NMO	OIML Certification System
OIML Member State United Kingdom of Great Britain and Northern Ireland	**OIML Certificate No.** **R76/2006-A-GB1-19.13** **Revision 1**

OIML CERTIFICATE ISSUED UNDER SCHEME A

OIML Issuing Authority	**NMO** **Stanton Avenue** **Teddington** **TW11 0JZ** **United Kingdom**
Person responsible:	**Mannie Panesar – Head of NMO**
Applicant	**Umano Medical Inc** **230 boulevard Nilus Leclerc** **L'Islet, QC G0R2C0** **Canada**
Manufacturer	**The applicant**
Identification of the certified type	**FL36-SC series and 200-0000 series** *(the detailed characteristics are defined in the Descriptive Annex)*

This OIML Certificate attests the conformity of the above identified type (represented by the sample(s) identified in the OIML type evaluation report) with the requirements of the following Recommendation of the International Organization of Legal Metrology (OIML):

OIML R 76-1, Edition: 2006

For accuracy class: III

Issue date: 18 August 2021

The OIML Issuing Authority

Grégory Glas
Lead Technical Manager
For and on behalf of the Head of NMO

This OIML Certificate relates only to metrological and technical characteristics of the type of measuring instrument covered by the relevant OIML Recommendation identified above.

This OIML Certificate does not bestow any form of legal international approval.

The conformity was established by the results of tests and examinations provided in the associated OIML type evaluation report:

No. P02444 revision 1 dated 18 August 2021 that includes 16 pages

The technical documentation relating to the identified type is contained in documentation file:

No. P02444-D dated 28 October 2019 and P02856-D dated 18 August 2021

OIML Certificate History

Revision No.	**Date**	**Description of the modification**
Revision 0	28 October 2019	Certificate first issued.
Revision 1	18 August 2021	Addition of Alternatives 1 and 2.

This revision replaces previous versions of the cretificate.

Important note:
Apart from the mention of the Certificate's reference number and the name of the OIML Member State in which the Certificate is issued, partial quotation of the Certificate and of the associated OIML type evaluation report(s) is not permitted, although either may be reproduced in full.

DESCRIPTIVE ANNEX

Characteristics of the instrument:

The Umano Medical bed FL36-SC series (Brand names OOK<Snow>, OOK<Snow>MH and OOK<Cocoon>) and 200-0000 series (Brand name Ook Snow ALL) are hospital beds incorporating a Class III, mains operated, self-indicating, Non-automatic Weighing Instrument. The height and surface contours of the bed are adjustable. The bed includes movable and latchable siderails, and control boards.

The hospital bed shall not be used for direct sales to the public.

Main features:

- Hospital bed, with weighing control and display functions on the footboard.
- TFT-LCD touch screen display.
- Angle indicators on two sideboards.
- Four load cells installed at the four corner positions of the bed base.
- Safety sides incorporating attendant controls, height control and surface contours control buttons.

Devices:

- Combined semi-automatic zero setting device and semi-automatic tare balancing device.
- "NET" displayed when tare is in operation below the weight value.
- Gravity compensation via an accelerometer sensor on the main board.

Load cell:

The four load cells are each a Vishay Tedea Huntleigh shear beam load cell
FL36-SC: model #PB-150, E_{max} = 150 kg.
200-0000: model #PB-250, E_{max} = 250 kg.

Operation

- Switch-on:

At switch-on, the display screen shows the status of the bed to ensure that the bed has no defect. Any error code would trigger a "!" warning and associated features would be disabled.

- Weigh function:

Weigh function operates to display and log patient weight. Weight is displayed for 1 minute before the display goes to sleeping mode.

The unstable / real time readings are showed with a round motion dots around them. Stable weights are displayed in larger fonts.

- Combined semi-automatic zero setting and tare function:

The bed can be zeroed provided that it is within ±2% of the maximum capacity around the calibrated zero.

When the weight is over 2% of the maximum capacity, the tare setting device operates and “NET” is displayed below the weight indication.

The system can display a log history of the different tare values, via the “Tare history” button, that were applied for reference to the medical staff.

- Under weight and over weight:

"Overload" is displayed instead of the weight indication if the weight is more than 277 kg for the FL36-SC, and 509 kg for the 200-0000.

"->0<-" and “0 kg” are displayed instead of the weight indication if the weight is within 0.25 e of Gross zero.

Negative weight less than -0.25e results an error message and the weighing function is prohibited.

“Underload” is displayed instead of the weight indication if the weight is between 0.25 e and Minimum capacity.

- “View log” function:

This function is used to show the latest 20 stabilised weights that were displayed after the button “weight” has been pressed. Values are stored in the bed’s EEPROM memory.

- “Tare history” function:

This function is to show the previous values of zero/tare but not allow to apply the previous values.

- “Change equipment” function

As it may be necessary to add or remove medical equipment to or from the weighing part of the bed, this function allows additional tare values to be weighed without affecting the net weight displayed. To cancel an existing Tare, the bed must be unloaded to zero and a zero must be performed.

- Scale system errors:

In case of error detected the text "ERR" is displayed instead of weight. (defective sensor, etc).
In case of the unstable weight, the error message of “weight unstable” is displayed.

The load cells are mounted on rod-ends bearing; the weighing platform may tilt with a maximum allowance of 0.5 degrees. In case the bed is on unlevel flooring more than 0.5 degrees, the text "Err- Bed in slope" is displayed instead of weight.

Each error is logged and available for review in the maintenance menu. The maintenance menu is password protected.

Technical data:

The instrument operates on a 230 VAC 50/60 Hz supply with an optional battery back-up not for any weighing function but the bed actuators only.

The operating temperature range for the instruments is +10 °C / +40 °C.

	FL36-SC	200-0000
OIML R76-1 Accuracy class	III	III
Maximum capacity, Max	272.5 kg	500 kg
Minimum capacity, Min	10 kg	20 kg
Verification scale interval, e =	0.5 kg	1 kg
Number of intervals n	545	500
Maximum tare, T	-Max	-Max

Software:

The software is installed as compiled code, as an executable file, and as such cannot be modified using common software tools Access to the legally relevant parameters and download of the software is protected by a password, a non-editable log ("calibration counter") provides evidence of intervention.

The calibration counter (calibration date) is in the format of MMM DDD YYYY HH:MM, for example Feb 7th 2019 11:25, and can be displayed via:

Main Menu → Preference → Maintenance → (Input Password "247") → Load Cell Values → Calibration values.

The software identification can be displayed by selecting Preferences / Maintenance / Software Versions.

The legally relevant part of the software shall be as follows:

	Scale Software	Display Software
FL36-SC	36-3400	36-3411
200-0000	36-3401	36-3411

Sealing:

Access to the Load cell cable and analogue to digital converting PCB are sealed by tamper evident sealing Labels.

The value of the calibration counter specified in Section 3.2 shall be written on the rating plate.

Alternatives:

Alternative 1:

Having a modified software as follows:

	Scale Software	Display Software
FL36-SC	36-3517	36-3503
200-0000	36-3518	36-3503

Alternative 2:

The instrument may have the following interface types:

- Ethernet
- USB

- Patient call
- WiFi