

# Addendum 1

For the following user guide v3.1:

- Bulk loader module for centrifuge units **cobas p 471** (43x / 66x)
- Bulk loader module for centrifuge units **cobas p 671** (67x) (also connected to BCM for cobas 8100)

## Name plate and safety label information

## Publication information

Publication version	Revision date	Change description
1.0	June 2020	New document

## Revisions

This addendum contains additional information for the Bulk loader module for centrifuge units **cobas p** 471 (43x / 66x) and **cobas p** 671 (67x) (also connected to BCM for cobas 8100) user guide v3.1.

It has been added following an update to the name plate and various safety labels following current labelling and safety concepts.

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## Affected instruments

System	User guide publication version*	Addendum date	Change description
Bulk loader module for <b>cobas p 471</b> (43x / 66x) (SN 752xxxxx)	3.1	June 2020	Updated name plates, safety labels, and 200 VA > 200 W
Bulk loader module for <b>cobas p 671</b> (67x) (SN 752xxxxx)	3.1	June 2020	Updated name plates, safety labels, and 200 VA > 200 W

\* For US customers, this addendum is applicable to the currently approved version of the aforementioned operator's manual found on the US Roche Diagnostics website.

Table 1: Affected instruments

Roche recommends you familiarize yourself with the new and/or revised content provided in this addendum.



If you print these pages, Roche recommends printing them single sided. In this way, you can easily insert the new and/or revised content in its appropriate locations in the existing document.

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## Additional information

The product has new:

- **Name plates:** New name plates have been issued for all systems with serial numbers starting, for example, 752xxxxx.
- **Safety labels:** Safety labels have been added following current labelling and safety concepts.
- **Power/voltage value:** 200 VA has been updated to 200 W.

## Abbreviations

The following abbreviations are used throughout this document:

Abbreviation	Definition
BCM	Bulk loader connection module
BLM	Bulk loader module
CE	CE marking is a certification mark that indicates conformity with health, safety, and environmental protection standards for products sold within the European Economic Area (EEA)
<b>cobas p 471</b>	<b>cobas p 471</b> (43x / 66x) bulk loader module for centrifuge unit
<b>cobas p 671</b>	<b>cobas p 671</b> (67x) bulk loader module for centrifuge unit
ETL	Electrical Testing Laboratories
GS1	Global Standard 1
GTIN	A Global Trade Item Number is a trade item identifier, developed by GS1, used to look up product information in a database
IEC	International Electrotechnical Commission
PE	Protective earthing
RSR	Roche Service representative

Table 2: Abbreviations

## Safety precautions

This section is an addition to the '*Safety precautions*' section (page 23) of the Bulk loader module for centrifuge units **cobas p 471** (43x / 66x) and **cobas p 671** (67x) (also connected to BCM for cobas 8100) user guide v3.1:



Pay attention to the following safety precautions!

To avoid serious or fatal injury, read and comply with the following safety precautions.

Always consult this publication when this symbol is shown in order to receive information about the nature of potential hazards and the actions that are necessary to avoid them.

Safety regulations IEC 61010-1 and the applicable national electrical safety guidelines must be observed. Safe operation and reliability of the system can only be ensured if:

- The electrical installation of the system meets appropriate IEC requirements.
- The detachable mains cable shall not be replaced with a mains cable that is inadequately rated.
- Note that only qualified personnel (for example, an electrician or the RSR) are allowed to replace the mains fuse.
- Prescribed installation is performed by a trained expert.
- Visual inspection, PE conductor test, insulation test, and leakage current test are carried out by qualified electrician if necessary (according to applicable safety guidelines).
- The system is operated in accordance with the operating instructions.

## Name plates

New name plates are required for all systems with serial numbers starting 752xxxxx.

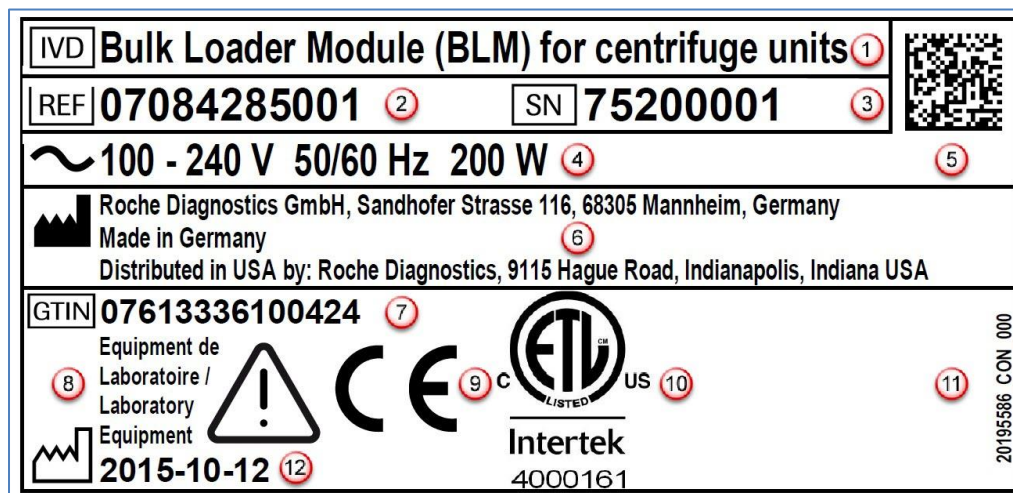


Figure 1: Name plate: BLM for **cobas p 471** (43x / 66x)

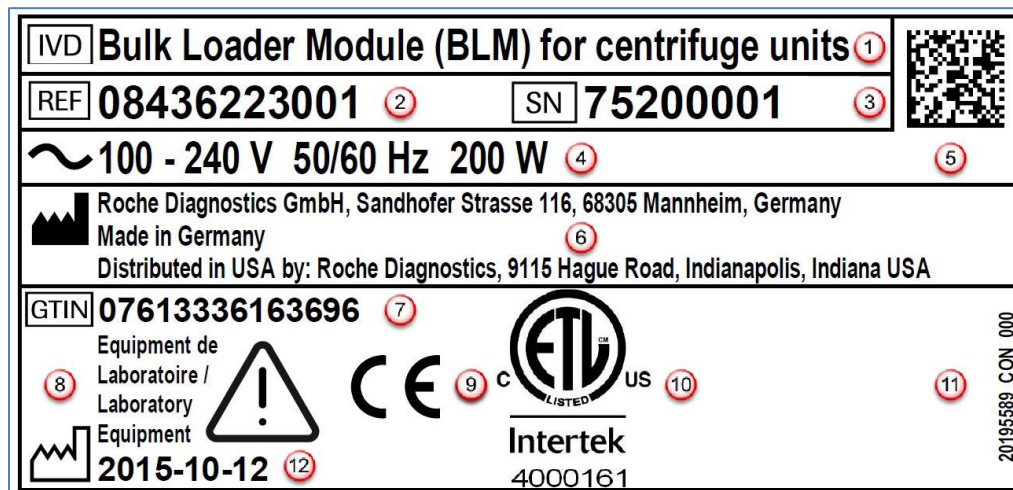


Figure 2: Name plate: BLM for **cobas p 671** (67x) (also connected to BCM for cobas 8100)

Table 3, below, describes the content of the name plates shown in Figure 1 and Figure 2.

No.	Description
1	<i>In vitro</i> Diagnostic (IVD) system name
2	System reference (article) number (included in 5, barcode)
3	System serial number (included in 5, barcode)
4	Required voltage, frequency, and power consumption
5	Unique Device Identification (UDI) machine readable barcode
6	Roche Diagnostics GmbH registered addresses: <ul style="list-style-type: none"> <li>• Mannheim: Legal Manufacturer</li> <li>• Indianapolis: US Distributor</li> </ul>
7	Global Trade Item Number (GTIN) (included in 5, barcode)
8	Equipment de Laboratoire / Laboratory Equipment
9	CE certification mark
10	Intertek ETL Listed Mark
11	Label ID
12	Date of Manufacture (DoM) (included in 5, barcode)

Table 3: Name plate content description

This is in addition to the content on:

- Page 46 of the BLM for **cobas p 471** (43x / 66x) user guide v3.1.
- Page 47 of the BLM for **cobas p 671** (67x) (also connected to BCM for cobas 8100) user guide v3.1.



## Power/voltage supply

200 VA on page 109 of the Bulk loader module for centrifuge units **cobas p 471** (43x / 66x) and **cobas p 671** (67x) (also connected to BCM for cobas 8100) user guide v3.1 has been updated to 200 W, as shown in Table 4, below:

Term	Value
Voltage (RMS values)	100 – 240 V AC (allowable tolerance $\pm 10\%$ )
Power frequency	60 / 50 Hz
Power consumption	200 W
Maximum power consumption	200 W (peaks less than or equal to 1 s)
Current	2.0 A
Maximum current	3.2 A (peaks less than or equal to 1 s)
Fuse - BLM connected to <b>cobas p 671</b> / BLM connected to BCM for <b>cobas® 8100</b>	T 2A H 250V (in accordance with IEC 127-2)
Fuse - BLM connected to <b>cobas p 471</b>	M 2A L 250V (in accordance with IEC 127-2)
Protection class	I
Overvoltage category	II
Pollution degree	2 (according to DIN IEC 664)

Table 4: Power/voltage supply

## Safety labels

Safety labels are used to indicate potential safety hazards and point out remaining risk. All safety labels on the module, and in areas accessible by the operator, are documented as shown in the examples below.

This is in addition to the content on pages 48 of the Bulk loader module for centrifuge units **cobas p 471** (43x / 66x) and **cobas p 671** (67x) (also connected to BCM for cobas 8100) user guide v3.1.



Figure 1: Safety labels on the **cobas p 471** (43x / 66x) and **cobas p 671** (67x) (also connected to BCM for cobas 8100) hopper cover



Figure 2: Biohazard label on the **cobas p 471** (43x / 66x) and **cobas p 671** (67x) (also connected to BCM for cobas 8100) hopper cover

## Care and maintenance procedures

Perform care and maintenance procedures as necessary.

NOTICE: Always switch the system off before performing care and maintenance work.  
Always remove the mains plug of the system from the mains supply!

Ensure you are familiar with the notes on hazards and precautions in section 'General safety information' before performing care and maintenance work.

Ensure that national, international and standard laboratory safety precautions are adhered to when performing care and maintenance work.

For detailed information about cleaning and maintenance, please refer to section 'Maintenance'.