An exhaustive manual for the Kilian Tablet Press Machine

Introduction to Romaco Kilian tablet press machines

All Kilian tablet press machines are designed exclusively for pressing tablets made from powdery materials. In addition to the main tablet press machine, the proper usage of the machines includes the use of different peripheral devices (e.g., IPC unit, deduster, metal detectors, and pressing compartment coating devices) which are necessary for producing tablets. Appropriate use also includes compliance with the operating instructions and with the cleaning and service instructions. Any other or additional use is not in line with the machine´s intended purpose. Kilian shall not be liable for any damages resulting therefrom. It is not in line with proper usage to operate the tablet press machines outside. The tablet press machines may only be operated in production mode only when all safety devices, as part of the safety equipment are in place, closed and locked. It is not permitted to bridge or render the safety devices otherwise inoperative. The tablet press machines may exclusively be used in line with its proper usage and in technically perfect condition. In doing so ensure that safety- and risk-conscious operation and strict observance of the operating instructions are maintained. Faults which may impair safety must be eliminated immediately!

Safety

To ensure the safe handling of the tablet press machine and to protect the operator, it is essential adhere to the following safety aspects:

- ✓ Regularly check the safety and protection devices
- ✓ Observe all safety instructions and hazard warnings
- ✓ Ensure all safety instructions and hazard warnings are complete and legible
- ✓ Read the operating instructions before start-up
- ✓ Keep the operating instructions available at any time
- ✓ Observe any regulation regarding accident prevention and environmental protection

- ✓ Stop the machine immediately in case of faults and report the fault
- ✓ Implement any changes as well as additions and modifications only after approval of Romaco Kilian
- ✓ Use original spare parts only
- ✓ Do not implement program changes of programmable controlling system
- ✓ Observe the specified periods for regular tests/inspections
- ✓ Read carefully the MSDS (Material safety data sheet)
- ✓ Be sure to handle the product safely
- ✓ Wear the appropriate personal protective equipment
- ✓ Remember if the main switch is switched off, individual components inside the control cabinet may still be under voltage

Safety devices on the Romaco Kilian tablet press machines

In the event of an accident or problem during processing, the tablet press machine can be stopped or switched off immediately with these safety devices.

Main switch
The main switch is a mechanically-operated, electrical component used to switch the machine on or off. If the main switch is switched off, individual components in the control cabinet may still be under electricity

Emergency stop button
The emergency stop button allows the machine to be made safe in dangerous situations or to prevent danger. By pressing the button, all machine movements are immediately stopped.

Safety switch
Safety switches are sensors that detect if a moved object is in a certain position. The working area is cladded with separating, mostly transparent guard doors, which are monitored with safety switches. When a guard door is

opened during automatic mode, the machine stops immediately. When a guard door is open, the machine cannot be started in automatic mode

Maintenance of safety devices

It is necessary that the effectiveness and proper function of the safety devices be checked prior to each use of the machine. It is strictly prohibited to manipulate the safety systems available in the machine and/or to render them inoperative. Regular maintenance and/or cleaning of the safety components must be carried out to ensure proper operation.

Additional safety instructions

Lubrication - Wrong and improper application of lubricants
Insufficient lubrication can result in damage to the machine or its components. When handling lubricants, observe the safety instructions applicable to the respective product. It is crucial that the lubricants are used exclusively, and that the required filling volumes and filling level heights are observed. It is important to drain the sump tank at regular intervals. The color of the waste oil should be monitored as major discolorations may indicate excessive loading, heat, or moisture as well as wear. Avoid blending different oil types. The lubricant information provided in the operation instructions should be carefully observed. Pneumatically supported grease guns should not be used for lubrication as the increased pressure in the lubricating system may cause leakages. Only manually operated grease guns should be used.

Pneumatics - Lines and components under pressure
Compressed air jets cause injuries to skin and eyes. Before working on the pneumatic system, the system must be depressurized. Wear appropriate personal protective equipment!

Danger points during format change and maintenance
It is of particular importance to consider critical danger points during maintenance or format changes.

Personal injury may occur at:

- die table during tool change or die table exchange
- fill shoe during emptying
- sliding carriage during die table exchange

Electrical energy
During maintenance it is essential to control the electrical cabinet and all terminal boxes.

Pull in / catch at
During the inspection of the flap for bad tablets at the metal check system and during the maintenance of the main gate at tablet chute, the hands can be pulled in or caught.

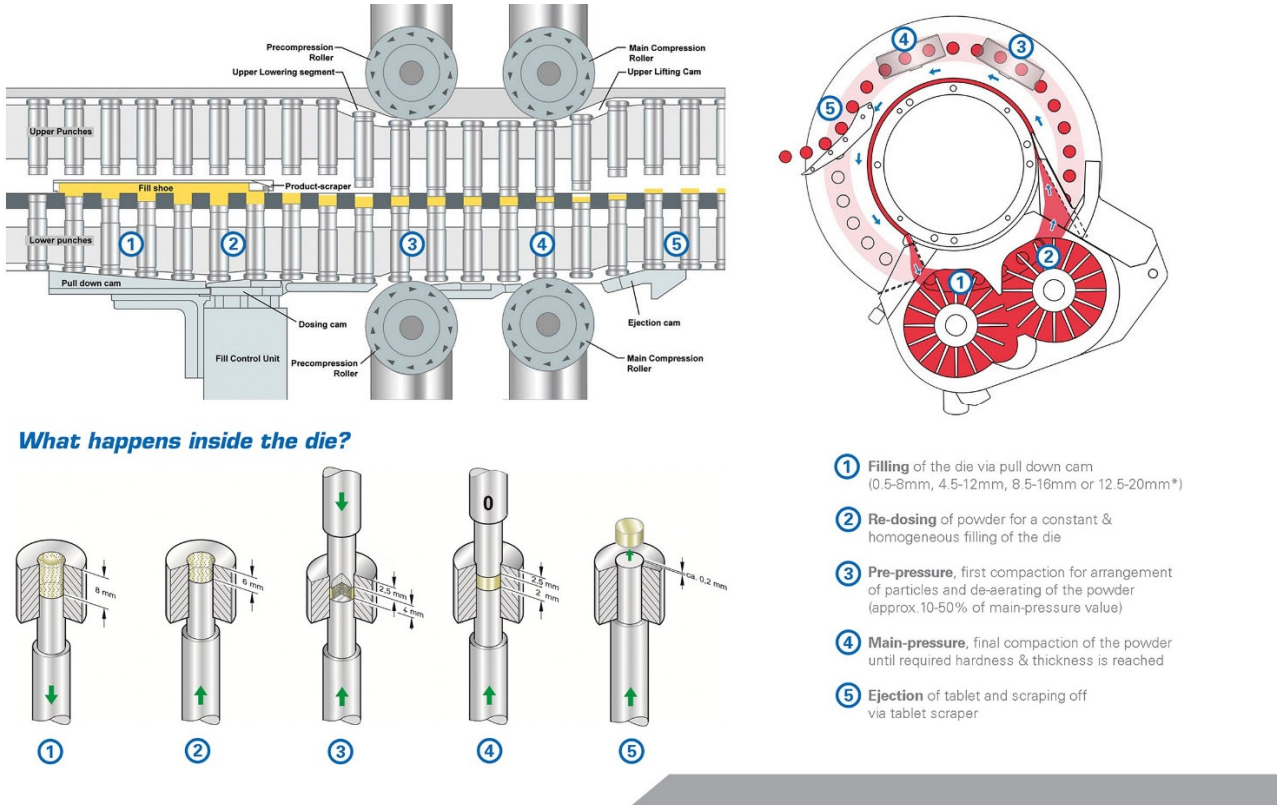
Installation conditions for Romaco Kilian tablet press machines

Note that the machine must be installed as determined when placing the order. Otherwise, Romaco Kilian doesn't assume any liability for possibly occurring faults or too short connecting cables. The space for installing the machine must be sufficient to enable the operation and maintenance of the machine. This includes that all windows and doors can be opened without hindrance and that access to the media and machine connections is ensured. Additionally, ensure that the emergency stop buttons on the tablet press machines, the control cabinets and any existing peripheral equipment are always accessible. Check the ventilation openings on the electrical control cabinets. A sufficient air circulation must be guaranteed. Make sure that a permissible floor load is guaranteed at the installation site of the machine, as described in the operating instructions.

The service site of the machines must feature the following characteristics:

- ✓ Sufficient floor load capacity
- ✓ Free accessibility of the machine from all sides
- ✓ Enough moving space for operating and service personal
- ✓ Possibility to completely open all hinged parts (windows and doors)
- ✓ Good illumination of service site
- ✓ Low-vibration environment
- ✓ No direct radiation from heaters or the sun
- ✓ Room temperature: +15 °C to +30 °C
- ✓ Relative humidity of air: 15 % to 85 % (indoor), without dew
- ✓ Altitude of the service site < 2000 m above sea level
- ✓ Area free of static electricity discharge and strong magnetic fields

Crucial components and process flow of Romaco Kilian tablet press machines



It is essential to understand the process flow and the operational mechanics of the tablet press machine to effectively identify and rectify any potential issues or malfunctions that may occur.

Fill shoe
The fill shoe is responsible for distributing the powder into the die hole via paddle wheels.

Pull down cam
The pull-down cam is located below the fill shoe. The pull-down cam allows you to select different fill ranges. It pulls down the punches to the deepest position within the current pull down cam range.

Dosing cam
The next component is the dosing cam, which is located after the pull-down cam. The dosing cam pushes back the punches to the final filling position, which corresponds to the final tablet weight. All this movement of punches and powder occurs within the fill shoe area.

Product scraper
The product scraper is located after the fill shoe. The product scraper scrapes the product into the recycling groove and another scraper with a kind of spoon, which is located before the fill shoe scrapes the product from the recycling groove back into the fill shoe, to reduce the product loss.

Control cam
The next important component is the control cam, located at the lower cam track. This follows the filling and redosing system. The control cam is not visible directly, as it is located on the outer side and in contact with the punch at the top of the punch head, which is used to pull them down. The control cam pulls down the lower punch including the powder within the die. This action creates space at the top of the die for the down coming upper punch. This results in the upper punch closing the die shortly after reaching the powder within the die for the pre-compression.

Pre-pressure
The pre-pressure represents the initial stage of the product compaction. During the pre-pressure phase, air is removed from the product. By ensuring effective deaeration of the product and applying optimal pre-pressure forces, the objective is to achieve superior hardness for the final tablet. By modifying the upper punch penetration

value, it is possible to alter the distance between the punch tip and the die wall at the conical opening of the die. However, it is important to note that insufficient upper punch penetration may result increased product loss.

Main pressure
The second and final compaction stage is crucial for achieving the desired tablet thickness and hardness.

Tablet ejection cam
Following the main compaction, the ejection cam at the lower cam track is activated, pushing the tablet out of the die to a position that can be adjusted. Our standard ejection position value is 0.3 mm.

Getting started

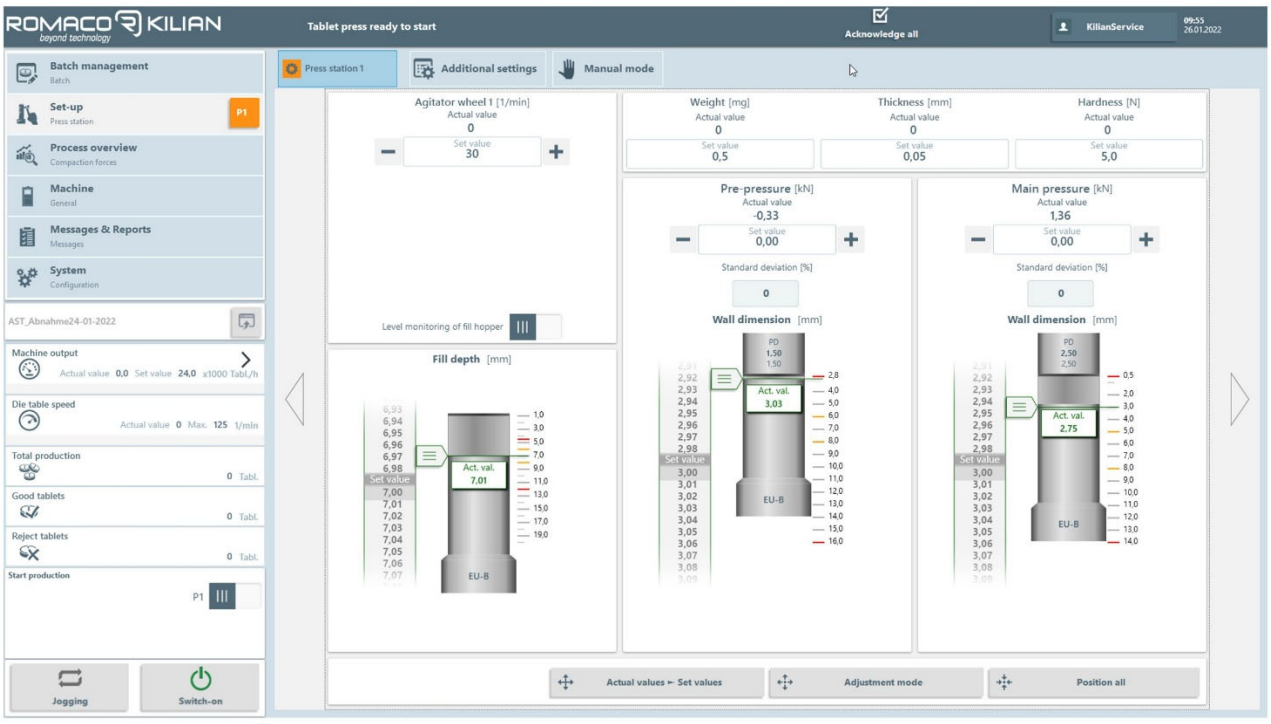
First cleaning

After unpacking, thoroughly clean the tablet press (see the operation instructions for cleaning details). It is essential to remove any preservative and anticorrosive agents completely.

Operating material

Prior to each commissioning, please check all lubricants and other operating materials and refill as required.

Starting the system



To start the system, switch the main switch to the "ON" position. All operational status indicator lights will illuminate, indicating that the control has been started. The start-up process is indicated by a white progress bar in the lower area of the start screen. Once the starting procedure has finished, the “Set-up” menu will be displayed.

How to set up a Romaco Kilian Tablet Press Machine?

The tablet press machine is ready to start production. The compression tooling has been installed, the ejection cam and tablet scraper have been adjusted, the fill shoe support (base plate on which the fill shoe is mounted) has been correctly adjusted, powder is in the filling hopper, the butterfly valve is open, active batch identification is enabled, the correct value for compaction force tolerance (e.g., +/- 20%) and correct machine output speed have been entered at the operating terminal.

1. Verify that the press settings are correct and that the machine is ready to run and does not over press the powder or stops via tool overload. If you begin with a filling depth of e.g., 8mm, set the tablet wall dimension pre-pressure to 6mm, the tablet wall dimension main-pressure to 3-4mm and set the fill shoe speed to 60rpm.
2. First, the weight of the tablet is set by adjusting the filling depth. Start the machine, take out sample tablets, stop the machine and check the weight. Always take 10 sample tablets and divide the measured value by 10, as this is more accurate. If the weight is below the target value, increase the filling depth. Conversely, if the weight is above the target value, reduce the filling depth until it reaches the target value.
3. The tablets are of course much too soft. The next step is to adjust the thickness and hardness of the tablet. To determine the hardness of the tablet it is recommended to use a hardness tester. To ensure an accurate result, at least 5 samples should be tested. The thickness of the tablets is determined with a caliper gauge, with 2 to 3 measurements sufficient. Start the machine, take out sample tablets, stop the machine and check the tablets. Once the desired tablet thickness and hardness have been achieved, reduce the main pressure to reduce the tablet wall dimension.
4. The next step is to set the pre-compression by adjusting the tablet wall dimension. Start the machine and check the actual pre-pressure compaction force value on the control panel. To increase the pre-compression, reduce the tablet wall dimension pre-pressure. The pre-pressure compression force value is typically within the range of 10 to 50% of the main compression force value.
5. Control the homogeneous filling of the dies by using the main pressure compression force graphic on the control panel. Should larger deviations be identified (looks like a wave), adjust the speed of the fill shoe. Increase the speed in 10rpm steps until the compression force graphic looks linear. The speed should be as low as possible, to prevent product separation or destruction by the agitator wheels.
6. Once the previous steps have been completed, press the “Set point = actually value” button on the control panel and switch the running machine to production mode.

** if the tablet press machine is not fully automated, the adjustment is done by hand wheels*

Maintenance and Cleaning

Service schedules

Service schedules can also be found in the operation instructions. The proposed times are based on a standard production day of 8 hours. For your convenience, we have divided the tasks into the categories “daily”, “weekly”, “monthly”, “soiling”, “fault” and “product change”.

Daily service schedules

- ✓ Filter: Visual check for state
- ✓ Compression chamber: Vacuum cleaning of product residues
- ✓ Windows inside surfaces: Cleaning
- ✓ Tablet chute: Cleaning and check of rotary magnets functionality
- ✓ Blow out nozzle: Cleaning of hoses, valves and blow-out bore
- ✓ Tool – Oil trap caps at upper punches: Check condition and fit at punches

Weekly service schedules

- ✓ Control elements: Visual check of lamp and check of emergency stop button functionality
- ✓ Fill shoe / Agitator wheels: Visual check of deposits, wear, bending of agitator wheels and smooth running of bearings
- ✓ Covering segment with product scraper: Visual check of wear and smooth running
- ✓ Fill tube: Cleaning and visual check
- ✓ Hydraulic unit: Check of oil level
- ✓ Filter / Filter mat: Cleaning and visual check
- ✓ Machine compartment: Check for oil slicks or heavy pollution / dirt
- ✓ Die table / V-seals: Visual check and lubrication after each cleaning
- ✓ Measuring points / Force measurement: Check switch-off function of limit value indicators by reducing upper limit
- ✓ Pneumatics connections and lines: Visual check of connections for air leakage
- ✓ Suction unit: Cleaning of hoses and suction nozzle
- ✓ Lubrication system / Sump tank: Visual check and emptying of sump tank
- ✓ Lubrication system / Lubrication pump: Check lubricant level
- ✓ Tool / Scraper: Visual check and inspection

Monthly service schedules

- ✓ Upper / Lower pressure rollers: Visual check of wear and smooth running
- ✓ Upper pressure rollers: Lubricate with grease gun (only for pressure rollers with lubricating nipple)
- ✓ Upper / Lower cam track: Visual check of wear of punch guides
- ✓ Fill shoe base: Visual check of distance to the die table and wear of scrapers
- ✓ Hydraulics / Lines: Check for tightness and oil loss
- ✓ Filter / Fan: Visual check of functionality
- ✓ Machine compartment: Check for oil slicks or heavy pollution
- ✓ Machine compartment / Motor: Check temperature (main drive and fill shoe motor)
- ✓ Machine compartment / Safety switch: Check of condition and test of safety switches
- ✓ Machine compartment / Tank of cooling unit: Check make-up fill of cooling liquid, if necessary
- ✓ Die table / Punch bores: Visual check and cleaning with brush and oil slightly
- ✓ Pneumatics / Water separator: Visual check and emptying of container
- ✓ Tool / Shafts: Check and measure wear, polish, replace as required

Service when the machine is soiled / polluted / dirty

- ✓ Upper / Lower cam track: Visual check and lubrication after cleaning or replacement
- ✓ Fill shoe / Covering segment with product scraper: Visual check of wear and smooth running
- ✓ Filter / Filter: Visual check for state
- ✓ Filter / Filter mat: Visual check and cleaning

- ✓ Filter / Fan: Visual check of functionality
- ✓ Machine compartment / Fan: Check of functionality
- ✓ Die table / Brake magnets: Visual check of functionality
- ✓ Die table / Punch bores: Visual check and cleaning with brush and oil slightly
- ✓ Die table / V-seals: Visual check and lubrication after each cleaning

Service at product change

- ✓ Upper / Lower pressure rollers: Visual check of wear and smooth running
- ✓ Upper / Lower cam track: Visual check of wear of punch guides
- ✓ Fill shoe / Agitator wheels: Visual check of deposits, wear, bending of agitator wheels and smooth running of bearings
- ✓ Fill shoe / Housing: Visual check of wear of sealing segment
- ✓ Fill shoe / Covering segment with product scraper: Visual check wear and smooth running
- ✓ Fill tube: Visual check and cleaning
- ✓ Filter / Fan: Visual check of functionality
- ✓ Machine compartment / Fan: Visual check of function

Maintenance and cleaning attention

Cleaning agent	Water, up to 80 °C	Water, demineralised, up to 30 °C	Alkaline and acid pharmaceutical cleaning agents	Mild soap solution	Hydrogen peroxide, up to 30 %	Soda lye 25 %	Sulphuric acid 10 %	Phosphoric acid 50 %	Oxalic acid	Alcohol, up to 30 %	Ammonia solution
Stainless steel	☑	☑	☑	☑	☑	☑	☑	☑	☑	☑	☑
FKM	☑	☑	Please observe the respective specification of the cleaning agent!	☑	☑	☐	☑	☑	☑	☑	☐
NBR	☑	☑		☑	■	☐	☐	☐	☐	☑	■
PA	☑	☑		■	■	■	■	■	■	☐	☑
PEEK	☑	☑		☑	☑	☑	☐	☑	☑	☑	☑
PET	☐	☑		☑	☑[1]	■	■	■	■	☑	■
PMMA	☑	☑		☑[2]	☐	☐	☐	☐	☐	■	■
POM	☑	☑		☑	☑	☑	☐	■	☐	☑	☑
PTFE	☑	☑		☑	☑	☑	☑	☑	☑	☑	☑
PUR	☐[3]	☑		☐	☐	☐	☐	☐	■	☐	■
PVDF	☑	☑		☑	☑	■	☑	☑	☑[3]	☑	☐[4]
Silicones	☑	☑		☑	☑	☐	☐	☐	☑	☑	☑

☑: resistant
☐: resistant within certain limits
■: non-resistant

[1] max. 25 °C; time unlimited
[2] 30 °C; time unlimited
[3] up to 50 °C
[4] max. 10 %

Risk of material damage for acrylic glass parts (PMMA)!
Note that alcohol can cause fissures in PMMA, so we advise against using it for cleaning!

Cleaning / preservation of the tools
For punch preservation, we recommend "deconex HT 1191" from Borer Chemie, CH-4528 Zuchwil. This cleaning and anticorrosive agent is food-grade and can be used for manual cleaning as well as cleaning in an ultrasonic bath.

Danger for unauthorized persons and non-instructed personnel
Unauthorized persons who were not instructed to carry out servicing and cleaning tasks on the tablet press are unaware of the potential hazards in the work area. Servicing and cleaning work on the tablet press may only be carried out by qualified staff or by someone instructed under the supervision of qualified staff. Keep unauthorized persons away from the hazard and working area. In case of doubt address the persons and banish them from the hazard and working area.

Interrupt the work as long as unauthorized persons are present in the hazard and working area.

Danger to life! Personal danger through risk of electric shocks
The machine operates at voltages of > 220 V with correspondingly high amperages. As amperages above 30 mA may be fatal, please take reasonable precautions! Before maintenance and cleaning work, switch off the tablet press with the main switch. Secure the main switch against being switched on unintentionally. Attach appropriate warning signs.

Surface damage through improper cleaning agents!
Cleaning agents with a pH value of 9 or higher can affect surfaces! Avoid using any solvent-based, scouring or abrasive cleaning agents. Only use such cleaning agents approved by Romaco Kilian. Follow the operation instructions.

Hazard through corrosive or toxic cleaning agents!
Avoid coming into contact with corrosive or toxic substances, as the cleaning agents and disinfectants and possibly their vapours can damage the skin, eyes and mucous membranes. When using cleaning agents, wear the appropriate protective equipment in compliance with the manufacturer's specification.

Openings not covered or closed, resp., when cleaning!
Prior to cleaning of the machine, ensure that all openings into which cleaning agents may not penetrate for safety and/or functional reasons are covered or closed. Do not use a steam jet or similar high-pressure apparatus! After cleaning remove all covers again. Observe the instructions in the documentation!

Dust suction without function!
There is an imminent explosion hazard due to the build-up of an inadmissibly high dust concentration in the compression chamber! Operate the machine only when the suction unit is switched on! Clean the inside of the pressing compartment at regular intervals in order to keep the dust concentration as low as possible! Please take the minimum performance of the dust suction device from the operation instructions.

Generation of ignition sources through improper maintenance, operation, and cleaning!
Do not operate the machine with damaged pressing tools! Fix all components in the compression chamber properly and pay attention that they do not slide on the rotor. Check the machine at least once per shift for visible damage and defects and eliminate these. Avoid sources of ignition (sparks, hot surfaces) which might ignite a possibly existing explosive atmosphere in the compression chamber. Avoid electrostatic charging when cleaning the plastic windows.

Troubleshooting

Method to determine the correct values for the compression force tolerance
- Switch the machine to the set-up mode
- Reduce the fill depth until the weight of the tablet is too low
- The percentage of deviation from the previously required press force value should then be used as the input value for the tolerance minus
- Increase the fill depth until the tablets are too heavy
- The percentage of deviation from the previously required press force value should then be used as the input value for the tolerance plus

Adjustment of tablet wall dimension

- Switch the machine to the set-up mode
- Take out one sample tablet and check the tablet thickness
- If the tablet thickness is too high, reduce the tablet wall dimension by the value that is too high
- Produce some new sample tablets and check the tablet thickness again, if the required values are matching

Tablet weight variation

Possible causes

- Inconsistent powder flow
- Variations in compression force
- Worn tooling

Solution

- Ensure the fill shoe is properly adjusted to deliver the correct amount of powder
- Verify that the compression force is within the specified range and consistent

Table Shape and appearance issues (capping)

Possible causes

- Insufficient pre-compression
- Excessive main pressure
- Poor powder flow

Solution

- Fine-tune the pre- and main-pressure to achieve the desired tablet shape
- Improve the powder flow to ensure that the powder is flowing smoothly and evenly into the die

Table Shape and appearance issues (lamination)

Possible causes

- Poor powder cohesion
- Excessive compression force
- Material sticking

Solution

- Consider adding binders or lubricants to improve powder properties
- Reduce the compression force if necessary
- Use appropriate lubricants to prevent material sticking

Tablet hardness issues (soft tablets)

Possible causes

- Insufficient compression force
- Poor powder properties
- Moisture content

Solution

- Increase the compression force to achieve the desired tablet hardness
- Consider adding binders or lubricants to improve powder properties
- Ensure the powder is at the correct moisture level

Tablet hardness issues (hard tablets)

Possible causes

- Excessive compression force
- Poor powder flow
- Material sticking

Solution

- Reduce the compression force if the tablets are too hard
- Improve the powder flow to ensure that the powder is flowing smoothly and evenly into the die
- Ensure proper lubrication by using appropriate lubricants to prevent material sticking

Conclusion

We trust that this comprehensive manual will provide you with the necessary knowledge and guidance to effectively operate your Romaco Kilian tablet press machine. Remember, consistent practice and adherence to safety guidelines will ensure optimal performance and longevity of your equipment. If you have any further questions or require additional assistance, please do not hesitate to contact our support team.