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This new report analyses cybersecurity and privacy requirements and measures in use of AI in medical imaging diagnosis of osteoporosis. The report describes the scenario fundamental principles (assets, actors processes etc.), identifies the security and privacy risks it poses, and finally cybersecurity and privacy controls, which counteract the identified risks.

## 1.1 STUDY OBJECTIVES

- medical imaging diagnosis
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## 1.2 METHODOLOGY

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### 1.2.1 Description of the scenario

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### 1.2.2 Identification of cybersecurity and privacy threats and vulnerabilities

### 1.2.3 Identification of cybersecurity and privacy controls

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## 1.3 TARGET AUDIENCE

- All actors (private or public):

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- AI technical community, AI cybersecurity and privacy experts and AI experts
- Cybersecurity and privacy community

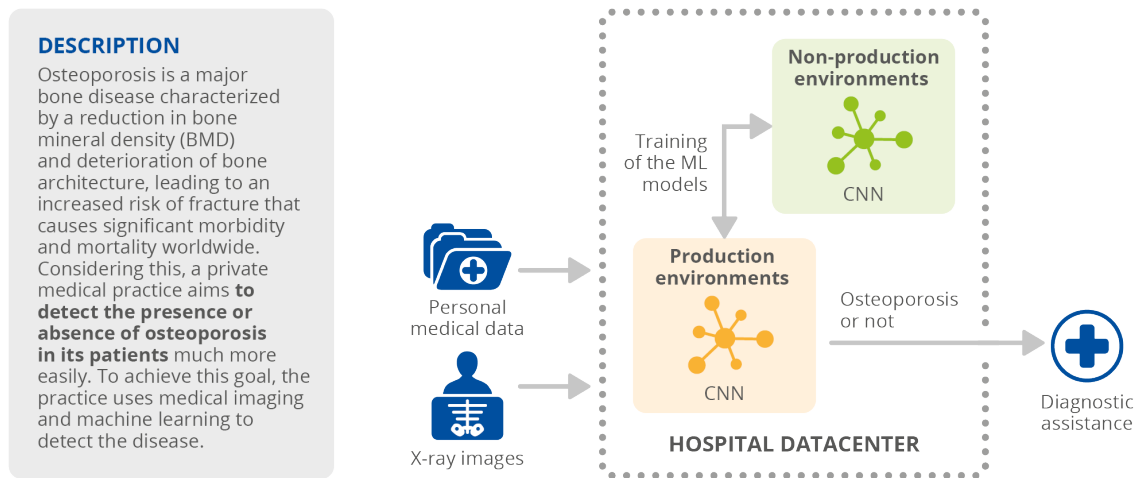
## 1.4 USING THIS DOCUMENT

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Figure 1:

## MEDICAL IMAGING



### DATA

#### Data used to build the model

- Historical X-rays of patients with or without osteoporosis
- Data related to age, gender, and body mass index of historical patients of the medical cabinet

#### Data used once the model is in production

- X-rays of patients who come for consultation
- Data related to age, gender, and body mass/ Fairness index of who come for consultation

### CYBERSECURITY AND PRIVACY REQUIREMENTS

#### Cyber requirements

- Availability ● Integrity ● Confidentiality ● Traceability

#### Privacy Requirements

- Availability ● Integrity ● Confidentiality ● Traceability
- Lawfulness
- Transparency
- Purpose limitation
- Data minimization
- Accuracy
- Storage limitation
- Security of personal data
- Database creation
- Compliance of the training model

- Critical ● High ● Low

### ACTORS

- Radiologists/medical practice
- Large tech companies
- Historical Patients
- New Patients
- Cloud provider
- Data scientists
- Developers and Data Engineers
- System and communication network's administrator

### ASSETS

- CNN-algorithm used
- Data lake - in the cloud
- Model server - in the cloud
- Scanner
- X-ray computer-aided diagnostic system. on-premises
- Integrated Development Environment
- Libraries
- Communication protocols and network



**2.1 PURPOSE AND CONTEXT**

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**2.2 HIGH-LEVEL DESCRIPTION**

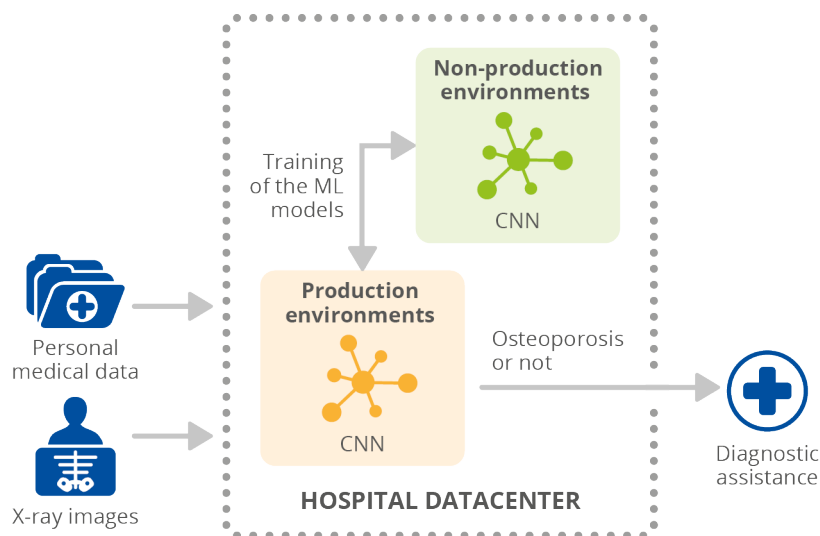
to detect the potential presence of osteoporosis by giving the radiologist a probability that the bone contains the disease

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**Figure 2:**



## 2.3 ACTORS AND ROLES

**Figure 3:**

Actor	Role	Description
Radiologists/medical practice	End Users and Data Owner ( <b>Data Controller</b> )	
Large tech companies	Model Provider	
Historical Patients (before the occurrence of the diagnosis)	Data Provider	
New Patients (during the occurrence of the diagnosis)	Data Provider	
Cloud Provider	Cloud Provider	
Data Scientists	Data Scientists	
Developers and Data Engineers	Developers and Data Engineers	



System and communication Network Administrator	Network Administrators	
--	------------------------	--

## 2.4 PROCESSED DATA

Figure 4:

Data	Data type	Source / data provider	Data Procurement
onymised		historical patients' radiographies former patients.	
pseudonymised		patients. former	
		patients.	
		patient	

## 2.5 MACHINE LEARNING ALGORITHMS

(CNN) Convolutional Neural Network

Augmenting Osteoporosis Imaging with Machine Learning.



Figure 5:

Learning paradigm	Subtype	Algorithm	Type of data ingested	Description

## 2.6 ASSETS

Figure 6:

Type of asset	Asset	Description
Models		
Environment tools	<i>in the cloud</i>	
	<i>in the cloud</i>	
	<i>– on- premises</i>	

## 2.7 OVERALL PROCESS



**Data collection**

**which must be annotated**

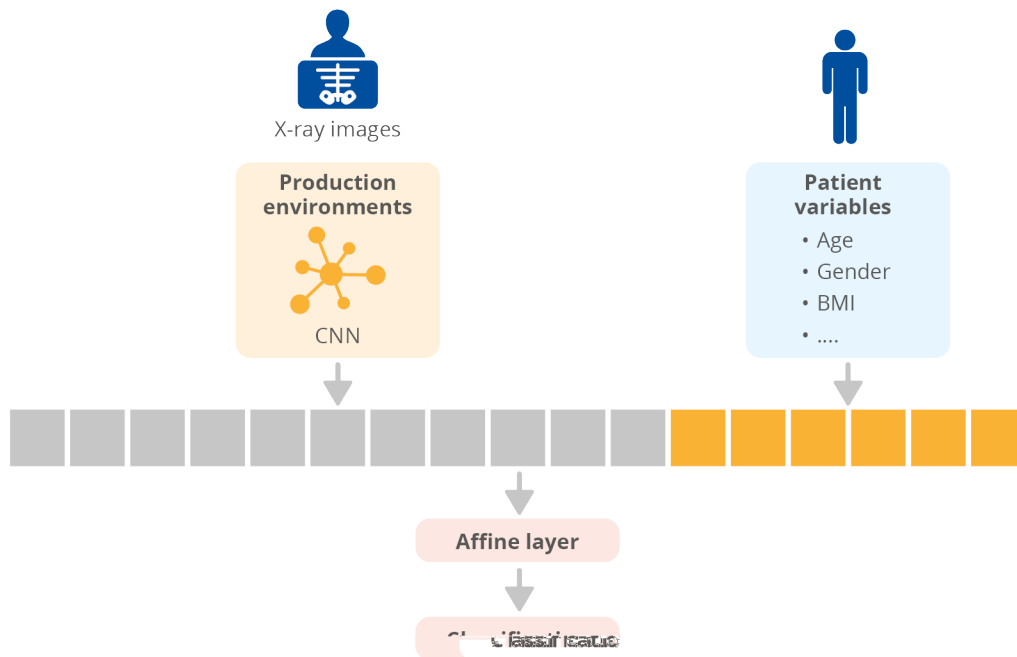
**Data cleaning and data pre-processing**  
cleaned  
pre-processing.

**Model design and implementation**





**Figure 7:**



The input of the network

the output of the network

Model training, model testing and optimisation  
the training method

Model Evaluation  
evaluate the model

Model Deployment



Monitoring and inference

Figure 8:

Steps	Description	Actors	Assets
Data Collection			
Data Cleaning			
Data pre-processing			
Model design and implementation			
Model training			



Model testing			
Optimization			
Model evaluation			
Model deployment			
Monitoring and inference			

## 2.8 PRIVACY AND CYBERSECURITY REQUIREMENTS

### Cybersecurity requirements

Figure 9:

	Level	Explanation
Availability	Low	
Integrity	Critical	
Confidentiality	Critical	



Traceability	High	
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## Privacy requirements

personal data are processed when patients come to the practice and are diagnosed for osteoporosis, adding information like last name, name, and consultation date in the patient's file

the following privacy requirements and recommendations should be satisfied

**Figure 10:**

Requirements	Explanation
Lawfulness, fairness, and transparency	<p>Lawfulness:</p> <p>Fairness:</p> <p>Transparency:</p>
Purpose limitation	



Data minimisation	
Accuracy	
Storage limitation	
Security of personal data (Integrity and Confidentiality)	

**Figure 11:**

Recommendations	Explanation
Database creation	
Compliance of the training model (i.e. before production)	

**Figure 12:**

Criteria	Does it match the criteria?	Justification




Figure 13:

	Level	Explanation
Availability	Low	
Integrity	Critical	
Confidentiality	Critical	
Traceability	High	



### 3.1 THREAT CONTEXTUALISATION

reputation degradation      lawsuit  
company and physical and permanent injury for the patient

- 
- 

degradation and a lawsuit,      reputation

targeted advertising.      Phishing attempts,  
Unique a07.7 (alnt)-5 0.7 (n) 1 Tf-5 (and )TJh onl(al)-1 ((e)-7 (d gc)-3 (asv-5 (o per)-n 5 (y)-3 ( of



**Figure 14:**

### COMPROMISE OF DIAGNOSTIC SYSTEM COMPONENTS

#### LOSS REP INV PHISH

- Weak access control
- Use of vulnerable components
- Poor access rights management process

#### DATA DISCLOSURE

##### LOSS REP INV PHISH

- Disclosure of sensitive data for ML algorithm training
- Lack of control of Data processor (including external stakeholder)
- Poor data management

#### LACK OF TRANSPARENCY

##### INV

- Lack of controls to ensure the adequacy of the purpose and its current use
- Lack of detail on the purposes and justification for their legitimacy
- Lack of privacy by design

#### NO RESPECT OF STORAGE LIMITATION

##### PHYS

- Lack of accuracy criteria
- Poor data management
- Lack of privacy by design

### EVASION

#### REP PHYS

- Lack of detection of abnormal inputs
- Lack of training based on adversarial attacks
- Use of a widely known model allowing the attacker to study it

### POISONING

#### REP PHYS

- Lack of control for poisoning
- No detection of poisoned samples in the training dataset
- Use of uncontrolled data

### DIVERSION OF PURPOSE

#### LOSS INV PHISH

- Existing biases in the ML model or in the data
- Lack of controls to ensure that data is used only for the purposes defined
- Lack of privacy by design

#### NO RESPECT OF STORAGE LIMITATION

##### LOSS PHISH

- Lack of data deletion mechanisms
- Lack of data retention policy
- Lack of privacy by design

### HUMAN ERROR

#### LOSS REP INV PHISH

- Lack of security by design
- Weak access control
- Poor data management

### UNLAWFUL AND UNFAIR PROCESSING

#### INV FEEL

- Absence of an identified data controller
- Lack of practical means and justification for the legal basis
- Lack of privacy by design

### NO RESPECT OF DATA MINIMIZATION

#### INV

- Lack of measures to prevent further Lack of controls to ensure that the data collected are minimal for the purposes intended
- Lack of necessary data selection
- Lack of pseudonymization

### NO RESPECT OF COMPLIANCE OF THE TRAINING MODEL

#### LOSS REP INV

- Lack of review of treatment by a dedicated committee to check fairness
- Lack of privacy by design

### IMPACTS

- LOSS: loss of unique targeted opportunities  
 REP: Reputation degradation  
 PHISH: Phishing attempts, targeted advertising  
 PHYS: Physical and permanent injury  
 FEEL: feeling of infringement of fundamental rights  
 INV: Significant sense of invasion of privacy

## 3.1.1 Compromise of diagnostic system components

degradation      lawsuit  
 privacy   phishing attempts, or targeted advertising  
 opportunities.

reputation  
 significant feeling of invasion of  
 unique targeted







reputation degradation      lawsuit  
physical and permanent injury

### 3.1.6 Unlawful Processing

a significant feeling of invasion of privacy

### 3.1.7 Unfair processing

with discriminations created by the treatment such as  
better diagnosis of osteoporosis for men than for women, for example.

a feeling of infringement of fundamental rights.

### 3.1.8 Lack of transparency

significant feeling of invasion of privacy.

### 3.1.9 Diversion of purpose

targeted advertisements  
significant feeling of invasion of privacy      unique  
targeted opportunities.

### 3.1.10 No respect of data minimisation

significant feeling of invasion of privacy

### 3.1.11 No respect of accuracy

temporary or permanent physical injury of the patient.



### 3.1.12 No respect of storage limitation

targeted advertising      unique targeted opportunities.

### 3.1.13 No respect of compliance of the training model

reputation degradation      lawsuit  
significant feeling of invasion of privacy      phishing attempts, or targeted advertising      unique targeted opportunities.

### 3.1.14 Synthesis of possible impacts and associated threats

Figure 1:

Impact	Severity	Type	Associated Threats
Physical and permanent injury and harm	High		
Lawsuit	High		
Reputation degradation	High		
Phishing attempts, targeted advertising	High		
Loss of unique targeted opportunities	High		



Significant feeling of invasion of privacy	Moderate		
Feeling of infringement of fundamental rights	Moderate		

### 3.2 VULNERABILITIES ASSOCIATED TO THREATS AND AFFECTED ASSETS

Figure 2:

Vulnerabilities	Threats	Actors	Assets Involved
Absence of an identified data controller			
Contract with a low security third party			
Disclosure of sensitive data for ML algorithm training			
Existing biases in the ML model or in the data			
Lack of auditability of processing			
Lack of accuracy criteria			
Lack of documentation			



Lack of pseudonymisation			
Lack of consideration of attacks to which diagnostic systems could be exposed			
Lack of consideration of real-life conditions in training the model			
Lack of control for poisoning			
Lack of control of Data processor (including external stakeholder)			
Lack of control over model performance			
Lack of controls to ensure that data is used only for the purposes defined			
Lack of controls to ensure that the data collected are minimal for the purposes intended			
Lack of controls to ensure the adequacy of the purpose and its current use			



Lack of data deletion mechanisms			
Lack of data for increasing robustness to poisoning			
Lack of data retention policy			
Lack of detail on the purposes and justification for their legitimacy			
Lack of detection of abnormal inputs			
Lack of justification and traceability of decisions taken			
Lack of justification for the collection of individual personal data collected			
Lack of measures to prevent further data collection			
Lack of necessary data selection			
Lack of practical means and justification for the legal basis (legitimate interest)			
Lack of security by design			
Lack of privacy by design			
Lack of review of treatment by a dedicated committee to check fairness			



Lack of security process to maintain a good security level of the components of the diagnostic system			
Lack of traceability of actions and/or modifications made to the assets on which rely personal data			
Lack of training based on adversarial attacks			
Lack of transparency on the purpose, the exact data that are collected, and how they are processed.			
Lack of verification that the data is adequate, relevant and not excessive for the purpose of making a diagnostic			
Model easy to poison			
No detection of poisoned samples in the training dataset			
Poor consideration of evasion attacks in the model design implementation			
Poor access rights management process			

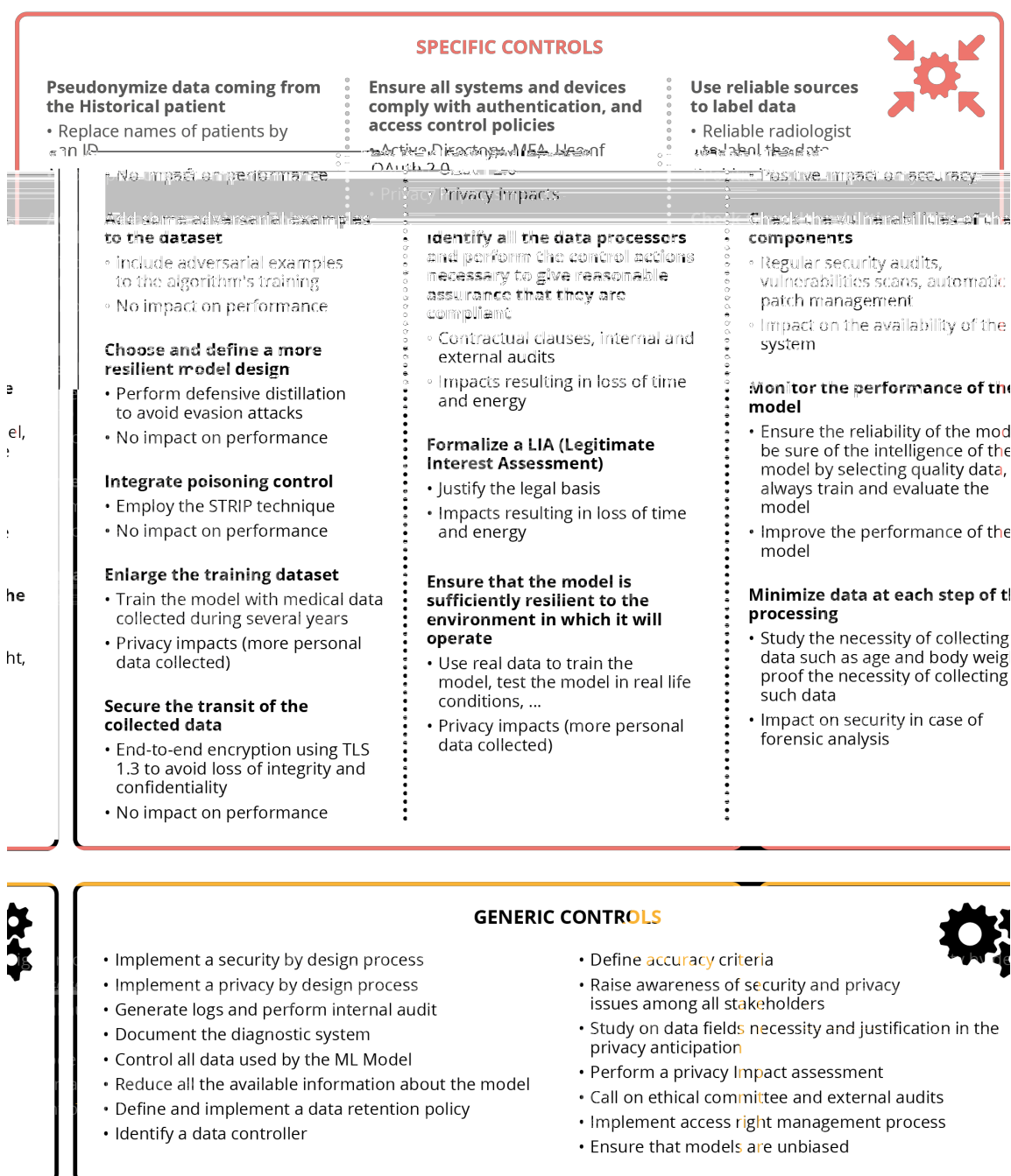


Poor data management			
Too much information available on the model			
Unprotected sensitive data on test environments			
Use of uncontrolled data			
Use of unreliable sources to label data			
Use of unsafe data or models (e.g., with transfer learning)			





Figure 17:



#### 4.1 IMPLEMENT A SECURITY BY DESIGN PROCESS

Type	Associated Vulnerabilities	Threats it mitigate
		<ul style="list-style-type: none"> <li></li> <li></li> <li></li> <li></li> </ul>

#### 4.2 DOCUMENT THE DIAGNOSTIC SYSTEM

Type	Associated Vulnerabilities	Threats it mitigate
		<ul style="list-style-type: none"> <li></li> <li></li> <li></li> <li></li> <li></li> </ul>

impact system performance, cybersecurity, or privacy.

This control does not



### 4.3 CHECK THE VULNERABILITIES OF THE COMPONENTS USED AND IMPLEMENT PROCESSES TO MAINTAIN SECURITY LEVELS OF ML COMPONENTS OVER TIME

Type	Associated Vulnerabilities	Threats it mitigate
	<ul style="list-style-type: none"> <li></li> <li></li> <li></li> </ul>	<ul style="list-style-type: none"> <li></li> <li></li> </ul>

This control would impact the availability of the system, thus its performance, as it may be audited or even updated.

### 4.4 ADD SOME ADVERSARIAL EXAMPLES TO THE DATASET

Type	Associated Vulnerabilities	Threats it mitigate

This control does not impact performance or privacy.



#### 4.5 CHOOSE AND DEFINE A MORE RESILIENT MODEL DESIGN

Type	Associated Vulnerabilities	Threats it mitigate

This control does not impact performance or privacy.

#### 4.6 INTEGRATE POISONING CONTROL IN THE TRAINING DATASET

Type	Associated Vulnerabilities	Threats it mitigate
	<ul style="list-style-type: none"> <li>•</li> <li>•</li> </ul>	

This control does not impact system performance, cybersecurity, or privacy.

#### 4.7 ENLARGE THE TRAINING DATASET

Type	Associated Vulnerabilities	Threats it mitigate

In this case, privacy is negatively impacted because enlarging the data set means taking even more personal data which could be stolen by an attacker.

#### 4.8 SECURE THE TRANSIT OF THE COLLECTED DATA

Type	Associated Vulnerabilities	Threats it mitigate
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This control won't have any impact on  
privacy or performance of the system.

#### 4.9 CONTROL ALL DATA USED BY THE ML MODEL

Type	Associated Vulnerabilities	Threats it mitigate
	<ul style="list-style-type: none"> <li>•</li> <li>•</li> </ul>	

#### 4.10 IMPLEMENT ACCESS RIGHT MANAGEMENT PROCESS

Type	Associated Vulnerabilities	Threats it mitigate
		<ul style="list-style-type: none"> <li>•</li> <li>•</li> <li>•</li> <li>•</li> </ul>



**4.11 ENSURE ALL SYSTEMS AND DEVICES COMPLY WITH AUTHENTICATION, AND ACCESS CONTROL POLICIES**

Type	Associated Vulnerabilities	Threats it mitigate
	<ul style="list-style-type: none"><li></li></ul>	<ul style="list-style-type: none"><li></li><li></li><li></li><li></li></ul>

**4.12 MONITOR THE PERFORMANCE OF THE MODEL**

Type	Associated Vulnerabilities	Threats it mitigate
Cybersecurity		<ul style="list-style-type: none"><li></li><li></li></ul>



This will have an impact on the performance of the model in the sense that by applying this control, the model is always efficient and reliable.

**4.13 REDUCE THE AVAILABLE INFORMATION ABOUT THE MODEL**

Type	Associated Vulnerabilities	Threats it mitigate
	<ul style="list-style-type: none"> <li></li> <li></li> </ul>	

This control could have an impact on privacy

**4.14 IDENTIFY A DATA CONTROLLER FOR THE MEDICAL DATA PROCESSING**

Type	Associated Vulnerabilities	Threats it mitigate
		<ul style="list-style-type: none"> <li></li> <li></li> <li></li> </ul>

the control improves the privacy of users without impacting the performance of the model.



#### 4.15 PSEUDONYMISE DATA COMING FROM THE HISTORICAL PATIENT

Type	Associated Vulnerabilities	Threats it mitigate
	<ul style="list-style-type: none"><li>•</li><li>•</li></ul>	

This control does not impact on security or performance.

#### 4.16 GENERATE LOGS AND PERFORM INTERNAL AUDIT

Type	Associated Vulnerabilities	Threats it mitigate
	<ul style="list-style-type: none"><li>•</li><li>•</li><li>•</li></ul>	<ul style="list-style-type: none"><li>•</li><li>•</li><li>•</li><li>•</li><li>•</li><li>•</li></ul>





#### 4.17 IDENTIFY ALL THE DATA PROCESSORS FOR THE MEDICAL DATA PROCESSING AND PERFORM THE CONTROL ACTIONS NECESSARY TO GIVE REASONABLE ASSURANCE THAT THEY ARE COMPLIANT

Type	Associated Vulnerabilities	Threats it mitigate
	<ul style="list-style-type: none"> <li></li> <li></li> </ul>	<ul style="list-style-type: none"> <li></li> <li></li> </ul>

The impact this control could have for the medical practice would be a loss of time and energy spent to formalise documents, and complete the assessments and audits.

#### 4.18 PERFORM A PRIVACY IMPACT ASSESSMENT

Type	Associated Vulnerabilities	Threats it mitigate
	<ul style="list-style-type: none"> <li></li> <li></li> <li></li> </ul>	

Such analysis may possibly impact the performance of the scenario



#### 4.19 DEFINE AND IMPLEMENT A DATA RETENTION POLICY

Type	Associated Vulnerabilities	Threats it mitigate
	<ul style="list-style-type: none"> <li>•</li> <li>•</li> </ul>	

this control can have an impact on the performance of this scenario.

#### 4.20 STUDY ON DATA FIELDS NECESSITY AND JUSTIFICATION IN THE PRIVACY POLICY

Type	Associated Vulnerabilities	Threats it mitigate
	<ul style="list-style-type: none"> <li>•</li> <li>•</li> </ul>	<ul style="list-style-type: none"> <li>•</li> <li>•</li> <li>•</li> </ul>

#### 4.21 FORMALIZE A LIA (LEGITIMATE INTEREST ASSESSMENT)

Type	Associated Vulnerabilities	Threats it mitigate
Privacy	<ul style="list-style-type: none"> <li>•</li> <li>•</li> </ul>	



	•	
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#### 4.22 MINIMISE DATA AT EACH STEP OF THE PROCESSING; COLLECT ONLY WHAT IS NEEDED WHEN NEEDED

Type	Associated Vulnerabilities	Threats it mitigate
	• •  •	

#### 4.23 IMPLEMENT A PRIVACY BY DESIGN PROCESS

Type	Associated Vulnerabilities	Threats it mitigate
		• • • • •

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#### 4.24 CALL ON ETHICAL COMMITTEE AND EXTERNAL AUDITS

Type	Associated Vulnerabilities	Threats it mitigate

#### 4.25 DEFINE ACCURACY CRITERIA

Type	Associated Vulnerabilities	Threats it mitigate

Such a measure  
does not affect this scenario.

#### 4.26 ENSURE THAT THE MODEL IS SUFFICIENTLY RESILIENT TO THE ENVIRONMENT IN WHICH IT WILL OPERATE

Type	Associated Vulnerabilities	Threats it mitigate

- 
- 
- 



•

#### 4.27 RAISE AWARENESS OF SECURITY AND PRIVACY ISSUES AMONG ALL STAKEHOLDERS

Type	Associated Vulnerabilities	Threats it mitigate
		<ul style="list-style-type: none"> <li>•</li> <li>•</li> <li>•</li> <li>•</li> <li>•</li> <li>•</li> <li>•</li> <li>•</li> </ul>

This control does not directly impact performance of the system.

#### 4.28 USE RELIABLE SOURCES TO LABEL DATA

Type	Associated Vulnerabilities	Threats it mitigate

This control will have a positive impact on accuracy since the dataset will be correctly labelled.

#### 4.29 ENSURE THAT MODELS ARE UNBIASED

Type	Associated Vulnerabilities	Threats it mitigate



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control could improve performance of the system over longer periods

This privacy

4.30 SUMMARY

Figure 18:

Control name and type	Associated Vulnerabilities	Threat mitigated	Privacy and security requirements addressed















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**medical imaging in osteoporosis diagnosis supported by Artificial Intelligence (AI) is presented**

**AI can be very beneficial for the industries areas it applies to, it can also have quite a significant impact for security and privacy**

**depending on the context of the scenario, the same threats apply differently and have different levels of impact.**

**the entire cybersecurity and privacy context (requirements, threats, vulnerabilities, and controls) must be adapted to the context and reality of the individual organization**



## A.1 CYBERSECURITY AND PRIVACY SEVERITY SCALES

Availability	
Low	few days or less
Moderate	a day or less
High	half a day or less
Critical	few hours or less

Integrity	
Low	does not need to be identified or corrected
Moderate	corrected must be identified but not necessarily
High	must be identified and corrected
Critical	No degradation

Confidentiality	
Low	accessed by everyone
Moderate	restricted to internal staff and trusted partners
High	restricted to employees having an organisation or functional link with the process
Critical	restricted to a very limited number of individuals



Traceability			
Low	absence of traces is acceptable		
Moderate	Actions identified		
High	actions dated	imputable	actors identified and
Critical		actions probative value	legally enforceable time stamped

## A.2 CYBERSECURITY SCALE OF IMPACT

Severity <sup>29</sup>	
1 - Low	
2 - Moderate	
3 - High	
4 - Critical	

## A.3 PRIVACY SCALE OF IMPACT

Severity <sup>30</sup>	
1 - Low	
2 - Moderate	
3 - High	
4 - Critical	



**A.4 PRIVACY REQUIREMENTS CRITERIA**

Requirements	Article
Lawfulness, fairness and transparency	
Purpose limitation	
Data minimisation	
Accuracy	
Storage limitation	
Security of personal data (integrity and confidentiality)	

—

Recommendations	Details
Database creation	
Compliance of the training model (i.e. before production)	

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## ABOUT ENISA

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