consistent with focal changes in the bone structure of the thoracic spine	**Signs of pathology are present:** A. 1. Periosteal reaction 2. A focus of the altered MR signal in the structure of vertebrae B. (for preliminary phase only) A presence of focal changes in the bone structure of the spine, confirmed by 2 experts by consensus.		**Obligatory** – probability of signs of the foci of altered MR signal of the vertebrae' bone structure	Number	Apache Kafka, message
				Obligatory – localization of identified foci with indication of the vertebra name	Contour/mask	DICOM
					Text	Apache Kafka, message, DICOM SR
				Obligatory – measurement of anterior-posterior, transverse and vertical size of the foci of the vertebrae' bone structure (in mm)	Number	DICOM SR
		Signs of pathology are absent: absence of the indicated MRI signs		**Obligatory** – a presence or absence of contrast if post-contrast series is available	Text	Apache Kafka message + DICOM

SOURCES:

V.N. Kornienko, Diagnostic neuroradiology/V.N. Kornienko, I.N. Pronin. - M., Publishing house Andreeva T.M., 2007. - 1327 p

Baseline diagnostic requirements for AI service results to identify focal changes in the bone structure of the spine on MRI

Diagnostic study	Clinical task being performed by AI service	Preliminary phase (retrospective study) – signs of studies of the calibration dataset	Main phase (prospective study) – signs for which positive and negative results of the AI service are expected	Content of the AI service response	AI service response format	A form of the AI-service response provision
Magnetic resonance imaging of the lumbosacral spine	Detection of MRI signs consistent with focal changes in the bone structure of the lumbosacral spine	**Signs of pathology are present:** A. 1. Periosteal reaction 2. A focus of the altered MR signal in the structure of vertebrae B. (for preliminary phase only) A presence of focal changes in the bone structure of the spine, confirmed by 2 experts by consensus.		**Obligatory** – probability of signs of the foci of altered MR signal of the vertebrae' bone structure	Number	Apache Kafka, message
				Obligatory – localization of identified foci with indication of the vertebra name	Contour/mask	DICOM
					Text	Apache Kafka, message, DICOM SR
				Obligatory – measurement of anterior-posterior, transverse and vertical size of the foci of the vertebrae' bone structure (in mm)	Number	DICOM SR
		Signs of pathology are absent: absence of the indicated MRI signs		**Obligatory** – a presence or absence of contrast if post-contrast series is available	Text	Apache Kafka message + DICOM

SOURCES:
V.N. Kornienko, Diagnostic neuroradiology/V.N. Kornienko, I.N. Pronin. - M., Publishing house Andreeva T.M., 2007. - 1327 p

Baseline diagnostic requirements for AI service results to identify chondromalacia on MRI

Diagnostic study	Clinical task being performed by AI service	Preliminary phase (retrospective study) – signs of studies of the calibration dataset	Main phase (prospective study) – signs for which positive and negative results of the AI service are expected	Content of the AI service response	AI service response format	A form of the AI-service response provision
Magnetic resonance imaging of the knee	Detection of MRI signs consistent with areas of damaged articular cartilages (chondromalacia) along the articular surfaces of the knee and patellofemoral joints	**Signs of pathology are present on native MRI scans:** A. 1. foci of altered MR signal on PD FS pulse sequences; 2. defects, fibrillation, delamination, superficial cracks no more than 50% in depth of the cartilage thickness in the articular cartilage on PD FS pulse sequences; 3. defects, fibrillation, delamination, superficial cracks more than 50% in depth of the cartilage thickness in the articular cartilage on PD FS pulse sequences; 4. deep articular cartilage defect to the level of the cortical bone on PD FS pulse sequences. B. (for preliminary phase only) A presence of focal changes in the bone structure of the spine, confirmed by 2 experts by consensus.		**Obligatory** – probability of chondromalacia in the study	Number	Apache Kafka, message
				Obligatory – contouring of areas of altered signal from articular cartilage	Contour/mask	DICOM
				Obligatory – contouring of defects, areas of thinning of the articular cartilage	Contour/mask	DICOM
				Obligatory – measurement of the depth of the articular cartilage defect	Number	DICOM SR, Apache Kafka Message
				Obligatory – measurement of two linear dimensions of the articular cartilage defect	Number	DICOM SR, Apache Kafka Message
		Signs of pathology are absent: absence of the indicated MRI signs		**Obligatory** – determination of the chondromalacia stage	Number	Apache Kafka message + DICOM,

SOURCES:
1. "ICRS Cartilage Injury Evaluation Package" ICRS - International Cartilage Repair Society - 2000
2. "Comparison of Clinical and Semiquantitative Cartilage Grading Systems in Predicting Outcomes After Arthroscopic Partial Meniscectomy" doi.org/10.2214/AJR.19.22285
3. https://radiopaedia.org/articles/modified-outerbridge-grading-of-chondromalacia

Basic diagnostic requirements for the results of AI services for automating routine measurements of the uterus on MRI

Diagnostic study	Clinical task being performed by AI service	Preliminary phase (retrospective study) – signs of studies of the calibration dataset	Main phase (prospective study) – signs for which positive and negative results of the AI service are expected	Content of the AI service response	AI service response format	A form of the AI-service response provision
Magnetic resonance imaging of the pelvis	Automation of routine measurements of the uterus (body and cervix – position, dimensions, deviations)	**Measurable indicators:** 1. dimensions of the body and cervix of the uterus relative to its axis: longitudinal, transverse (bilateral), vertical (perpendicular to the longitudinal axis in the sagittal plane); 2. position of the uterus: a. version – the angle between the cervix of uterus and the axis of vagina, b. flexion – the angle between the axis of body and the axis of cervix of the uterus; 3. uterus location – a direction of the uterus body relative to the midline of the pelvis; 4. endometrium – thickness; 5. transition zone – thickness; 6. myometrium – thickness. 7. Optional: ovaries – length, width and height.		**Obligatory** – type of the uterus position (version and flexion)	Text	DICOM SR , Apache Kafka Message
				Obligatory – location of the uterus (lateroversion)	Text	DICOM SR , Apache Kafka Message
				Obligatory – linear dimensions of the body and cervix of the uterus (longitudinal, transverse and vertical/anterior-posterior)	Text	DICOM, DICOM SR , Apache Kafka Message
				Obligatory – endometrial thickness	Text	DICOM, DICOM SR , Apache Kafka Message
				Obligatory – thickness of the transition zone	Text	DICOM, DICOM SR , Apache Kafka Message
				Obligatory – myometrial thickness	Text	DICOM, DICOM SR , Apache Kafka Message
				Obligatory – in the absence of uterus, a note about the absence of a target organ	Text	DICOM, DICOM SR , Apache Kafka Message
				Optional – ovaries: length, width and height in mm	Text	DICOM, DICOM SR , Apache Kafka Message

SOURCES:

Hulse P., Carrington B. MRI manual of pelvic cancer. // Martin Dunitz Taylor & Francis group, - 2004

Basic diagnostic requirements for the results of AI services for automating routine measurements of the prostate gland on MRI

Diagnostic study	Clinical task being performed by AI service	Preliminary phase (retrospective study) – signs of studies of the calibration dataset	Main phase (prospective study) – signs for which positive and negative results of the AI service are expected	Content of the AI service response	AI service response format	A form of the AI-service response provision
Magnetic resonance imaging of the prostate gland	Automation of routine measurements of the prostate gland (dimensions)	**Measurable indicators:** 1. Dimensions in mm: sagittal (anteroposterior), frontal (transverse), vertical (longitudinal) 2. Gland volume in cm3		**Obligatory** – dimensions in mm: sagittal (anteroposterior), frontal (transverse), vertical (longitudinal)	Text	DICOM, DICOM SR, Apache Kafka Message
				Obligatory – volume in cm3	Text	DICOM, DICOM SR , Apache Kafka Message

SOURCES:

1. M.A.Sharia Tomography methods in diagnosis of the prostate diseases. Medical imaging, 2009. №1-3, p.48-59 2. Hulse P., Carrington B. MRI manual of pelvic cancer. // Martin Dunitz Taylor & Francis group, - 2004