

3

Technical Features

This chapter describes the composition of the MG2 line owned by the customer and the technical and functional features of each component.

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1. Chapter revisions

The table below shows the various chapter revisions that have been made with a description of the modifications made, the authors and the dates of writing, checking and approval.

Vers.	Written by	Checked by	Approved by	Modifications
1.0	Technical Documentation Department Daniele Meluzzi (4/11/05)	Technical Documentation Department Carlo Gardini (4/11/05)	Project Co-ordination Lorenzo Tancini (4/11/05)	First version for S/N 4608 obtained from Master version 3.0
2.0	Technical Documentation Department Daniele Meluzzi (12/01/2006)	Mechanic engineer Mauro Morara (12/01/2006)	Technical Documentation Department Manager Carlo Gardini (13/01/2006)	First upgrade for S/N 4608 obtained from Master version 3.0 - New description for the universal tablet unit parts.

2. Introduction

MG2 machine modularity The main feature of the machines produced by MG2 is their modularity which enables various production demands to be met.

Definition of line Line means the set of the following components which usually make up the products supplied by MG2.

- **Base machine (basic structure and dosing units)**
- **accessory devices**
- **Control cabinet**
- **Services unit**
- **Accessory machines**

The structure of the machine complies with the requirements of Directive EEC 98/37 as amended, and is based on GMP (Good Manufacturing Practice) standards.



NOTE: The main functional features of each component in the line are described.

The technical specifications of the various components in the line are given in a special paragraph at the end of the chapter.



IMPORTANT: In some cases, the drawings and images used within the chapter are purely illustrative and may not refer to the specific line or configuration purchased by the customer

3. Line layout

The diagram shows an example of components and relative dimensions of a typical MG2 line.

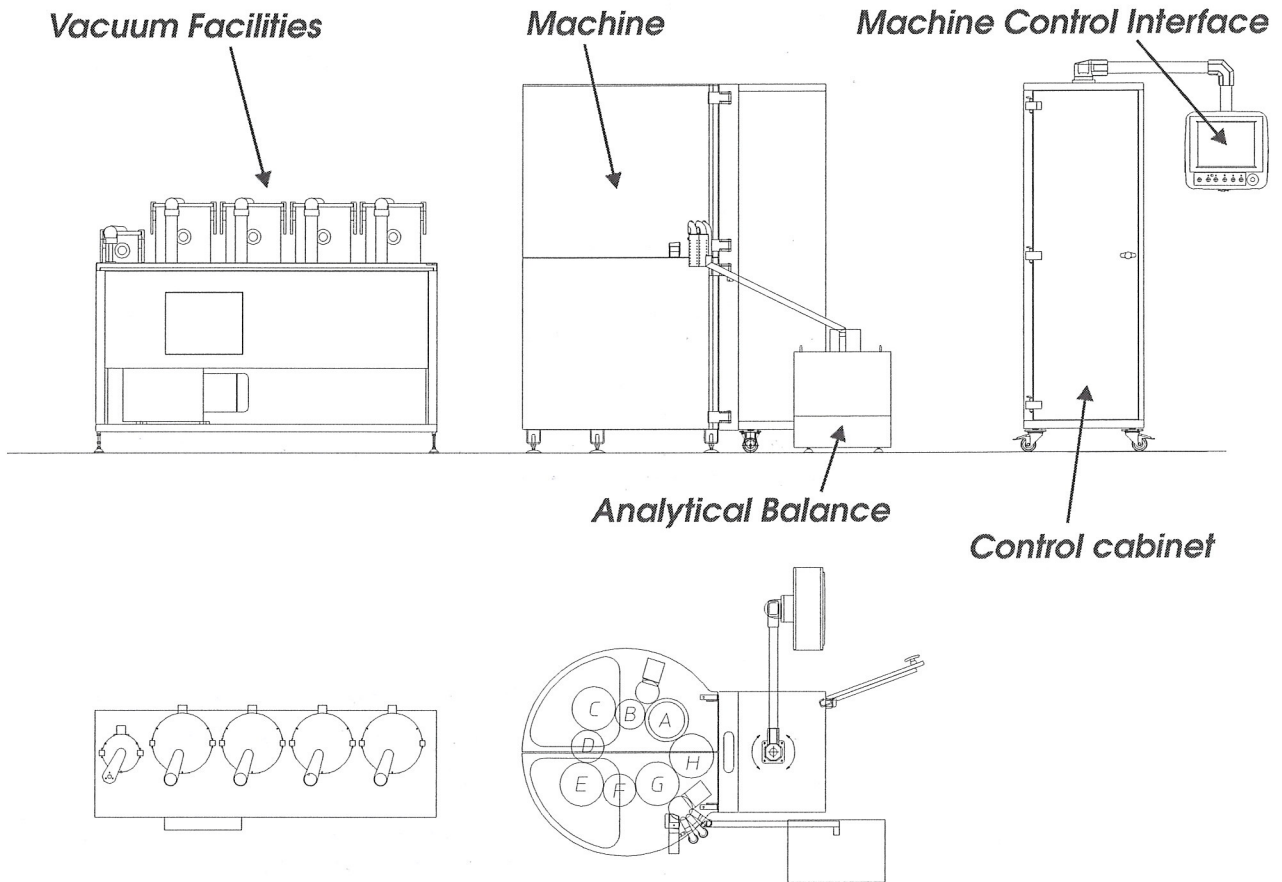



Figure 1 – An example of line layout

 The detailed layout of the components purchased by the customer with an indication of size is supplied separately either on paper or CD-ROM according to customer requirements.

4. Intended use of the line; improper uses

The line is configured to satisfy the customer's dosing requirements. The manufacturer must be contacted if a machine is to be used for a different purpose.

The machines are fitted with safety devices to protect the operator from injury.



CAUTION: Use of the machines for operations not envisaged by the manufacturer, tampering with the safety controls and any operation which modifies the original features of the machine or makes it perform functions not envisaged, may damage mechanical components and operating logic and can constitute a hazard for the operator.

The guarantee for the line components is considered null and void if the machine is used for any purpose other than the one intended.

4.1 Safety recommendations



The materials and substances used on the machine can give rise to the following types of hazard:

- **Danger deriving from contact or inhalation of fluids, gas, vapours, fumes and powders with harmful, toxic, corrosive and/or irritating effects.**
- **Fire and explosion hazards.**
- **Biological (e.g. moulds) and microbiological (virus or bacteria) hazards.**



CAUTION: The machine described in this manual is a capsule filling machine designed to fill hard gelatine capsules with pharmaceutical products. No other use is authorized



CAUTION: Observe safety precautions at all times. Use masks, goggles, gloves and all other items of personal protective equipment indicated for the type of product being processed.



CAUTION: The use of harmful products or substances which can in some way endanger the health of the operator must be indicated to the manufacturer at the time of ordering. The handling of products that can be harmful for the health and/or safety of the personnel operating the machine must be regulated by the customer who must be aware of the characteristics of the product being processed.

The line machines have minimum and maximum production limits defined at the time of installation. Failure to adhere to these limits may result in damage to the machine and a deterioration of product quality making it unsuitable for consumption.



CAUTION: The MG2 technical service should be consulted before making any changes to the machine functioning limits.



CAUTION: Personnel operating the machine must not wear loose garments or objects that could get caught up in moving parts.



CAUTION: If the products being handled require particular processing conditions, the appropriate precautions must be taken before starting up the machine to prevent pollution or injury to personnel.

5. Line components

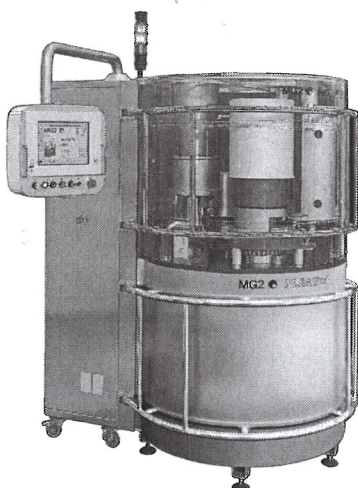
The MG2 line can be divided into the following main components:

- *Capsule filling machine*
- *Accessory machines and devices*
- *Electric cabinet (control cabinet)*
- *Services cabinet (suction and vacuum)*

5.1 Capsule filling machine

The capsule filling machine line can be divided into the following components (described in the relevant paragraphs):

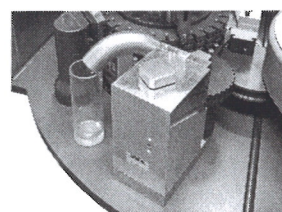
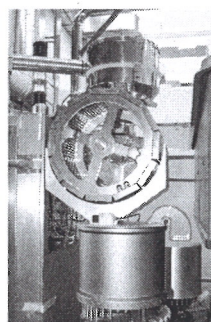
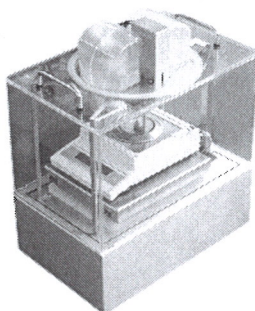
- *Machine base, motor and drive transmission*
- *Hoods and protective guards*
- *Capsule infeed, positioning and opening unit*
- *Capsule lid transfer unit*
- *Intermediate units*
- *Dosing units*
- *Capsule joining, closing and ejection unit*
- *System/Operator interface and control system (MCI)*



5.2 Accessory devices

The capsule-filling machine can be fit with the following accessory devices and machines.

- *Capsule infeed unit (OPTIONAL)*
- *Product infeed unit (OPTIONAL)*
- *Capsule infeed SR/I selector (OPTIONAL)*
- *Statistical weight control system SWC/S (OPTIONAL)*
- *Statistical weight control system SWC (OPTIONAL)*
- *100% weight control system NETT (OPTIONAL)*



5.3 Ancillary machines

The capsule-filling machine can be fit with the following ancillary machines.

- **Capsule infeed unit CFS (OPTIONAL)**
- **Filled capsule outfeed selector SR/O (OPTIONAL)**
- **Capsule selector/polisher at product outfeed TPS2000 (OPTIONAL)**



 Ancillary machines are described in the **ANCILLARY MACHINES** chapter of this manual.

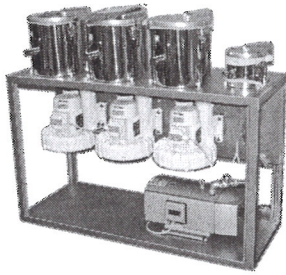
5.4 Electrical/control cabinet

The electrical cabinet is made up of the following:

- **Machine power components and connected devices**
- **Line control components**
- **Control panel with IPC (Touch Screen)**

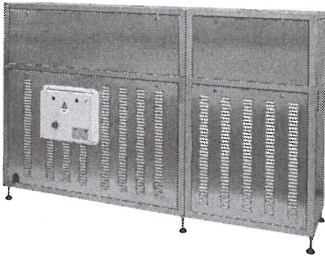



5.5 Services cabinet



The services cabinet supplies the suction and vacuum services necessary for the functioning of the capsule filling machine to which it is connected. It basically consists of:

- **Support structure**
- **Suction heads**
- **Vacuum pump (OPTIONAL)**
- **Suction unit for TPS2000 (OPTIONAL)**



 Service cabinet is more detailed described are described in the **SERVICE CABINET** paragraph in this manual.

6. Capsule filling machine

The **PLANETA/PLANETA 100** is a compact, high-speed capsule filling machine designed to dose a pre-set quantity of product in hard gelatine capsules.



Speed production

The nominal production speed of the machine is 6,000, 12,000, 25,000, 50,000, 100,000 capsules/hour (depending on machine and product characteristics).

Parts in contact with the product



All machine parts in contact with the product being dosed and with the capsules are made from stainless steel or bio-compatible materials. The machine composition conforms to the requirements of Directive EEC 98/37 as amended and is based on GMP (Good Manufacturing Practice) standards.

Machine control

The machine is managed by the newly designed man/machine interface system, named **MCI** (*Machine Control Interface*).

PLANETA weight control system

To guarantee production, the **PLANETA** is fitted with a statistical weight control system **SWC/S** or **SWC** to check the weight of filled capsules. It can also be fitted with a total (100%) control system for the net weight of the product dosed into the full capsules **NETT**.

PLANETA 100 weight control system

To guarantee production, the **PLANETA 100** is fitted with a statistical weight control system **SWC** to check the weight of

filled capsules. It can also be fitted with a total (100%) control system for the net weight of the product dosed into the full capsules **NETT**.

Mechanical functional principles

The mechanical design of the machine is based on continuous rotary movement. All the mechanical units rotate in phase and all the operating components function simultaneously. Their rotation is continuous, without any interruption or interval between the different operations.

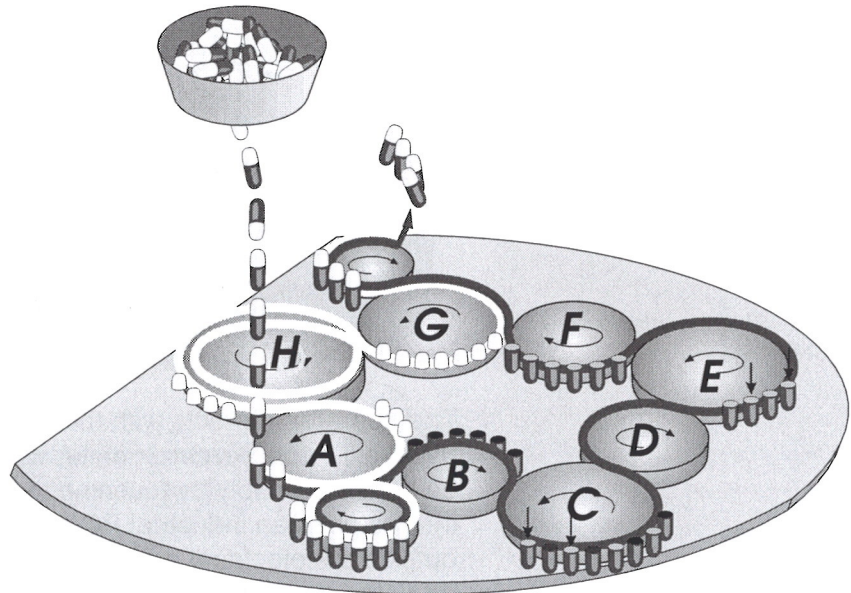


Figure 2 – Schematic representation of the PLANETA capsule cycle from empty capsule infeed to filled capsule outfeed.

The mechanical movements utilise air jets, suction and vacuum needed to correctly handle (open, hold, eject) and clean the capsules. The machine guarantees capsule integrity and maximum dosing precision.

PLANETA The machine can dose:

- **Powder**
- **Pellets**
- **Tablets**
- **Microtablets**

The machine structure integrates the electrical cabinet and the "touch screen" control panel mounted on a hinged arm. The machine's essential parts are described below.

6.1 Control and man/machine interface

The machine is controlled by a **man/machine interface system** called *Machine Control Interface (MCI)*.



Figure 3 – System control and interface monitor.

The operator interacts with the machine control system using a **Touch Screen** monitor which enables functions to be selected simply by touching the screen. The monitor is integrated in an industrial PC mounted on a hinged arm outside the electrical cabinet. The system can be fitted with a printer connected directly to the main control unit.

The **MCI** system can have different hardware and software configurations depending on the user's needs and the components purchased.

Machine control functions

There is a continuous exchange of data between the MCI software and the machine control PLC. The system enables the operator to manage all production functions (for example: machine speed adjustment, lot opening, etc.).

Weight control functions

The MCI system also integrates the automatic weight control functions. The weight control system identifies the weight of the product dosed into the capsules. The system also acquires and controls "On Line" data to enable analysis and controls aimed at ensuring production quality.

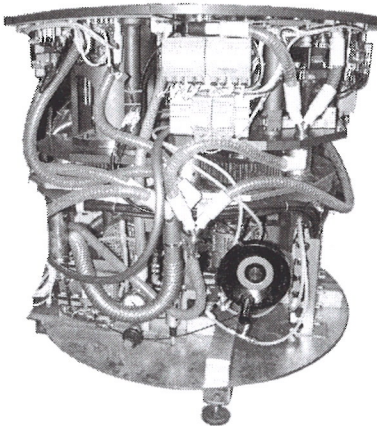


Figure 4 – Example of the machine base with the protective guards removed.

6.2 Machine base

The part of the capsule-filling machine below the machine surface (*base*) houses:

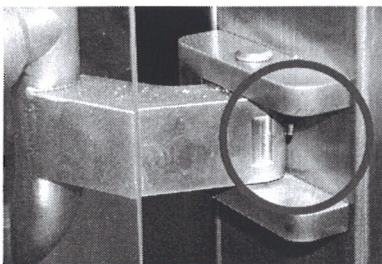
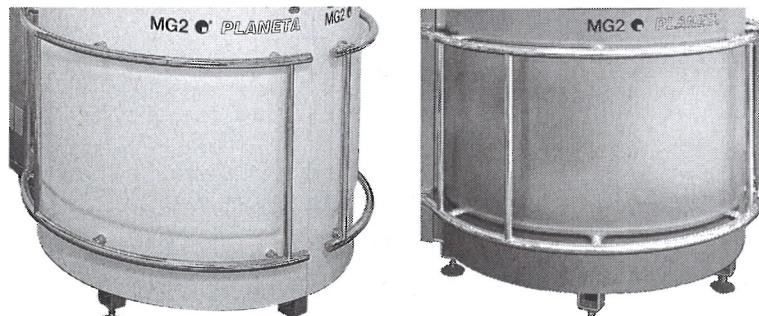
- **Lower components of the units**
- **Motor and drive transmission components**
- **Pneumatic system**
- **Suction/vacuum system**
- **Lubrication system**
- **Electronic components for communication between the control cabinet, the machine sensors and the various controlled parts \ line**

All of the machine parts are assembled on a stainless steel frame.

6.3 Guards



The entire structure below the machine deck is protected by **ABS** or **Stainless steel guards** reinforced by stainless steel **roll-bars**.

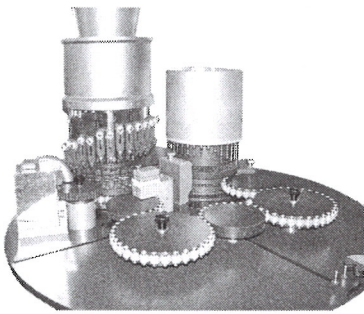


The guard windows open on lateral side hinges and are fitted with safety devices.

The safety microswitches stop the machine whenever the guards are opened while the machine is running (see alongside).

The guards can be opened to gain access to all parts of the machine below the machine deck for any maintenance and other operations.

6.4 Part above the machine deck



The structure above the machine deck houses the capsule handling and dosing units. These are as follows:

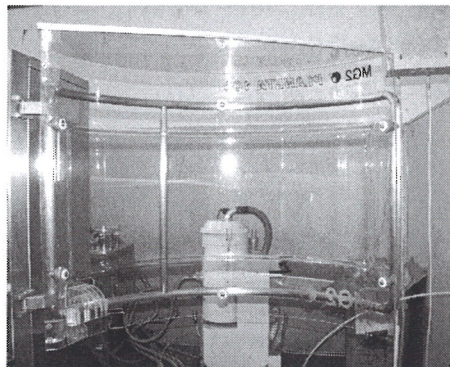
- **Capsule feeding/positioning/opening unit**
- **Capsule lid transfer unit**
- **Intermediate units**
- **Dosing units**
- **Capsule joining/closing unit**
- **Machine and dosing unit sensors**
- **Exit chutes**

6.5 Hoods



The movement of the capsule handling and dosing units could be a source of danger for the operator.

Therefore, the entire structure above the machine deck is protected by non-toxic impact-proof **polycarbonate hoods** reinforced by stainless steel **roll-bars**.



The hoods open on side hinges and are fitted with safety devices: safety microswitches that stop the machine if the hood is opened while the machine is running. The hoods can be opened to access all points above the machine deck for any maintenance and other operations.



The protective hood is a safety component and as such it is fitted with devices to prevent access to the machine if the operating conditions are unsafe. Do NOT modify the hood. The hood safety devices cannot be disabled in any machine functioning mode. Do NOT modify the hood.