

POLMON

SYNCHRONIZED WIRELESS CLOCK NETWORK

PRODUCT DETAILS

Product Brief:

Polmon Range of clocks are designed to use especially in critical Areas likes Pharma Production Plants Flame proof areas, Clean Rooms etc.The Polmon clocks are designed in different sizes and Enclosures to meet different functional areas of Pharmaceuticals

Polmon clocks are made primarily with 2 different Technologies.

- 1. Serial RS-485 Multi drop**
- 2. RF wireless Network**

1. Need of Synchronized clocks

According to the FDA, industry activities covered by this regulation include—but are not limited to:

- Laboratory and manufacturing practices; clinical and pre-clinical research; adverse event reporting; Product tracking; and Pre- and post-marketing submissions and reports.

...Part 11 Requirements and their Secure Time Management Implications

Part 11 requires companies regulated by the FDA to employ procedures and controls that ensure the authenticity, integrity - and when appropriate - the confidentiality of electronic records. Further, systems must be in place to ensure that individuals cannot readily repudiate signed records as illegitimate. A key to complying with this requirement is to implement appropriate Secure Time Management (STM) practices.

"Section 11.10(e), requires controls and procedures to include the "[use] of

Secure, computer-generated time-stamped audit trails to independently record the date and time of operator entries and actions that create, modify, or delete electronic records..." - FDA Guidance on 21 CFR Part 11 (emphasis added).

Organizations can comply with this requirement by taking inventory of IT systems that process these messages and transactions and then equipping critical systems with technology that ensures the integrity of audit trails.

Ensuring system reference to "good" time. "It is extremely important for time stamps to be based on computer system clocks that are accurate and reliable." -

FDA Guidance on 21 CFR Parts 11.

Substantial language in the guidance document is devoted to tracking and maintaining time zone data. The implication for globally distributed information systems is not trivial; coordinating time stamps generated in different time zones is onerous. Fortunately, there is a concept of "world time" based on Coordinated Universal Time, or UTC - the internationally recognized time standard that replaced the former international standard, Greenwich Mean Time.

UTC is recognized as a global standard by all nations that signed the "Treaty of the Meter." UTC is readily available via Global Positioning System (GPS) or other easy access methods. Use of UTC as the basis for time stamping audit trails covered by 21 CFR Part 11 greatly reduces the effort and expense associated with time zone and system time coordination. UTC represents the "gold standard" for time synchronization.

Synchronizing all relevant systems to good time. **"Computer clocks should be set correctly and continue to be set correctly.** You should establish and follow procedures to ensure that computer clocks are set properly. For example, computers on a network should automatically synchronize their clocks with that of a designated network computer (e.g. as part of the process of logging on to the network). The network **"master clock" or timeserver should, itself, be synchronized to a recognized standard computer clock.** Computers not connected to a network should have their clocks synchronized to a recognized standard clock and should be periodically verified against the standard clock." - **FDA Guidance on 21 CFR Part 11.**

This can be accomplished by installing secure NTP (Network Time Protocol) servers to synchronize clocks on all networked computers to a UTC reference point. (NOTE: The NTP server must be secured, and access from everyone except select system administrators must be blocked.) Connected devices can execute a communication with the NTP server at reasonable, pre-defined intervals, such as once per hour, once per each quarter-hour, etc. When the NTP server identifies an incorrect time during one of these communications, it automatically resets the clock in the server or computer.

· Signing (or stamping) the time of all transactions and/or events by integrating time-stamping servers into the information flow of relevant processes so that it is not possible to detach the content of the event from its time-based reference point.

"Section 11.50(a)(2) requires signed electronic records to contain information

Associated with the signing that clearly indicates, among other things, the date and time when the signature was executed. Section 11.50(b) requires the date and time when the signature was executed to be included as part of any human readable form of the electronic record -- such as electronic display or printout." - FDA 21 CFR Part 11 Language (emphasis added).

Applications that maintain their own secure logs can produce a clean audit trail when all clocks are synchronized to "good" time. Logs incorporating "good" time are able to produce a valid representation of the time order of events that have taken place in the application. With time synchronization to UTC, log files from all computers and applications will be based on a single accurate and secure time source, so there is an accurate representation of activity on the entire network no matter where on a globally distributed network the logged events occur.

...System Clock Security

The FDA requires that companies detect inappropriate changes to computer clocks by establishing and following procedures to detect and deter inappropriate changes to computer clocks. For example, employees should be made aware that unauthorized changes to clock settings are serious, unacceptable actions. The FDA believes employee training and awareness programs are especially important where computer systems lack a technical means of preventing people from changing clock settings.

"Persons responsible for system security should periodically conduct unannounced checks of computer clocks to detect and deter unauthorized clock changes. In addition, time stamps on electronic records should be spot checked for anomalies that might indicate inappropriate clock settings. For example, if the time stamps in an audit trail show a date and time of record modification that is earlier than the date and time of record creation, this discrepancy might indicate that there have been unauthorized clock modifications." - FDA 21 CFR Part 11 Languages.

Software operating systems, such as Windows NT and Windows 2000, have settings that allow a network administrator to prevent users from changing clock settings. For environments - such as Windows 95 or 98 - that do not offer this capability, the system administrator needs to develop and enforce policies that discourage clock tampering.

...Conclusion

The guidance documents issued to clarify the "21 CFR Part 11" regulation articulate the U.S. Food and Drug Administration are thinking about the systems and processes that organizations it regulates should have in place to ensure the time integrity of electronic records. **It is clear that the FDA has made the integrity of the "time-order" of events in processes subject to regulation as a high order priority. The FDA's call for secure, time stamped audit trails of regulated process is unambiguous.**

Regulated organizations need to take concrete steps to become compliant with the intent of the guidance document. Proven systems and procedures exist to support compliance. Commercial-off-the-shelf NTP servers are available at reasonable prices that make worldwide synchronization to UTC (or other authoritative time sources) simple and cost effective.

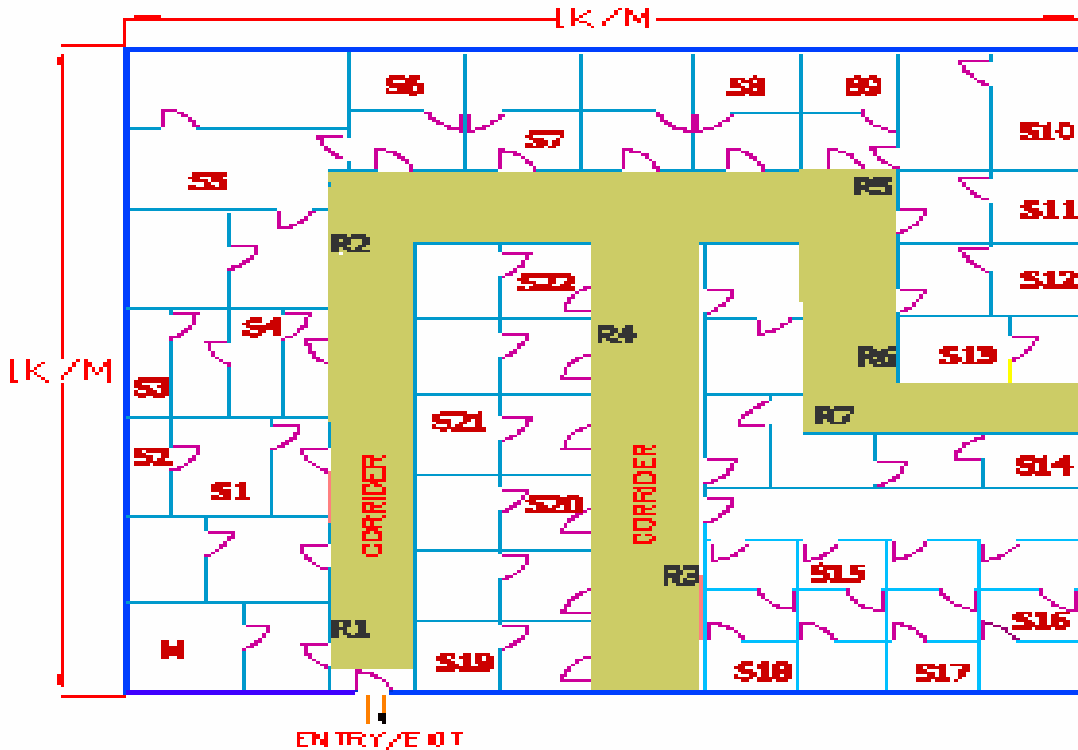
With a bit of thought and planning, and minimal expense, regulated organizations can take the "bite" out of compliance activities with regard to meeting FDA criteria for time integrity.

For More information about 21 CFR Part 11, visit the Food and Drug Administration's web site at: www.fda.gov/ora/compliance_ref/part11/default.htm.

Polmon Presence in Providing Synchronized Wireless Clocks solutions

POLMON is the first Company to provide synchronized clocks solution for Pharmaceuticals Industry. Polmon has made all range of clocks to fulfill rapidly changing Pharma Industry requirements as per FDA recommendations.

CLEAN ROOM WIRELESS CLOCKS



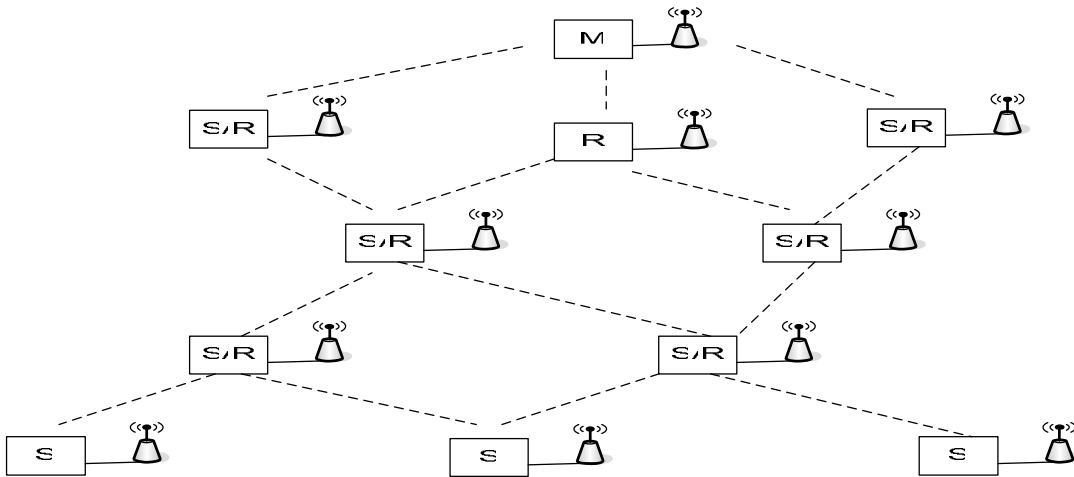
M ----- Master Clock S1 to S17 ----- Slave clock

R1 to R7 ----- Repeater

Advantages of RF communication:

- Reduces the Cabling cost
- Reduces the Installation and commissioning time
- Provides flexibility in adding more no. of slave clocks in Network.
- Increase the network size

Network Topology Model



M -- Master S/R -- Slave and Router/Repeater S -- Slave. R -- Router/Repeater

Unique features of Polmon Wireless Clock Network

- The above drawn Polmon wireless network RF mesh network
- The Mesh network is more advantage compare to other topologies which will increase the network range
- This type of Wireless network is more advantage for Pharma clean rooms where the rooms are closed with SS or Modular wall.
- The wireless network works on 433 MHz RF mesh network.
- Depends on the configuration each Device in the Network (excluding Master) works as Slave cum repeater or Slave end device.
- Polmon Wireless clocks is having Both the options to communicate on RF as well as on RS-485 Networks, which will provide flexibility in synchronizing clocks thru RS-485 cable network where ever RF is not reachable or RF is not allowed.
- Single Polmon wireless master clock supports both existing Polmon Clock network as well as wireless Clock network.
- Polmon wireless clocks are having inbuilt RTC to display exact time of Master incase of Communication synchronization is missing.
- Polmon Wireless Master Clock is synchronized with GPS time.
- Polmon wireless clock SS Faceplate designed to meet especially Pharmacy Clean room Requirements

GPS Real Time Sync. Master

Model No: TM630M-R

***GPS Master in Synchronized Clock Systems



The POLMON GPS Digital Synchronized Clock System is a perfect solution for a wide range of applications where accurate, synchronized time is required for Regulatory (FDA) etc. All the clocks can display the same real time, whether in the office, Production Blocks, warehouse, Canteen of Industries. These clocks find wide applications in areas of Manufacturing Industries, Hospitals, API's, Formulations, Clean Rooms, Colleges, and Schools etc.

Advantages of Interfacing GPS clock;

1. Improves the accuracy of time
2. Synchronizes with Universal time as per FDA recommendations
3. Reduces the manual entry errors

Synchronized Master Clock (TM630M) operates with highly stable and accurate time and synchronizes the Synchronized Real Time Clock Network every Second up to 32-Slave clocks i.e. TM621S/TM622S/TM632S without repeater. The multiple clocks are interfaced on Multi drop, 3 wires RS485 Network, which reduces the cable. The SS enclosure makes it suitable for wide Pharma & Clean Room applications.

FEATURES: -

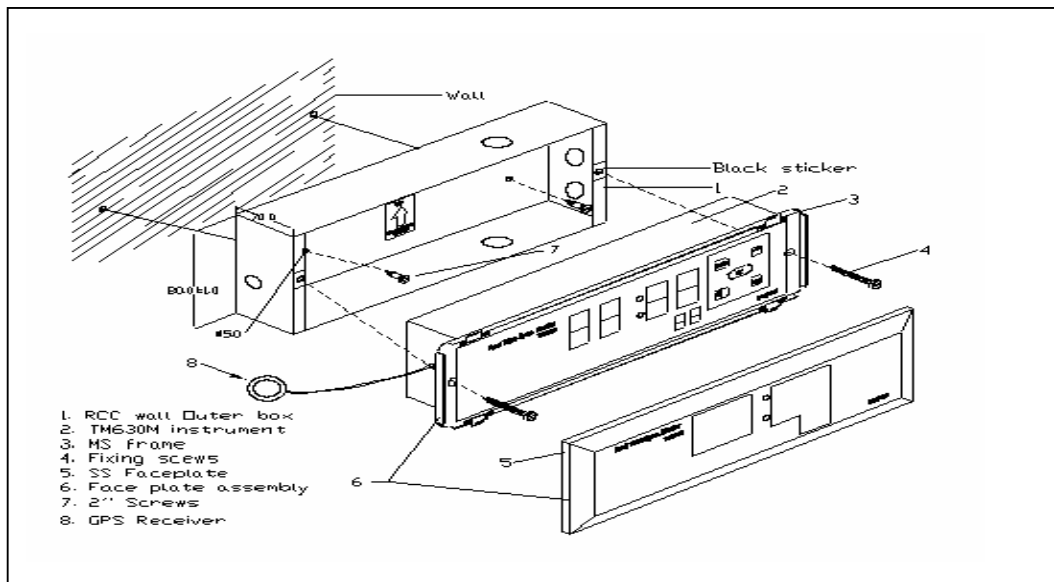
- Synchronizes Slaves with in a Second.
- GPS Master Synchronization with GPS time.
- Specially Designed for Clean Room Environment
- Flicker-free Bright Red Seven Segment LED Display
- Microcontroller Based Master clock
- User friendly – Master setting Update facility by Tactile Switches
- Secured Time Settings with PASSWORD.
- Power Failures may stop the display but not updating the Time due to in-built Battery provision with 10 Years of Operational Battery Life.
- Time Displays in 24 Hrs Format (HH:MM:SS)
- Auto change over to internal RTC Clock working in case of GPS failure.
- Red filter Transparent overlay facilitates Wide Viewing Angle
- Drives 32 Slave Clocks with out RS485 Repeater
- Maximum 247 with Repeaters for every 31 Slave Clocks in Rs-485 Mode and Maximum no. of slaves are based on signal strength

Specifications

Model No	TM 630M-R
Display	Two 0.8" Red Seven Segment LED to Display 'Hours'
	Two 0.8" Red Seven Segment LED to Display 'Minutes'
	Two 0.5" Red Seven Segment LED to Display 'Seconds'
Accuracy	+/-100 milli seconds with respect to UTC.
Communication	RS- 485 (3 wire)
Time Setting	Through Key Pad
Controller	Built in Embedded with Industrial performance
Time Format	24 Hrs Modes
Environmental Ratings	Operating Temperature : 0 - 50° C
Mechanical	Dimensions : See the mechanical Drawings
	Weight : 0.8 Kg (Approx)
	Face plate : Flush Mounting SS 304
	Enclosure material : Mild Steel
Mounting	Brick wall concealed mounting, Modular wall mounting
Operating Voltage	220V, 50 Hz, ± 5 %, 6 W.

GPS Receiver

Max.no.Channels for GPS time	Max.50 Channels. (Presently there are only 24 satellite
Hot start	2 Sec.
Warm start	45 Sec(Avg.)
Cold start	45 Sec(Avg.)
Protocol	NMEA standard.
Antenna Type	Active.
Antenna wire length	3/5 Meters
GPS Model	NEO-5Q-0-001



GPS Real Time Wireless Sync. Master

Model No: TM640M-R

***GPS Master in wireless Synchronized Clock



The POLMON GPS Digital wireless Synchronized Clock System is a perfect solution for a wide range of applications where accurate, synchronized time is required as per Regulatory (FDA) All the clocks can display the same real time, whether in the office, Production Blocks, warehouse, Canteen of Industries. These clocks find wide applications in areas of Manufacturing Industries, Hospitals, API's, Formulations, Clean Rooms, Colleges, and Schools etc.

Advantages of Interfacing GPS clock;

1. Improves the accuracy of time
2. Synchronizes with Universal time as per FDA recommendations
3. Reduces the manual entry errors

Synchronized Master Clock (TM640M) operates with highly stable and accurate time and synchronizes the Synchronized Real Time Clock Network with No. of wire less slave clocks. Slave clocks i.e. TM621S/TM622S/TM632S using RS-485 or TM642 /TM644S using wireless slave clocks. The multiple clocks are interfaced on Multi drop, 3 wires RS485 Network or RF wireless, which reduces or avoids the cable. The SS enclosure makes it suitable for wide Pharma Clean Room applications.

FEATURES: -

- Time Synchronizes with Slaves for every Second.
- GPS Master Synchronization with GPS time.
- Specially Designed for Clean Room Environment
- Flicker-free Bright Red Seven Segment LED Display
- Microcontroller Based Master clock
- User friendly – Master setting Update facility by Tactile Switches
- Secured Time Settings with PASSWORD.
- Power Failures may stop the display but not updating the Time due to in-built Battery provision with 10 Years of Operational Battery Life.
- Time Displays in 24 Hrs Format (HH:MM:SS)
- Auto change over to internal RTC Clock working in case of GPS failure.
- Red filter Transparent overlay facilitates Wide Viewing Angle
- Drives 32 Slave Clocks with out RS485 Repeater using RS-485 comm.
- Maximum 247 with Repeaters for every 31 Slave Clocks using RS-485 Comm.
- In case of RF wireless communication, `n` No. of Slaves can be connected using Wireless Mesh network

Specifications

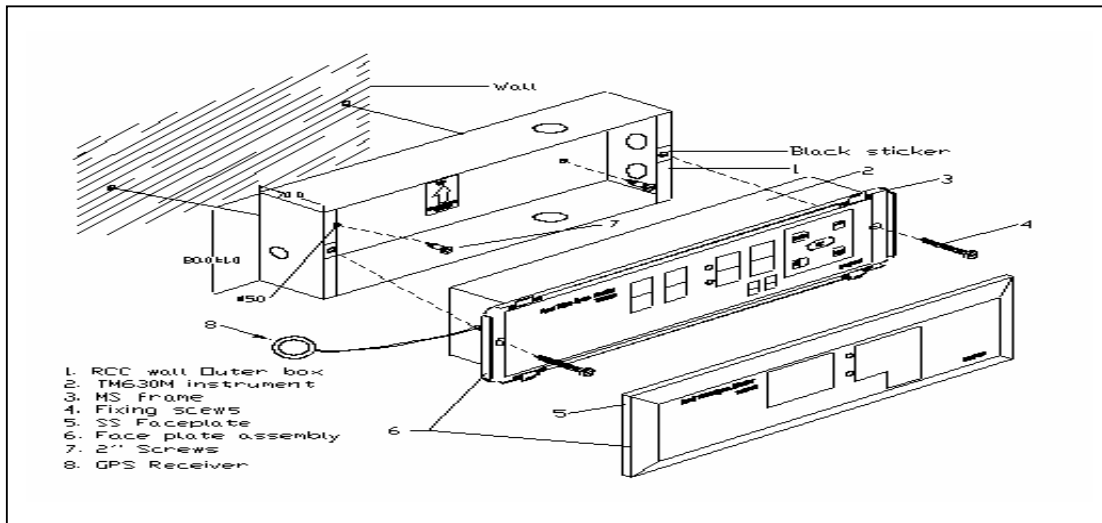
Model No	TM 640M-R
Display	Two 0.8" Red Seven Segment LED to Display 'Hours'
	Two 0.8" Red Seven Segment LED to Display 'Minutes'
	Two 0.5" Red Seven Segment LED to Display 'Seconds'
Accuracy	+/- 1 seconds with respect to UTC.
Communication	RS- 485 (3 wire)
Time Setting	Through Key Pad
Controller	Built in Embedded with Industrial performance
Time Format	24 Hrs Mode .
Environmental Ratings	Operating Temperature : 0 - 50° C
Mechanical	Dimensions : See the mechanical Drawings
	Weight : 0.8 Kg (Approx)
	Face plate : Flush Mounting SS 304
	Enclosure material : Mild Steel
Mounting	Brick wall concealed mounting, Modular wall mounting
Operating Voltage	220V, 50 Hz, ± 5 %, 6 W.

GPS Receiver

Max.no.Channels for GPS time	Max.50 Channels. (Presently there are only 24 satellite
Hot start	2 Sec.
Warm start	45 Sec(Avg.)
Cold start	45 Sec(Avg.)
Protocol	NMEA standard.
Antenna Type	Active.
Antenna wire length	3/5 Meters
GPS Model	NEO-5Q-0-001

RF communication

- Modulation Frequency : 433 MHz
- Line of sight : 600 Meters
- Antenna Gain : 2dBi
- Antenna Type : Omni directional
- Antenna Fixing : Instrument Inbuilt
- RF Power Output : +13dBm



WIRELESS SYNCHRONIZED DIGITAL SLAVE CLOCK (2")

Model No: TM642S

The POLMON Digital Synchronized Clock System is a perfect solution for a wide range of applications where accurate, synchronized time is required for Regulatory (FDA) etc. All the clocks can display the same real time, whether in the office, Production Blocks, warehouse, Canteen of Industries. These clocks find wide applications in areas of Manufacturing Industries, Hospitals, API's, Formulations, Clean Rooms, Colleges, and Schools etc.

Synchronized Clocks series of Slave Clocks with 0.8-inch, 2-inch displays are specially designed with SS faceplates, Modular wall mounting compatible for Pharma & Clean room & 4-inch Flame Proof & Weather Proof clocks are designed for all Industries, Colleges, Schools etc.

Features:

- One second synchronization with master clock.
- Bright, flicker – free seven segments LED display.
- Displays time in HH:MM Format.
- Micro controller based digital communication device.
- Best suited for clean room applications.
- Works in stand – alone mode if network failure.
- Indication of network failure with blinking display with time.
- 2" display visible up to 100 feet.



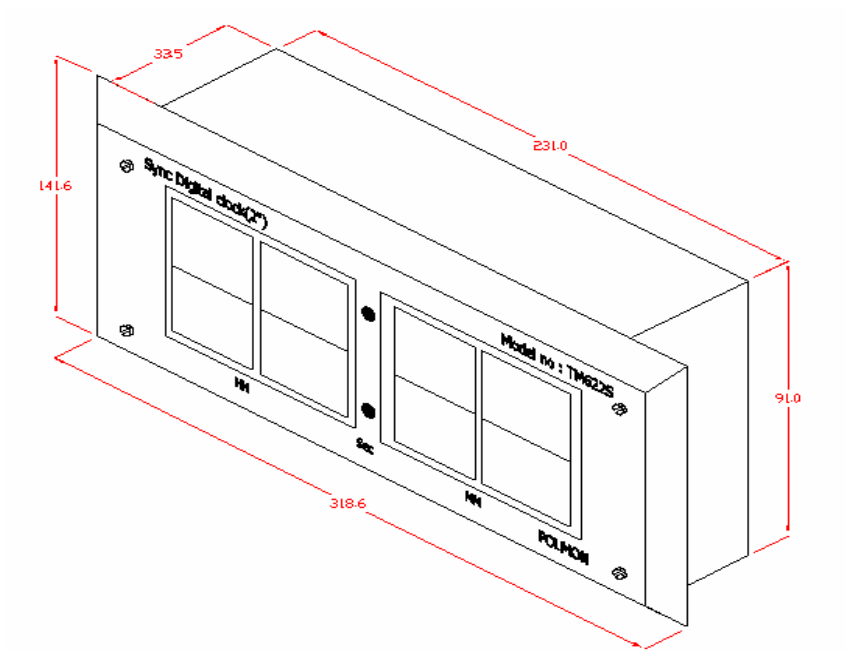
SPECIFICATIONS:

Model No	TM642S
Display	2" Seven Segment LED Display (Red) (For Hrs & Mins) Two 5mm flashing LEDs indicates seconds count
Accuracy (Synchronization)	Depends on master clock +/- 1 sec
Accuracy in Stand alone Mode	+/- 1minute per a Month when there is Sync. Comm. With Master clock
Communication	RS-485 & RF Communication
Time	Master Clock time/Programmable quartz clock with internal battery backup
Controller	Built in Embedded with industrial performance
Operating voltage	220 Volts AC 50 Hz, 10VA
Time Synchronization	Every second
Time Format	24 hour mode
Power Consumption	25W
Environmental Ratings	Operating temperature: 0 - 50°C
Mechanical	Dimensions: 318.6X141.6mm apprx. Weight: 1kg. (Approx). Face plate: SS Face Plate. Enclosure material: MS Siemens gray powder coated.
Mounting	1) Brick Wall concealed Mounting., 2) Modular Wall Concealed Mounting

RF communication

- Modulation Frequency : 433 MHz
- Line of sight : 600 Meters
- Antenna Gain : 2dBi
- Antenna Type : Omni directional
- Antenna Fixing : Instrument Inbuilt
- RF Power Output : +13dBm

Mechanical dimensions



WIRELESS SYNCHRONIZED DIGITAL SLAVE CLOCK (2")

Model No: TM652S

The POLMON Digital Synchronized Clock System is a perfect solution for a wide range of applications where accurate, synchronized time is required. Now all your clocks can display the same real time, whether in the office, factory, warehouse or canteen.

TM632S series of clocks are synchronized every second with master clock on RS485 network. Even if network failure they operate in stand- alone mode with in built real time clock.

The large super - bright 2- inch Red LED displays are easy to read and visible from across large distances. The clocks are designed for pharma clean room applications with SS faceplates.

FEATURES:

- One second synchronization with master clock.
- Bright, flicker – free seven segments LED display.
- Displays time in HH:MM:SS Format.
- Micro controller based digital communication device.
- Best suited for clean room applications.
- Works in stand – alone mode if network failure.
- Indication of network failure with blinking display with time.
- 2” display visible up to 100 feet.



SPECIFICATIONS:

Display	2” Seven Segment LED Display (Red) for HH:MM:SS
Accuracy(Sync)	Depends on master clock. +/- 1 sec. with respect to Master
Accuracy in stand alone mode	+/- 1 minutes per month Max. When there is no Sync. Comm. With Master
Communication	RS-485 & RF Comm.
Time & Calendar	Programmable quartz clock with internal battery backup
Controller	Built in Embedded with industrial performance
Operating voltage	100 to 220 Volts AC 50 Hz/60Hz
Time Synchronization	Every second
Time Format	24 hour mode based on master clock
Environmental Ratings	Operating temperature: 0 - 50°C
Mechanical	Dimensions: mm appr.: 338X92X40 (LXHxD)
	Weight: 1kg. (Approx).
	Face plate: Flush mounting SS .
	Enclosure material: Mild steel.
Mounting	Brick Wall concealed Mounting./Modular wall mounting

RF communication

- Modulation Frequency : 433 MHz
- Line of sight : 600 Mtrs
- Antenna Gain : 2dBi
- Antenna Type : Omni directional
- Antenna Fixing : Instrument Inbuilt
- RF Power Output : +13dBm

Mechanical dimensions

