User manual for the Briganti Nomogram

Briganti 2012 Nomogram

Briganti 2017 Nomogram

Briganti 2019 Nomogram

Briganti 2023 Nomogram

Version 1.0, April 2026, in English

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1. The Evidencio platform

The Evidencio platform facilitates the creation, use, validation and implementation of medical prediction algorithms and clinical decision support tools. This User Manual specifically relates to the Briganti Nomogram, (which covers the Briganti 2012 Nomogram, Briganti 2017 Nomogram, Briganti 2019 Nomogram, and Briganti 2023 Nomogram). The User Manual can also be referred to as the Instructions For Use (IFU). The Briganti Nomogram meets the requirements laid down in: Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU. Compliance with the applicable regulations is provided by means of declaration of conformity. Throughout this manual CE-marked content and the term medical device are used interchangeably.

2. Disclaimer

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⚠ 3. Warnings for CE-marked content

Calculations alone should never dictate patient care, and are no substitute for professional judgement. See our full disclaimer on: https://www.evidencio.com/disclaimer. This tool is only to be used by healthcare professionals in a clinical setting, and is not for patient use.

Always read the intended use before using this tool.

Always make sure the patient complies with the clinical indications and clinical contra-indications as stated on the Evidencio website, and in **paragraphs 6.3.1** and **6.3.2** of this user manual respectively.

Before reading the result, double check the filled in values to prevent errors.

Results that concern risk percentages, do not guarantee certain outcomes. When there is a risk present, do not expect an event to not occur at all, even if the risk is very small. Conversely, a high risk does not guarantee that an event will occur.

This algorithm is only intended for use in settings where the usage and result of an algorithm are never immediately needed.

The data used to perform the calculations is stored by Evidencio to enhance algorithm function and allow issues to be traceable for further improvements. For details, see the privacy policy on our website at: https://www.evidencio.com/privacy-policy.

3.1. Notice to the user

Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the country in which you, the reader, are established. A competent authority is the institute that governs all issues related to medical devices in a country.

Please contact Evidencio when you suspect any malfunction or changes in the performance of a medical device. Do not use the device, until Evidencio replies to your message that it is safe to start using it again.

4. Device description Briganti Nomogram

The Briganti Nomogram is intended to support clinical decision making regarding prostate cancer by estimating the risk that an extended Pelvic Lymph Node Dissection (ePLND) and biopsy would identify positive for a tumor in patients with clinically localized prostate cancer (PCa).

The Briganti Nomogram consists of four different mathematical algorithms, described in four different scientific publications, published in 2012, 2017, 2019, and 2023. The singular term Briganti Nomogram is used for clarity and brevity when something applies to all 4 versions. Differences between the separate devices will be mentioned when applicable. The MDSW's underlying mathematical formula is a logistic regression model.

The Briganti 2012 Nomogram model predicts the probability of pelvic lymph node invasion for patients undergoing extended pelvic lymphadenectomy based on pretreatment prostate-specific antigen (PSA), clinical stage, primary and secondary biopsy Gleason score, and percentage of positive cores. Biopsy for determination of percentage of positive cores was done through transrectal ultrasound-guided prostate biopsy.

The Briganti 2017 Nomogram model predicts the probability of pelvic lymph node involvement for patients with localized PCa with clinical stage obtained according to digital rectal examination and transrectal ultrasound-guided prostate biopsy. It is an updated version of the Briganti 2012 Nomogram model that also includes the percentages of positive cores with the highest grade and lowest grade.

The Briganti 2019 Nomogram predicts the probability of pelvic lymph node involvement for patients with Clinically Localized Prostate Cancer Diagnosed with Magnetic Resonance Imaging-targeted and Systematic Biopsies. The current model is applicable exclusively to men with a positive MRI-targeted biopsy with concomitant systematic biopsy, as currently indicated by guidelines. Moreover, the risk of LNI should not be estimated using this model for individuals who were diagnosed via systematic biopsy with a negative MRI-targeted biopsy. For these patients, predictive tools developed using data for men diagnosed with systematic biopsy such as the Briganti 2012 Nomogram and Briganti 2017 Nomogram are more suitable.

The Briganti 2023 Nomogram predicts the probability of pelvic lymph node involvement for patients with miN0M0 disease undergoing radical prostatectomy (RP) and ePLND. It was developed by Gandaglia et al. in a population of 458 patients with miN0M0 disease who underwent radical prostatectomy (RP) and ePLND between 2017 and 2022 at twelve centres worldwide (Austria, Belgium, China, Germany, Italy, the Netherlands, Spain, and Switzerland). It was externally validated by Gandaglia et al. in 2026 in a population of 282 patients PCa patients with miN0 disease undergoing RP and ePLND in ten centers between 2016 and 2023.

The calculation of the algorithm is performed by communication with the Evidencio platform, hosted at www.evidencio.com. The algorithm is also accessible by 3rd party applications through the API and iFrame implementation. The Evidencio platform is managed under Evidencio's certified quality management system that ensures the correctness of calculations and availability of its services.

The Summary of Safety and Performance for this device will be made available via EUDAMED once the relevant module is fully operational. In the meantime, the Summary of Safety and Performance can be requested from the manufacturer and will be provided without undue delay.

4.1. Lifetime, residual risks and side effects

The Briganti Nomogram is software, and does not expire. The lifetime is initially set at 5 years from certification, if the state of the art does not change in such a way as to negatively affect the benefit-risk of the device, the lifetime can be extended.

No steps are required to be undertaken by the user to decommission a product when it is taken off the market. If the lifetime is not extended, a notice will be placed on the algorithm page on the platform. When a device is taken off the market, users may be informed about this (e.g. through e-mail).

Evidencio has identified a series of risks associated with the use of this algorithm.

The Briganti Nomogram is a low-risk device, there are no noticeable risks involved outside of possible mis-estimation of patient risk of Lymph Node Involvement, and all residual risks are accepted.

Most risks can be defined into two main groups, depending on their outcome.

a) The risk calculation was wrong or;
b) The MDSW prediction algorithm is inaccessible.

A wrong risk calculation can be the result of erroneous input values or an error in the mathematical calculation. Technical risks, including the erroneous calculations or the inaccessibly due to a technical error, have been mitigated when possible. These measures focussed on reducing the risks' probability and severity. Concluding that the risks could not be mitigated further, the residual risks were classified as *low-level and acceptable.*

The Briganti Nomogram does not have any direct side effects.

5. Electronic label

The electronic label of this device contains the following information:

CE 2797	**Name of the device**	Briganti Nomogram
	**Manufacturer information**	Evidencio B.V., Irenesingel 19, 7481 GJ Haaksbergen, The Netherlands
LOT	**LOT number** Briganti 2012 Nomogram Briganti 2017 Nomogram Briganti 2019 Nomogram Briganti 2023 Nomogram	 V-2.0-1555.26.04.28 V-3.0-1555.26.04.28 V-4.0-1555.26.04.28 V-5.0-1555.26.04.28
UDI	**UDI number** Briganti 2012 Nomogram Briganti 2017 Nomogram Briganti 2019 Nomogram Briganti 2023 Nomogram	 (01)08720938015205(8012)v2.0(4326)260428(240)1555 (01)08720938015199(8012)v3.0(4326)260428(240)1555 (01)08720938015182(8012)v4.0(4326)260428(240)1555 (01)08720938015403(8012)v5.0(4326)260428(240)1555
IVD	**IVD indication**	*In vitro* diagnostic medical device

The electronic label can be found on the Evidencio website, see also section **I** and **Figure 5** in **Chapter 10**.

The electronic label on the website further contains the option to download the **User Manual** and **Declaration of conformity** (DoC).

5.1. LOT number

The LOT number indicates the algorithm version, the algorithm identifier, and the algorithm publication date. Publication date is indicated as YY.MM.DD.

5.2. UDI number

Stands for Unique Device Identifier (UDI) number, which is an international tool that helps users identify and find information on products. Evidencio's UDI's have the following format:

(01)[UDI-DI number](8012)[versionnumber](4326)[releasedate](240)[identificationnumber]

The UDI-DI (Device Identifier) number is a unique numeric code. For each medical device of Evidencio, a unique UDI-DI is ascribed. This UDI-DI is used as an "access key" for information stored in a unique device identification database (UDID). Information on Evidencio's medical devices can be found by searching for the UDI-DI number in the following data base: https://gepir.gs1.org/index.php/search-by-gtin.

The version number, also part of the UDI, is linked to one of the 4 device sub-models. Version 2.X for the Briganti 2012 Nomogram, Version 3.X for the Briganti 2017 Nomogram, version 4.X for the Briganti 2019 Nomogram, and version 5.X for the Briganti 2023 Nomogram.

6. Intended purpose

6.1. Intended use

The Briganti Nomogram is an algorithm intended to use PSA, Clinical T-stage, Primary Gleason Grade, Secondary Gleason Grade, and Percentage of positive Cores to estimate the risk that an extended Pelvic Lymph Node Dissection (ePLND) and biopsy would identify positive for a tumor in patients with clinically localized prostate cancer (PCa), in order to support healthcare professionals with decisions surrounding extended pelvic lymphadenectomy.

The Briganti Nomogram is medical device software that automates the calculation of the formula. It requires quantitative and qualitative inputs to provide a quantitative output (a risk percentage).

The Briganti Nomogram is not intended to replace clinical decision-making; it can only provide information to the healthcare professional on the estimation of the risk that an ePLND and biopsy would identify positive for a tumor in patients with clinically localized prostate cancer. The healthcare professional can use this information to support clinical decision-making regarding optimal treatment options of the patient. In practice, this typically entails the decision to perform an extended lymph node dissection.

Additional remarks on the intended use

The medical device software (MDSW) includes four algorithms, the Briganti 2012 Nomogram, Briganti 2017 Nomogram, Briganti 2019 Nomogram, and Briganti 2023 Nomogram algorithms.

6.2. Clinical benefit

The benefits and risks associated with the use of the Briganti Nomogram for the patient are indirect. The benefits arise from clinical decisions made using the Briganti Nomogram in combination with other clinical and patient-specific factors. The Briganti Nomogram can result in the following clinical benefit:

- The Briganti Nomogram can assist in risk stratification of patients.

6.3. Intended target population and exclusion

The Briganti Nomogram is intended to be used for patients who fit the clinical indications and contra-indications listed below.

6.3.1. Clinical indications

The Briganti Nomogram should be used for patients who meet the following inclusion criteria:

- Patients with clinically localized PCa.

6.3.2. Clinical contra-indications

The Briganti Nomogram should not be used for patients who meet the following exclusion criteria:

- Patients with incomplete pathologic or biopsy data required for calculation of (one of the) Briganti Nomogram(s).

6.4. User profile

The result of the Briganti Nomogram is intended to be reviewed and interpreted by healthcare professionals. Results shall always be reviewed and interpreted by healthcare professionals, in the context of the patient's clinical history and other diagnostic test results. Healthcare professionals do not require additional training prior to the use of the medical device. The device is not intended for use by patients on their own.

6.5. Intended use environment

The MDSW can be used as made available on the Evidencio platform in any actively supported web-browser on personal computers, mobile devices, or tablet PCs. Users can manually enter the required input data through the user interface. In addition, the MDSW is available as an embedded view via Evidencio's iFrame representation. Automated calculation of the device is enabled through Evidencio's API. The device is only intended for use in healthcare settings where the immediate application and outcomes of the device are not required. The device is not intended to be used at the bedside of the patient.

6.6. Physical interaction

The MDSW is stand-alone software and does not come into contact with any bodily or other material of the patient, user or otherwise.

6.7. History/ versions of the MDSW

The versions of the Briganti Nomogram concerned in this document were developed by Briganti et al. in 2012. Gandaglia et al. in 2017, Gandaglia et al. in 2019, and Gandaglia et al. in 2023, resulting in the Briganti 2012 Nomogram, Briganti 2017 Nomogram, Briganti 2019 Nomogram, and Briganti 2023 Nomogram versions respectively.

7. Additional information

7.1. Details

Algorithm author	T. A. Hueting	
Root algorithm ID	1555	
	Version number	**Revision date**
Briganti 2012 Nomogram	2.0	2026-04-28
Briganti 2017 Nomogram	3.0	2026-04-28
Briganti 2019 Nomogram	4.0	2026-04-28
Briganti 2023 Nomogram	5.0	2026-04-28
Speciality	Oncology, Urology	
Algorithm type	Logistic Regression	
MeSH terms	• Prostate Cancer • Lymphadenectomy	

7.2. Input variables

To perform the calculations successfully, the Briganti Nomogram requires the input variables as listed in **Table 1**.

Table 1. Variables used as input for the Briganti Nomogram.

Name	Description	Type	Range (step size)	Units
Briganti 2012 Nomogram				
PSA	Prostate Specific Antigen	Continuous	0-50 (0.1)	*ng/ml*
Clinical T-stage	Tumor stage	Categorical	Stage T1 Stage T2 Stage T3	
Primary Gleason Grade	Primary biopsy Gleason grade of the tumor	Categorical	≤3 ≥4	
Secondary Gleason Grade	Secondary biopsy Gleason grade of the tumor	Categorical	≤3 ≥4	
Percentage of Positive Cores	Percentage of positive cores taken during transrectal ultrasound-guided prostate biopsy	Continuous	0-100 (0.1)	*%*
Briganti 2017 Nomogram				
Preoperative PSA	Preoperative Prostate Specific Antigen	Continuous	0-50 (0.1)	*ng/ml*
Clinical T stage	Tumor stage	Categorical	Clinical Stage T1 Clinical Stage T2 Clinical Stage T3	
Biopsy Gleason Grade group		Categorical	1 2 3 4 5	
Percentage of positive cores with highest-grade PCA	Percentage of cores in the biopsy with the highest-grade disease	Continuous	0-100 (0.1)	*%*
Percentage of positive cores with lower grade PCA	Percentage of cores in the biopsy with the lowest-grade disease	Continuous	0-90 (0.1)	*%*
Briganti 2019 Nomogram				
Preoperative PSA	Preoperative Prostate Specific Antigen	Continuous	0-50 (0.1)	*ng/ml*
Clinical stage at mpMRI	Clinical stage at multiparametric Magnetic Resonance Imaging	Categorical	Organ confined	

			Extracapsular extension Seminal vesicle invasion	
Maximum lesion diameter at mpMRI	The lesion with the highest PI-RADS score or the one with the largest diameter for lesions with the same PI-RADS score.	Continuous	0-45 (1)	*mm*
Biopsy Gleason grade group at MRI-targeted biopsy		Categorical	1 2 3 4 5	
Percentage of cores with clinically significant PCa at systematic biopsy	Percentage of cores with clinically significant PCa, defined as grade group ≥2.	Continuous	0-100 (0.1)	*%*
Briganti 2023 Nomogram				
Preoperative PSA	Preoperative Prostate Specific Antigen	Continuous	0-50 (0.1)	*ng/ml*
Clinical stage at mpMRI	Clinical stage at multiparametric Magnetic Resonance Imaging	Categorical	Organ confined Extracapsular extension Seminal vesicle invasion	
Maximum lesion diameter at mpMRI	The lesion with the highest PI-RADS score or the one with the largest diameter for lesions with the same PI-RADS score.	Continuous	0-45 (1)	*mm*
Biopsy Gleason Grade		Categorical	1 2 3 4 5	
Percentage of cores with clinically significant PCa at systematic biopsy	Percentage of positive cores at systematic biopsy.	Continuous	0-100 (0.1)	*%*

7.3. Algorithm

The Briganti Nomogram is composed of four logistic regression models. The equations can also be found in the original documents provided by Briganti and Gandaglia et al. The logistic regression models take the following form:

$$P = \frac{e^{X\beta}}{1+e^{X\beta}}$$ **Equation 1.**

In this equation, Xβ represents the combination of the individual values (x) with the beta coefficients and the intercept, while the x represents the input variables. For non-continuous variables, the end values are shown below in order.

Table 2. Logistic Regression coefficients used for the Briganti Nomogram.

Briganti 2012 Nomogram		**Briganti 2017 Nomogram**		**Briganti 2019 Nomogram**		**Briganti 2023 Nomogram**	
Variable	**Beta Coefficient / Value**	**Variable**	**Beta Coefficient / Value**	**Variable**	**Beta Coefficient / Value**	**Variable**	**Beta Coefficient / Value**
Intercept	-5.34	Intercept	-5.8717	Intercept	-4.5974	Intercept	-4.807

PSA	0.036331929	Preoperative PSA	0.0826	Preoperative PSA	0.0416	Preoperative PSA	0.0085
Clinical T-stage Stage T1 Stage T2 Stage T3	 0 0.590006422 1.994700313	Clinical T-stage Clinical stage T1 Clinical stage T2 Clinical stage T3	 0 0.8489 1.055	Clinical stage at mpMRI Organ confined Extracapsular extension Seminal vesicle invasion	 0 1.2214 1.4672	Clinical stage at mpMRI Organ confined Extracapsular extension Seminal vesicle invasion	 0 0.7288 1.3835
Primary Gleason Grade ≤3 ≥4	 0 1.295822458	Biopsy Gleason Grade Group 1 2 3 4 5	 0 0 2.2664 2.6753 2.6753	Maximum lesion diameter at mpMRI	0.0311	Maximum lesion diameter at mpMRI	0.0489
Secondary Gleason Grade ≤3 ≥4	 0 0.371563556	Percentage of positive cores with highest-grade PCa	0.0268	Biopsy Gleason grade group at MRI-targeted biopsy 1 2 3 4 5	 0 0 1.2032 1.8063 1.8063	Biopsy Gleason Grade 1 2 3 4 5	 0 0 0 0 0.8757
Percentage of positive cores	0.027128667	Percentage of positive cores with lower grade PCa	0.0140	Percentage of cores with clinically significant PCa at systematic biopsy	0.0119	Percentage of cores with clinically significant PCa at systematic biopsy	0.0160

7.4. Result interpretation

Primary outcome

The primary output of this device is given as a calculated risk of Lymph Node Involvement as a percentage with one decimal.

Calculations alone should never dictate patient care, and are no substitute for professional judgement. See the Evidencio website for the full disclaimer; https://www.evidencio.com/disclaimer/.

7.5. Study characteristics

7.5.1. Briganti 2012 Nomogram

From derivation study:

"The Briganti 2012 Nomogram model was published in 2012, as a routine update to the previous Briganti model to stay up to date. The patient characteristics for the data used to derive the nomogram is included below:

Clinical and pathologic data were prospectively gathered for 588 patients treated with RP and ePLND between September 2006 and October 2010 at the San Farraele Scientific institute's hospital. All patients were subjected to detailed preoperative evaluation consisting of prostate-specific antigen (PSA) assay (Abbott AxSYM PSA assay; Abbott Laboratories, Abbott Park, IL, USA), clinical stage assessed by the attending urologist (according to the 2002 American Joint Committee on Cancer staging system), and transrectal ultrasound-guided prostate biopsy. In addition to Gleason sum, the total number of cores taken as well as the number and the percentage of positive cores were recorded for each patient. All men had histologically proven PCa and underwent RP preceded by ePLND, regardless of PCa characteristics."

Table 3. This table contains information on the patient group data used to derive the Briganti 2012.

NAME	Q1	MEDIAN	Q3	UNIT
Age at surgery (pN0 patients)	60.3	65.2	70.6	years
Age at surgery (pN1 patients)	60.3	65.3	69.5	years
Preoperative PSA (pN0 patients)	4.7	7.5	8.7	ng/ml
Preoperative PSA (pN1 patients)	6.2	12.8	12.5	ng/ml
Cores taken overall (pN0 patients)	14	17	24	cores
Cores taken overall (pN1 patients)	12	15.5	18	cores
Positive cores overall (pN0 patients)	3	6	10	cores
Positive cores overall (pN1 patients)	6	10.5	14	cores
Percentage of positive cores overall (pN0 patients)	16.7	33.3	57.1	%
Percentage of positive cores overall (pN1 patients)	51.0	78.6	100	%
Lymph nodes removed (pN0 patients)	15	19	25	nodes
Lymph nodes removed (pN1 patients)	16	21	28	nodes
Positive lymph nodes	1	2	3	nodes

Table 4. This table contains categorical characteristics on the patient group data used to derive the Briganti 2012

NAME	SUBSET / GROUP	NR. OF PATIENTS
Lymph node involvement	pN0	539
Lymph node involvement	pN1	49
Clinical stage (pN0 patients)	T1	360
Clinical stage (pN0 patients)	T2	164
Clinical stage (pN0 patients)	T3	15
Clinical stage (pN1 patients)	T1	13
Clinical stage (pN1 patients)	T2	20
Clinical stage (pN1 patients)	T3	16
Primary Gleason Grade pN0	≤3	466
Primary Gleason Grade pN0	≥4	73
Secondary Gleason grade pN0	≤3	466
Secondary Gleason grade pN0	≥4	73
Primary Gleason grade pN1	≤3	22
Primary Gleason grade pN1	≥4	27
Secondary Gleason grade pN1	≤3	20
Secondary Gleason grade pN1	≥4	29
Pathologic stage pN0	pT2	427
Pathologic stage pN0	pT3a	84
Pathologic stage pN0	pT3b	28
Pathologic stage pN0	pT4	0
Pathologic stage pN1	pT2	4
Pathologic stage pN1	pT3a	13
Pathologic stage pN1	pT3b	30

Pathologic stage pN1	pT4	2
Pathologic Gleason score pN0	2-6	222
Pathologic Gleason score pN0	7	260
Pathologic Gleason score pN0	8-10	43
Pathologic Gleason score pN0	missing	14
Pathologic Gleason score pN1	2-6	1
Pathologic Gleason score pN1	7	22
Pathologic Gleason score pN1	8-10	20
Pathologic Gleason score pN1	Missing	6

7.5.2. Briganti 2017 Nomogram

From derivation study:

"After Institutional Review Board approval, clinical and pathologic data were prospectively collected for 2872 patients treated with open or robot-assisted RP and ePLND for localized PCa between January 2011 and July 2016 at a single tertiary referral center. Patients with complete data who underwent centralized biopsy specimens review performed by two high-volume dedicated uropathologists selected (n = 681). No patients received neoadjuvant hormonal therapy. All cases were performed by six surgeons with at least 200 cases at the beginning of data collection who were trained by the same surgeon and applied the same anatomical template for ePLND. The fibrofatty tissue along the external iliac vein was dissected, the lateral limit being the genitofemoralis nerve. Proximally, an ePLND was performed up to and included the crossing between the ureter and common iliac vessels. Lymph nodes along as well as medially and laterally to the internal iliac vessels were removed. All fibrofatty tissue within the obturator fossa was removed, and the Marcille's triangular lumbosacral fossa was dissected free. All specimens were submitted for pathologic evaluation in multiple packages according to their anatomical location and were evaluated by dedicated uropathologists according to a previously described methodology."

Table 5. This table contains information on the patient group data used to derive the Briganti 2017.

NAME	Q1	MEDIAN	Q3	UNIT
Age at surgery (pN0 patients)	60	65	70	years
Age at surgery (pN1 patients)	59	65	71	years
Preoperative PSA (pN0 patients)	4.5	6.4	7.9	ng/ml
Preoperative PSA (pN1 patients)	6.1	10.8	21	ng/ml
Cores taken overall (pN0 patients)	12	14	20	cores
Cores taken overall (pN1 patients)	12	14	18	cores
Percentage of positive cores overall (pN0 patients)	14.3	31.6	50.0	%
Percentage of positive cores overall (pN1 patients)	42.8	62.5	85.7	%
Positive cores with highest-grade PCa (pN0 patients)	13.2	25	45.0	%
Positive cores with highest-grade PCa (pN1 patients)	31.9	50	81.8	%
Positive cores with lower-grade PCa (pN0 patients)	16.6	25	41.6	%
Positive cores with lower-grade PCa (pN1 patients)	23.3	33.3	51.8	%
Lymph nodes removed (pN0 patients)	8	15	21	nodes
Lymph nodes removed (pN1 patients)	15	20	27	nodes
Positive lymph nodes	1	1	4	nodes
Year of Surgery	2013	2014	2015	Years
Maximum percentage of single core involvement with highest-grade PCa pN0	10	30	60	%
Maximum percentage of single core involvement with highest-grade PCa pN1	40	75	90	%
Maximum percentage of single core involvement with lower-grade PCa pN0	20	40.9	61.1	%
Maximum percentage of single core involvement with lower-grade PCa pN1	31.2	76.8	93.4	%
Total tumor length pN0	0.35	1.3	2.93	cm
Total tumor length pN1	2.6	4.9	8.9	cm
Total biopsy length pN0	16.4	20.0	26.0	cm
Total biopsy length pN1	17.1	20.0	23.4	cm
Percentage of tumor in biopsy cores pN0	1.7	6.8	15.8	%
percentage of tumor in biopsy cores pN1	11.3	27.8	45.6	%

Tumor length of highest-grade PCa pN0	0.3	1.12	2.7	cm
Tumor length of highest-grade PCA pN1	4.2	2.0	7.8	cm
Tumor length of lower-grade PCa pN0	0.41	0.9	1.95	cm
Tumor length of lower-grade PCa pN1	1.18	2.1	4.51	cm
Maximum percentage of single core involvement with lower-grade PCa pN0	20	40.9	61.1	%
Maximum percentage of single core involvement with lower-grade PCa pN1	31.2	76.8	93.4	%
Total tumor length pN0	0.35	1.3	2.93	cm
Total tumor length pN1	2.6	4.9	8.9	cm

Table 6. This table contains categorical characteristics on the patient group data used to derive the Briganti 2017

NAME	SUBSET / GROUP	NR. OF PATIENTS
Lymph node involvement	pN0	602
Lymph node involvement	pN1	79
Clinical stage (pN0 patients)	T1	357
Clinical stage (pN0 patients)	T2	222
Clinical stage (pN0 patients)	T3	23
Clinical stage (pN1 patients)	T1	18
Clinical stage (pN1 patients)	T2	42
Clinical stage (pN1 patients)	T3	19
Biopsy Gleason grade group (pN0 patients)	1	260
Biopsy Gleason grade group (pN0 patients)	2	233
Biopsy Gleason grade group (pN0 patients)	3	65
Biopsy Gleason grade group (pN0 patients)	4	33
Biopsy Gleason grade group (pN0 patients)	5	11
Biopsy Gleason grade group (pN1 patients)	1	1
Biopsy Gleason grade group (pN1 patients)	2	14
Biopsy Gleason grade group (pN1 patients)	3	28
Biopsy Gleason grade group (pN1 patients)	4	15
Biopsy Gleason grade group (pN1 patients)	5	21
Surgical technique	Open	205
Surgical technique	Robot-assisted	476
Gleason grade group on final pathology (pN0 patients)	1	130
Gleason grade group on final pathology (pN0 patients)	2	272
Gleason grade group on final pathology (pN0 patients)	3	128
Gleason grade group on final pathology (pN0 patients)	4	26
Gleason grade group on final pathology (pN0 patients)	5	46
Gleason grade group on final pathology (pN1 patients)	1	6
Gleason grade group on final pathology (pN1 patients)	2	7
Gleason grade group on final pathology (pN1 patients)	3	12
Gleason grade group on final pathology (pN1 patients)	4	13
Gleason grade group on final pathology (pN1 patients)	5	41
Pathologic stage (pN0 patients)	pT2	423
Pathologic stage (pN0 patients)	pT3a	153
Pathologic stage (pN0 patients)	pT3b/pT4	24
Pathologic stage (pN1 patients)	pT2	4
Pathologic stage (pN1 patients)	pT3a	26
Pathologic stage (pN1 patients)	pT3b/pT4	49
Positive surgical margins	pN0 patients	90
Positive surgical margins	pN1 patients	41
Site of LNI	Obturator fossa	42
Site of LNI	Internal iliac region	20
Site of LNI	External iliac region	34
Site of LNI	Common iliac region	9
Site of LNI	Presacral area	7

7.5.3. Briganti 2019 Nomogram

From derivation study:

"After institutional review board approval, 581 patients who underwent MRI-targeted biopsy and radical prostatectomy (RP) with extended Pelvic Lymph Node Dissection (ePLND) between 2016 and 2018 at five European tertiary referral centers were retrospectively identified. mpMRI and MRI-targeted biopsies were routinely recommended to patients with a clinical suspicion of PCa according to the judgment of the treating physician. Only patients with a positive MRI-targeted biopsy were selected (n = 516). Among those, patients with incomplete biopsy or pathologic data (n = 19) were excluded. This resulted in a final population of 497 patients.

No patients received neoadjuvant hormonal therapy. Surgery was routinely proposed as a treatment option at each center. The decision to perform RP was left to the clinical judgment of the treating physician after discussion with each patient regarding the potential benefits and side effects of all available treatment modalities for the management of localized PCa. Only patients who underwent anatomically defined ePLND with removal of the obturator, internal iliac, and external iliac lymph nodes were included. All procedures were performed by high-volume surgeons at referral institutions. All specimens were submitted for pathologic evaluation in multiple packages and were evaluated by dedicated uropathologists."

Table 7. This table contains information on the patient group data used to derive the Briganti 2019.

NAME	Q1	MEDIAN	Q3	UNIT
Age at surgery (pN0 patients)	60	65	70	years
Age at surgery (pN1 patients)	60	64	71	years
Preoperative PSA (pN0 patients)	5.1	7.2	11	ng/ml
Preoperative PSA (pN1 patients)	6.7	11	21	ng/ml
Prostate volume (pN0 patients)	33	43	55	ml
Prostate volume (pN1 patients)	34	48	59	ml
Maximum index lesion diameter on mpMRI (pN0 patients)	9	10	14	mm
Maximum index lesion diameter on mpMRI	10	15	18	mm
Cores taken overall (pN0 patients)	14	16	18	cores
Cores taken overall (pN1 patients)	14	16	18	cores
Positive cores overall (pN0 patients)	3	5	8	cores
Positive cores overall (pN1 patients)	9	5	12	cores
Percentage of positive cores overall (pN0 patients)	20	33	50	%
Percentage of positive cores overall (pN1 patients)	36	55	80	%
Positive cores with highest-grade PCa (pN0 patients)	12	20	38	%
Positive cores with highest-grade PCa (pN1 patients)	24	40	60	%
Positive cores with lower-grade PCa (pN0 patients)	8	16	27	%
Positive cores with lower-grade PCa (pN1 patients)	10	21	30	%
Systematic cores taken (pN0 patients)	10	12	15	cores
Systematic cores taken (pN1 patients)	10	12	16	cores
Cores with csPCa on systematic biopsy (pN0 patients)	0	12	37	%
Cores with csPCa on systematic biopsy (pN1 patients)	17	42	76	%
Lymph nodes removed (pN0 patients)	10	15	20	nodes
Lymph nodes removed (pN1 patients)	13	17	24	nodes
Positive lymph nodes	1	1	2	nodes

Table 8. This table contains categorical characteristics on the patient group data used to derive the Briganti 2019

NAME	SUBSET / GROUP	NR. OF PATIENTS
Lymph node involvement	pN0	435
Lymph node involvement	pN1	62
Clinical stage (pN0 patients)	T1	335
Clinical stage (pN0 patients)	T2	96
Clinical stage (pN0 patients)	T3	4
Clinical stage (pN1 patients)	T1	30
Clinical stage (pN1 patients)	T2	21
Clinical stage (pN1 patients)	T3	11
PI-RADS score (pN0 patients)	3	121
PI-RADS score (pN0 patients)	4	235
PI-RADS score (pN0 patients)	5	79
PI-RADS score (pN1 patients)	3	4
PI-RADS score (pN1 patients)	4	26
PI-RADS score (pN1 patients)	5	32
Number of PI-RADS ≥3 lesions on mpMRI (pN0 patients)	1	299
Number of PI-RADS ≥3 lesions on mpMRI (pN0 patients)	2	91
Number of PI-RADS ≥3 lesions on mpMRI (pN0 patients)	3	27
Number of PI-RADS ≥3 lesions on mpMRI (pN0 patients)	≥4	18
Number of PI-RADS ≥3 lesions on mpMRI (pN1 patients)	1	38
Number of PI-RADS ≥3 lesions on mpMRI (pN1 patients)	2	20
Number of PI-RADS ≥3 lesions on mpMRI (pN1 patients)	3	3
Number of PI-RADS ≥3 lesions on mpMRI (pN1 patients)	≥4	1
Clinical stage on mpMRI (pN0 patients)	Organ-confined	358
Clinical stage on mpMRI (pN0 patients)	Extracapsular extension	49
Clinical stage on mpMRI (pN0 patients)	Seminal vesicle invasion	13
Clinical stage on mpMRI (pN1 patients)	Organ-confined	29
Clinical stage on mpMRI (pN1 patients)	Extracapsular extension	19
Clinical stage on mpMRI (pN1 patients)	Seminal vesicle invasion	14
Biopsy grade group overall (pN0 patients)	1	55
Biopsy grade group overall (pN0 patients)	2	236
Biopsy grade group overall (pN0 patients)	3	78
Biopsy grade group overall (pN0 patients)	4	45
Biopsy grade group overall (pN0 patients)	5	21
Biopsy grade group overall (pN1 patients)	1	1
Biopsy grade group overall (pN1 patients)	2	15
Biopsy grade group overall (pN1 patients)	3	16
Biopsy grade group overall (pN1 patients)	4	15
Biopsy grade group overall (pN1 patients)	5	15
Grade group on MRI-targeted biopsy (pN0 patients)	1	72
Grade group on MRI-targeted biopsy (pN0 patients)	2	225
Grade group on MRI-targeted biopsy (pN0 patients)	3	72
Grade group on MRI-targeted biopsy (pN0 patients)	4	46
Grade group on MRI-targeted biopsy (pN0 patients)	5	20
Grade group on MRI-targeted biopsy (pN1 patients)	1	1
Grade group on MRI-targeted biopsy (pN1 patients)	2	15
Grade group on MRI-targeted biopsy (pN1 patients)	3	16
Grade group on MRI-targeted biopsy (pN1 patients)	4	17
Grade group on MRI-targeted biopsy (pN1 patients)	5	13
Target cores taken on MRI-targeted biopsy (pN0 patients)	2	165
Target cores taken on MRI-targeted biopsy (pN0 patients)	3	94
Target cores taken on MRI-targeted biopsy (pN0 patients)	4	77
Target cores taken on MRI-targeted biopsy (pN0 patients)	≥5	99
Target cores taken on MRI-targeted biopsy (pN1 patients)	2	27
Target cores taken on MRI-targeted biopsy (pN1 patients)	3	18

Target cores taken on MRI-targeted biopsy (pN1 patients)	4	10
Target cores taken on MRI-targeted biopsy (pN1 patients)	≥5	7
Positive cores on MRI-targeted biopsy (pN0 patients)	1	111
Positive cores on MRI-targeted biopsy (pN0 patients)	2	173
Positive cores on MRI-targeted biopsy (pN0 patients)	3	69
Positive cores on MRI-targeted biopsy (pN0 patients)	≥4	82
Positive cores on MRI-targeted biopsy (pN1 patients)	1	5
Positive cores on MRI-targeted biopsy (pN1 patients)	2	32
Positive cores on MRI-targeted biopsy (pN1 patients)	3	16
Positive cores on MRI-targeted biopsy (pN1 patients)	≥4	9
Grade group on systematic biopsy (pN0 patients)	Negative	80
Grade group on systematic biopsy (pN0 patients)	1	100
Grade group on systematic biopsy (pN0 patients)	2	171
Grade group on systematic biopsy (pN0 patients)	3	44
Grade group on systematic biopsy (pN0 patients)	4	25
Grade group on systematic biopsy (pN0 patients)	5	15
Grade group on systematic biopsy (pN1 patients)	Negative	4
Grade group on systematic biopsy (pN1 patients)	1	6
Grade group on systematic biopsy (pN1 patients)	2	14
Grade group on systematic biopsy (pN1 patients)	3	15
Grade group on systematic biopsy (pN1 patients)	4	9
Grade group on systematic biopsy (pN1 patients)	5	14
Surgical technique	Open	43
Surgical technique	Robot-assisted	454
Gleason grade group on final pathology (pN0 patients)	1	15
Gleason grade group on final pathology (pN0 patients)	2	218
Gleason grade group on final pathology (pN0 patients)	3	147
Gleason grade group on final pathology (pN0 patients)	4	22
Gleason grade group on final pathology (pN0 patients)	5	30
Gleason grade group on final pathology (pN1 patients)	1	0
Gleason grade group on final pathology (pN1 patients)	2	3
Gleason grade group on final pathology (pN1 patients)	3	25
Gleason grade group on final pathology (pN1 patients)	4	4
Gleason grade group on final pathology (pN1 patients)	5	30
Pathologic stage (pN0 patients)	pT2	215
Pathologic stage (pN0 patients)	pT3a	180
Pathologic stage (pN0 patients)	pT3b/pT4	40
Pathologic stage (pN1 patients)	pT2	3
Pathologic stage (pN1 patients)	pT3a	20
Pathologic stage (pN1 patients)	pT3b/pT4	39
Positive surgical margins	pN0 patients	103
Positive surgical margins	pN1 patients	40

7.5.4. Briganti 2023 Nomogram

From derivation paper:

"After institutional review board approval, we identified 711 patients with intermediate- or high-risk PCa with a Prostate Imaging-Reporting and Data System (PI-RADS) _3 lesion on multiparametric magnetic resonance imaging (mpMRI) performed before prostate biopsy who underwent preoperative PSMA PET and were treated with RP with concomitant ePLND at 12 referral centers worldwide (Austria, Belgium, China, Germany, Italy, the Netherlands, Spain, and Switzerland) between 2017 and 2022. We excluded patients with cN1 or cM1 disease on abdominal CT (n = 17) or bone scans (n = 9) and those who received neoadjuvant therapies (n = 91). Patients with incomplete data on biopsy grade group or pN stage were also excluded (n = 4). For the purpose of our study, we excluded patients with nodal (n = 74, 13%) or distant (n = 58, 9.8%) suspicious lesions on preoperative PSMA PET. This resulted in a final population of 458 patients with miN0M0 PCA."

Table 9. This table contains information on the patient group data used to derive the Briganti 2023

NAME	Q1	MEDIAN	Q3	UNIT
Age at surgery (pN0 patients)	62	68	72	years
Age at surgery (pN1 patients)	63	68	72	years
Initial PSA (pN0 patients)	6	9	16	ng/ml
Initial PSA (pN1 patients)	6	11	20	ng/ml
Prostate volume (pN0 patients)	28	37	48	ml
Prostate volume (pN1 patients)	30	37	49	ml
Number of PI-RADS ≥3 lesions at mpMRI	1	1	2	lesions
Dmax of the index lesion at mpMRI (pN0 patients)	11	15	21	mm
Dmax of the index lesion at mpMRI (pN1 patients)	16	22	29	mm
Cores taken (pN0 patients)	12	14	16	cores
Cores taken (pN1 patients)	9	12	15	cores
Positive cores (pN0 patients)	4	6	9	cores
Positive cores (pN1 patients)	6	7	10	cores
Percentage of positive cores (pN0 patients)	29	50	64	%
Percentage of positive cores (pN1 patients)	50	67	83	%
Positive cores with highest-grade PCa (pN0 patients)	12	21	39	%
Positive cores with highest-grade PCa (pN1 patients)	21	42	60	%
Positive cores with lower-grade PCa (pN0 patients)	0	11	29	%
Positive cores with lower-grade PCa (pN1 patients)	0	7	23	%
Target cores taken (pN0 patients)	2	4	5	cores
Target cores taken (pN1 patients)	3	4	5	cores
Positive cores at TBx (pN0 patients)	1	3	4	cores
Positive cores at TBx (pN1 patients)	2	3	4	cores
SBx cores taken (pN0 patients)	10	12	12	cores
SBx cores taken (pN1 patients)	8	12	12	cores
Cores with csPCa at SBx (pN0 patients)	20	40	58	%
Cores with csPCa at SBx (pN1 patients)	42	58	78	%
SUVmax (pN0 patients)	7	12	22	
SUVmax (pN1 patients)	8	14	22	
Lymph nodes removed (pN0 patients)	10	15	22	nodes
Lymph nodes removed (pN1 patients)	14	18	26	nodes
Positive lymph nodes	1	1	1	nodes

Table 10. This table contains categorical characteristics on the patient group data used to derive the Briganti 2023

NAME	SUBSET / GROUP	NR. OF PATIENTS
Lymph node involvement	pN0	405
Lymph node involvement	pN1	53
Clinical stage (pN0 patients)	cT1	160
Clinical stage (pN0 patients)	cT2	186
Clinical stage (pN0 patients)	cT3	16
Clinical stage (pN1 patients)	cT1	12
Clinical stage (pN1 patients)	cT2	23
Clinical stage (pN1 patients)	cT3	9
PI-RADS score (pN0 patients)	PI-RADS 3	30
PI-RADS score (pN0 patients)	PI-RADS 4	163
PI-RADS score (pN0 patients)	PI-RADS 5	212
PI-RADS score (pN1 patients)	PI-RADS 3	2
PI-RADS score (pN1 patients)	PI-RADS 4	8
PI-RADS score (pN1 patients)	PI-RADS 5	43
Clinical stage on mpMRI (pN0 patients)	Organ-confined	284
Clinical stage on mpMRI (pN0 patients)	Extracapsular extension	83
Clinical stage on mpMRI (pN0 patients)	Seminal vesicle invasion	36
Clinical stage on mpMRI (pN1 patients)	Organ-confined	19

Clinical stage on mpMRI (pN1 patients)	Extracapsular extension	14
Clinical stage on mpMRI (pN1 patients)	Seminal vesicle invasion	19
Biopsy grade group (pN0 patients)	Grade group 1	17
Biopsy grade group (pN0 patients)	Grade group 2	53
Biopsy grade group (pN0 patients)	Grade group 3	102
Biopsy grade group (pN0 patients)	Grade group 4	162
Biopsy grade group (pN0 patients)	Grade group 5	71
Biopsy grade group (pN1 patients)	Grade group 1	1
Biopsy grade group (pN1 patients)	Grade group 2	5
Biopsy grade group (pN1 patients)	Grade group 3	14
Biopsy grade group (pN1 patients)	Grade group 4	13
Biopsy grade group (pN1 patients)	Grade group 5	20
Grade group at TBx (pN0 patients)	Negative	5
Grade group at TBx (pN0 patients)	Grade group 1	17
Grade group at TBx (pN0 patients)	Grade group 2	55
Grade group at TBx (pN0 patients)	Grade group 3	85
Grade group at TBx (pN0 patients)	Grade group 4	110
Grade group at TBx (pN0 patients)	Grade group 5	39
Grade group at TBx (pN1 patients)	Negative	0
Grade group at TBx (pN1 patients)	Grade group 1	1
Grade group at TBx (pN1 patients)	Grade group 2	6
Grade group at TBx (pN1 patients)	Grade group 3	5
Grade group at TBx (pN1 patients)	Grade group 4	6
Grade group at TBx (pN1 patients)	Grade group 5	13
Grade group at SBx (pN0 patients)	Negative	19
Grade group at SBx (pN0 patients)	Grade group 1	29
Grade group at SBx (pN0 patients)	Grade group 2	59
Grade group at SBx (pN0 patients)	Grade group 3	86
Grade group at SBx (pN0 patients)	Grade group 4	130
Grade group at SBx (pN0 patients)	Grade group 5	49
Grade group at SBx (pN1 patients)	Negative	1
Grade group at SBx (pN1 patients)	Grade group 1	1
Grade group at SBx (pN1 patients)	Grade group 2	4
Grade group at SBx (pN1 patients)	Grade group 3	9
Grade group at SBx (pN1 patients)	Grade group 4	9
Grade group at SBx (pN1 patients)	Grade group 5	13
Surgical technique	Open radical	22
Surgical technique	Laparascopic radical	8
Surgical technique	Robot-assisted	428
Gleason grade group at final pathology (pN0 patients)	Grade group 1	10
Gleason grade group at final pathology (pN0 patients)	Grade group 2	117
Gleason grade group at final pathology (pN0 patients)	Grade group 3	126
Gleason grade group at final pathology (pN0 patients)	Grade group 4	80
Gleason grade group at final pathology (pN0 patients)	Grade group 5	71
Gleason grade group at final pathology (pN1 patients)	Grade group 1	1
Gleason grade group at final pathology (pN1 patients)	Grade group 2	4
Gleason grade group at final pathology (pN1 patients)	Grade group 3	11
Gleason grade group at final pathology (pN1 patients)	Grade group 4	7
Gleason grade group at final pathology (pN1 patients)	Grade group 5	21
Pathologic stage (pN0 patients)	pT2	158
Pathologic stage (pN0 patients)	pT3a	184
Pathologic stage (pN0 patients)	pT3b/4	63
Pathologic stage (pN1 patients)	pT2	3
Pathologic stage (pN1 patients)	pT3a	17
Pathologic stage (pN1 patients)	pT3b/4	33
Positive surgical margins	pN0 patients	130

Positive surgical margins	pN1 patients	30

7.6. Supporting publication & Related files

Several relevant studies, such as the original derivation studies by Briganti and Gandaglia are contained in **Table 11.** These publications have tags to identify their link with the algorithm. Examples of relevant tags are; "Peer review", "Internal validation", "External validation", and "TRIPOD". Publications that have the tags: "Internal validation" or "External validation", contain data on the performance characteristics of the device.

Table 11. Overview of selection of supporting publications & Related files.

Original calculator Briganti 2012 Internal validation Peer review	**Updated Nomogram Predicting Lymph Node Invasion in Patients with Prostate Cancer Undergoing Extended Pelvic Lymph Node Dissection: The Essential Importance of Percentage of Positive Cores** *Alberto Briganti, Alessandro Larcher, Firas Abdollah, Umberto Capitanio, Andrea Gallina, Nazareno Suardi, Marco Bianchi, Maxine Sun, Massimo Freschi, Andrea Salonia, Pierre Karakiewicz, Patrizio Rigatti, Francesco Montorsi* https://www.sciencedirect.com/science/article/abs/pii/S0302283811012309 DOI: 10.1016/j.eururo.2011.10.044
Original calculator Briganti 2017 Internal validation Peer review	**Development and Internal Validation of a Novel Model to Identify the Candidates for Extended Pelvic Lymph Node Dissection in Prostate Cancer** *Gandaglia, G., Fossati, N., Zaffuto, E., Bandini, M., Dell'Oglio, P., Bravi, C. A., Fallara, G., Pellegrino, F., Nocera, L., Karakiewicz, P. I., Tian, Z., Freschi, M., Montironi, R., Montorsi, F., & Briganti, A.* https://www.sciencedirect.com/science/article/abs/pii/S0302283817302804?via%3Dihub 10.1016/j.eururo.2017.03.049
Original calculator Briganti 2019 Internal validation Peer review	**A Novel Nomogram to Identify Candidates for Extended Pelvic Lymph Node Dissection Among Patients with Clinically Localized Prostate Cancer Diagnosed with Magnetic Resonance Imaging-targeted and Systematic Biopsies** *Gandaglia, G., Ploussard, G., Valerio, M., Mattei, A., Fiori, C., Fossati, N., Stabile, A., Beauval, J. B., Malavaud, B., Roumiguié, M., Robesti, D., Dell'Oglio, P., Moschini, M., Zamboni, S., Rakauskas, A., De Cobelli, F., Porpiglia, F., Montorsi, F., Briganti, A.* https://www.europeanurology.com/article/S0302-2838(18)30753-X/abstract DOI: 10.1016/j.eururo.2018.10.012
Original calculator Briganti 2023 Internal validation External validation Peer review	**Identification of the Optimal Candidates for Nodal Staging with Extended Pelvic Lymph Node Dissection Among Prostate Cancer Patients Who Underwent Preoperative Prostate-specific Membrane Antigen Positron Emission Tomography. External Validation of the Memorial Sloan Kettering Cancer Center and Briganti Nomograms and Development of a Novel Tool** *Gandaglia, G., Barletta, F., Robesti, D., Scuderi, S., Rajwa, P., Gomez Rivas, J., Ibanez, L., Soeterik, T. F. W., Bianchi, L., Afferi, L., Kesch, C., Darr, C., Guo, H., Zhuang, J., Zattoni, F., Fendler, W., Marra, G., Stabile, A., Amparore, D., Huebner, N. A., Giesen, A., Joniau, S., Schiavina, R., Brunocilla, E., Mattei, A., Dal Moro, F., Moreno Sierra, J., Porpiglia, F., Picchio, M., van den Bergh, R., Shariat, S. F., Montorsi, F., Briganti, A.* https://pubmed.ncbi.nlm.nih.gov/37270378/ DOI: 10.1016/j.euo.2023.05.003

7.7. Analytical performance characteristics

To demonstrate the analytical performance of the Briganti Nomogram, evidence was collected based on four requirements. This led to the following results:

- A code review and functional test showed that the calculation of the online tool provides the exact same results as described in the paper by Briganti *et al*. (2012), Gandaglia *et al.* (2017), Gandaglia *et al.* (2019), and Gandaglia *et al.* (2023).
- Monthly uptime reports show that the device is available online with an uptime of at least 99%.
- The calculation time is within 2 minutes, otherwise an error is given to the manufacturer, this is analysed each 6 months in the analysis of quality data.
- Absence of unacceptable cybersecurity vulnerabilities.

7.8. Clinical performance characteristics

The performance evaluation of the Briganti Nomogram showed a C-statistic of 2012: 0.80 (95% CI: 0.76, 0.84), 2017: (95% CI: 0.75, 0.83), 2019: 0.76 (95% CI: 0.72, 0.80), 2023: >0.76. In terms of calibration, the Briganti Nomogram accurately predicted Lymph Node Involvement.

7.9. Release notes

The release notes for each publicly available version of the device can be found on the Evidencio website page for the Briganti Nomogram: https://www.evidencio.com/models/show/1555, selecting the correct device (version), and clicking on Release Notes. It is recommended to read these notes after a version update to see if these changes are relevant to you. Please make sure the correct algorithm version is selected.

8. Using the algorithm on the Evidencio website

Using the tool on the Evidencio website requires a stable internet connection. The tool was developed to work on the latest versions, as of the making of this manual, of the four most commonly used internet browsers; Google Chrome (version 135.0.7049.115 and higher), Mozilla Firefox (version 137.0.2 and higher), Microsoft Edge (version 135.0.3179.98 and higher), and Apple Safari (version 18.4 and higher). The medical device cannot be used in combination with Internet Explorer.

The tool can also be accessed on mobile devices running the most recent versions of the Android (version 15.0 and higher) and iOS (version 18.4.1 and higher) operating systems.

Correct functioning of the tool with earlier versions of these browsers cannot be guaranteed.

The personal computers, laptops, tablets or smartphones used should at least be able to have an internet connection and use the browsers mentioned above.

Furthermore, the algorithm may be used through the Evidencio iFrame representation of the calculator, as an embedded view, provided that the specific Evidencio guidelines for iFrame implementations of that algorithm are adhered to.

The Evidencio MDSW algorithms can be used with any browser settings that don't distort the regular display of websites, with a 50% to 500% zoom rate, and at a display minimal screen resolution starting from 800x600. However, factory recommended browser settings, 100% zoom rate and regular display resolution are recommended.

The MDSW is intended for authorised users only, and should not be used by unauthorised personnel.

This algorithm is only intended for use in settings where the usage and result of an algorithm are never immediately needed.

8.1. General algorithm landing page

An example of a medical device algorithm interface on the Evidencio platform is shown in **Figure 1**. The different sections indicated are explained in this chapter.

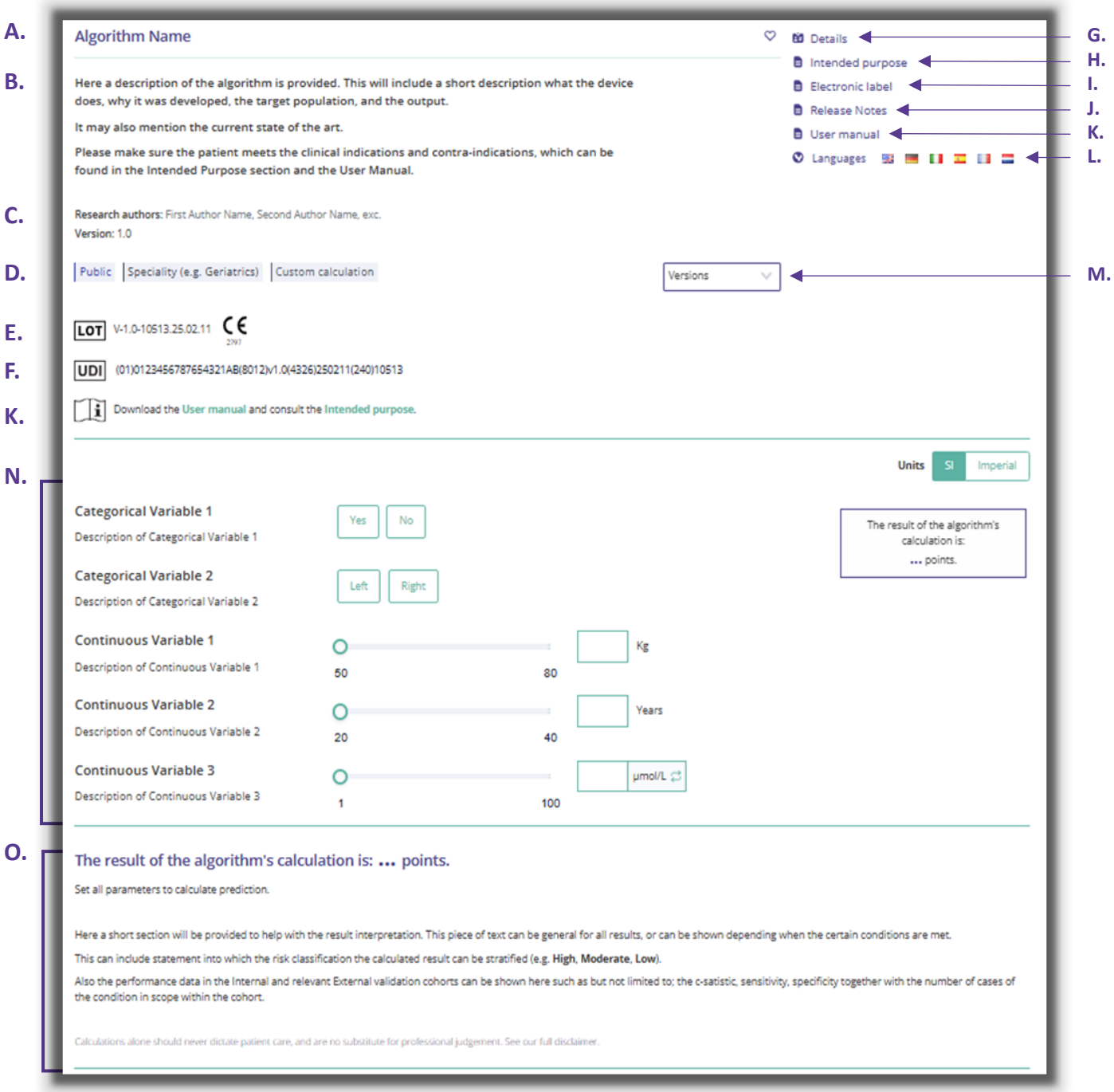

Figure 1. Example of an algorithm landing page on the Evidencio website.

A. Algorithm title

This is the title and name of the algorithm.

B. Algorithm description

This is a short description of the algorithm.

C. Research authors

These are the research authors of the paper that originally published the algorithm.

D. Algorithm tags

These are the tags that are assigned to the algorithm. Evidencio has the following status tags: “Draft”, “Public”, “Private”, “Under review”. Evidencio has the following algorithm type tags: “Composite algorithm”, “Sequential algorithm”, “API algorithm”. Evidencio has the following calculation method tags: “Linear regression”, “Logistic regression”, “Cox regression”, “RScript” and “Custom calculation”. Next to this, there are tags that indicate the specialty e.g. “Cardiology”.

E. LOT number

The LOT number indicated the algorithm version, the algorithm identifier, and the algorithm publication date. Publication date is indicated as YY.MM.DD.

Additionally, the CE mark is displayed next to the LOT number. This way, medical devices can be easily recognized.

F. UDI Number

For information on the UDI Number see **Section 5.2** on **page 6** of this user manual.

G. Details button

On the top right of the algorithm page, several clickable buttons are displayed that show a pop-up when clicked. The first button opens a pop-up concerning additional information about the algorithm. This pop-up has three sections: Details, Study characteristics and Supporting publications & related files.

Details

The first part of the additional information concerns the details of the algorithm as shown in **Figure 2**. This section may show the calculation if it is built as a mathematical formula and, if applicable, shows the conditions at which certain formulas are used.

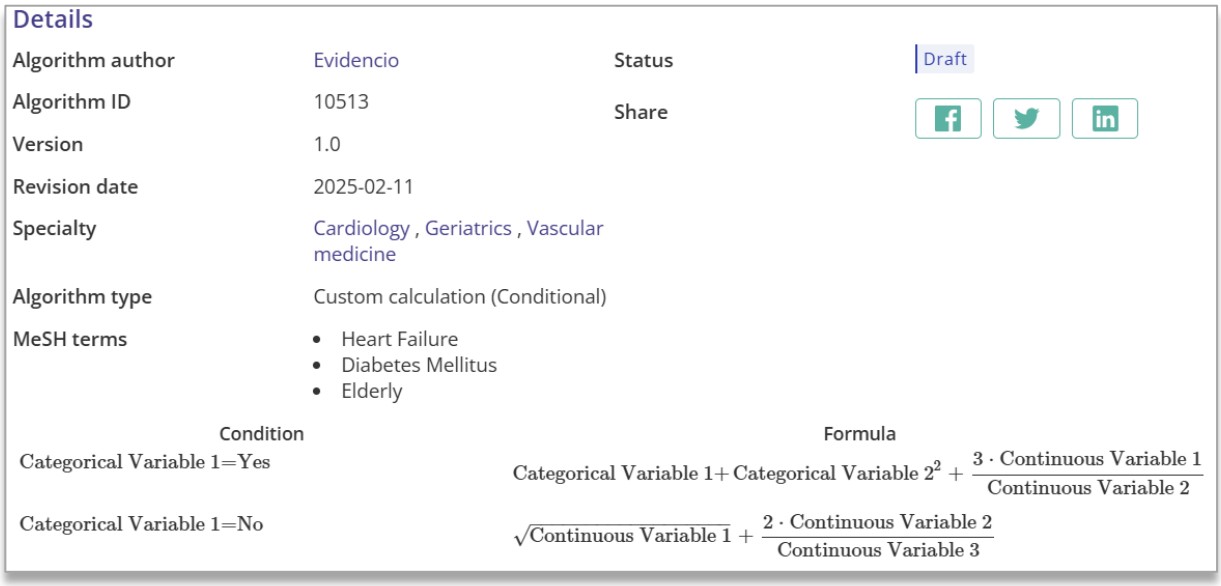

Figure 2. Example of first part of Details section.

Study Characteristics

Below the 'Details section' the section labelled "Study characteristics" provides information on the characteristics of the patient data used to derive and validate the algorithm. Additional information is provided on the methods used to develop and/or validate the algorithm. An example of the Study characteristics section can be seen in **Figure 3**.

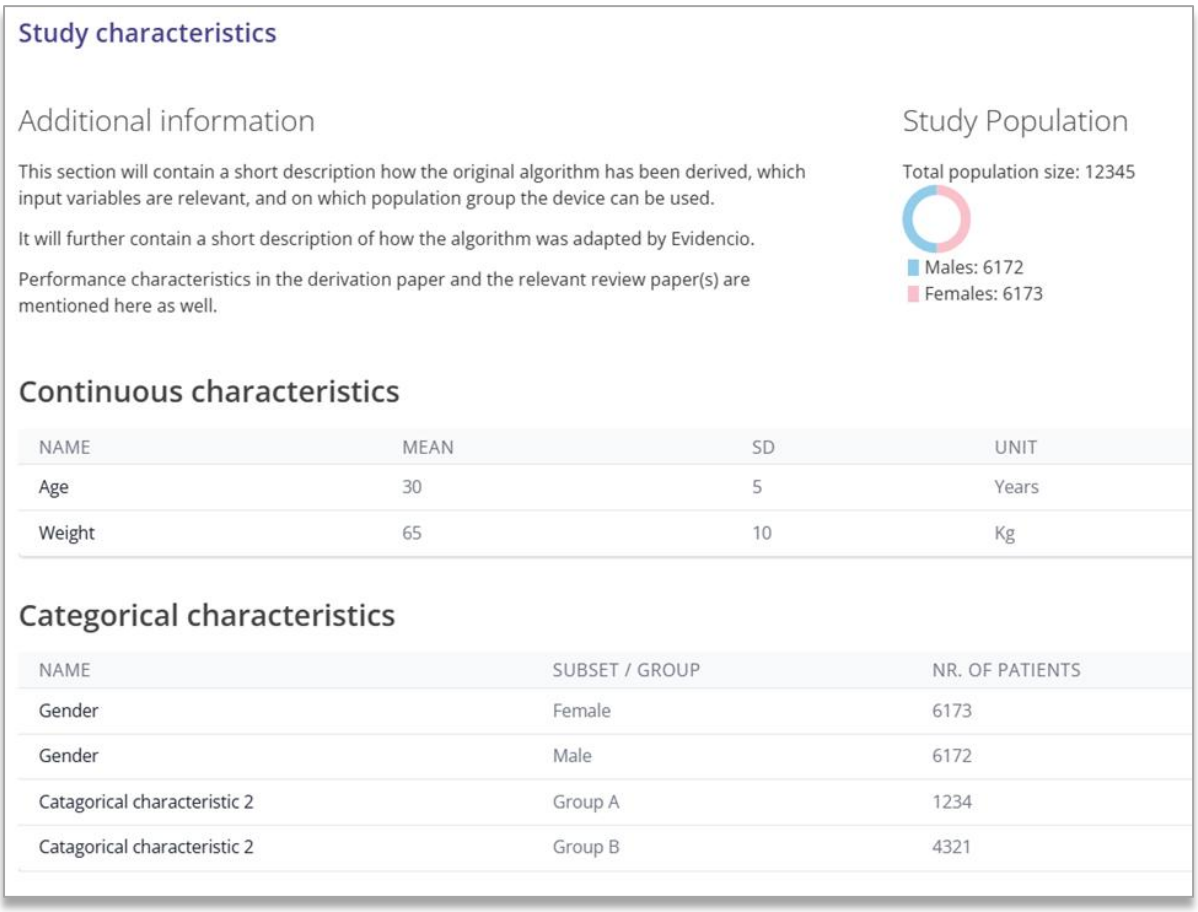

Figure 3. Example of the study characteristics section under the Details tab.

Supporting publications & Related files

An important part of the Study characteristics is the information on Supporting publications and related files. The list of related files and relevant tags can also be found in **Paragraph 7.6**. These sections can be found at the bottom of the Details-pop-up as shown in **Figure 4**.

Figure 4. Example of the Supporting publication & Related files section under the Details tab.

H. Intended purpose

Under this tab, the intended purpose can be found, containing a lot of information regarding the algorithm, its user, target population, clinical benefit, etc. This information is also provided in this manual and can be found in **Chapter 6** on **page 6**.

I. Electronic label

The electronic label button opens a pop-up with the location and address of Evidencio, the LOT number, the UDI number, the CE-mark, the medical device logo and a download link for the declaration of conformity of the medical device. The example of the electronic label is shown in **Figure 5**. The electronic label is unique for each algorithm comprising the Briganti Nomogram.

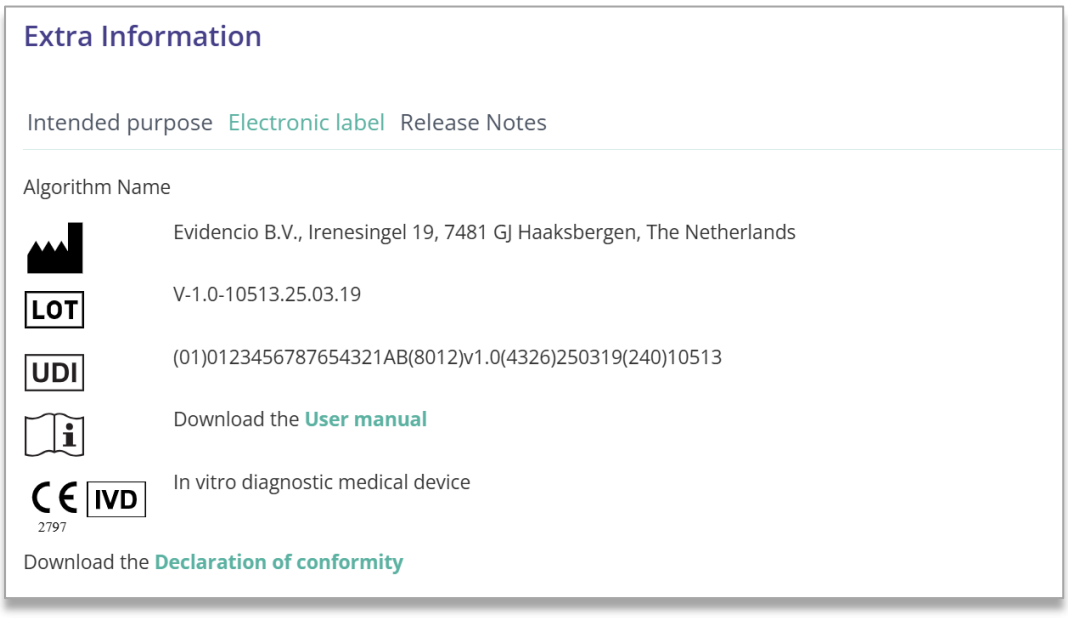

Figure 5. Example of an electronic label under the Electronic Label tab.

J. Release notes

Under this tab the most recent release notes can be found, noting the most significant changes between the versions of the algorithm found on the Evidencio website.

The 'Release Notes' button opens a pop-up with the latest release notes of the algorithm. Here you can find a list of the most significant changes over the different versions of the algorithm. Additionally, if there are any known residual anomalies the user should be aware of, they are listed here. It is recommended to read these notes after a version update to see if these changes are relevant to you.

K. User manual

This user manual can be found in three places: 1) under the short description of the algorithm on the Evidencio algorithm page, 2) on the right of the algorithm page, and 3) as a tab in the electronic label screen. Additionally, all versions of the user manual can be found in the general page for all user manuals for medical devices. The page can be found under the 'About' drop-down menu button as shown in **Figure 6**. The user manual page is shown in **Figure 7.** This version of the manual can be printed if required. If necessary, a paper version of the manual can be requested to be sent to you by mail. Evidencio's contact details are listed in **Chapter 11** of this user manual.

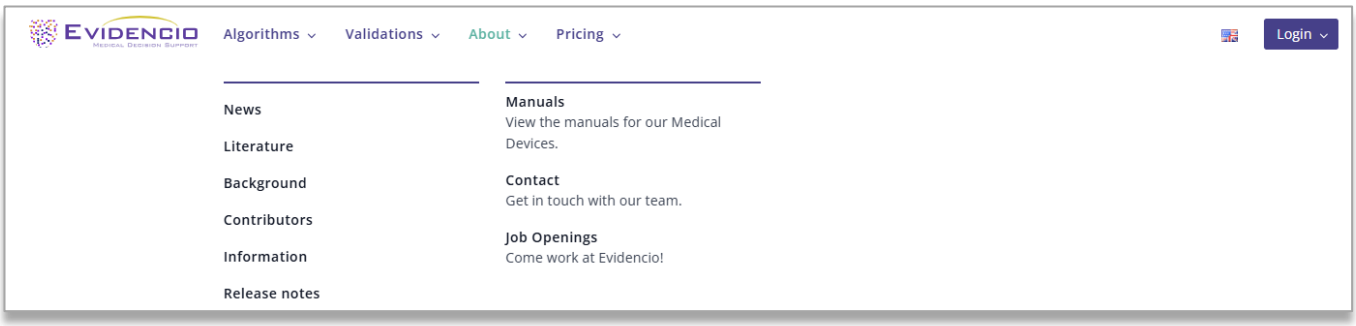

Figure 6. The drop-down menu where the user manual page can be found.

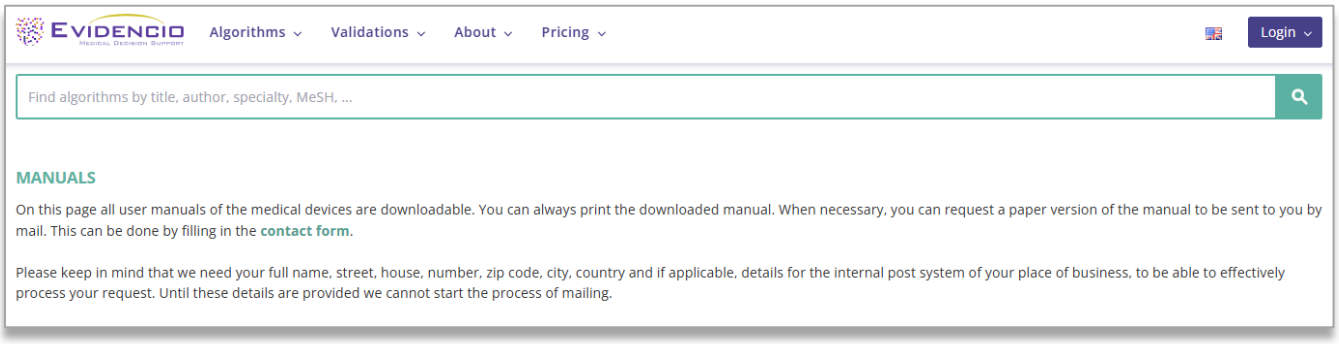

Figure 7. The user manual page for all user manuals.

L. Languages

Here an overview of languages in which the Briganti Nomogram is available is provided, any of which can be selected by clicking on the corresponding flag icon. The standard language on the Evidencio website is English.

Please note that, if a language is selected, only the user interface of the specific algorithm will be translated, other general features and information on the site might still be set to one of our primary languages English, German, and Dutch.

When you find mistranslations, irregularities, confusing or ambiguous use of language in English or any other language on the Evidencio website or in one of our manuals, please do not hesitate to contact us using the contact information provided at the end of this manual.

M. Algorithm & version selection

If available, clicking on the Version tab allows the user to select a different version of the Briganti Nomogram from a list as displayed in **Figure 8**. Please note that the algorithm currently selected is not presented in the dropdown menu.

Figure 8. Example of version selection tab.

N. Input section

The Evidencio platform allows two separate input variables; categorical variables and continuous variables.

Categorical variables

In the example shown in **Figure 9** and **Figure 10**, the example **Categorical Variable 1** concerns a categorical variable. The input that is wished to be used can be entered by clicking on either button. The selected button changes to green, as seen in **Figure 10**.

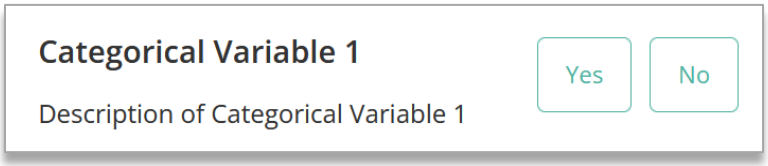

Figure 9. Example of a categorical variable, no button has been clicked and thus no input has been provided by the user.

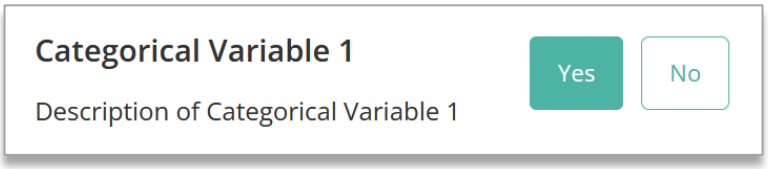

Figure 10. Example of a categorical variable, where the "Yes" button has been clicked.

Continuous variables

In the example shown in **Figure 11**, the **Continuous Variable 3**, exemplifies a continuous variable. The plausible ranges for which the algorithm is tested and deemed valid are used.

The details for a patient can be entered by sliding the button to the correct value, or by entering the correct value in the box on the right-hand side (i.e., where the 10.2 mg/dL is entered for the **Continuous Variable 3**).

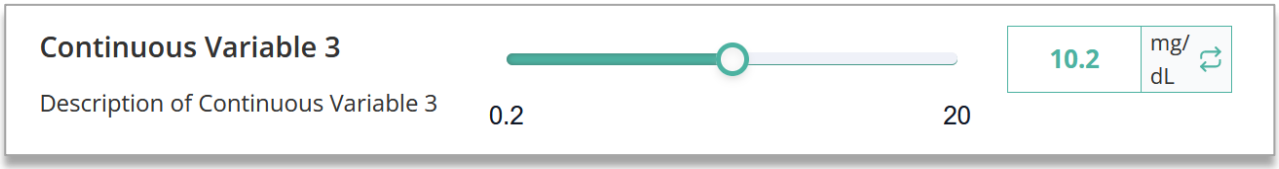

Figure 11. Example of a continuous variable, where "10.2 mg/dL" has been entered.

Unit conversion

Sometimes it is possible to use a unit conversion, by clicking on the unit when the green arrows are present. See **Figure 12** below where the unit has been clicked and switched.

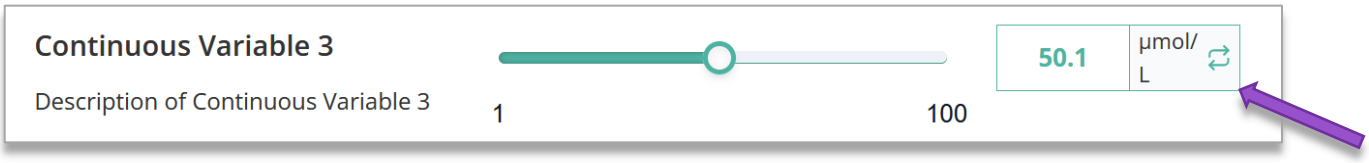

Figure 12. Example of a continuous variable where "50.1 $\mu mol/L$" has been entered.

Details on variable measurements

Directly underneath the name for each variable, additional details can be provided on, for example, the methods required to enter the correct value for each variable. Details may include but are not limited to; more detailed explanation of the variable, the ranges of the variables (for healthy individuals), or a description when a continuous variable should be true or false (cut-off values).

O. Result section

At the bottom of the algorithm landing page, the results of the algorithm are shown.

Calculations alone should never dictate patient care, and are no substitute for professional judgement. See our full disclaimer on: https://www.evidencio.com/disclaimer.

Result calculation

When all variables are filled in, and the user presses calculate, a result can be calculated. No result is displayed until all variables are filled in and the result section will indicate; *"Set all parameters to calculate prediction."*.

Result interpretation

In the result interpretation, a stratification may be provided based on the calculated results. Additional information about this stratification and the classification as found in the derivation and important validation cohorts may also be provided. An example of the information is shown in **Figure 13**.

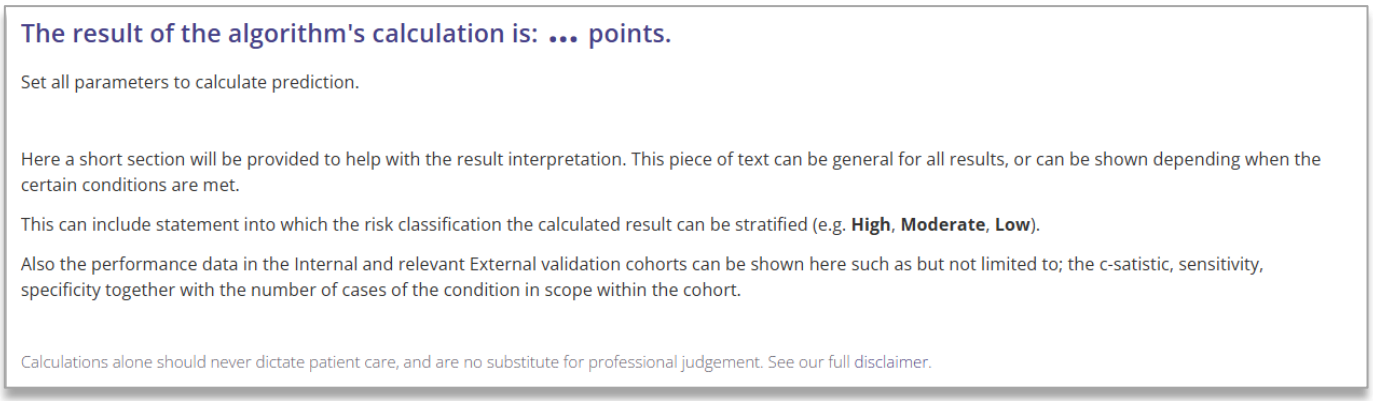

Figure 13. Example of the result display and information section.

9. Implementation of the algorithm through an API

The Briganti Nomogram can be used through Evidencio's API to allow for (automated) calculation of the risk of Lymph Node Involvement. In the case of use of the MDSW through the API, the user should take into account the different inputs for the algorithm, in order to properly interpret the results.

The information provided over the API is the same as the information that is displayed in the graphical user interface on the web application provided by Evidencio. In **Box 1** below, an example of a result from the Briganti Nomogram over the API is shown. The result concerns a JSON formatted text. The API for the Briganti Nomogram leverages the generic API that is provided for the Evidencio platform and therefore contains information that may be applicable for different software algorithms and devices. This means that not all of the details provided over the API may be relevant for the Briganti Nomogram.


```
{
  "CIPercentage": 0,
  "id": 1555,
  "author": "T. A. Hueting",
  "title": "Briganti 2012 Nomogram",
  "variables": {
    "9207106786": 22.7,
    "6022736103": 0.590006422,
    "8293843542": 1.295822458,
    "9210671788": 0.371563556,
    "9908333912": 40.9
  },
  "min": 24.1,
  "max": 24.1,
  "additionalResultSet": [],
  "mintxt": "24.1%",
  "maxtxt": "24.1%",
  "LCItxt": "No CI Info",
  "HCItxt": "No CI Info",
  "result": "24.1%",
  "resultText": "The calculated probability of Lymph Node Involvement is:",
  "postresultText": "",
  "formulaSegments": [],
  "conditionalResultArray": [],
  "conditionalResultText": "",
  "UDI": "(01)08720938015205(8012)v2.0(4326)260403(240)1555",
  "medicalDevice": "This is an in vitro diagnostic medical device. The electronic label is available at: https://www.evidencio.com/models/show/1555?v=2.0",
  "userManual": "Always refer to the user manual for correct use of the in vitro diagnostic medical device. The user manual can be found at: https://www.evidencio.com/manuals"
}
```


Box 1: Example of an API output for the Briganti Nomogram.

Table 12 shows a match between the separately listed items in the API output with the items listed on the graphical user interface on the Evidencio website (elaborated in **Chapter 8**).

Table 12. API and GUI items for the Briganti Nomogram.

API Item	GUI item	Comment
CIPercentage	N/A	Not applicable for the Briganti Nomogram as this feature is not used for the Briganti Nomogram.
id	Algorithm ID under 'details' ID used in the URL (www.evidencio.com/models/show/1555)	The ID is the Evidencio specific identification number of the algorithm.
author	Algorithm author under 'details'	Name of the Evidencio user who created the algorithm on the Evidencio platform.
title	Title of the algorithm (part A of figure 1).	-
variables	Input variables and their entered value. (part N. of figure 1)	The API displays the variables as unique IDs.
min	N/A	Depicts the lowest value when the result of the algorithm is a range. Since the Briganti Nomogram always displays a single value as a result, this value is the same as the 'result'.
max	N/A	Depicts the highest value when the result of the algorithm is a range. Since the Briganti Nomogram always displays a single value as a result, this value is the same as the 'result'.
additionalResultSet	N/A	N/A
mintxt	N/A	Same as 'min', but as a string.
maxtxt	N/A	Same as 'max', but as a string.
LCItxt	N/A	Not applicable for the Briganti Nomogram as this feature is not used for the Briganti Nomogram.
HCItxt	N/A	Not applicable for the Briganti Nomogram as this feature is not used for the Briganti Nomogram.
result	The main result of the algorithm, the Briganti Nomogram score.	-
resultText	The text displayed in front of the main result	e.g. "The calculated probability of Lymph Node Involvement is:"
postresultText	The text displayed behind the main result	-
formulaSegments	N/A	-
conditionalResultArray	N/A	-
conditionalResultText	N/A	-
UDI	Same as the UDI displayed in the GUI (section F. in figure 1).	-
medicalDevice	The electronic label (section I. in figure 1).	The API refers to the electronic label on the graphical user interface.
userManual	The user manual (section K. in figure 1).	The API refers to the location of the user manual at the user interface & Evidencio website).

Instructions on how to implement the API within a system are included in a separate document that is made available to the party performing the technical implementation. The party performing the integration of the Briganti Nomogram using the API should adhere to the requirements outlined in **1555-DOC-45 Instructions for API integration Briganti Nomogram.**

10. User manual revision history

Version	Revision notes
V1.0 APR-2026	Original version

11. Manufacturer details

Contact details of Evidencio:

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