

AVIATOR USER GUIDE

Aviator database is available at :

<https://hvs.tentelemed.com/Ctms-hvs/portal/login>



The screenshot shows the authentication page for CleanWEB. The header includes the CleanWEB logo and the tagline "The trusted information system for online clinical trials management" with flags for the UK and France. The main heading is "Authentification" with a lock icon. Below this, there is a message in French: "Pour accéder au site vous devez vous identifier. Vos codes d'accès personnels vous ont été envoyés lors de la création de votre compte. En cas d'oubli de codes d'accès, veuillez cliquer sur le lien 'Avez-vous oublié vos identifiants'." There are two input fields: "Identifiant" and "Mot de Passe". A blue "Connexion" button is positioned below the password field. At the bottom, there is a link "Avez-vous oublié vos identifiants ?" with a key icon.

Copyright © 2015 - Telemedicine Technologies S.A.S.

Enter your login and password
sended by

clinicaltrials@tentelemed.com

You arrive on your patient list

CleanWEB™

User : Stéphanie LEJEUNE - CRA Nurse Last Connection: 10/11/2015 13:04:45 Disconnect

Patients New Patient Queries Extraction Planning

Dashboard : AVIATOR New Edit Delete Requests : Bicuspid valve New Edit Delete

10 Patients found Export

Aortic valve	CTD	Moment	AV regurgitation	Moment	AV regurgitation	Moment
Bicuspid	FBN1 (Marfan syndrome)	Pre-operative	4 (severe)	Intra-operative pre-repair	4 (severe)	Intra-operative post-rep.
Bicuspid		Pre-operative	4 (severe)	Intra-operative pre-repair	4 (severe)	Intra-operative post-rep.
Bicuspid		Pre-operative	4 (severe)	Intra-operative pre-repair	4 (severe)	Intra-operative post-rep.
Bicuspid		Pre-operative	4 (severe)	Intra-operative pre-repair	4 (severe)	Intra-operative post-rep.
Bicuspid		Intra-operative post-repair	0 (none or trivial)			
Bicuspid		Intra-operative post-repair	0 (none or trivial)			
Bicuspid						
Bicuspid		Pre-operative	4 (severe)	Intra-operative pre-repair	4 (severe)	Intra-operative post-rep.
Bicuspid		Pre-operative	4 (severe)	Intra-operative pre-repair	4 (severe)	Intra-operative post-rep.
Bicuspid	Marfan syndrom without identified gene	Pre-operative				

Information
Contacts
eCRF
Directory
Charts
Configuration
Support

How to enter a new patient

CleanWEB™

User : Stéphanie LEJEUNE - CRA Nurse Last Connection: 12/11/2015 14:55:39 Disconnect

Patients **New Patient** Queries Duplicates Extraction Planning Export

Investigators in AVIATOR

Centre	Lastname :	Firstname :
001 - IMM	Lansac	Emmanuel
001 - IMM	LENZOTTI	Anne-Marine

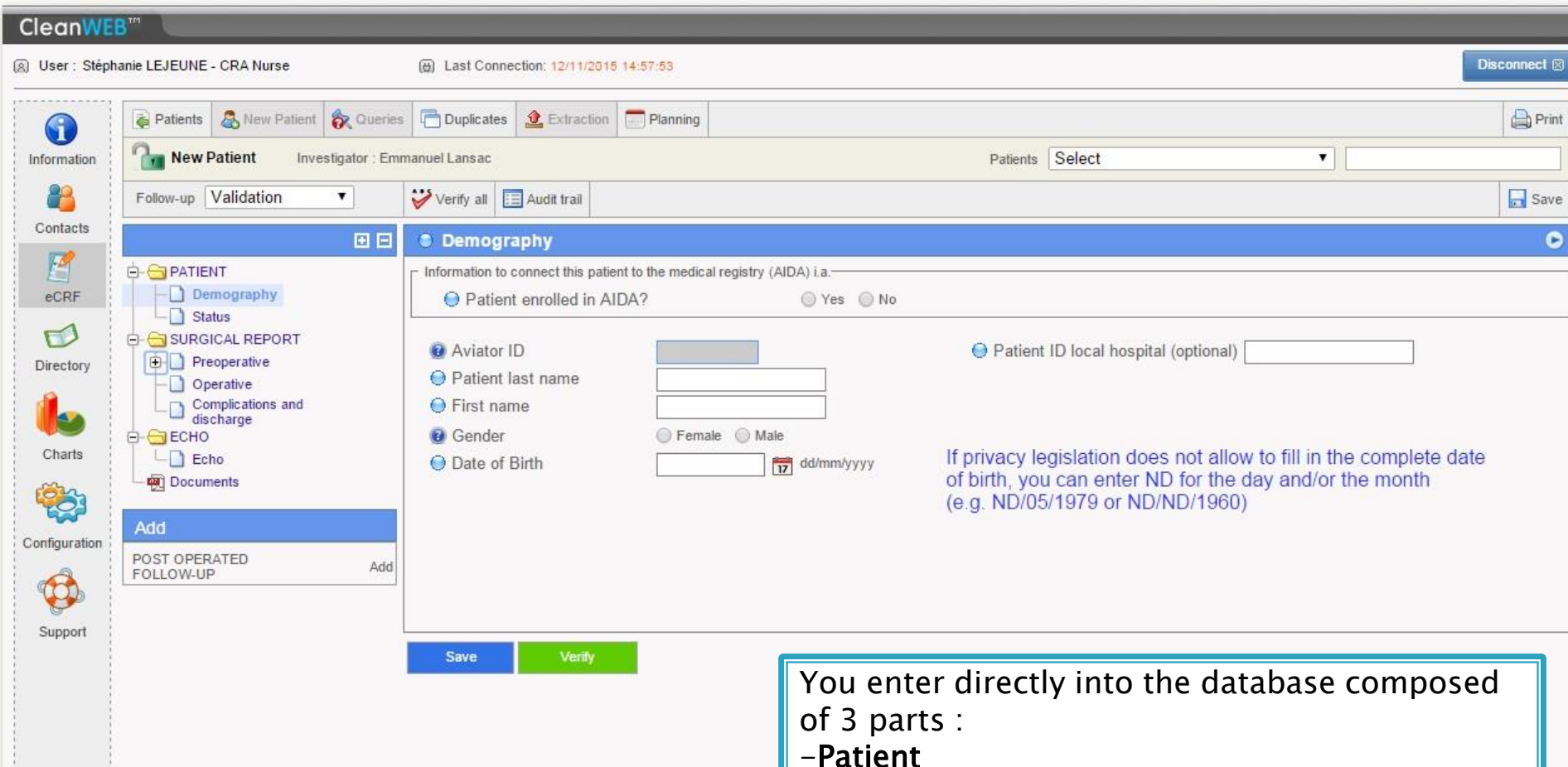
Selected investigator :

Select Cancel


Investigator	Centre
LENZOTTI	001
LANSAC	001
LANSAC	001
LENZOTTI	001
LENZOTTI	001
LENZOTTI	001
LENZOTTI	001
LENZOTTI	001
LENZOTTI	001
LENZOTTI	001
LANSAC	001
LENZOTTI	001
LENZOTTI	001
LENZOTTI	001

Click on « new patient » and select your name.

AVIATOR USER GUIDE



The screenshot displays the AVIATOR web application interface. At the top, the 'CleanWEB™' logo is visible on the left, and the user information 'User : Stéphanie LEJEUNE - CRA Nurse' and 'Last Connection: 12/11/2015 14:57:53' is shown. A 'Disconnect' button is located in the top right corner. The main navigation bar includes 'Patients', 'New Patient', 'Queries', 'Duplicates', 'Extraction', and 'Planning'. The 'New Patient' section is active, showing 'Investigator : Emmanuel Lansac' and a 'Patients' dropdown menu set to 'Select'. Below this, there are options for 'Follow-up' (set to 'Validation'), 'Verify all', and 'Audit trail'. The left sidebar contains icons for 'Information', 'Contacts', 'eCRF', 'Directory', 'Charts', 'Configuration', and 'Support'. The main content area is titled 'Demography' and contains the following fields and options:

- Information to connect this patient to the medical registry (AIDA) i.a.:
- Patient enrolled in AIDA? Yes No
- Aviator ID:
- Patient ID local hospital (optional):
- Patient last name:
- First name:
- Gender: Female Male
- Date of Birth:  dd/mm/yyyy

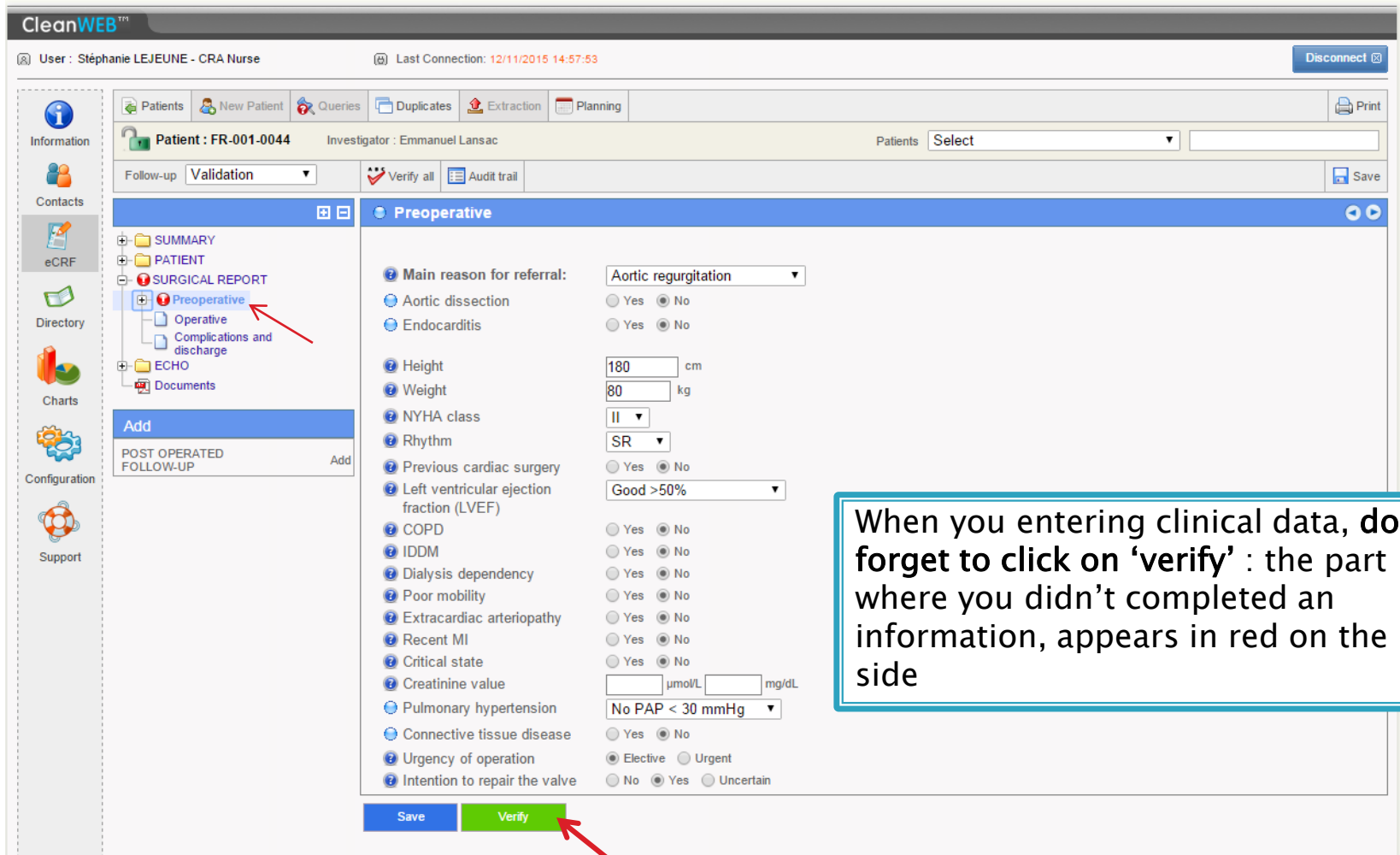
A note states: 'If privacy legislation does not allow to fill in the complete date of birth, you can enter ND for the day and/or the month (e.g. ND/05/1979 or ND/ND/1960)'. At the bottom of the form, there are 'Save' and 'Verify' buttons. Below the form, there is an 'Add' section with a table:

Add	
POST OPERATED FOLLOW-UP	Add

You enter directly into the database composed of 3 parts :

- Patient
- Surgical report : preoperative, operative and discharge
- Echo : All the echos (preop, post op and follow up) are shown as a table in this section.

AVIATOR USER GUIDE



CleanWEB™

User : Stéphanie LEJEUNE - CRA Nurse Last Connection: 12/11/2015 14:57:53 Disconnect

Patients New Patient Queries Duplicates Extraction Planning Print

Patient : FR-001-0044 Investigator : Emmanuel Lansac Patients: Select

Follow-up: Validation Verify all Audit trail Save

Preoperative

- SUMMARY
- PATIENT
- SURGICAL REPORT
 - Preoperative** (highlighted with red arrow)
 - Operative
 - Complications and discharge
- ECHO
- Documents

Add

POST OPERATED FOLLOW-UP Add

Main reason for referral: Aortic regurgitation

Aortic dissection Yes No

Endocarditis Yes No

Height 180 cm

Weight 80 kg

NYHA class II

Rhythm SR

Previous cardiac surgery Yes No

Left ventricular ejection fraction (LVEF) Good >50%

COPD Yes No

IDDM Yes No

Dialysis dependency Yes No

Poor mobility Yes No

Extracardiac arteriopathy Yes No

Recent MI Yes No

Critical state Yes No

Creatinine value μmol/L mg/dL

Pulmonary hypertension No PAP < 30 mmHg

Connective tissue disease Yes No

Urgency of operation Elective Urgent

Intention to repair the valve No Yes Uncertain

Save Verify (highlighted with red arrow)

When you entering clinical data, don't forget to click on 'verify' : the part where you didn't completed an information, appears in red on the left side

Don't forget also to click on 'save' before going to a new part

AVIATOR USER GUIDE

CleanWEB™

User : Stéphanie LEJEUNE - CRA Nurse Last Connection: 12/11/2015 14:57:53 Disconnect

Patients New Patient Queries Duplicates Extraction Planning Print

Patient : FR-001-0044 Investigator : Emmanuel Lansac Patients: Select

Follow-up: Validation Verify all Audit trail Save

Follow-up

Status at Follow-up Death Alive

Follow-up date: dd/mm/yyyy

NYHA:

Rhythm:

Antiplatelets Yes No

Oral anticoagulants Yes No

AV related reintervention Yes No

Other cardiac reoperation Yes No

Aortic complication Yes No

AV endocarditis non operated Yes No

AV thrombosis non operated Yes No

Vascular thromboembolic event:

Major bleeding Yes No

PM implantation Yes No

Other complication Yes No

Save Verify

Information

Contacts

eCRF

Directory

Charts

Configuration

Support

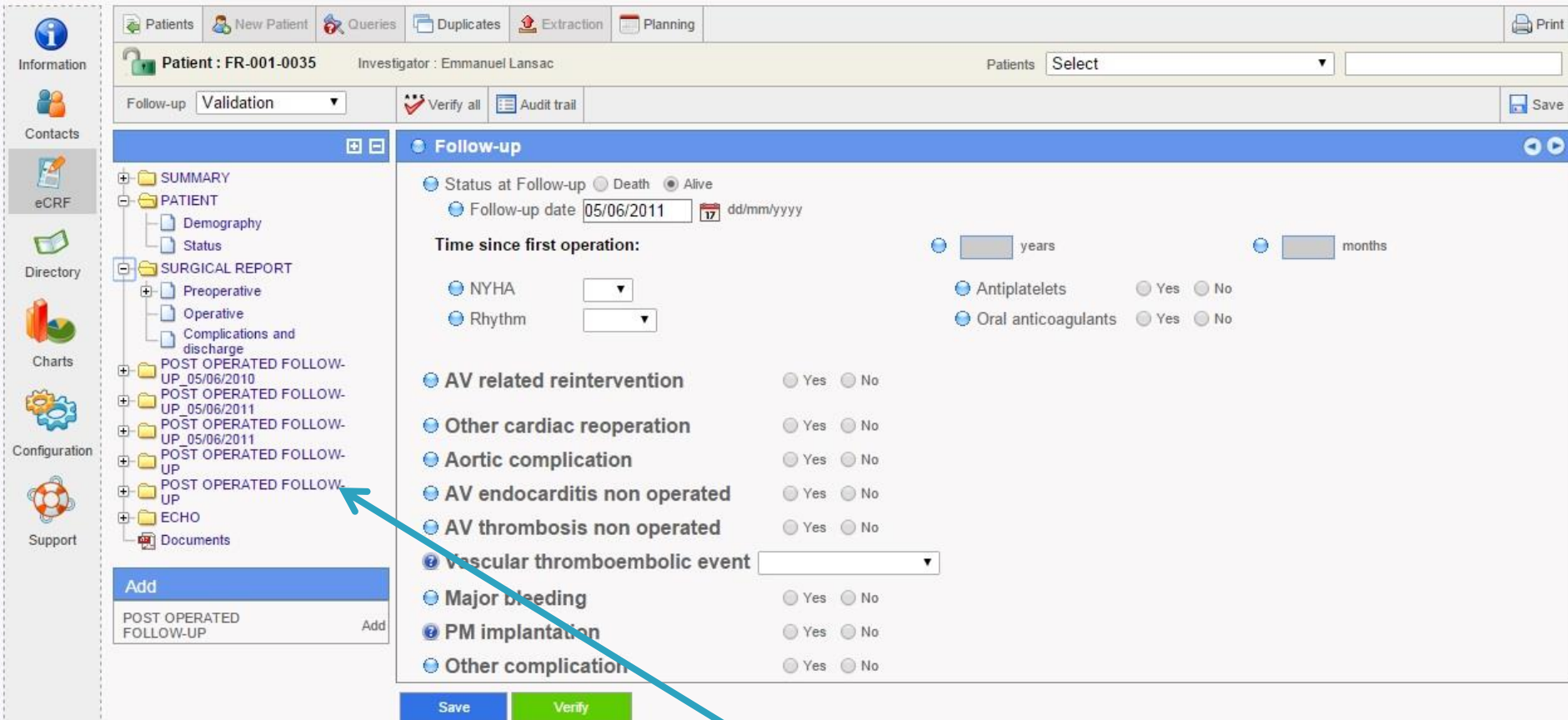
- SUMMARY
- PATIENT
- SURGICAL REPORT
- POST OPERATED FOLLOW-UP
 - Follow-up
 - Health survey
- ECHO
- Documents

Add

POST OPERATED FOLLOW-UP Add

If you want to add a new follow up, you need to click on 'Add' icon

AVIATOR USER GUIDE

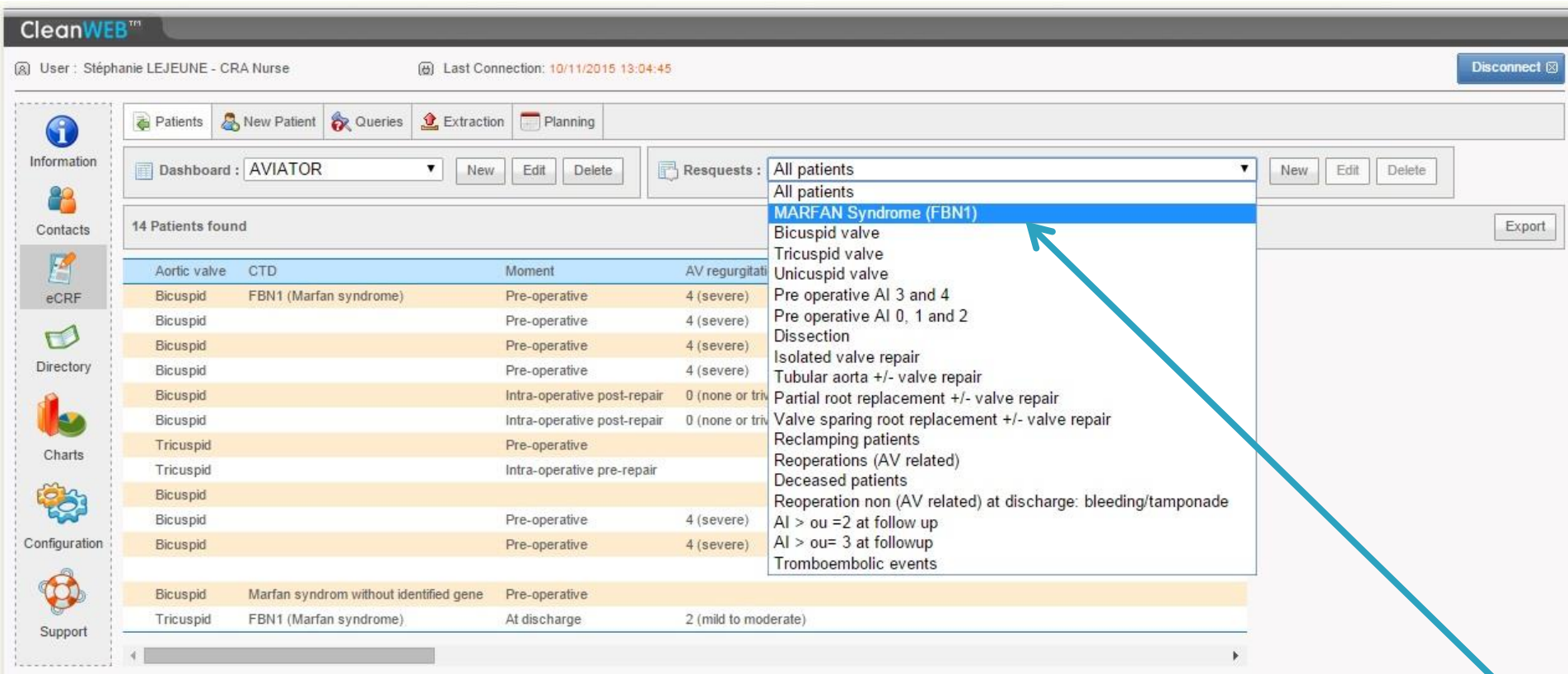


The screenshot displays the AVIATOR software interface. At the top, there is a navigation bar with icons for Patients, New Patient, Queries, Duplicates, Extraction, and Planning. Below this, the patient information is shown: Patient: FR-001-0035, Investigator: Emmanuel Lansac. The main area is divided into a left sidebar and a main content area. The sidebar contains a tree view with folders for SUMMARY, PATIENT (Demography, Status), SURGICAL REPORT (Preoperative, Operative, Complications and discharge), and several POST OPERATED FOLLOW-UP entries with dates. A blue arrow points from a text box to the 'POST OPERATED FOLLOW-UP' folder in the sidebar. The main content area is titled 'Follow-up' and contains various form fields and radio buttons for tracking patient status, time since operation, and specific complications. At the bottom of the main area, there are 'Save' and 'Verify' buttons.

You can add as many follow up you want. The date of each follow appears on the left side.

AVIATOR USER GUIDE

From your home page, you can filter your patients by criteria :



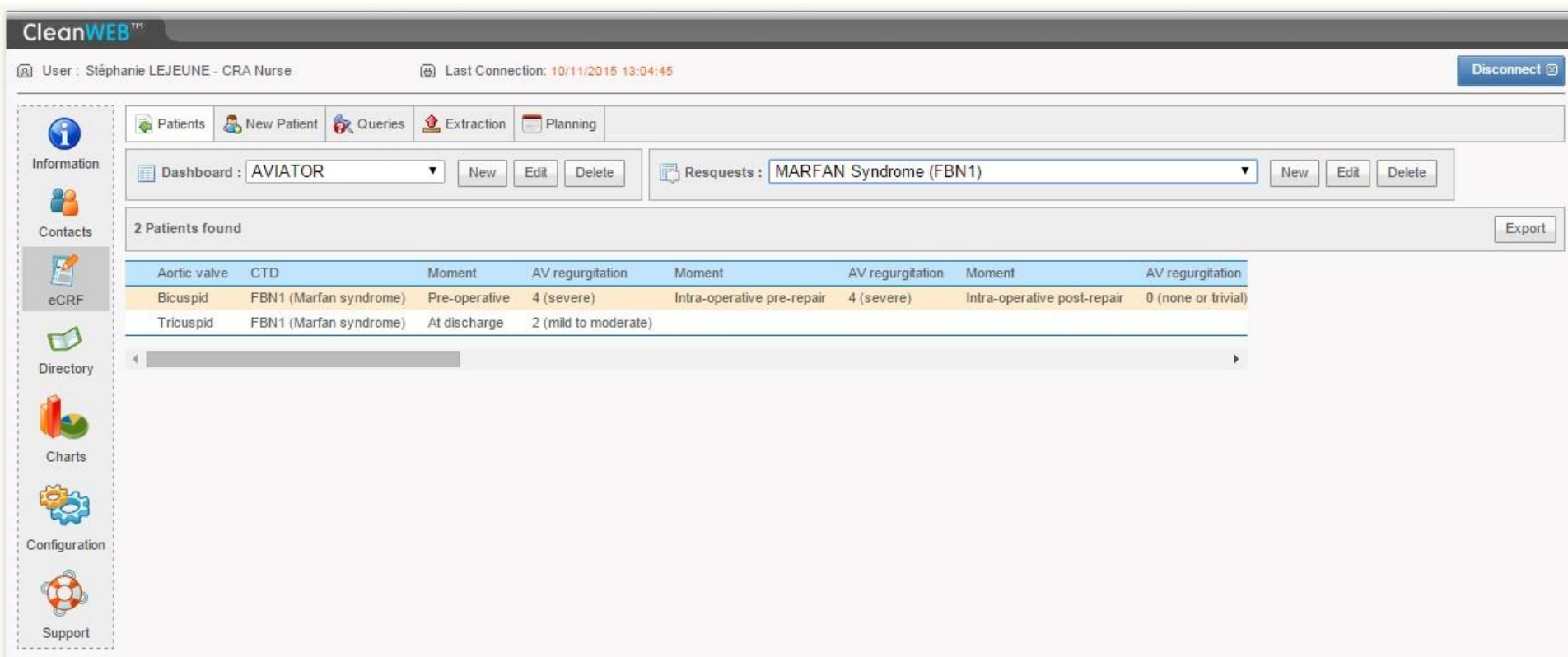
The screenshot shows the CleanWEB™ AVIATOR interface. At the top, the user is identified as Stéphanie LEJEUNE - CRA Nurse, with a last connection time of 10/11/2015 13:04:45. The main navigation bar includes buttons for Patients, New Patient, Queries, Extraction, and Planning. Below this, the dashboard is set to AVIATOR, and there are buttons for New, Edit, and Delete. A dropdown menu for 'Requests' is open, showing a list of predefined criteria. A blue arrow points to the 'MARFAN Syndrome (FBN1)' option in the dropdown. The main content area displays a table of 14 patients found, with columns for Aortic valve, CTD, Moment, and AV regurgitation. The table lists various patient records, including those with Bicuspid, Tricuspid, and Marfan syndrome.

Aortic valve	CTD	Moment	AV regurgitation
Bicuspid	FBN1 (Marfan syndrome)	Pre-operative	4 (severe)
Bicuspid		Pre-operative	4 (severe)
Bicuspid		Pre-operative	4 (severe)
Bicuspid		Pre-operative	4 (severe)
Bicuspid		Intra-operative post-repair	0 (none or tri)
Bicuspid		Intra-operative post-repair	0 (none or tri)
Tricuspid		Pre-operative	
Tricuspid		Intra-operative pre-repair	
Bicuspid			
Bicuspid		Pre-operative	4 (severe)
Bicuspid		Pre-operative	4 (severe)
Bicuspid	Marfan syndrom without identified gene	Pre-operative	
Tricuspid	FBN1 (Marfan syndrome)	At discharge	2 (mild to moderate)

A predefined list is created and you just have to select the criteria you want, for example Patients with Marfan Syndrome

AVIATOR USER GUIDE

From your home page, you can filter your patients by criteria :



The screenshot shows the CleanWEB AVIATOR interface. At the top, the user is identified as Stéphanie LEJEUNE - CRA Nurse, with a last connection time of 10/11/2015 13:04:45. The interface includes a navigation menu on the left with options like Information, Contacts, eCRF, Directory, Charts, Configuration, and Support. The main content area features a search bar with 'AVIATOR' selected in the dashboard dropdown and 'MARFAN Syndrome (FBN1)' selected in the requests dropdown. Below the search bar, it indicates '2 Patients found' and provides an 'Export' button. A table displays the search results:

Aortic valve	CTD	Moment	AV regurgitation	Moment	AV regurgitation	Moment	AV regurgitation
Bicuspid	FBN1 (Marfan syndrome)	Pre-operative	4 (severe)	Intra-operative pre-repair	4 (severe)	Intra-operative post-repair	0 (none or trivial)
Tricuspid	FBN1 (Marfan syndrome)	At discharge	2 (mild to moderate)				

You get a table with Marfan Syndrome only

AVIATOR USER GUIDE

From your home page, you can filter your patients by criteria :

The screenshot shows the CleanWEB AVIATOR interface. At the top, the user is identified as 'Stéphanie LEJEUNE - CRA Nurse' with a last connection time of '10/11/2015 13:04:45'. The main navigation bar includes 'Patients', 'New Patient', 'Queries', 'Extraction', and 'Planning'. Below this, there are search filters: 'Dashboard : AVIATOR' and 'Requests : MARFAN Syndrome (FBN1)'. The results section shows '2 Patients found' and a table with the following data:

Aortic valve	CTD	Moment	AV regurgitation	Moment	AV regurgitation	Moment	AV regurgitation
Bicuspid	FBN1 (Marfan syndrome)	Pre-operative	4 (severe)	Intra-operative pre-repair	4 (severe)	Intra-operative post-repair	0 (none or trivial)
Tricuspid	FBN1 (Marfan syndrome)	At discharge	2 (mild to moderate)				

Or you get a table with patients with bicuspid valve...